PI: **RESNIC, DANIEL**	Title: RAI CONDOM: Feasibility & Acceptability Study, Phase 1 Pilot Clinical Research	
Received: 01/08/2009	FOA: PA08-050	Council: 05/2009
Competition ID: VERSION-2A-FORMS	FOA Title: PHS 2008-02 OMNIBUS SOLICITATION OF THE NIH, CDC, AND FDA FOR SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS (PARENT SBIR [R43/R44])	
1 R43 AI084145-01A1	Dual:	Accession Number: 3129634
IPF: 10004934	Organization: STRATA VARIOUS	
Former Number: 1R43HD062420-01	Department: Product Design	
IRG/SRG: ZRG1 AARR-G (15)B	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 531,071 Year 2: 131,711	Animals: Y Humans: Y Clinical Trial: Y Exemption: 30 HESC: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:	*Organization:*	*Role Category:*
Daniel Resnic	Strata Various Product Design	PD/PI
Pamina Gorbach	Regents of the University of California	Other (Specify)-co-Investigator
Alen Voskanian MD	Regents of the University of California	Consultant

Additions for Review

Other	Resnic Introduction.pdf	The introduction was submitted with the cover letter and was not inserted in the grant file.	03/24/2009

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

2. DATE SUBMITTED	Applicant Identifier
01/07/2009	
3. DATE RECEIVED BY STATE	**State Application Identifier**

1. * TYPE OF SUBMISSION

❍ Pre-application ❍ Application
● Changed/Corrected Application

4. Federal Identifier
1R43HD050805-01A1

5. APPLICANT INFORMATION *** Organizational DUNS:**799212931

* Legal Name: Strata Various Product Design
Department: Product Design & Development
Division: Marketing
* Street1: 311 North Robertson Blvd
Street2: Suite 318
* City: Beverly Hills
County: Los Angeles
* State: CA: California
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: 90211

Person to be contacted on matters involving this application

Prefix:	* First Name:	Middle Name:	* Last Name:	Suffix:
Mr.	Daniel		Resnic	

* Phone Number: 310-305-2984
Fax Number: 440-508-2984
Email: resnicpi@gmail.com

6. * EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)*:
330546236

7. * TYPE OF APPLICANT
R: Small Business

8. * TYPE OF APPLICATION: ● New
❍ Resubmission ❍ Renewal ❍ Continuation ❍ Revision

Other (Specify):

Small Business Organization Type
❍ Women Owned ❍ Socially and Economically Disadvantaged

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)*:

* Is this application being submitted to other agencies? ❍ Yes ● No
What other Agencies?

9. * NAME OF FEDERAL AGENCY:
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
RAI CONDOM: Feasibility & Acceptability Study, Phase 1 Pilot Clinical Research

12. * AREAS AFFECTED BY PROJECT *(cities, counties, states, etc.)*
Global impact

13. PROPOSED PROJECT:

* Start Date	* Ending Date
07/01/2009	12/31/2010

14. CONGRESSIONAL DISTRICTS OF:

a. * Applicant	b. * Project
30	30

15. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix:	* First Name:	Middle Name:	* Last Name:	Suffix:
Mr.	Daniel		Resnic	

Position/Title: Owner/CFO
* Organization Name: Strata Various Product Design
Department: Product Design
Division: R&D
* Street1: 311 North Robertson Blvd
Street2: Suite 318
* City: Beverly Hills
County: Los Angeles
* State: CA: California
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: 90211
* Phone Number: 310-305-2984
Fax Number: 440-508-2984
* Email: resnicpi@gmail.com

16. ESTIMATED PROJECT FUNDING	
a. * Total Estimated Project Funding	$731,199.00
b. * Total Federal & Non-Federal Funds	$731,199.00
c. * Estimated Program Income	$0.00

17. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

18. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● * I agree

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

19. Authorized Representative

Prefix:	* First Name:	Middle Name:	* Last Name:	Suffix:
Mr.	Daniel		Resnic	

* Position/Title: Owner/CFO
* Organization Name: Strata Various Product Design
Department: Design
Division: R&D
* Street1: 311 North Robertson Blvd
Street2: Suite 318
* City: Beverly Hills
County: Los Angeles
* State: CA: California
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: 90211
* Phone Number: 310 305-2984
Fax Number: 440 508-2984
* Email: resnicpi@gmail.com

*** Signature of Authorized Representative**

Daniel Resnic

*** Date Signed**

01/08/2009

20. Pre-application File Name: Mime Type:

21. Attach an additional list of Project Congressional Districts if needed.

File Name: Mime Type:

424 R&R and PHS-398 Specific
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RESEARCH & RELATED Project/Performance Site Location(s)

Project/Performance Site Primary Location

Organization Name: Strata Various Product Design

* Street1: 311 North Robertson Blvd.		Street2: Suite 318
* City: Beverly Hills	County: Los Angeles	* State: CA: California
Province:	* Country: USA: UNITED STATES	* Zip / Postal Code: 90211

Project/Performance Site Location 1

Organization Name: Regents of the University of California

* Street1: 1080 Wilshire Blvd.		Street2: Suite 540
* City: Los Angeles	County: Los Angeles	* State: CA: California
Province:	* Country: USA: UNITED STATES	* Zip / Postal Code: 90095-7353

Project/Performance Site Location 2

Organization Name: Medco Products, Inc.

* Street1: 3863 East Eagle Drive		Street2:
* City: Anaheim	County: Orange	* State: CA: California
Province:	* Country: USA: UNITED STATES	* Zip / Postal Code: 92807

Project/Performance Site Location 3

Organization Name: UCLA Care Clinic

* Street1: 1399 S. Roxbury Drive		Street2: Suite 100
* City: Los Angeles	County: Los Angeles	* State: CA: California
Province:	* Country: USA: UNITED STATES	* Zip / Postal Code: 90035

Project/Performance Site Location 4

Organization Name: California Family Health Council

* Street1: 3660 Wilshire Blvd.		Street2: Suite 600
* City: Los Angeles	County:	* State: CA: California
Province:	* Country: USA: UNITED STATES	* Zip / Postal Code: 90000

File Name	Mime Type

Additional Location(s)

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved?	● Yes ○ No	
1.a. If YES to Human Subjects		
Is the IRB review Pending?	● Yes ○ No	
IRB Approval Date:		
Exemption Number:	_ 1 _ 2 _ 3 _ 4 _ 5 _ 6	
Human Subject Assurance Number	00004642	
2. * Are Vertebrate Animals Used?	● Yes ○ No	
2.a. If YES to Vertebrate Animals		
Is the IACUC review Pending?	● Yes ○ No	
IACUC Approval Date:		
Animal Welfare Assurance Number	41-R-0061	
3. * Is proprietary/privileged information included in the application?	● Yes ○ No	
4.a. * Does this project have an actual or potential impact on the environment?	○ Yes ● No	
4.b. If yes, please explain:		
4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?	○ Yes ○ No	
4.d. If yes, please explain:		
5.a. * Does this project involve activities outside the U.S. or partnership with International Collaborators?	○ Yes ● No	
5.b. If yes, identify countries:		
5.c. Optional Explanation:		

6. * Project Summary/Abstract	3410-1_ABSTRACT.pdf	Mime Type: application/pdf
7. * Project Narrative	450-1_NARRATIVE.pdf	Mime Type: application/pdf
8. Bibliography & References Cited	6706-BIBLIOGRAPHY.pdf	Mime Type: application/pdf
9. Facilities & Other Resources		
10. Equipment		
11. Other Attachments	9816-LTR-Viral_Barrier_Eval-Nelson_3_9_08.pdf	Mime Type: application/pdf
11. Other Attachments	5151-AppTec_Animal_Cert.pdf	Mime Type: application/pdf
11. Other Attachments	2913-Report-_Condom_Test___Dimension_Determination_of_Rubber_Condoms,_ASTM_3492_-_390327.pdf	Mime Type: application/pdf
11. Other Attachments	270-Report-_Condom_Test___Tensile,_ASTM_3492_-_391161.pdf	Mime Type: application/pdf
11. Other Attachments	367-Report-_Condom_Test__Evaluation_of_Leakage_in_Condoms_390323.pdf	Mime Type: application/pdf
11. Other Attachments	1742-Report-_Condom_Test_Tensile,_ASTM_3492391281.pdf	Mime Type: application/pdf
11. Other Attachments	974-Report-_Cytotoxicity____MEM_elution_L929_cells_24_hrs_extraction_with_48_hrs._incubatio_390325.pdf	Mime Type: application/pdf
11. Other Attachments	2710-Report-_Cytotoxicity____MEM_elution_L929_cells_24_hrs_extraction_with_72_hrs._incubatio_390318.pdf	Mime Type: application/pdf
11. Other Attachments	3723-Report-_Irritation____Intracutaneous_Toxicity_(Subcontracted)_391904.pdf	Mime Type: application/pdf
11. Other Attachments	3591-Report-_Irritation_Vaginal-Musocal_390326.pdf	Mime Type: application/pdf
11. Other Attachments	9076-Report-_Sensitization___Local_Lymph_Node_Assay_-LLNA-(Subcontracted)_390321.pdf	Mime Type: application/pdf
11. Other Attachments	6583-Report-_Systemic_Toxicity____Material_Mediated_Pyrogen_(Subcontracted)_391906.pdf	Mime Type: application/pdf
11. Other Attachments	1364-Report-_Systemic_Toxicity___Systemic_Injection_(Subcontracted)_391905.pdf	Mime Type: application/pdf
11. Other Attachments	598-Report-_Tear_Resistance_of_Rubber_and_Elastomerics_391162.pdf	Mime Type: application/pdf
11. Other Attachments	9839-Akron-_Origami_Final_Burst_Report_-_PN_75851_October_29,_2007_(2).pdf	Mime Type: application/pdf
11. Other Attachments	6438-Quote-Genotox_+_Muscle_Implantation_Tests_Quote_-_9-29-08.pdf	Mime Type: application/pdf
11. Other Attachments	4923-Viral_Lab_Report_391160.pdf	Mime Type: application/pdf

11. Other Attachments	8863-QUOTE_-_KEVI_N__COMRAS_-_Origami_RAI_-_12_18_08.pdf	Mime Type: application/pdf
11. Other Attachments	5806-Quote_RAI_UCLA_str-dreJPR35385-2_-_12-26-08.pdf	Mime Type: application/pdf
11. Other Attachments	828-Quote-Ed_Gemma_Origami_RAI_Phase_I_-_1_3_09.pdf	Mime Type: application/pdf
11. Other Attachments	6766-Quote-Medco_Quote_Origami_RAI_-_1-01-09.pdf	Mime Type: application/pdf
11. Other Attachments	8766-4_Preliminary_Studies.pdf	Mime Type: application/pdf
11. Other Attachments	7532-Quote-Condomania_RAI.pdf	Mime Type: application/pdf
11. Other Attachments	5753-Quote_Hanscom.pdf	Mime Type: application/pdf

ABSTRACT: The purpose of this project is to research, refine and test three prototypes of the ORIGAMI RAI CONDOM™, an RAI (receptive anal intercourse) condom made of a biocompatible, viral-impermeable silicone, which may provide better sensation and less breakage than latex products and provide maximum protection against viral transmission. Three prototypes will be injection-molded and pre-clinically tested for biocompatibility and structural integrity.

The ORIGAMI RAI CONDOM™ is intended to: 1. Facilitate a pleasurable and safe RAI sexual experience for both partners, 2. Increase the acceptability of condoms among those who practice anal intercourse and are at risk of HIV / STIs, 3. Encourage and increase consistent and correct use for those who practice anal intercourse and 4. Provide a receptive-partner-controlled strategy for HIV prevention.

Upon completion of pre-clinical testing and identification of safe and biocompatible prototypes, we propose to conduct Two human volunteer studies will be conducted: 1. A **User Preference Study**, to identify a preferred prototype, comparing measures of user preference of the three prototypes among 30 volunteers, in a non-coital context and 2. a **Couples Acceptability & Performance Study (CAP)** to investigate the acceptability and performance of the "preferred" prototype during anal intercourse among 24 couples.

PROJECT NARRATIVE

To introduce an urgently needed, effective HIV prevention strategy for RAI (receptive anal intercourse), the primary objective of this Study is to research the feasibility and acceptability of the ORIGAMI RAI CONDOM™: a new biocompatible, viral-impermeable, silicone, anorectally inserted condom, intended to provide an alternative to male latex condoms and increase acceptability and compliance for consumers at risk of HIV/STIs. Its user-friendly design is intended to introduce a pleasurable, more acceptable, receptive-partner-controlled barrier and to encourage its use.

4. Preliminary work done by the Key Investigators

4.1 Related R & D - Prototype Development

ORIGAMI MALE CONDOM™

Thickness: 1.1 mm

W 45 mm

L 160 mm

The inventor, Daniel Resnic (PI of this proposed study), developed the ORIGAMI ELASTOMER™ silicone for the ORIGAMI MALE CONDOM™ (< LEFT) in 2006.

To date, Phase I research of the ORIGAMI MALE CONDOM™ [1,14,] (See Sec 22) has demonstrated that a male condom made of the ORIGAMI ELASTOMER™ silicone, can be extremely durable (660 psi), resistant to UV light and exposure to air, withstands temperatures up to 425°F, has a potentially high extended shelf life, is viral-impermeable and non-allergenic.

4.2 Specific Aims for the Clinical Evaluation of the Origami Male Condom™:

Phase I clinical testing of the Origami Male Condom™ (formerly known as 'Comfort Condom') was divided into two parts. The specific aims of Part 1, the Condom Feasibility & Design Study were to compare the safety, acceptability, and performance of three prototype condoms to inform the development of a perfected Origami Male Condom™. The specific aims of Part II, the Performance and Acceptability Study, were to compare the safety, acceptability, and performance of the perfected Origami Male Condom™ with a commercial latex control condom (TrojanEnz™).

4.3 Results of the Condom Feasibility & Design Study (Part I) and the Performance and Acceptability Study (Part II):

Part I : Condom Feasibility & Design Study Results

Part I enrolled 10 couples to use three prototypes of the Origami Male Condom™ for two acts of intercourse each (60 condoms total). A lubricant was added to the inside of all condoms to facilitate a unique, non-rolled donning procedure. Couples also applied additional study lubricant to the penis or vagina to enhance intercourse sensation.

Couples used THREE prototype designs (53 total condoms used);

ORIGAMI Version 1	ORIGAMI Version 2	ORIGAMI Version 3
18 Smooth/No-strap	17 Textured/No-strap	18 Textured/Strap

There were no reported condom breaks or slip offs. Although couples encountered few instances of slipping along the penis, leaking, or stretching, bunching was reported during 26% of condom uses. Couples had difficulty donning 26% of the study condoms.

Male partners reported discomfort during seven uses while female partners reported discomfort during nine uses. All discomforts resolved at the conclusion of intercourse and none required treatment.

Although a number of couples liked the study condoms, about half of both male and female partners indicated that they would not recommend the study condom. The most common complaints were thickness and difficulty donning the condom.

An additional analysis was performed to determine whether penis size affected condom performance. Smaller penis circumference was associated with donning problems (41% uses vs 20% uses), bunching (47% uses vs 17% uses), male discomfort (24% uses vs 3% uses), and female discomfort (47% uses vs 3% uses). Shorter penis length was also associated with donning problems and discomfort but was particularly related to condom bunching (61% uses vs 0% uses).

Part I: Extension Study Results

A small Part I Extension Study was conducted to test a fourth version of the Origami Male Condom™ which was modified to improve donning and reduce bunching. The **ORIGAMI Version 4** condom was shorter (14cm vs 18.5cm) and narrower (5.5cm vs 6.5cm) than the first three condom prototypes. This version had a smooth texture and a scrotal strap and was packaged in foil to prevent evaporation of the Astroglide™ commercial lubricant contained within.

Nine of the original 10 couples from the Part 1 Study participated in the Extension Study. Each couple used two **ORIGAMI Version 4** condoms for intercourse (18 total). Couples reported no trouble unrolling the **Version 4** condom and there were no reports of condom bunching, the two most frequent problems with the first three prototype condoms. One Version 4 condom broke during intercourse which the couple attributed to a defect which they noticed only after completing intercourse. Also, one **Version 4** condom slipped completely off the penis during intercourse. The couple reported that the tip of this condom had retained an air pocket which suggests that the condom may not have been donned properly. Males reported mild, transient discomfort during 22% of uses. In all cases (4 uses), the discomfort was attributed to the scrotal strap. Sixty-seven (67%) of the male partners and (77%) of the female partners reported that they were open to purchasing the **Version 4 Origami Male Condom**™ .

Part II: Performance and Acceptability Study Results

Thirty-six (36) couples were enrolled in Part II. Participants averaged 27 years of age. Approximately 43% were non-Hispanic white, 27% Hispanic, 11% Asian, and 9% African-American. Two-thirds of the couples were either married or living together. Approximately 80% of participants had at least some college education. One couple was disqualified because they provided inaccurate responses on their initial histories. One couple withdrew from the study after using only one set of condoms (Table 1).

Two types of condoms were used; TojanEnz™ latex and ORIGAMI MC™ silicone. Out of 108 condoms of each type available for use, condom use reports were submitted for 102 Origami Male Condoms™ and 100 control condoms (TrojanEnz™). Three Origami Male Condoms™ were not used for vaginal intercourse because the male partner lost his erection (2 condoms) or found the fit too tight (1 condom). Four TrojanEnz™ control condoms were not used for vaginal intercourse because the condom could not be unrolled (1 condom) or the fit was too tight (3 condoms). No condoms of either type broke before, during, or after intercourse. One Origami Male Condom™ and two TrojanEnz™ control condoms slipped off during intercourse. One TrojanEnz™ control condom slipped off during withdrawal.

Thus, the total clinical failure rate for the Origami Male Condom™ was 1.0% (1/99) compared to 3.1 (3/93) for the TrojanEnz™ control condom. Other performance problems included: slippage along the penis shaft during intercourse (17% Origami™, 10% TrojanEnz™ control); stretching out (4% Origami™, 8% TrojanEnz™ control); and bunching (5% Origami™, 13% TrojanEnz™ control).

Male partners reported discomfort during 37% of the uses or attempted uses of the Origami Male Condom™ compared to 29% of control condom uses. Over 80% of the male discomforts associated with the Origami™ condom were described as constriction (21%), pinching (18%), or decreased sensitivity (45%). Female partners reported discomfort during 32% of uses of the Origami Male Condom™ compared to 22% of uses of the control condom. Increased complaints about dryness accounts for much of the additional Origami Male Condom™ discomforts (22% Origami Male Condom™, 14% TrojanEnz™ control). All discomforts resolved without treatment within one hour after intercourse.

Participants rated the Origami Male Condom™ and control condoms on a list of condom characteristics using a 10-point scale where “1" indicated the worst response “10" indicated the best response (Table 2). The mean rating for the two condom types was nearly identical (males: Origami™ 5.5, TrojanEnz™ control 5.7; females: Origami™ 5.7, TrojanEnz™ control 5.9). Males favored the Origami Male Condom™ for feel of the internal lubrication (6.1 vs 5.8), lack of smell (6.1 vs 4.9), comfort (5.7 vs 5.1), and condom fit (5.9 vs. 5.6).

Conversely, males gave higher ratings to the control condom for ease of putting on (6.9 vs. 6.3), appearance (6.1 vs. 5.6), texture (5.9 vs. 5.0), sensitivity (4.8 vs. 4.2), overall sexual experience (6.0 vs. 5.0). Males also tended to rate the Origami Male Condom™ as too thick compared to the control condom. Female partner ratings followed a similar pattern to the male ratings except that they rated the comfort of the control condom more highly than the Origami Male Condom™ (5.8 vs. 5.2). Sixty-two percent (62%) of the male partners indicated that they would consider purchasing the Origami Male Condom™ compared to 55% of the female partners.

After using both sets of study condoms, participants were asked which condom type they preferred. Approximately one-third of both male and female participants preferred the Origami Male Condom™ over the TrojanEnz™ latex control condo.

Summary

The Origami Male Condom™ performed well in the Phase I trial with no clinical breaks and only one slip off among approximately 100 uses. The total clinical failure rate for the Origami Male Condom™ was 1.0% (1/99) compared to 3.1 (3/93) for the control condom. Couples reported no trouble unrolling the **Version 4** condom and there were no reports of condom bunching, the two most frequent problems with the first three prototype condoms. In addition, one-third of participants preferred the Origami Male

Condom to the TrojanEnz™ latex condom, a best selling commercial condom and more than half of both male and female partners indicated that they would consider purchasing the Origami Male Condom™. We believe that the Origami Male Condom™ has proven its readiness for advancing to a Phase II evaluation.

"Progress Through Innovation, Technology and Customer Satisfaction"

AKRON RUBBER DEVELOPMENT LABORATORY, INC.
2887 Gilchrist Road • Akron, Ohio 44305
1-800-830-ARDL • (330) 794-6600 • FAX (330) 794-6610
Website: www.ardl.com • E-mail: info@ardl.com

October 26, 2007

• TEST REPORT •

PN 75851

PO

Physical Testing Department

Prepared For:

Mr. Daniel Resnic
Strata Various Product Design
311 North Robertson Blvd. #318
Beverly Hills, CA 90211

Prepared By: _____
Sandy Jones
Project Technician

Approved By: _____
Jim Drummond
Physical Testing, Manager

An A2LA Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
ISO 9001:2000 Registered
Member of ACIL: The American Council of Independent Laboratories

ACCREDITED
A Testing Lab

ISO 9001:2000
Registered

MEMBER ACIL

"Progress Through Innovation, Technology and Customer Satisfaction"

AKRON RUBBER DEVELOPMENT LABORATORY, INC.
2887 Gilchrist Road • Akron, Ohio 44305
1-800-830-ARDL • (330) 794-6600 • FAX (330) 794-6610
Website: www.ardl.com • E-mail: info@ardl.com

October 26, 2007

Mr. Daniel Resnic
Strata Various Product Design

SUBJECT: Physical testing on material submitted by the above company.
PO#

RECEIVED: Forty (40) silicone condoms identified as Origami™.

AIRBURST, ASTM D 3492-03, PARA. 6.3
40 pcs tested
See attached data sheets

	ORIGAMI
Pressure, kPa	
Mean	2.603
Standard Deviation	0.257
Volume, L	
Mean	26.101
Standard Deviation	5.52

Prepared By: Sandy Jones
Sandy Jones
Project Technician

Approved By: Jim Drummond
Jim Drummond
Physical Testing, Manager

ARDL is accredited by A2LA for the test methods listed on the attached scope

Inflation Test Report 10/26/2007

File	Batch #	Technician	Started
STRATAPN75851	ORIGAMI	Sandy	10/26/2007 11:54:55 AM

Batch Description
ORIGAMI SILICONE

 # Valid 40 **# Tested** 40 **# Aborted** 0

	Rounding	Limits	Non-Comp	Mean	Median	SD	Min	Max
Pressure	0.100 kPa	0.100 kPa	0	2.603 kPa	2.600 kPa	0.257 kPa	1.900 kPa	3.100 kPa
Either			0					
Volume	0.50 L	0.10 L	0	26.10 L	27.00 L	5.52 L	13.50 L	34.00 L

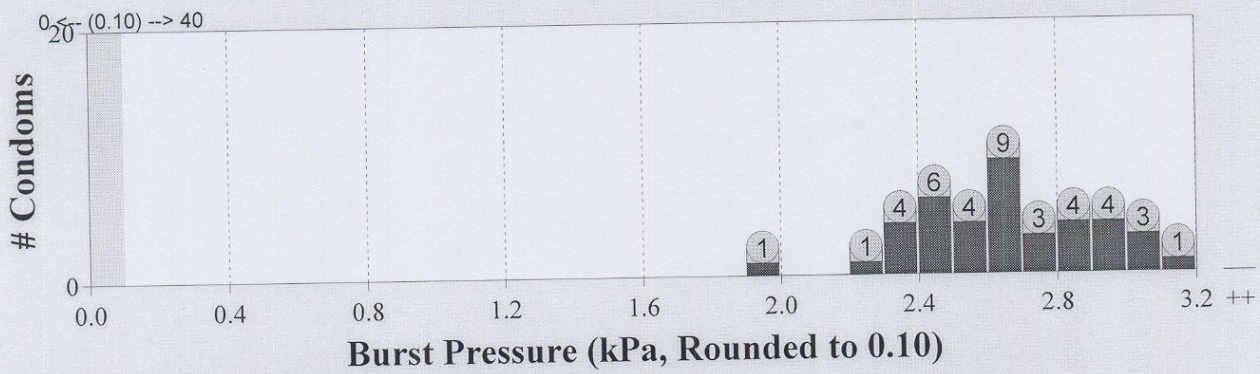
#	Head #	Pressure (kPa)	Volume (L)	Time (s)	Status	Comment
1	6	2.300	33.000	1:12.40		
2	5	2.900	34.000	1:14.50		
3	3	2.400	22.000	0:49.50		
4	4	2.300	30.000	1:06.00		
5	2	2.300	32.000	1:10.30		
6	1	2.500	33.500	1:13.09		
7	6	2.500	34.000	1:14.09		
8	4	1.900	13.500	0:29.39		
9	5	2.400	30.000	1:05.90		
10	3	2.400	29.500	1:06.00		
11	2	2.500	26.000	0:56.79		
12	6	2.300	18.000	0:39.40		
13	1	2.500	32.000	1:09.80		
14	5	2.900	24.500	0:53.79		
15	4	2.400	30.500	1:06.80		
16	3	2.600	22.000	0:49.50		
17	2	2.700	27.500	1:00.90		
18	1	2.700	25.000	0:54.00		
19	3	3.000	25.500	0:57.40		
20	4	2.600	27.000	0:58.90		
21	5	2.600	29.000	1:03.40		
22	6	2.600	28.000	1:01.09		
23	3	2.900	22.500	0:50.50		
24	4	3.100	22.000	0:48.70		
25	5	2.800	29.000	1:03.29		
26	6	2.600	30.000	1:05.90		
27	1	2.800	25.500	0:55.79		
28	2	3.000	28.000	1:01.20		
29	3	2.600	22.500	0:50.70		
30	4	2.700	29.500	1:04.40		
31	5	2.800	24.500	0:53.40		

Inflation Test Report 10/26/2007

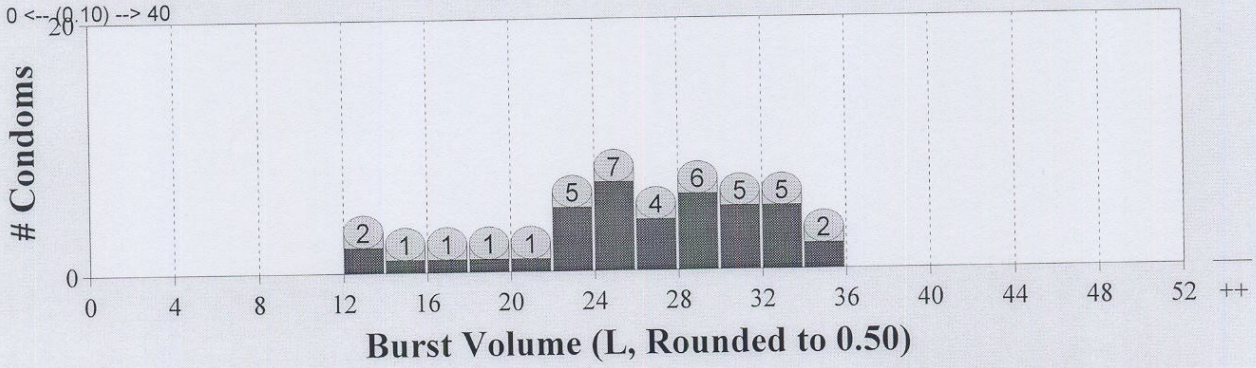
#	Head #	Pressure (kPa)	Volume (L)	Time (s)	Status	Comment
32	6	2.600	27.000	0:58.79		
33	3	2.800	20.500	0:46.59		
34	2	2.400	25.000	0:55.09		
35	1	2.900	30.500	1:06.90		
36	2	2.200	14.500	0:31.39		
37	1	2.400	32.000	1:09.59		
38	2	2.600	24.000	0:52.90		
39	5	3.000	13.500	0:30.10		
40	4	2.600	17.000	0:37.40		

STRATAPN75851

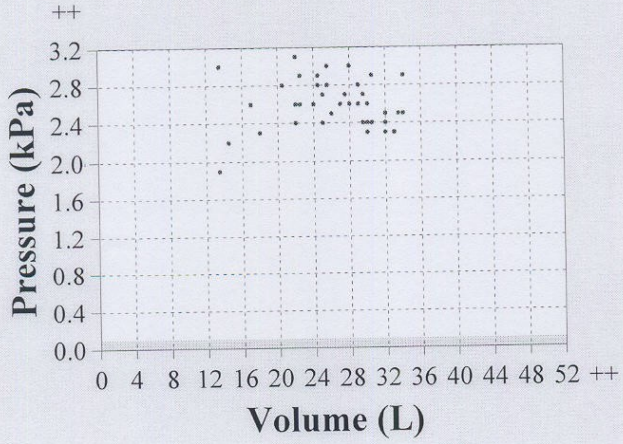
Pressure Histogram



Volume Histogram



Pressure/Volume Plot



Technician	Sandy
Date	10/26/2007 11:54:55 AM
Batch #	ORIGAMI
Batch Description	ORIGAMI SILICONE

	Pressure	*Volume*
Valid Results	40	
Limits	0.100 kPa	0.10 l
Rounding	0.100 kPa	0.50 l
Non-Compliers	0	0
Either	0	
Mean	2.603 kPa	26.10 l
Median	2.600 kPa	27.00 l
SD	0.257 kPa	5.52 l
Min	1.900 kPa	13.50 l
Max	3.100 kPa	34.00 l

Corrections
(None)

PRINTED - 10/26/2007 12:47:53 PM # Heads - 6 Akron Rubber Development Laboratory Licence #120 (3.0.2.17) Page 1 of 1

EXPIRATION DATE: SEPTEMBER 28, 2010

USDA

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Animal Care

This is to certify that APPTEC LABORATORY SERVICES LLC

is a registered CLASS R RESEARCH FACILITY under the

Animal Welfare Act

(7 U.S.C. 2131 et seq.)

Certificate No. 41-R-0061

Customer No. 15690

Deputy Administrator

11 Mar 2008

NELSON LABORATORIES

Prepared For:
Dan Resnic
STRATA VARIOUS PRODUCT DESIGN
311 N. Robertson Blvd. #318
Beverly Hills CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City UT 84123-6600
801-290-7500

Dear Dan:

A preclinical "Condom Viral Barrier Evaluation" was completed at Nelson Laboratories, Inc. (NLI) on 11 Oct 2007, under NLI Lab #391160, for the Origami Condom™ NIH Phase 1 Feasability Study. The evaluation for determining barrier properties of condoms to virus penetration was conducted according to Attachment A of the FDA "Testing Guidance for Male Condoms Made from New Material" comparing twenty Origami Condom™ test samples (Silicone) and twenty predicate condom samples (Latex) as controls. The predicate condoms must be a product approved for and sold in the US market.

The condom viral barrier evaluation employs a procedure for determining the barrier properties of test condoms (silicone) and predicate condoms (latex). The test consists of filling the condom with a suspension of Phi-X174 bacteriophage (smaller than HIV) maintained at approximately 2 x 10^8 plaque forming units (PFU)/mL, and suspending the condom in sterile simulated serum. The condom is then held under pressure at 60 mmHg (1.28 pounds per square inch gauge (psig)) for 30 minutes. After the exposure period the sterile simulated serum (liquid surrounding condom) is assayed to determine whether any challenge virus penetrated the membrane barrier per milliliter of serum.

Results of the condom viral barrier evaluation had an outcome of one failure out of twenty predicate condoms (5% failures - Latex) with 5 PFU/mL and no failures out of the twenty Origami Condom™ test samples (0% failures - Silicone). For a complete report please refer to NLI Lab #391160. A complete Study Outline is described on page 2.

Please let me know if you have any questions. I can be reached at (801) 290-7866 or hfontanet@nelsonlabs.com. Thank you for testing with Nelson Laboratories, Inc.

Sincerely,

Hilda M. Fontanet, B.S.
Aerobiology Study Director

HF/mlb

NELSON LABORATORIES

STUDY OUTLINE:

The FDA guidelines recommend twenty condoms from three lots and twenty predicate condoms as controls. The predicate condoms should be of comparable construction and design as the test condoms and must be a product approved for the US market. The PHI-X174 challenge virus level shall be maintained at approximately 2×10^8 PFU/mL.

Tests will be performed at 37 ± 2°C. This will be accomplished using a temperature regulated vessel connected to a circulating water bath. The surface tension of the internal and external solutions will be adjusted to about 40-45 dynes/cm [Nm^{-1}] by addition of a commercially available surfactant, to approximately simulate the surface tension of human plasma and body fluids.

Test condoms will be rinsed with simulated serum prior to tests to remove any lubricant or virucidal substances present. The rinsing procedure has been validated in prior studies and found to be effective.

Test condoms will be challenged to a minimum challenge level of 14 cm [5½ inches]. This is designed to challenge a significant portion of the condom and comply with FDA published standards for evaluation of condoms by the water test.

The test condoms will be challenged with a challenge suspension sufficient to provide a minimum liquid level of 14 cm [5½ inches] from the bottom of the condom. Condoms will be pressurized to a water column equivalent of 90 cm (1.28 ± 0.02 psig). The exterior fluid surrounding the test condom will be assayed quantitatively (plaque assays). The quantitative procedure provides data on the number of virus particles penetrating per mL of condom fluid. The challenge suspension also contains a red dye that allows visual observations to be made during testing.

Test system controls will include both negative and positive control samples. Positive controls will consist of condoms containing pierced holes in the condoms as detailed later. The negative controls will consist of condoms tested without challenge. This control is important in validating the sealing technique of the test controls.

The negative control samples are designed to prove control in testing conditions such as environment, condom and media, *E.coli*, and assembly process. The environment is tested by using both bottle and plate controls and testing for challenge.

The challenge virus is characterized below:

VIRUS	SIZE (µm)	ENVELOPE	STRUCTURE
PHI-X174	0.027	No	Icosahedral

NELSON LABORATORIES

Test positive control samples will consist of condoms with pierced 0.12 mm holes in triplicates adding the challenge and plaque assaying for results. This method of control is followed from the FDA testing guidelines and shown to be very sensitive in obtaining results. Other positive controls consist of spotting the challenge for purity, test the consistency of the challenge by doing in-condom titer at time 0 and 30 minutes, and finally show control of adsorption and inhibition with spike/neutralization test.

REFERENCES:

Zinsser Microbiology. 1980. W. K. Joklik, H.P. Willett and D.B. Amos, eds. Appleton-Century-Crofts, New York.

Regulatory Program for Rubber Prophylactics, Dry and lubricated; Skin Prophylactics; and Nylon Prophylactics. Jul 1957. Food and Drug Administration.

Carey, R., W. Herman, B. Herman, B. Krop, and J. Casamento. 1989. "A Laboratory Evaluation of Standard Leakage Tests for Surgical & Examination Gloves". J. Clin. Eng. 14:#2, 133-143.

"A Laboratory Evaluation of Standard Leakage Tests for Surgical & Examination Gloves". J. Clin. Eng. 14:#2, 133-143.

K E V I N C O M R A S
MEDICAL ILLUSTRATION | PRODUCT ANIMATION
130 Meriden Road Boonton, NJ 07005 USA
Studio 973-335-9789 Cell 973-610-4746
sarmoc@aol.com

December 18, 2008

Mr. Daniel Resnic
STRATA VARIOUS PRODUCT DESIGN
311 North Robertson Blvd Suite #318
Beverly Hills, CA 90211
resnicpi@gmail.com

RE: Medical Illustration Proposal
Phase 1 Feasibility Study: Origami RAI Condom

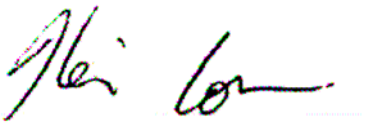
Illustrate product prototypes and sequential design alterations (3-6 revisions)
Design illustrated universal user instructions.

Develop related 3-D animated, rotatable images in Solid Works, JPEG images, .iges files of product prototypes per client specifications.

Quote: $8,700.

Terms: 10% Down at the start of the project. Balance due upon approval of final delivery
Client satisfaction is guaranteed.

Sincerely,



Kevin Comras

Eric A. Hanscom, Attorney at Law

6994 El Camino Real, #204 Carlsbad, CA 92009
Phone: 852.2838.3399 Fax: 852.2838.3107
Email: eric@erichanscom.com
Web Site:: www.EricHanscom.com

Other Offices in Hong Kong and Bangkok

January 4, 2009

Mr. Daniel Resnic
Strata Various Product Design
ORIGAMI CONDOMS™
311 North Robertson Blvd. Suite 318
Beverly Hills, CA 90211

RE : ORIGAMI RAI Condom™; Phase I Study

Dear Dan:

Congratulations on your Phase I study success. The Law Offices of Eric Hanscom will be happy to consult for your Phase I study of the ORIGAMI RAI Condom™. As you are aware from our previous work, variations from your original patent application will likely require some discussion before you proceed with any significant modifications.

In that regard we would like to offer advice to your study in the capacity of legal consultant. Our fees are at the rate of $250./ Hr. Based on our earlier conversations you may expect to utilize approximately 20 hours of consultation time. This is for consultation only and will not cover any actual patent work, CIT research or filings.

We are happy to be a part of your continued success with these important projects. Please include this letter of support in your grant application to the National Institutes of Health.

Sincerely,

Eric Hanscom

26 December 2008
Quote No. JPR35385-2

Dan Resnic
Strata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211
Phone: 310-305-2984
Fax: 440-508-2984
e-mail: resnicpi@gmail.com

Dear Dan:

Thank you for your interest in Nelson Laboratories, and for giving us an opportunity to offer a quote for your testing. Standard sample recommendations and turnaround time are given below.

ORIGAMI RAI CONDOM:

Condom barrier test **Test Code CDM110**
Bacteriophage with controls – qualitative & quantitative test
Sets of 20 required; predicate device also required (set of 40 = 20 test and 20 predicate)

40 condoms (each $300) $12,000.00
Turnaround Time: 38 days
Sample Amount: 20 test and 20 predicate

60 condoms (each $280) $16,800.00
Turnaround Time: 42 days
Sample Amount: 30 test and 30 predicate

>80 condoms, each condom $260.00
Turnaround Time: 50-60 days
Sample Amount: >40 test and >40 predicate

R&D sets of novel condoms, each condom $365.00
Turnaround Time: Consult NLI
Sample Amount: Minimum 20 recommended

Total for 60 condoms tested GLP $19,320.00

Condom tensile and elongation test, ASTM D3492-02 **Test Code CDM120**
Includes tensile and force at break.
Tensile test, sample preparation and conditioning $100.00
Each sample $30.00

Total for 13 samples tested GLP $765.00
Turnaround Time: 10 days
Sample Amount: Min. 13 samples per type/lot

Condom burst test, ISO4074 **Test Code CDM130**

This test determines air burst volume and air burst pressure.

Burst test, sample preparation and conditioning $100.00
Each sample $30.00

Total for 13 samples tested GLP $765.00
Turnaround Time: 7 days
Sample Amount: Min. 13 samples per type/lot

Dimensions of rubber condoms, ASTM D3492-02 **Test Code CDM140**

Each sample $15.00

Total for 13 samples tested GLP $470.00
Turnaround Time: 10 days
Sample Amount: Min. 13 samples per type/lot

Evaluation of leakage in condoms, ISO 4074 (Freedom from Holes) **Test Code CDM150**

Leak test: test set-up and sample preparation $275.00
1-99 samples, each $4.50

Total for 13 samples tested GLP $608.50
Turnaround Time: 10-12 days
Sample Amount: Min. 13 samples per type/lot

Tear resistance of condoms, ASTM D3492 **Test Code PHY225**

Tear resistance test: test set-up and sample preparation $100.00
Each condom $30.00

Total for 13 samples tested GLP $765.00
Turnaround Time: 10-12 days
Sample Amount: Min. 13 samples per type/lot

Accelerated Aging study, per accelerated year **Test Code PKG110**

For accelerated aging Nelson Labs offers controlled environments. Controlled aging chambers are set at 55% relative humidity and 55˚C.

Aging cost is determined by the number of weeks and storage space used in the chamber.

Per day $22.00
For 2 year aging (13 weeks (91 days) x 7 days/week x $22/day) $2,002.00

Total for 2 years accelerated aging tested GLP $2,302.30
Turnaround Time: Aging time plus 7-10 days to final report
Sample Amount: Dependent on aging parameters and post-aging test requirements

Condom tensile and elongation test, ASTM D3492-02 **Test Code CDM120**
Includes tensile and force at break.

Tensile test, sample preparation and conditioning.....$100.00
Each sample.....$30.00

Total for 13 samples tested FDA GLP.....$765.00
Turnaround Time: 10 days
Sample Amount: Min. 13 samples per type/lot

Note that this is to be performed on the body of the condom only (post-aging) This portion of the quote is for Biocompatibility testing. This portion reflects GLP (Good Laboratory Practice) prices. Studies with an addition sign (+) are subcontracted to another facility. The sample amounts for the Biocompatibility are not in terms of units, but rather surface area. These amounts are in accordance with ISO 10993. I have included the sample areas for each test that you have requested.

Cytotoxicity: MEM Elution (ISO/USP): 48 hours incubation **Test Code CTX110**
Turnaround Time: 7 days.....GLP $405.00
Sample Amount: 1 complete device, each device must be 120 cm^2 or 4 grams

Cytotoxicity: MEM Elution (ISO/USP): 72 hours incubation **Test Code CTX115**
Turnaround Time: 7 days.....GLP $405.00
Sample Amount: 1 complete device, each device must be 120 cm^2 or 4 grams

Note: Sponsor needs to decide which time exposure is needed.

+Sensitization: Local Lymph Node Assay (w/2 extracts) **Test Code SCX120**
Turnaround Time: 4-6 weeks.....GLP $7,100.00
Sample Amount: 6 complete devices, each device must be 120 cm^2 or 4 grams

+Irritation: Vaginal Irritation (ISO) (w/2 extracts) **Test Code SCX260**
Turnaround Time: 4-5 weeks.....GLP $3,750.00
Sample Amount: 5 complete devices, each device must be 120 cm^2 or 4 grams

+Irritation: Intracutaneous Reactivity (ISO) (w/2 extracts) **Test Code SCX210**
Turnaround Time: 4 weeks.....GLP $895.00
Sample Amount: 2 complete devices, each device must be 120 cm^2 or 4 grams

+Systemic Toxicity: Systemic Injection (ISO/USP) (w/2 extracts) **Test Code SCX310**
Turnaround Time: 4 weeks.....GLP $705.00
Sample Amount: 2 complete devices, each device must be 120 cm^2 or 4 grams

+Systemic Toxicity: Material Mediated Pyrogen (ISO) **Test Code SCX320**
Turnaround Time: 4 weeks.....GLP $680.00
Sample Amount: 450 cm^2 or 30 grams

The following three Genotoxicity tests are all required to satisfy the ISO 10993-3 requirement.

Genotoxicity: Ames test (w/ 2 extracts) **Test Code GTX110**
Turnaround Time: 5 weeks ..... GLP $2,760.00
Sample Amount: 240 cm^2 or 8 grams

Genotoxicity: Chromosomal Aberration (w/2 extracts) **Test Code GTX220**
Turnaround Time: 8-9 weeks ..... GLP $13,800.00
Sample Amount: 4 complete devices, each device must be 120 cm^2 or 4 grams

+Genotoxicity: Mouse Lymphoma (w/2 extracts) **Test Code SCX530**
Turnaround Time: 6 weeks ..... GLP $9,100.00
Sample Amount: 2 complete devices, each device must be 120 cm^2 or 4 grams

There are five time points offered for implantation. The duration of the test should reflect patient exposure.

+Implantation w Histopathology: (ISO) 1 Week Observation **Test Code SCX610**
Turnaround Time: 7 weeks ..... GLP $2,150.00
Sample Amount: 14, 1 x 1 x 10 mm strips

+Implantation w Histopathology: (ISO) 2 Week Observation **Test Code SCX620**
Turnaround Time: 8 weeks ..... GLP $2,350.00
Sample Amount: 14, 1 x 1 x 10 mm strips

+Implantation w Histopathology: (ISO) 4 Week Observation **Test Code SCX630**
Turnaround Time: 10 weeks..... GLP $2,800.00
Sample Amount: 14, 1 x 1 x 10 mm strips

+Implantation w Histopathology: (ISO) 8 Week Observation **Test Code SCX640**
Turnaround Time: 15 weeks..... GLP $3,350.00
Sample Amount: 14, 1 x 1 x 10 mm strips

+Implantation w Histopathology: (ISO) 12 Week Observation **Test Code SCX650**
Turnaround Time: 19 weeks..... GLP $4,500.00
Sample Amount: 14, 1 x 1 x 10 mm strips

Note: Sponsor needs to decide which contact duration (including repeat contact) is needed.

Samples with a thickness greater than 0.5 mm require half of the sample amount for all listed studies in order to comply with ISO 10993 specifications.

Please note that samples with large surface area or weight may accrue additional charges for extraction media. Surface area is the preferred method for determining sample amount. If surface area data is available please provide it at time of sample submission. Devices with complex surface areas may incur additional charges if Nelson performs the calculations. We can also use weight as an alternative. Please indicate the method you would like to use upon sample submission.

Total estimated cost (only Ames test, not including implantation)..... **$42,055.80**
Total estimated cost (all three genotoxicity tests, not including implantation).... **$64,955.80**

FDA GLP fee, (optional) per study ..... *as indicated above*
Final reports intended for submission to the U.S. Food and Drug Administration (FDA) in support of a marketing request may need to be conducted under the current Good Laboratory Practices (cGLP) regulations of the specific agency. Sponsors should notify the laboratory prior to initiation of such tests and this should be done on the Sample Submission Form checkbox for GLP / Non-GLP. GLP is a value-added service which includes QA master file tracking of samples, QA audit of test phase and QA/GLP statement in the final report. Additional time may be required for the QA review.

If you have any questions regarding this price quote or test information please contact me. Thank you for testing with Nelson Laboratories, Inc.

Regards, ***Expiration date: 28 Feb 2009***

Jason Smith
Sales Manager
Nelson Laboratories, Inc.
e-mail: jrsmith@nelsonlabs.com
Phone: 801.290.7522

Justin Pate
Regional Representative – West
Nelson Laboratories, Inc.
e-mail: jpate@nelsonlabs.com
Phone: 801.290.7523

STAT fees, (optional) per study.....Generally 50% additional
STAT fees are for expedited testing (minimum fee, $50.00). Due to compendia and scientific requirements, certain studies may not qualify for STAT testing.

Prepayment Requirements: A 50% prepayment is due for new clients before work can begin. For projects that are large or extended (>3 months), partial or phase completion payments may be required.

With a current account, clients are invoiced after their studies are completed and results are issued. Studies over $5,000.00 will normally require a 50% prepayment to help cover the initial set-up and test costs for these studies. Balances past due (over 30 days) must be brought current before new work will be accepted.

A 100% prepayment is due for international clients before work can begin.

Forms of Payment: We accept wire transfers, checks drawn on U.S. Banks, or Visa, Master Card, and American Express credit cards. For questions regarding credit applications or wire transfer routing, please contact Nelson Laboratories' Accounting Department at accounting@nelsonlabs.com. A $25 handling charge will be applied to wire transfer payments.

Turnaround Time Terms:
The quoted turnaround time is for standard testing. Any issues that may cause non-standard testing situations, or testing difficulties due to the nature of the sample may cause the turnaround time to be greater.

Purchase Orders:
Purchase orders are generally recommended. A purchase order is required for all studies over $3,000. All POs may be sent to the Nelson accounting department via email (accounting@nelsonlabs.com) or by Attn: Accounting to fax 801-290-7998.

Shipping Information:
A copy of the submission form is available at www.nelsonlabs.com. Please include a completed submission form when sending samples to the lab. Full sample identification should also be included as this will identify the test article in the final report.

Ship to
Attn: Login Department
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123 USA

Terms of Payment
Terms are net 30 days from date of invoice. A charge of $25.00 will be incurred for each returned check.

Cancellation Fees
A purchase order and full payment for partial billings is required where the client has requested initiation of a study and subsequently cancels the study. In order to cover costs, a charge of $25.00 is assessed at the time a study is cancelled in addition to any work already completed on the project.

A full description of Nelson Laboratories' terms and conditions can be found at www.nelsonlabs.com/conditions.jsp.

America's first Condom Store™

Corporate Office
1011 N Orange Dr.
Los Angeles, CA 90038
Phone 323-969-0102
Fax 323-969-0119
adam@condomania.com

December 28, 2008

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd, Suite 318
Beverly Hills, CA 90211

RE: ORIGAMI RAI Condom™; Phase I Feasibility Study

Project Consultation

Discuss proposed product design modifications with the Consortium, the inventor and mechanical engineers from the consumers' preference perspective.

Est. cost: **$12,060.** (67 hours at $180. / hour

Sincerely,

Adam Glickman, CEO

E. GEMMA
INDUSTRIAL DESIGNER

Structural Packaging Design
Display and Exhibit Design
Concept Visualization
Product Design
CAD Services
Ideation
Identity

Estimate #890772

January 3, 2009

Mr. Daniel Resnic
STRATA VARIOUS PRODUCT DESIGN
311 North Robertson Blvd Suite #318
Beverly Hills, CA 90211
resnicpi@gmail.com

Quote # 805788-1

RE: Mechanical Engineering Drawing Proposal;
ORIGAMI RAI Condom, Phase I Feasibility Study

- 3-D product drawings, alterations & revisions.
- Develop related 3-D mechanical engineering drawings for product molds.
- Design consultations with client and Mold Builder.
- Rotatable images; **.iges** files, **JPEG** files, as needed.

Cost Per Prototype	Estimated Qty Prototypes	Extension
$12,200	1, plus revisions	$12,200.

Sincerely,

Edward Gemma,
E. Gemma, Industrial Designer

P.O. BOX 3258 ◦ MILFORD, CT 06460 ◦ TEL & FAX: 203-877-8547 ◦ EMAIL: EG_IND_DESIGN@YAHOO.COM

30 September 2008
Quote No. JPR27484-1

Dan Resnic
STRATA VARIOUS PRODUCT DESIGN
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211
Phone: 310-305-2984
Fax: 440-508-2984
E-mail: dan.resnic@gmail.com

Dear Dan:

Thank you for your interest in Nelson Laboratories, and for giving us an opportunity to offer a quote for your testing. This quote reflects Non-GLP and GLP (Good Laboratory Practice) prices. Studies with an addition sign (+) are subcontracted to another facility.

Please note that for projects over $5000 a 50% prepayment is required before testing can begin. To make prepayment, please contact our accounting department at 801-290-7507 or accounting@nelsonlabs.com.

The following three Genotoxicity tests are all required to satisfy the ISO 10993-3 requirement.

Genotoxicity: Ames test (w/ 2 extracts) **Test Code GTX110**
Turnaround Time: 5 weeks ..... Non-GLP $2,400.00
Sample Amount: 240 cm^2 or 8 grams ..... GLP $2,760.00

Genotoxicity: Chromosomal Aberration (w/2 extracts) **Test Code GTX220**
Turnaround Time: 10-12 weeks ..... Non-GLP $12,000.00
Sample Amount: 4 complete devices ..... GLP $13,800.00
Each device must be 120 cm^2 or 4 grams

+Genotoxicity: Mouse Lymphoma (w/2 extracts) **Test Code SCX530**
Turnaround Time: 6 weeks ..... Non-GLP $8,575.00
Sample Amount: 2 complete devices, each device must be 120 cm^2 or 4 grams .. GLP $9,100.00

There are five time points offered for implantation. The duration of the test should reflect patient exposure.

+Implantation w Histopathology: (ISO) 1 Week Observation **Test Code SCX610**
Turnaround Time: 7 weeks ..... Non-GLP $2,000.00
Sample Amount: 14, 1 x 1 x 10 mm strips ..... GLP $2,150.00

+Implantation w Histopathology: (ISO) 2 Week Observation **Test Code SCX620**
Turnaround Time: 8 weeks ..... Non-GLP $2,200.00
Sample Amount: 14, 1 x 1 x 10 mm strips ..... GLP $2,350.00

+Implantation w Histopathology: (ISO) 4 Week Observation **Test Code SCX630**
Turnaround Time: 10 weeks ..... Non-GLP $2,650.00
Sample Amount: 14, 1 x 1 x 10 mm strips ..... GLP $2,800.00

30 September 2008
Quote No. JPR27484-1

+Implantation w Histopathology: (ISO) 8 Week Observation **Test Code SCX640**
Turnaround Time: 15 weeks..... Non-GLP $3,250.00
Sample Amount: 14, 1 x 1 x 10 mm strips..... GLP $3,350.00

+Implantation w Histopathology: (ISO) 12 Week Observation **Test Code SCX650**
Turnaround Time: 19 weeks..... Non-GLP $4,250.00
Sample Amount: 14, 1 x 1 x 10 mm strips..... GLP $4,500.00

Samples with a thickness greater than 0.5 mm require half of the sample amount for all listed studies in order to comply with ISO 10993 specifications.

Please note that samples with large surface area or weight may accrue additional charges for extraction media. Surface area is the preferred method for determining sample amount. If surface area data is available please provide it at time of sample submission. Devices with complex surface areas may incur additional charges if Nelson performs the calculations. We can also use weight as an alternative. Please indicate the method you would like to use upon sample submission.

FDA GLP fee, (optional) per study ..... *as indicated above*
Final reports intended for submission to the U.S. Food and Drug Administration (FDA) in support of a marketing request may need to be conducted under the current Good Laboratory Practices (cGLP) regulations of the specific agency. Sponsors should notify the laboratory prior to initiation of such tests and this should be done on the Sample Submission Form checkbox for GLP / Non-GLP. GLP is a value-added service which includes QA master file tracking of samples, QA audit of test phase and QA/GLP statement in the final report. Additional time may be required for the QA review.

If you have any questions regarding this price quote or test information please contact me. Thank you for testing with Nelson Laboratories, Inc.

Regards,

Expiration date: 31 Dec 2008

Justin Pate, B.S.
Regional Representative – Mountain/West
Nelson Laboratories, Inc.
e-mail: jpate@nelsonlabs.com
Phone: 801.290.7523

STAT fees, (optional) per study.....Generally 50% additional
STAT fees are for expedited testing (minimum fee, $50.00). Due to compendia and scientific requirements, certain studies may not qualify for STAT testing.

Prepayment Requirements: A 50% prepayment is due for new clients before work can begin. For projects that are large or extended (>3 months), partial or phase completion payments may be required.

With a current account, clients are invoiced after their studies are completed and results are issued. Studies over $5,000.00 will normally require a 50% prepayment to help cover the initial set-up and test costs for these studies. Balances past due (over 30 days) must be brought current before new work will be accepted.

A 100% prepayment is due for international clients before work can begin.

Forms of Payment: We accept wire transfers, checks drawn on U.S. Banks, or Visa, Master Card, and American Express credit cards. For questions regarding credit applications or wire transfer routing, please contact Nelson Laboratories' Accounting Department at accounting@nelsonlabs.com. A $25 handling charge will be applied to wire transfer payments.

Turnaround Time Terms:
The quoted turnaround time is for standard testing. Any issues that may cause non-standard testing situations, or testing difficulties due to the nature of the sample may cause the turnaround time to be greater.

Purchase Orders:
Purchase orders are generally recommended. A purchase order is required for all studies over $3,000. All POs may be sent to the Nelson accounting department via email (accounting@nelsonlabs.com) or by Attn: Accounting to fax 801-290-7998.

Shipping Information:
A copy of the submission form is available at www.nelsonlabs.com. Please include a completed submission form when sending samples to the lab. Full sample identification should also be included as this will identify the test article in the final report.

Ship to
Attn: Login Department
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123 USA

Terms of Payment
Terms are net 30 days from date of invoice. A charge of $25.00 will be incurred for each returned check.

Cancellation Fees
A purchase order and full payment for partial billings is required where the client has requested initiation of a study and subsequently cancels the study. In order to cover costs, a charge of $25.00 is assessed at the time a study is cancelled in addition to any work already completed on the project.

A full description of Nelson Laboratories' terms and conditions can be found at www.nelsonlabs.com/conditions.jsp.

Medco Products, Inc.

3863 East Eagle Drive, Anaheim, CA 92807
Tel: 714.630.1920 Fax: 714.630.7022
dennis@medcoproducts.com
www.medcoproducts.com

January 2, 2009 QUOTE # **0779COM-DE**

Dan Resnic
Strata Various Product Design
ORIGAMI CONDOMS
311 North Robertson Blvd. # 318
Beverly Hills, CA 90211

Dear Dan,

This is a quotation you requested to construct a single cavity LIM tool to produce the **Origami RAI Condom**, which will be mounted onto Medco's Mold Base. We will need to use steel Molds to accommodate a near seamless parting line. The quote covers the three prototypes, revisions sample production and packaging for your feasibility study

ORIGAMI RAI CONDOM™ Prototypes

PROTOTYPES	MATERIAL	Silicone Thickness	Silicone Durometer: Condom Body	Silicone Durometer: Condom Collar
Prototype 1	ORIGAMI ELASTOMER-0134™	1.1 mm	10 Duro	20 Duro
Prototype 2	ORIGAMI ELASTOMER-8034™	1.2 mm	08 Duro	15 Duro
Prototype 3	ORIGAMI ELASTOMER-5034™	1.4 mm	05 Duro	10 Duro

No. of Cavities:	Single Cavity	
Part Description:	**Origami RAI Condom**	
Part Number:	N/A	
Type of mold:	LIM (Liquid Injection Molding)	
Mold Base:	Medco's mold bases	
Guided Ejection	Yes	
Type of Cavity and Core:	Nak-55 (Pre-heat treated tool Steel)	
Tooling Cost:	$ 18,850.	$ 28,850.
Minimum tool life	100,000 (If Mold stays with Medco's facility)	
Delivery:	6-7 Wks	
Part Materials:	Origami Elastomer Silicone	
New cavity or core:	$ 8,500. (3 alternates)	$ 25,500.
Mold Costs per Revision:	$ 800. (NOT A NEW CAVITY)	$ 4,800.
Mold Sample Run:	$ 1,350. (Per Each of 6 VERSIONS)	$ 8,100.

Part pricing for Silicone Condom:

250/Order	*500/Order*	*1000/Order*	*2500/Order*	**Qty. 260**	
$ 8.55	*$ 7.35*	*$ 6.25*	*$ 5.10*	$ 1,326.	$ 1,326.

Sterilization estimated cost per unit:	$ 3.00 ea.	$ 780.
Packaging estimated cost per unit:	$ 6.35 ea.	$ 1,651.
Production setup cost:	$ 350.	$ 350.
Sub TOTAL ESTIMATED COSTS:		
TOTAL ESTIMATED COSTS:		**$ 80,357.**

Terms and conditions on tooling: 50% upon placing purchase order and 50% after acceptance of first article. No production runs or engineering changes will be processed until original tooling has been approved for final payment. Delivery date commences after receipt of deposit. Sales Tax will be added on final billing.

Sincerely,

Dennis Bui

NELSON LABORATORIES

Prepared For:
Dan Resnic
Strata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123-6600
801-290-7500

DIMENSIONS AND TENSILE PROPERTIES OF RUBBER CONDOMS – FINAL REPORT

Laboratory Number:	390327
Procedure Number:	STP0068 REV 03
Standard Method:	ASTM D3492
Sample Source:	Strata Various Product Design
Sample Identification:	ORIGAMI SILICONE CONDOM - SVPD Lot #94 P.O. #SVPD-080207-002
Deviations:	None
Statement of Uncertainty:	Available upon request
Sample Received Date:	17 Aug 2007
Lab Phase Start Date:	11 Sep 2007
Lab Phase Completion Date:	16 Oct 2007
Report Issue Date:	17 Oct 2007

RESULTS:

The results are reported in Tables 1-2.

Jennifer Gygi, B.S. SM(NRM)
Study Director

16 Oct 2007
Study Completion Date

JAG/ad

NELSON LABORATORIES

TABLE 1. Results
ORIGAMI SILICONE CONDOM - SVPD

SAMPLE IDENTIFICATION	LENGTH (mm)	WIDTH (mm)	MEDIAN THICKNESS (mm)
1	175	52	0.62
2	175	52	0.60
3	175	52	0.52
4	175	52	0.60
5	175	52	0.57
6	175	52	0.56
7	175	52	0.63
8	175	52	0.62
9	175	52	0.63
10	175	52	0.57
11	175	52	0.62
12	175	52	0.55
13	175	52	0.59

NELSON LABORATORIES

TABLE 2. Results
Trojan Latex Condom

SAMPLE IDENTIFICATION	LENGTH (mm)	WIDTH (mm)	MEDIAN THICKNESS (mm)
1	185	52	0.11

NELSON LABORATORIES

Prepared For:
Dan Resnic
Strata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123-6600
801-290-7500

DIMENSIONS AND TENSILE PROPERTIES OF RUBBER CONDOMS – FINAL REPORT

Laboratory Number:	391161
Procedure Number:	STP0068 REV 03
Standard Method:	ASTM D3492
Sample Source:	Strata Various Product Design
Sample Identification:	ORIGAMI SILICONE CONDOM - SVPD Lot #94 P.O. #SVPD-080207-002
Deviations:	Yes; refer to Table 1.
Statement of Uncertainty:	Available upon request
Sample Received Date:	23 Aug 2007
Lab Phase Start Date:	10 Sep 2007
Lab Phase Completion Date:	16 Oct 2007
Report Issue Date:	17 Oct 2007

RESULTS:

The results are reported in Tables 1-2.

Jennifer Gygi, B.S. SM(NRM)
Study Director

19 Oct 2007
Study Completion Date

JAG/ad

NELSON LABORATORIES

TABLE 1. Results
ORIGAMI SILICONE CONDOM - SVPD

SAMPLE IDENTIFICATION	ELONGATION AT BREAK (%)	TENSILE STRENGTH (MPa)	BREAKING FORCE (N)
1	755.7	3.49	67.06
2	747.6	2.94	58.75
3	744.3	3.24	63.57
4	773.6	3.32	63.71
5	728.0	3.14	60.27
6	750.8	3.08	65.29
7	716.6	2.66	54.26
8	768.7	3.44	68.75
9	739.4	3.56	65.50
10	763.8	3.28	61.64
11	772.0	3.39	65.14
12	772.0	3.67	69.07
13	789.9	3.49	71.18
Mean	755.6	3.28	64.17
Standard Deviation	20.48	0.28	4.62

Note: The samples showed irregular thickness which exceeded the requirements as outlined in the standard, this is a deviation from the standard test protocol (STP).

NELSON LABORATORIES

TABLE 2. Results
Trojan Latex Condom

SAMPLE IDENTIFICATION	ELONGATION AT BREAK (%)	TENSILE STRENGTH (MPa)	BREAKING FORCE (N)
1	773.6	20.99	83.97

NELSON LABORATORIES

Prepared For:
Dan Resnic
Strata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123-6600
801-290-7500

CONDOM LEAK TEST – FINAL REPORT

Laboratory Number:	390323
Protocol Number:	200702596 REV 01
Standard Method:	ASTM D3492 / ISO 4074
Sample Source:	Strata Various Product Design
Sample Identification:	ORIGAMI SILICONE CONDOM - SVPD Lot #94 P.O. #SVPD-080207-002
Deviations:	None
Statement of Uncertainty:	Available upon request
Protocol Approval Date:	15 Oct 2007
Sample Received Date:	17 Aug 2007
Lab Phase Start Date:	23 Oct 2007
Lab Phase Completion Date:	24 Oct 2007
Report Issue Date:	25 Oct 2007

The condoms were filled with 300 mL of water that was tempered between 20-40°C. The condom was allowed to hang for 1 minute and then inspected. The condom was then bent to a 90 degree angle and inspected. Any leakage was documented.

RESULTS:

The results are reported in Table 1-2.

Jennifer Gygi, B.S. SM(NRM)
Study Director

26 Oct 2007
Study Completion Date

JAG/mcx

NELSON LABORATORIES

TABLE 1. Results
Origami Silicone Condom - SVPD

SAMPLE ID	RESULT
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
11	0
12	0
13	0

'0' No Evidence of Bubble Emission
'+' Evidence of Bubble Emission

NELSON LABORATORIES

TABLE 2. Results
Trojan Non-Lubricated Latex

SAMPLE ID	RESULT
1	0

'0' No Evidence of Bubble Emission
'+' Evidence of Bubble Emission

NELSON LABORATORIES

Prepared For:
Dan Resnic
Strata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123-6600
801-290-7500

GENERAL TENSILE TESTING OF FABRIC, PLASTIC, AND OTHER MATERIALS – FINAL REPORT

Laboratory Number:	391281
Procedure Number:	STP0066 REV 03
Sample Source:	Strata Various Product Design
Sample Identification:	ORIGAMI SILICONE CONDOM-SVPD Lot #94 P.O. #SVPD-080207-001
Deviations:	None
Statement of Uncertainty:	If applicable, available upon request
Crosshead Speed:	12 inch/min
Grip Distance:	1 inch
Grip Type:	Pneumatic (2 inch jaw faces)
Sample Received Date:	24 Aug 2007
Lab Phase Start Date:	10 Sep 2007
Lab Phase Completion Date:	16 Oct 2007
Report Issue Date:	17 Oct 2007

RESULTS:

The scrotal retention strap was cut off the condom, then cut in to and pulled across its diameter. The results are reported in Tables 1-2.

Jennifer Gygi, B.S. SM(NRM)
Study Director

16 Oct 2007
Study Completion Date

lz/ad

NELSON LABORATORIES

TABLE 1. Results
ORIGAMI SILICONE CONDOM-SVPD

SPECIMEN NUMBER	MAXIMUM LOAD (N)	EXTENSION (mm)
1	15.91	283.97
2	18.21	325.12
3	15.09	268.73
4	17.25	301.24
5	10.98	203.23
6	20.56	332.23
7	20.40	318.52
8	19.82	331.22
9	22.07	341.38
10	14.92	288.54
11	17.78	320.55
12	20.22	329.69
13	13.14	229.62
Mean	17.41	298.00
Standard Deviation	3.27	42.47

NELSON LABORATORIES

TABLE 2. Results
Trojan Latex Condom

SPECIMEN NUMBER	MAXIMUM LOAD (N)	EXTENSION (mm)
1	49.87	379.48

NELSON LABORATORIES

Prepared For:
Dan Resnic
STRATA VARIOUS PRODUCT DESIGN
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123-6600
801-290-7500

MEM ELUTION – FINAL REPORT

Laboratory Number:	390325
Procedure Number:	STP0032 REV 02
Sample Source:	STRATA VARIOUS PRODUCT DESIGN
Type of Test:	Solid
Sample Identification:	Origami Silicone Condom-SVPD Lot #94 P.O. #SVPD-080207-003
Deviations:	None
Statement of Uncertainty:	If applicable, available upon request
Cell Line:	Mouse Heteroploid Connective Tissue (L-929)
Incubation Period:	48 ± 3 hours at 37 ± 1°C
Method of Scoring:	Cytopathic Effect (0-4)
Amount Tested/Sample Extract:	94.6 cm^2 / 15.8 mL
Sample Received Date:	17 Aug 2007
Lab Phase Start Date:	17 Aug 2007
Lab Phase Completion Date:	21 Aug 2007
Report Issue Date:	22 Aug 2007

TABLE 1. Results

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
NEGATIVE CONTROL	0	0	0	0
MEDIA CONTROL	0	0	0	0
POSITIVE CONTROL	4	4	4	4
SAMPLE	0	0	0	0

Technical Reviewer

Thor S. Rollins, B.S. RM(NRM)
Study Director

22 Aug 2007
Study Completion Date

jyr

NELSON LABORATORIES

Prepared For:
Dan Resnic
STRATA VARIOUS PRODUCT DESIGN
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123-6600
801-290-7500

MEM ELUTION – FINAL REPORT

Laboratory Number:	390318
Procedure Number:	STP0032 REV 02
Sample Source:	STRATA VARIOUS PRODUCT DESIGN
Type of Test:	Solid
Sample Identification:	Origami Silicone Condom - SVPD Lot #94 P.O. #SVPD-080207-003
Deviations:	None
Statement of Uncertainty:	If applicable, available upon request
Cell Line:	Mouse Heteroploid Connective Tissue (L-929)
Incubation Period:	72 ± 3 hours at 37 ± 1°C
Method of Scoring:	Cytopathic Effect (0-4)
Amount Tested/Sample Extract:	94.6 cm^2 / 15.8 mL
Sample Received Date:	17 Aug 2007
Lab Phase Start Date:	17 Aug 2007
Lab Phase Completion Date:	22 Aug 2007
Report Issue Date:	22 Aug 2007

TABLE 1. Results

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
NEGATIVE CONTROL	0	0	0	0
MEDIA CONTROL	0	0	0	0
POSITIVE CONTROL	4	4	4	4
SAMPLE	0	0	0	0

Technical Reviewer

Thor S. Rollins, B.S. RM(NRM)
Study Director

22 AUG 2007
Study Completion Date

jyr

NELSON LABORATORIES

05 Oct 2007

Daniel Resnic
Strata Various Product Design
311 North Robertson Blvd. #318
Beverly Hills, CA 90211

Dear Daniel,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

NELSON NUMBER: 391904

TESTING LAB: AppTec Laboratory Services

TYPE OF TEST: ISO Intracutaneous Reactivity Test

SAMPLE IDENTIFICATION:
Origami Silicone Condom – SVPD Lot #94

If you have any questions, please feel free to call any of our Subcontracting personnel at 801-963-2600 or 800-826-2088. Thank you for testing with Nelson Laboratories, Inc.

Jennifer Shaw
Jennifer Shaw, B.S.
Subcontracting Coordinator

05 Oct 2007
Sign Date

Nelson Laboratories Incorporated
P. O. Box 17557, Salt Lake City, UT 84117-0557 • 6280 South Redwood Road, Salt Lake City, UT 84123-6600
Telep... ...ttendant: 800-963-6280 or 801-...
Web site: www.nelsonlabs.com • e-mail: info@nelsonlabs.com

St. Paul

Report

NON-GLP
FINAL STUDY REPORT

STUDY TITLE

ISO INTRACUTANEOUS REACTIVITY TEST

TEST ARTICLE IDENTIFICATION

Origami Silicone Condom - SVPD
Lot # 94

STUDY COMPLETION DATE

October 3, 2007

PERFORMING LABORATORY

AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

SPONSOR

Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123

PROJECT NUMBER

64425

NLI #

391904

Reference PO # APP-2007

NEL05

64425

jshaw@nelsonlabs.com

ISO INTRACUTANEOUS REACTIVITY TEST RESULTS

Test Article Name:	Origami Silicone Condom - SVPD
Lot/Batch #:	94
NLI #:	391904
Stability:	Not Applicable
Sterilization Method:	Dry Heat: 400°F for 4 hours
Storage Conditions:	Room Temperature
Safety Precautions:	Standard Precautions

Date Sample Received:	09/04/07
Study Completion Date:	10/03/07

PURPOSE: The purpose of this test was to determine if chemicals that may leach or be extracted from the test material were capable of causing local irritation in the dermal tissues of the rabbit.

TEST SAMPLE PREPARATION: A representative sample of the test article was cut into pieces, placed into test tubes and prepared at a ratio of 60 cm^2 to 20 mL of extraction vehicle. The test article was extracted for 72 ± 2 hours at 37 ± 1° C. The test article consisted of clear silicone.

EXPERIMENTAL METHODS SUMMARY: Two (2) New Zealand White rabbits *(Oryctolagus cuniculus)* each received five (5) sequential 0.2 mL intracutaneous injections along either side of the dorsal mid-line with the test article extract on one side and the concurrent vehicle control on the other. The irritation reactions were scored at 24 ± 2, 48 ± 2 and 72 ± 2 hours post-injection on each rabbit for evidence of erythema and edema. The erythema and edema scores were totaled separately for the test article and control extracts. Each total score was divided by 12 (2 animals x 3 observation periods x 2 scoring categories) to determine the overall mean score for each test extract versus each corresponding control. According to ISO 10993-10, the requirements of the test are met if the difference between the test article and the control mean score is 1.0 or less.

RESULTS:

Extract Vehicle	Test Article Mean Score	Control Mean Score	Comparative Results
0.9% Normal Saline (NS)	0	0	0
Cottonseed Oil NF (CSO)	2.5	2.5	0

CONCLUSION: The test article is considered a **non-irritant.**

TECHNICAL REFERENCES

ISO 10993-10: 2002 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-type Hypersensitivity, Pages 23–25.

ISO 10993-12: 2002 Standard, Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials.

United States Pharmacopeia (USP) 30, 2007, Section 88, Biological Test, *In Vivo* Intracutaneous Test, Pages 117-118.

Approval: Michelle Dietzel Date: 10/3/07

Michelle Dietzel, BS – Study Director

2540 Executive Drive • St. Paul, MN 55120 • 888.794.0077 • 651.675.2000 • Fax: 651.675.2009

NELSON
LABORATORIES

16 Nov 2007

Daniel Resnic
Stata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Dear Daniel,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

NELSON NUMBER: 390326

TESTING LAB: AppTec Laboratory Services

TYPE OF TEST: ISO Mucosal (Vaginal) Irritation Test

SAMPLE IDENTIFICATION:
Origami Silicone Condom – SVPD Lot #94

If you have any questions, please feel free to call any of our Subcontracting personnel at 801-963-2600 or 800-826-2088. Thank you for testing with Nelson Laboratories, Inc.

Jennifer Shaw, B.S.
Subcontracting Coordinator

16 Nov 2007
Sign Date

Nelson Laboratories Incorporated
P. O. Box 17557, Salt Lake City, UT 84117-0557 • 6280 South Redwood Road, Salt Lake City, UT 84123-6600
Telephone: 801-963-2600 • Fax: 801-963-2630 • Operator: 800-826-2088 • Auto Attendant: 800-963-6280 or 801-963-5799
Web site: www.nelsonlabs.com • e-mail: info@nelsonlabs.com

St. Paul

Report

NON-GLP
FINAL STUDY REPORT

STUDY TITLE

ISO MUCOSAL (VAGINAL) IRRITATION TEST

TEST ARTICLE IDENTIFICATION

Origami Silicone Condom - SVPD
Lot # 94

STUDY COMPLETION DATE

November 15, 2007

PERFORMING LABORATORY

AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

SPONSOR

Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123

PROTOCOL

910790K

PROJECT NUMBER

63717

NLI#

390326

Reference PO # APP-2007

NEL05

63717

jshaw@nelsonlabs.com

2540 Executive Drive • St. Paul, MN 55120 • 888.794.0077 • 651.675.2000 • Fax: 651.675.2009

ISO MUCOSAL (VAGINAL) IRRITATION TEST RESULTS

Test Article Name:	Origami Silicone Condom - SVPD
Lot/Batch #:	94
NLI#:	390326
Stability:	Not Applicable
Sterilization Method:	None
Storage Conditions:	Room Temperature
Safety Precautions:	Standard Precautions
Intended Use/Application:	Unknown

Date Sample Received:	08/22/07
Study Initiation Date:	08/22/07
Study Completion Date:	11/15/07

PURPOSE: The purpose of this study was to evaluate the irritation potential of a test article that is designed for use in human mucosal tissue using the ISO Vaginal Mucosal Irritation test.

TEST SAMPLE PREPARATION: The test article was cut into pieces, placed into test tubes and prepared at a ratio of 60 cm^2 to 20 mL of extraction vehicle. The sample was extracted for 72 ± 2 hours at 37 ± 1 °C. The extracts were cooled, shaken well and decanted into sterile, dry, glass vessels. The extracts were used within 24 hours of removal from the extraction oven. The test article consisted of clear rubber.

EXPERIMENTAL METHODS SUMMARY: Test article extracts of Normal Saline and Cottonseed Oil were instilled into the vaginal vault of three (3) rabbits per extract vehicle for five consecutive days. Additionally, control vehicle was administered to three control animals per control vehicle for five consecutive days. During the five-day exposure, the vaginal tissue was observed and scored for erythema, exudate, and edema. After the five-day exposure, the animals were sacrificed and the vaginal tissue removed. The tissue was observed macroscopically and scored for irritation and injury to the epithelial layer. The tissue was placed in 10% neutral buffered formalin and submitted for histopathology.

Daily Observations and Scoring: Prior to the first dose and each daily dose, the external vaginal tissue of each animal was observed for erythema, exudate and edema according to the scoring system in Table 1 to obtain a Primary Irritation Score. For each animal, the Primary Irritation Scores for erythema, exudate, and edema were added together at each time point following dosing and divided by the total number of observations (15) to obtain that animal's Irritation Score. The Irritation Scores of all animals in each test and control group were added together and divided by the number of animals in each group to obtain the Cumulative Irritation Index. These observations may assist in the histopathology evaluation. Animal health observations were recorded daily throughout the study period.

Termination: The rabbits were sacrificed by lethal injection with a sodium pentobarbital based solution (Euthasol) the day after the last dose and the vaginal tissue was carefully removed.

Explant Scoring: After explanting the vaginal vault, the cylindrical tissue was opened longitudinally and examined for vascular congestion, signs of general irritation and injury to the epithelial layer and necrosis. The vaginal tissues were placed in a container with 10% Neutral Buffered Formalin. The pathologist used a scoring system to evaluate microscopically the irritation effects on the tissue.

EVALUATION: The macroscopic scores were used to aid the pathologist and the conclusion was based on the microscopic evaluation of the tissue by the pathologist. The microscopic evaluation scores for all the animals in the test group were added and divided by the total number of observations to obtain a test group average. The microscopic evaluation scores for all the animals in the control group were added and divided by the total number of observations to obtain a control group average. The maximum score is 16. The microscopic control group average was subtracted from the test group average to obtain the Irritation Index. The irritation is classified according to the Irritation Index listed in Table 2.

RESULTS:

Gross: The difference between the test and control daily vaginal observations was 0.0 for the Normal Saline extract and 0.5 for the Cottonseed Oil extract (Tables 3 and 4). Macroscopic observations conducted at necropsy were typical for this type of procedure (Tables 5 and 6).

Microscopic: None of the test or control animals had a score higher than '7'. This indicates a valid test. The Irritant Rank Score was '0' for the Normal Saline extract and '2' for the Cottonseed Oil extract. The Final Pathology Report is attached to this report.

ANALYSIS AND CONCLUSION: Based on the requirements of this study, the Normal Saline extract of the test article, Origami Silicone Condom – SVPD, Lot # 94, was classified as a non-irritant. The Cottonseed Oil extract of the test article was classified as a minimal irritant.

Carroll D. Arnett, Ph. D. – Study Director

Date: 11-15-07

TECHNICAL REFERENCES:

ISO 10993-10: 1995 Standard, "Biological Evaluation of Medical Devices, Part 10-Tests for Irritation and Sensitization", Annex D, pp. 20-26.

Holzapfel, W., Buxton, H., (1958), Sensitivity to Vaginal Jellies, Journal of the American Pharmaceutical Association, XLVII, pp. 423 - 426.

Eckstein, P., Jackson, H.C.N., Millman, N., and Sabrero, A.J., (1969), Comparisons of Vaginal Tolerance Tests of Spermicidal Preparations in Rabbits and Monkeys, Journal of Reproduction and Fertility, Volume 20, pp. 85 – 93.

Kaminsky, M, Willigan, D.A.,(1982), pH and the Potential Irritancy of Douche Formulations to the Vaginal Mucosa of the Albino Rabbit and Rat, Food and Chemical Toxicology, Volume 20, pp. 193 - 196.

TABLE 1: DAILY EXTERNAL EVALUATION OF VAGINAL IRRITATION

OBSERVATIONS	NUMERICAL GRADING
ERYTHEMA	
No Redness	0
Slight Redness	1
Redness with Distinct blood vessels	2
Deep redness accompanied with numerous engorged blood vessels	3
EXUDATE	
No pus	0
Few small globules of pus	1
Large globules of pus	2
Large amounts of pus and or sloughed tissue exuding from the vulva	3
EDEMA	
No swelling of the vulva	0
Slight swelling of the vulva less than twice its size	1
Swelling of the vulva to twice its size	2
Swelling of the vulva greater than twice its size	3

TABLE 2: IRRITATION INDEX

AVERAGE SCORE	ADJECTIVAL DESCRIPTION
0	None
1 to 4	Minimal
5 to 8	Mild
9 to 11	Moderate
12 to 16	Severe

TABLE 3: DAILY VAGINAL SCORING (NORMAL SALINE)

ANIMAL #	Group	DAY 0			DAY 1			DAY 2			DAY 3			DAY 4			DAY 5			TOTAL	IRRITATION SCORE	CII
		ER	EX	ED	ER	EX	ED	ER	EX	ED	ER	EX	ED	ER	EX	ED	ER	EX	ED			
5003	Test	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	0	1	5	0.3	
5002	Test	1	0	0	1	0	1	1	0	0	1	0	0	1	0	0	1	0	0	6	0.4	0.5
5001	Test	1	0	0	2	0	0	2	0	0	2	0	0	2	0	0	2	0	0	10	0.7	
5005	Control	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0.1	
5011	Control	1	0	0	2	1	2	2	0	1	2	0	1	2	0	1	2	0	1	17	1.1	0.5
5008	Control	0	0	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	5	0.3	
														Difference (test – control)							0.0	

TABLE 4: DAILY VAGINAL SCORING (COTTONSEED OIL)

ANIMAL #	Group	DAY 0			DAY 1			DAY 2			DAY 3			DAY 4			DAY 5			TOTAL	IRRITATION SCORE	CII
		ER	EX	ED	ER	EX	ED	ER	EX	ED	ER	EX	ED	ER	EX	ED	ER	EX	ED			
5006	Test	1	0	0	1	0	0	2	0	0	2	0	2	2	0	2	2	0	2	15	1.0	
5010	Test	0	0	0	1	0	1	1	0	2	1	0	2	2	0	3	2	0	3	18	1.2	0.8
5012	Test	0	0	0	1	0	1	0	0	1	0	0	0	1	0	0	0	0	0	4	0.3	
5014	Control	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0.1	
5013	Control	0	0	0	1	0	1	1	0	1	1	0	1	1	0	1	1	0	1	10	0.7	0.3
5015	Control	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0.1	
														Difference (test – control)							0.5	

ER = Erythema
EX = Exudate
ED = Edema
CII = Cumulative Irritation Index

TABLE 5: VAGINAL TISSUE MACROSCOPIC OBSERVATIONS (NORMAL SALINE)

ANIMAL #	GROUP	MACROSCOPIC OBSERVATION
5003	Test	Macroscopically normal
5002	Test	Macroscopically normal
5001	Test	Macroscopically normal
5005	Control	Macroscopically normal
5011	Control	Macroscopically normal
5008	Control	Macroscopically normal

TABLE 6: VAGINAL TISSUE MACROSCOPIC OBSERVATIONS (COTTONSEED OIL)

ANIMAL #	GROUP	MACROSCOPIC OBSERVATION
5006	Test	Mild vascular congestion
5010	Test	Mild vascular congestion; lining appears thickened
5012	Test	Mild vascular congestion
5014	Control	Mild vascular congestion
5013	Control	Moderate vascular congestion
5015	Control	Macroscopically normal

APPTEC HISTOLOGY LABORATORY

FINAL PATHOLOGY REPORT

APPTEC PROJECT NUMBER
63717

STUDY TITLE:
ISO Mucosal (Vaginal) Irritation Test

TEST ARTICLE IDENTIFICATION:
Origami Silicone Condom – SVPD
Lot Number 94

SPONSOR
Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123

PROTOCOL
910790K

SUBMITTED BY:
Cindy Dingee, DVM
AppTec Pathology Services
2540 Executive Drive
St. Paul, MN 55120
(651) 675-2000

SUBMITTED TO:
Carroll Arnett, PhD
AppTec
2540 Executive Drive
St. Paul, MN 55120

REPORT DATE:
11-15-07

Purpose

The purpose of this study was to evaluate the irritation potential of a test article that is designed for use in human mucosal tissue using the ISO Vaginal Mucosal Irritation test.

A Normal Saline and Cottonseed Oil test article extract was administered to three test animals each (albino rabbits (*Oryctolagus cuniculus*), New Zealand White strain, female) for five consecutive days. Additionally, the control vehicles, Normal Saline and Cottonseed Oil, were administered to three control animals each, for five consecutive days. During the five-day exposure, the vaginal tissue was observed and scored for erythema, exudate and edema. After the five-day exposure, the animals were sacrificed and the vaginal tissue removed. The tissue was observed macroscopically and scored for irritation and injury to the epithelial layer. The vaginal tissue was placed in 10% neutral buffered formalin and submitted to AppTec Histology Laboratory for histology processing. A numerical comparison of the test and control tissue microscopic scores was conducted to categorize the irritation reaction as indicated in the ISO 10993-10 guidelines.

Test Samples: Origami Silicone Condom – SVPD, Lot Number 94

Origami Silicone Condom – SVPD
Lot Number 94 and Normal Saline Extract

Rabbit #
5001
5002
5003

Origami Silicone Condom – SVPD
Lot Number 94 and Cottonseed Oil Extract

Rabbit #
5006
5010
5012

Control Samples: Normal saline and Cottonseed Oil

Normal Saline	Cottonseed Oil
Rabbit #	Rabbit #
5005	5013
5008	5014
5011	5015

Hematoxylin and eosin (H&E) stained sections of the vaginal tissue were prepared by the AppTec Histology Laboratory from all animals and consisted of control and test sites from the cervical, middle and caudal regions of the vagina. A veterinary pathologist microscopically evaluated H&E stained tissue sections.

Conclusion

Under the conditions of this ISO Vaginal Mucosal Irritation Study and based on the Irritation Index as shown in Table 1, the Test Article, **Origami Silicone Condom – SVPD, Lot Number 94**, was considered a non-irritant when compared to the control article, **Normal Saline**, and a minimal irritant when compared to the control article, **Cottonseed Oil**. There was an increase in the number of leukocytes, and amount of vascular congestion and edema in the test article tissue sections.

Cindy Dingee, DVM., Veterinary Pathologist — Date: 11/15/07

Table 1: Histopathologic Evaluation
ISO Vaginal Irritation Test of Origami Silicone Condom – SVPD, Lot Number 94 and Normal Saline

	TEST ARTICLE			CONTROL		
ANIMAL #	**5001**	**5002**	**5003**	**5005**	**5008**	**5011**
Epithelium	0	0	0	0	0	0
Leukocytes	1	1	1	1	1	1
Vascular Congestion	1	3	1	1	1	1
Edema	2	0	2	1	2	2
Total	4	4	4	3	4	4
Group Mean*	4			4		

* The mean is rounded to nearest whole number. The values listed below are applied to develop a ranking score.

Epithelium		Leukocytes (per HPF)		Vascular Congestion		Edema	
Intact	0	Absent	0	Absent	0	Absent	0
Cell degeneration or flattening	1	Minimal (< 25)	1	Minimal	1	Minimal	1
Metaplasia	2	Mild (26-50)	2	Mild	2	Mild	2
Focal erosion	3	Moderate (51-100)	3	Moderate	3	Moderate	3
Generalized erosion	4	Marked (>100)	4	Marked	4	Marked	4

HPF = high power field

Interpretation: Average Test Article Score 4 (-) Average Control Score 4 = Irritant Rank* 0
*Negative values are treated as 0.

Conclusion: Under the conditions of this study and based upon the group means comparison above, the test article was considered:

X Nonirritant (0.0)
_____ Minimal Irritant (1-4)
_____ Mild Irritant (5-8)
_____ Moderate Irritant (9-11)
_____ Severe Irritant (12 - 16)

Table 1: Histopathologic Evaluation
ISO Vaginal Irritation Test of Origami Silicone Condom – SVPD, Lot Number 94 and Cottonseed Oil

	TEST ARTICLE			CONTROL		
ANIMAL #	**5006**	**5010[1]**	**5012**	**5013**	**5014**	**5015**
Epithelium	0	0	0	0	0	0
Leukocytes	1	1	2	1	1	1
Vascular Congestion	2	2	3	2	2	2
Edema	1	3	2	2	1	1
Total	4	6	7	5	4	4
Group Mean*	6			4		

* The mean is rounded to nearest whole number. The values listed below are applied to develop a ranking score.

Epithelium		Leukocytes (per HPF)		Vascular Congestion		Edema	
Intact	0	Absent	0	Absent	0	Absent	0
Cell degeneration or flattening	1	Minimal (< 25)	1	Minimal	1	Minimal	1
Metaplasia	2	Mild (26-50)	2	Mild	2	Mild	2
Focal erosion	3	Moderate (51-100)	3	Moderate	3	Moderate	3
Generalized erosion	4	Marked (>100)	4	Marked	4	Marked	4

HPF = high power field

Interpretation: Average Test Article Score 6 (-) Average Control Score 4 = Irritant Rank* 2
*Negative values are treated as 0.

Conclusion: Under the conditions of this study and based upon the group means comparison above, the test article was considered:

_____ Nonirritant (0.0)
X Minimal Irritant (1-4)
_____ Mild Irritant (5-8)
_____ Moderate Irritant (9-11)
_____ Severe Irritant (12 - 16)

Additional Notes or Comments:

1 – There was a small focus of cellular debris on the surface of the mucosa. The epithelium covering the mucosa was normal.

(For Laboratory Use Only)

AppTec Study # 63717

PROTOCOL TITLE: **ISO MUCOSAL (VAGINAL) IRRITATION TEST**

TEST CODE: **910790**

PERFORMING LABORATORY: AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

EFFECTIVE DATE: 7 June 2007

EXACT COPY
INITIALS: JB DATE: 11/15/07

GLP PROTOCOL: **910790K**

Carroll L. Arnett

Technical Management

Quality Assurance has reviewed this protocol for compliance with applicable regulatory requirements and internal procedures.

2540 Executive Drive • St. Paul, MN 55120 • 888.794.0077 • 651.675.2000 • Fax: 651.675.2005

ISO MUCOSAL (VAGINAL) IRRITATION TEST

1.0 PURPOSE

The Mucosal Irritation Test is designed to evaluate the irritation potential of a test article that is designated for use on human mucosal tissue.

2.0 TEST FACILITY:

AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

3.0 SCHEDULING AND DISCLAIMER OF WARRANTY

3.1 Test protocol initiation is generally within 10 working days after receipt of the test article and a signed AppTec Biocompatibility Test Request Form. The Client Approval Form and the test request form serve as addenda to this protocol. Written notification of the proposed initiation and completion dates will be provided at the time the test article and signed protocol and request form are received by the laboratory. The estimated testing time is 6 days. With the histopathology analysis, there will be an additional 3-5 weeks to complete the study. Verbal results will be available from the Study Director upon completion of the pathology with the written final study report to follow approximately 10 working days after completion of the study.

3.2 If a test, or a portion of it, must be repeated due to failure by AppTec to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls or failure to meet assay validity requirements, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test article and test system require modifications due to complexity and difficulty of testing.

3.3 If the Sponsor requests a repeat test, they will be charged for an additional test.

3.4 Neither the name of AppTec nor any of its employees are to be used in advertising or other promotion without written consent from AppTec.

3.5 The Sponsor is responsible for any rejection of the final report by the regulatory agency concerning report format, pagination, etc. To prevent rejection, the Sponsor should carefully review the AppTec final report and notify AppTec of any perceived deficiencies in these areas before submission of the report to the regulatory agency. AppTec will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

4.0 TEST ARTICLE CHARACTERIZATION

The Sponsor is responsible for all test and control article characterization data as specified in the Good Laboratory Practices (GLP) regulations. The identity, strength, stability, purity, and chemical composition of the test article is solely the responsibility of the Sponsor. The Sponsor is responsible for supplying to the testing laboratory results of these determinations and any others that may directly impact the testing performed by the testing laboratory, prior to initiation of testing. Furthermore, it is the responsibility of the Sponsor to ensure that the test article submitted for testing is representative of the final product that will be subjected to materials characterization. Any special requirements for handling or storage must be arranged in advance of receipt and the test article must be received in good condition.

5.0 JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM

The albino rabbit has been used historically for vaginal irritation studies. Due to the sensitivity of the vaginal epithelial cells and the ease of handling, the albino rabbit is the preferred test system. This animal species is recommended by the International Organization for Standardization (ISO) document 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Sensitization, Annex B.

6.0 PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM

6.1 Species/Strain: Albino rabbits (*Oryctolagus cuniculus*) / New Zealand White strain

6.2 Source: A certified commercial vendor will be used as the animal source.

6.3 Weight Range: Each rabbit used in the study will weigh a minimum of 2 kg.

6.4 Age: The rabbits will be young adults, but no particular age is required.

6.5 Number: A total of six (6) rabbits will be used per extract.

6.6 Sex: Only females can be used for the study; they will be nulliparous and not pregnant.

6.7 Animal Identification: Cage cards will be labeled and individual rabbits will be identified per AppTec SOP: ILS-0110, Animal Identification (current version).

6.8 IACUC Protocol / Approval Date
07-124A / May, 2007

6.9 Husbandry

6.9.1 Receipt And Acclimation
Receipt will be according to AppTec SOP: ILS-0092, Receiving Shipments of Animals (current version). The animals will be acclimated for a minimum of 5 days under the same conditions as the actual test.

6.9.2 Housing
One rabbit will be housed per cage. Housing dimensions will comply with NIH and AAALAC International guidelines for this species.

6.9.3 Environment
The environmental conditions in the animal rooms will be maintained according to AppTec SOP: ILS-0018, Environmental Conditions in the Animal Facility (current version). The temperature and photo-period will meet the AAALAC International and NIH recommendations for these species. The laboratory and animal rooms will be maintained as limited-access facilities.

6.9.4 Diet
Animals will be supplied with certified commercial rabbit feed. There are no known contaminants present in the feed expected to interfere with the test results.

6.9.5 Water

Potable water will be supplied from the St. Paul municipal water supply. There are no known contaminants present in the water expected to interfere with the test results.

6.9.6 USDA Animal Welfare Act

In order to satisfy the USDA Animal Welfare Act, the Sponsor agrees that this testing is required in order to satisfy a state or federal regulatory requirement or is scientifically necessary. Further, such testing is not an unnecessary duplication of a previous test submission by the Sponsor. In addition, the duration of test is determined by the cited test references and will not exceed the time limits contained therein. This procedure was reviewed and approved by AppTec's Institutional Animal Care and Use Committee (IACUC) in compliance with the Animal Welfare Act.

It has been determined that no sedation, analgesia, or anesthesia is necessary in this procedure. In the unlikely event that an animal should become injured, euthanasia, or veterinary care will be conducted according to AppTec SOP: ILS-0233, Proper Handling of Sick and Moribund Animals (current version) and current veterinary medical practices. The objectives of the study will be given full consideration prior to any decisions and the study Sponsor will be advised.

6.10 Testing is performed in strict adherence to AppTec Standard Operating Procedures (SOPs) which have been constructed to cover all aspects of the work including, but not limited to, receipt, identification, log-in and tracking of test article(s). Additionally, each test is assigned a unique Project Number. This number is used for identification during the course of the test.

7.0 EXPERIMENTAL DESIGN

The Vaginal Mucosal Irritation test is designed to evaluate the irritation potential of a test article that is designated for use on human mucosal tissue. The test article and negative control will be administered to the test animals, daily for five (5) consecutive days. The day after the final dose, the animals will be sacrificed and the vaginal tissue explanted. Representative transmural samples will be taken and processed and sectioned for microscopic evaluation. A numerical comparison of the test and control tissues will categorize the test article as indicated in the ISO 10993-10 guidelines.

8.0 TEST METHOD

8.1 Selection Of Animals

Animals selected for the study are from a larger pool of animals. They will be examined to insure that they meet the specified weight requirements and are not exhibiting abnormal clinical signs prior to test dosing. Each vulva will be scored according to Table 2. If any exudate is present, or there is a score greater than '1' for erythema or edema, the animal will not be used for testing. Animals selected for this study may have been used previously in accordance with AppTec SOP: ILS-0095, Animal Reuse (current version) [See Section 20.0]. Selected animals will be weighed to the nearest 0.1 kg and assigned to groups as indicated below.

GROUP ASSIGNMENT	
Test	(3 animals / test article or extract vehicle)
Vehicle Control	(3 animals / vehicle)

8.2 Test And Control Article Preparation

8.2.1 Solid Test Articles To Be Extracted

The Sponsor submitted test article will be prepared and extracted as indicated on the AppTec Biocompatibility Test Request Form attached to this protocol and according to AppTec SOP TRG-0300, Preparation of Biomaterials for Extraction and ALS-0260 Sample Extraction Procedures (current versions). Vehicle controls will be prepared and extracted concurrently with the test article for each phase of the test. The extractions will be stored at room temperature and used within 24 hours of preparation.

8.2.2 Liquid Test Articles

Liquid test articles will be tested neat unless otherwise indicated on the AppTec Biocompatibility Test Request Form attached to this protocol by the Sponsor. Controls will be specified on the Test Request Form.

8.2.3 Test Article To Be Intravaginally Inserted As A Solid Or Gel

The Sponsor submitted test article will be prepared / inserted as indicated on the AppTec Biocompatibility Test Request Form attached to this protocol. Controls will be similarly prepared / inserted, as appropriate.

8.3 Test And Control Article Administration

8.3.1 Preparation Of The Test Animals

Each animal will be weighed and its vulva evaluated according to Table 2 prior to the first dosing. The animals will be restrained during the dosing procedure.

8.3.2 Instillation Of The Test And Control Dose

Test solutions will be instilled into the vaginal vault of three (3) test rabbits with a blunt tipped cannula or a feeding syringe. The tip will be moistened with a small amount of sterile lubricant. The liquid dose for each test rabbit will be 1.0 mL, unless otherwise instructed by the Sponsor. Test materials that are inserted as an intravaginal implant will be placed approximately 1.5 to 2 inches into the vaginal vault unless otherwise instructed by the Sponsor. Three (3) control animals will be similarly dosed with 1.0 mL of the appropriate control vehicle. Each animal will be dosed daily for five consecutive days. Implants may be removed daily after 1 hour exposure, as appropriate. An external assessment of irritation will be made prior to each dose. A general overview of the test is listed in Table 1. Dosing will be performed daily at approximately 24 ± 2 hour intervals.

TABLE 1: OVERVIEW OF THE TEST DESIGN

DAY	ACTIVITY
0	Conduct initial observation / Weigh animals; Dose animals with 1 mL (test / control)
1	Conduct initial observation / Dose animals with 1 mL (test / control)
2	Conduct initial observation / Dose animals with 1 mL (test / control)
3	Conduct initial observation / Dose animals with 1 mL (test / control)
4	Conduct initial observation / Dose animals with 1 mL (test / control)
5	Conduct observation / Sacrifice Animals / Remove vaginal tissue Send to Histology Lab.

8.4 Termination

On Day 5, approximately 24 ± 2 hours after the fifth dose, after the final observation period, the animals will be observed and humanely euthanized by lethal injection of a pentobarbital based solution.

8.5 Observations

8.5.1 Clinical Observations

a. Daily health observations will be recorded throughout the study period.

b. Prior to the first dose and each daily dose, the external vaginal tissue of each animal will be observed for erythema, exudate and edema according to the scoring system in Table 2. Animals who score greater than '1' may require consultation with the facility veterinarian prior to dosing. Rabbits are induced ovulators and stimulation from dosing can induce ovulation. Also, external changes in vulva characteristics can be indicative of estrus stages.

8.5.2 Tissue Observations

a. After termination, the vaginal tissue will be carefully removed and a suture tied at the cranial end. The vagina will be opened longitudinally exposing the mucosal surface.

b. The vaginal mucosa will be observed grossly for signs of general irritation and injury. These observations will be recorded on the worksheet in narrative form for the benefit of the evaluating pathologist.

c. Each vagina will be placed in 10% neutral buffered formalin and allowed to fix.

d. A pathologist, using the scoring and classification system established for mucosal irritation within ISO 10993-10:2002 (see Table 3), will evaluate the irritant effects of the test article on the vaginal tissue.

TABLE 2: DAILY EXTERNAL EVALUATION OF VAGINAL IRRITATION

OBSERVATIONS	NUMERICAL GRADING
ERYTHEMA	
No Redness	0
Slight Redness	1
Redness with Distinct blood vessels	2
Deep redness accompanied with numerous engorged blood vessels	3
EXUDATE	
No pus	0
Few small globules of pus	1
Large globules of pus	2
Large amounts of pus and or sloughed tissue exuding from the vulva	3
EDEMA	
No swelling of the vulva	0
Slight swelling of the vulva to less than twice its size	1
Swelling of the vulva to twice its size	2
Swelling of the vulva to greater than twice its size	3

TABLE 3 - MICROSCOPIC CLASSIFICATION SYSTEM FOR A VAGINAL TISSUE REACTION

REACTION	NUMERICAL GRADING
EPITHELIUM	
Normal, intact	0
Cell degeneration or flatting	1
Metaplasia	2
Focal erosion	3
Generalized erosion	4
LEUKOCYTE INFILTRATION (PER HIGH POWER FIELD)	
Absent	0
Minimal – less than 25	1
Mild – 26 to 50	2
Moderate – 51 to 100	3
Marked – greater than 100	4
VASCULAR CONGESTION	
Absent	0
Minimal	1
Mild	2
Moderate	3
Marked, with disruption of vessels	4
EDEMA	
Absent	0
Minimal	1
Mild	2
Moderate	3
Marked, with disruption of vessels	4

IRRITATION INDEX	
Average Score	**Adjectival description**
0	None
1 to 4	Minimal
5 to 8	Mild
9 to 11	Moderate
12 to 16	Severe

9.0 METHOD FOR CONTROL OF BIAS: Not applicable.

10.0 DATA ANALYSIS: For each animal, the scores obtained from daily clinical observations of erythema, exudate, and edema at each time point following dosing are added together and divided by the total number of observations (15) to obtain that animal's Irritation Score. The Irritation Scores of all animals in each test and control group will be added together and divided by the number of animals in each group to obtain the Cumulative Irritation Index. These observations may assist in the pathology evaluation.

11.0 STATISTICAL METHODS: None used.

12.0 ASSAY VALIDITY

The final interpretation of the results will be based heavily on the assessment by the study pathologist. The daily observations and explant observations are conducted as an aid to the final assessment.

A total score greater than '9' for the microscopic evaluation of a control animal may indicate trauma at dosing and may require a retest if other test or control animals have similar high scores.

13.0 TEST EVALUATION

13.1 Macroscopic Evaluation

The macroscopic (gross) changes of the vaginal tissue mucosal surfaces will be recorded and described comparing the test and the control animals.

13.2 Histologic Evaluation

The microscopic evaluation scores for all the animals in the test group will be added and divided by the total number of observations to obtain a test group average. The microscopic evaluation scores for all the animals in the control group will be added and divided by the total number of observations to obtain a control group average. The maximum average score is 16.

The microscopic control group average will be subtracted from the test group average to obtain the Irritation Index. The irritation will be classified according to the Irritation Index listed in Table 3.

13.3 Repeat Assays

A test will be repeated in part or in total if a control failure occurs.

14.0 PROTOCOL CHANGES

If it becomes necessary to make changes in the approved protocol, the revisions and reasons for changes will be documented, signed by the Study Director, dated, maintained with the protocol and reported to the Sponsor. If an event occurs which may have an effect on the validity of the study, the Sponsor will be notified as soon as is practical. If the Study Director is unable to complete the study, an alternate Study Director with full responsibility and authority regarding the study will be assigned.

15.0 FINAL REPORT

The final report will include but will not be limited to: the date of the study initiation and completion, the purpose as stated in the approved protocol, changes in the approved protocol, identification of the test system and a description of the test material, a description of the methods used in preparing the test material, the test animal, the macroscopic observations, and histologic evaluation. The study conclusions will be based on an overall assessment of the study results.

16.0 RECORD RETENTION

16.1 Study Specific Documents

All of the original raw data developed exclusively for this study shall be retained according to AppTec Laboratory Services' standard operating procedures for archival. These original data include, but are not limited to the following:

16.1.1 All handwritten and equipment generated raw data for control(s) and test article(s).
16.1.2 Any protocol amendments/deviation notifications.
16.1.3 Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
16.1.4 Original signed protocol.
16.1.5 Certified copy of final study report.
16.1.6 Study-specific SOP deviations made during the study.
16.1.7 Animal health records and daily clinical observations.

16.2 Facility Specific Documents

The following records shall also be retained according to AppTec Laboratory Services' standard operating procedures for archival. These documents include, but are not limited to, the following:

16.2.1 SOPs which pertain to the study conducted.
16.2.2 Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.
16.2.3 Methods which were used or referenced in the study conducted.
16.2.4 If conducted under GLP compliance, QA reports for each QA inspection with comments.
16.2.5 Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
16.2.6 Current job descriptions and summary of experience and training for all personnel involved in the study.
16.2.7 Records of analysis of food and water.

17.0 REFERENCES

17.1 Eckstein, P., Jackson, H.C.N., Millman, N., and Sabrero, A.J., (1969), "Comparisons of Vaginal Tolerance Tests of Spermicidal Preparations in Rabbits and Monkeys," *Journal of Reproduction and Fertility*, Volume 20, pp. 85 – 93.

17.2 Holzapfel, W., Buxton, H., (1958), "Sensitivity to Vaginal Jellies," *Journal of the American Pharmaceutical Association*, XLVII, pp. 423 - 426.

17.3 ISO 10993-10: 2002 Standard, "Biological Evaluation of Medical Devices, Part 10-Tests for Irritation and Sensitization", Annex B, pp. 38-40.

17.4 Kaminsky, M.; Willigan, D.A.; (1982), "pH and the Potential Irritancy of Douche Formulations to the Vaginal Mucosa of the Albino Rabbit and Rat," *Food and Chemical Toxicology*, Volume 20, pp. 193-196.

18.0 COMPLIANCE

18.1 Animal Husbandry

AAALAC International and NIH guidelines as reported in the "Guide for the Care and Use of Laboratory Animals", National Research Council - ILAR, Revised 1996; (OPRR), "Public Health Service Policy on Humane Care and Use of Laboratory Animals", Health Research Extension Act of 1985 (Public Law 99-158), Revised 1986; USDA, Department of Agriculture, Animal and Plant Health Inspection Service, 9 CFR, Parts 1, 2 and 3, Animal Welfare, Final Rule 1989.

18.2 GLP Status

If the Sponsor chooses to conduct the study under GLP compliance (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies), the study will be inspected during at least one phase and the final report will be audited by the AppTec Quality Assurance Unit.

19.0 TEST ARTICLE IDENTIFICATION

Test article information to be included in the final report will be provided solely by the Sponsor on the AppTec Test Request Form attached to this protocol.

20.0 ANIMAL SELECTION / REUSE

☐ Previously used rabbits (e.g., pyrogen test or blood donor) may be selected for this study.
☐ Naive animals only will be used for this study.

21.0 TEST ARTICLE DISPOSITION

It is the responsibility of the Sponsor to retain a sample of the test material. All unused test material will be discarded following study completion unless otherwise requested by Sponsor.

NELSON
LABORATORIES

04 Oct 2007

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd., No. 318
Beverly Hills, CA 90211

Dear Daniel,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

NELSON NUMBER: 390321

TESTING LAB: AppTec Laboratory Services

TYPE OF TEST: Murine Local Lymph Node Assay (LLNA)

SAMPLE IDENTIFICATION:
Origami Silicone Condom –SVPD, Lot# 94

If you have any questions, please feel free to call any of our Subcontracting personnel at 801-963-2600 or 800-826-2088. Thank you for testing with Nelson Laboratories, Inc.

Jennifer Shaw

Jennifer Shaw, B.S.
Subcontracting Coordinator

04 Oct 2007
Sign Date

Nelson Laboratories Incorporated
P. O. Box 17557, Salt Lake City, UT 84117-0557 • 6280 South Redwood Road, Salt Lake City, UT 84123-6600
Telephone: 801-963-2600 • Fax: 801-963-2630 • Operator: 800-826-2088 • Auto Attendant: 800-963-6280 or 801-963-5299
Web site: www.nelsonlabs.com • e-mail: info@nelsonlabs.com

St. Paul

Report

NON-GLP
FINAL STUDY REPORT

STUDY TITLE

MURINE LOCAL LYMPH NODE ASSAY (LLNA)

TEST ARTICLE IDENTIFICATION

Origami Silicone Condom - SVPD
Lot # 94

STUDY COMPLETION DATE

October 3, 2007

PERFORMING LABORATORY

AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

SPONSOR

Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123

PROJECT NUMBER

63716

NLI#:

390321

Reference PO # APP-2007

NEL05

63716

jshaw@nelsonlabs.com

MURINE LOCAL LYMPH NODE ASSAY (LLNA) TEST RESULTS

Test Article Name:	Origami Silicone Condom - SVPD
Lot/Batch #:	94
NLI#:	390321
Stability:	Not Applicable
Sterilization Method:	Non-sterile
Storage Conditions:	Room Temperature
Safety Precautions:	Standard Precautions

Date Sample Received:	08/22/07
Study Completion Date:	10/03/07

PURPOSE: The intent of this procedure is to assess the dermal sensitization potential of a test article using the Murine Local Lymph Node Assay (LLNA).

EXPERIMENTAL METHODS SUMMARY: This study was designed to evaluate the skin sensitization potential of a test article by administering an extract of the test article to the skin of mice and measuring the proliferation of cells in lymph nodes draining the exposure site. The test article extract, vehicle control solution, or a known sensitizer, either 2,4-dinitrobenzenesulfonic acid (DNBS) or 2,4-dinitrochlorobenzene (DNCB) was applied to the dorsal surface of the ears of mice daily for three days. On Day 5 following initiation of treatment, the animals were administered [*methyl*-^{3}H]-thymidine ([^{3}H]TdR) by tail vein injection. Five hours later the mice were sacrificed, and the radioactivity incorporation into lymphocytes was determined as a measure of cell proliferation.

TABLE 1-TIME COURSE OF ASSAY

DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6
T	T	T	-	-	^{3}H	C

T = Topical application of test substance/vehicle.
- = No treatment
^{3}H = 0 hrs – Administration of approximately 20 µCi of [^{3}H]TdR.
+ 5 hrs – Sacrifice and harvest, lymph node cell preparation.
C = Determination of [^{3}H]TdR incorporation into lymph node cells.

DEVIATIONS/AMENDMENTS: None.

TEST SAMPLE PREPARATION: A representative sample of the test article was cut into pieces, placed into test tubes and prepared at a ratio of 60 cm^2 to 20 mL of extraction vehicle. The test article consisted of clear rubber. The test article was extracted in Normal Saline (NS) and dimethyl sulfoxide (DMSO) at 37 ± 1 °C with agitation for 72 ± 2 hours.

EXTRACT VEHICLE	VEHICLE AMOUNT	TEST ARTICLE AREA
Dose 1 - 0.9% Normal Saline (NS)	39.6 mL	118.8 cm^2
Dose 2 - 0.9% Normal Saline (NS)	39.6 mL	118.8 cm^2
Dose 3 - 0.9% Normal Saline (NS)	39.6 mL	118.8 cm^2

EXTRACT VEHICLE	VEHICLE AMOUNT	TEST ARTICLE AMOUNT
Dose 1 - Dimethyl sulfoxide (DMSO)	39.6 mL	118.8 cm^2
Dose 2 - Dimethyl sulfoxide (DMSO)	39.6 mL	118.8 cm^2
Dose 3 - Dimethyl sulfoxide (DMSO)	39.6 mL	118.8 cm^2

VEHICLE MATERIALS:	LOT #:	SUPPLIED BY:
0.9% Normal Saline (NS)	53-153-JT	Hospira
Dimethyl sulfoxide (DMSO)	10085CH	Sigma-Aldrich

The test article extracts were cooled, shaken well, and decanted into sterile, dry, glass vessels. Saline extracts and saline controls were mixed with the detergent Pluronic L-92 to facilitate dose delivery. The extracts were used within 24 hours of preparation

TABLE 2-ANIMAL NUMBERS AND TREATMENT GROUPS

AQUEOUS DOSE GROUP	CAGE NUMBER	# DOSED	ANIMAL ID NUMBERS
Negative Control	1	5	1 - 5
Positive Control (20% DNBS)	2	5	11 - 15
Test Article	3	5	21 - 25

NON-AQUEOUS DOSE GROUP	CAGE NUMBER	# DOSED	ANIMAL ID NUMBERS
Negative Control	4	5	1 - 5
Positive Control (0.5% DNCB)	5	5	11 - 15
Test Article	6	5	21 - 25

HEALTH OBSERVATIONS

Each animal was observed daily for general health and clinical signs of toxicity according to AppTec SOP ILS-0134, Survival Check (current version). Animal weights were recorded on Days 0 and 5 (Table 3). Attention was paid to the ears for gross evidence of irritation (inflammation).

TABLE 3 - MEAN BODY WEIGHT (g) AND BODY WEIGHT CHANGE (g)

DOSE GROUP	AQUEOUS		
	DAY 0	DAY 5	CHANGE
Negative Control	21.2	22.7	1.5
Positive Control (20% DNBS)	22.4	23.8	1.4
Test Article	21.6	22.6	1.0
DOSE GROUP	**NON-AQUEOUS**		
	DAY 0	DAY 5	CHANGE
Negative Control	21.5	22.7	1.2
Positive Control (0.5% DNCB)	20.3	21.3	1.0
Test Article	22.7	24.0	1.3

ASSESSMENT OF CELL PROLIFERATION

On the fifth day following initiation of dosing with test or control article each animal was injected with approximately 20 µCi of [^{3}H]TdR via tail vein. This radioisotope is rapidly incorporated into mitotically active cells (dividing lymphocytes). The isotope injection is a critical phase and intravenous delivery was monitored by the inclusion of 0.1% Evans Blue dye. The auricular lymph nodes were then dissected bilaterally, isolated lymph node cells prepared, and radioactivity incorporation measured. The lymph nodes from each mouse were pooled but individual animal data were collected and remained separate from the other animals on test. The Stimulation Index (SI) was calculated by dividing the average radioactivity of the test article group by the average radioactivity of the control group.

ASSAY VALIDITY

The assay is considered valid if the Stimulation Index for the positive control was greater than 3.0 and there was good delivery of radioisotope to all animals counted. Insufficient delivery of isotope may necessitate exclusion of that animal as invalid. Sound scientific judgment was applied to all data for final conclusions.

TEST EVALUATION

Positive Response

The test article may be considered a potential skin sensitizer if its Stimulation Index is greater than or equal to 3.0. Values at or very near 3.0 (3.01-3.30) may justify additional dose response testing to

verify results. Overall evaluation encompassed the SI, statistical analysis, toxicity, vehicle consistency, and the controls.

Equivocal Response
Any equivocal response was clarified by considering statistical analyses, structural relationships, available toxicity information, and dose selection and may necessitate additional testing to confirm.

RESULTS

General Animal Health
All of the animals on study were in good health and most gained weight over the course of the study (Table 3).

TABLE 4-RADIOISOTOPE UPTAKE AND STIMULATION INDEX –AQUEOUS (NS)

TREATMENT & ANIMAL ID	[^{3}H]-THYMIDINE UPTAKE (DPM)	MEAN DPM (± σ)	STIMULATION INDEX
Negative Control; 1	55.9	113.9 ± 45.6	1.00
Negative Control; 2	78.6		
Negative Control; 3	144.4		
Negative Control; 4	165.4		
Negative Control; 5	125.2		
Positive Control; 11	774.9	639.5 ± 274.9	5.61
Positive Control; 12	509.7		
Positive Control; 13	888.3		
Positive Control; 14	218.3		
Positive Control; 15	806.1		
Test Article Extract; 21	119.7	91.1 ± 30.0	0.80
Test Article Extract; 22	68.4		
Test Article Extract; 23	127.9		
Test Article Extract; 24	68.1		
Test Article Extract; 25	71.6		

TABLE 5-RADIOISOTOPE UPTAKE AND STIMULATION INDEX – NON-AQUEOUS (DMSO)

TREATMENT & ANIMAL ID	[^{3}H]-THYMIDINE UPTAKE (DPM)	MEAN DPM (± σ)	STIMULATION INDEX
Negative Control; 1	165.0	258.5 ± 172.4	1.00
Negative Control; 2	58.9		
Negative Control; 3	300.5		
Negative Control; 4	247.7		
Negative Control; 5	520.2		
Positive Control; 11	7,801.4	5,914.4 ± 1,757.5	22.88
Positive Control; 12	6,469.4		
Positive Control; 13	3,779.9		
Positive Control; 14	7,154.2		
Positive Control; 15	4,367.3		
Test Article Extract; 21	189.5	185.5 ± 62.3	0.72
Test Article Extract; 22	128.2		
Test Article Extract; 23	287.8		
Test Article Extract; 24	144.6		
Test Article Extract; 25	177.3		

Lymph Node Response
The Stimulation Index for the positive controls were 5.61 and 22.88 respectively for the aqueous NS extract and non-aqueous DMSO extract (Tables 4 and 5).

ANALYSIS AND CONCLUSION
The Normal Saline (NS) test article extract gave a stimulation index of 0.80 (Table 4). The Dimethyl sulfoxide (DMSO) test article extract gave a stimulation index of 0.72 (Table 5). Statistical comparison by analysis of variance (ANOVA) shows no significant difference between the test extracts and the negative controls ($p = 0.378$, for NS; $p = 0.399$ for DMSO). Based on these findings the test article was not a potential sensitizer. This indicates that the requirements of the Murine Local Lymph Node Assay have been met by Nelson Laboratories, Inc. Origami Silicone Condom - SVPD, Lot # 94. The test article is considered negative for evidence of dermal sensitization.

Approval: Carroll D. Arnett Date: 10-3-07
Carroll D. Arnett, Ph. D. Study Director

TECHNICAL REFERENCES
American Society for Testing and Materials (ASTM) Designation: F619-03. "Standard Practice for Extraction of Medical Plastics" (2003).

American Society for Testing and Materials (ASTM) Designation: F2148-07. "Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)" (2007).

Dearman, Rebecca J.; Wright, Zoë M.; Basketter, David A.; Ryan, Cindy A.; Gerberick, G. Frank; and Kimber, Ian. "The Suitability of Hexyl Cinnamic Aldehyde as a Calibrant for the Murine Local Lymph Node Assay," Contact Dermatitis 44: pp. 357-361 (2001).

Gerberick, G. Frank; Ryan, Cindy A.; Kimber, Ian; Dearman, Rebecca J.; Lea, Linda J.; and Basketter, David A.. "Local Lymph Node Assay: Validation Assessment for Regulatory Purposes," American Journal of Contact Dermatitis 11: pp. 3-18 (2000).

ICCVAM Immunotoxicology Working Group Recommended Protocol for the Murine Local Lymph Node Assay (LLNA): Testing of Chemicals for Contact Sensitizing (Allergic Contact Dermatitis [ACD]) Potential, January 2001.

Ryan, C. A., Cruse, L. W.; Skinner, R. A.; Dearman, R. J.; Kimber, I.; and Gerberick, G.F. "Examination of a Vehicle for Use with Water Soluble Materials in the Murine Local Lymph Node Assay," Food and Chemical Toxicology 40: pp. 1719-1725 (2002).

United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Health Effects Test Guidelines. "OPPTS 870.2600 Skin Sensitization" (2003).

Organisation for Economic Co-operation and Development, OECD Guidelines for Testing Chemicals, Guideline 429: Skin Sensitisation: Local Lymph Node Assay, adopted April 24, 2002.

NELSON LABORATORIES

12 Oct 2007

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Dear Daniel,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

NELSON NUMBER: 391906

TESTING LAB: AppTec Laboratory Services

TYPE OF TEST: Materials Mediated Rabbit Pyrogen Test

SAMPLE IDENTIFICATION:
Origami Silicone Condom – SVPD Lot #94

If you have any questions, please feel free to call any of our Subcontracting personnel at 801-963-2600 or 800-826-2088. Thank you for testing with Nelson Laboratories, Inc.

for

Jennifer Shaw, B.S.
Subcontracting Coordinator

12 OCT 2007
Sign Date

Nelson Laboratories Incorporated
P. O. Box 17557, Salt Lake City, UT 84117-0557 • 6280 South Redwood Road, Salt Lake City, UT 84123-6600
Telephone: 801-963-2600 • Fax: 801-963-2630 • Operator: 800-826-2088 • Auto Attendant: 800-963-6280 or 801-963-5299

St. Paul

Report

NON-GLP
FINAL STUDY REPORT

STUDY TITLE

MATERIALS MEDIATED RABBIT PYROGEN TEST

TEST ARTICLE IDENTIFICATION

Origami Silicone Condom - SVPD
Lot # 94

STUDY COMPLETION DATE

October 10, 2007

PERFORMING LABORATORY

AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

SPONSOR

Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123

PROJECT NUMBER

64426

NLI#

391906

Reference PO # APP-2007

NEL05

64426

jshaw@nelsonlabs.com

MATERIALS MEDIATED RABBIT PYROGEN TEST RESULTS

Test Article Name:	Origami Silicone Condom - SVPD
Lot/Batch #:	94
NLI#:	391906
Stability:	Not Applicable
Sterilization Method:	Dry Heat: 400°F for 4 hours
Storage Conditions:	Room Temperature
Safety Precautions:	Standard Precautions

Date Sample Received:	09/04/07
Study Completion Date:	10/10/07

PURPOSE: This test was used to evaluate the test article for the presence of materials mediated pyrogens.

TEST SAMPLE PREPARATION: A representative sample of the test article was cut into pieces, placed into a depyrogenated Erlenmeyer Flask to produce a testing ratio of 60 cm^2 to 20 mL of extraction vehicle. The test article consisted of silicone condom.

Extraction: The sample preparation was extracted for 72 ± 2 hours at 37 ± 1 °C. The extract was cooled, shaken well and decanted into a depyrogenated (dry heat sterilized) glass vessel. The test article extract had small hair like particles throughout. The extract was used within 24 hours of preparation.

EXPERIMENTAL METHODS SUMMARY: The test article extract was injected into the marginal ear vein of three (3) New Zealand White rabbits *(Oryctolagus cuniculus)* at a dose ratio of 10.0 mL extraction to 1.0 kg body weight. Rectal temperatures were recorded for each animal prior to injection and at 30-minute intervals between 1 and 3 hours after injection. The test article was considered non-pyrogenic if none of the animals show an individual temperature increase of 0.5°C or more at any reading period above its respective baseline temperature.

RESULTS:

ANIMAL #	4485	4475	4472
Weight (kg)	2.9	3.4	3.2
Dose (ml)	29	34	32
BASELINE TEMP (°C)	**39.8**	**39.8**	**39.8**
1.0 hr Temp (°C)	39.8	39.7	39.7
1.5 hr Temp (°C)	39.9	39.7	39.6
2.0 hr Temp (°C)	39.8	39.7	39.7
2.5 hr Temp (°C)	39.8	39.7	39.7
3.0 hr Temp (°C)	39.7	39.7	39.7
MAX TEMP RISE (°C)	**0.1**	**0.0**[a]	**0.0**[a]

[a] Negative values were reported as zero (0)

CONCLUSION: TEST ARTICLE IS NON-PYROGENIC.

Bich Nguyen, BS – Study Director Date: 10/10/07

TECHNICAL REFERENCES:

ISO 10993-11: 2006 American National Standard adopted from ISO Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity.

ISO 10993-12: 1996 Standard, Biological Evaluation of Medical Devices, Part 12-Sample Preparation and Reference Materials.

United States Pharmacopeia, USP 30: 2007, Section 151 Pyrogen Test, p. 135-136.

NELSON LABORATORIES, INC.
TEST SAMPLE SUBCONTRACTING
ARCHIVE RELEASE FORM

LAB NUMBER: 391906 SPONSOR: Strata Vanas Product Design

[X] SUBCONTRACTOR APPROVAL FORM
[X] SUBCONTRACTOR ACKNOWLEDGMENT/DOCUMENTATION
[ ] COPY OF PROTOCOL (OPTIONAL) [X] N/A
[X] COPY OF FINAL REPORT
[X] APPROPRIATE SIGNATURES ON ALL DOCUMENTS

I HAVE REVIEWED THIS DATA FILE

REVIEWED BY: : DATE: 12 Oct 2007

SOP/QAU/046J.1-5/122005

NELSON
LABORATORIES

02 Oct 2007

Daniel Resnic
Strata Various Product Design
311 N Robertson Blvd. #318
Beverly Hills, CA 90211

Dear Daniel,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

NELSON NUMBER: 391905

TESTING LAB: AppTec Laboratory Services

TYPE OF TEST: ISO Acute Systemic Injection Test

SAMPLE IDENTIFICATION:
Origami Silicone Condom – SVPD Lot #94

If you have any questions, please feel free to call any of our Subcontracting personnel at 801-963-2600 or 800-826-2088. Thank you for testing with Nelson Laboratories, Inc.

Jennifer Shaw

Jennifer Shaw, B.S.
Subcontracting Coordinator

02 Oct 2007
Sign Date

Nelson Laboratories Incorporated
P. O. Box 17557, Salt Lake City, UT 84117-0557 • 6280 South Redwood Road, Salt Lake City, UT 84123-6600
Telephone: 801-963-2600 • Fax: 801-963-2630 • Operator: 800-826-2088 • Auto Attendant: 800-963-6280 or 801-963-5299
Web site: www.nelsonlabs.com • e-mail: info@nelsonlabs.com

St. Paul

Report

NON-GLP
FINAL STUDY REPORT

STUDY TITLE

ISO ACUTE SYSTEMIC INJECTION TEST

TEST ARTICLE IDENTIFICATION

Origami Silicone Condom - SVPD
Lot # 94

STUDY COMPLETION DATE

October 1, 2007

PERFORMING LABORATORY

AppTec Laboratory Services
2540 Executive Drive
St. Paul, MN 55120

SPONSOR

Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123

PROJECT NUMBER

64427

NLI#

391905

Reference PO # APP-2007

NEL05

64427

jshaw@nelsonlabs.com

ISO ACUTE SYSTEMIC INJECTION TEST RESULTS

Test Article Name:	Origami Silicone Condom - SVPD
Lot/Batch #:	94
NLI#:	391905
Stability:	Not Given
Sterilization Method:	Dry Heat: 400° F for 4 hours
Storage Conditions:	Room Temperature
Safety Precautions:	Standard Precautions
Extraction Conditions:	72 ± 2 hours at 37 ± 1°C

Date Sample Received:	09/04/07
Study Completion Date:	10/01/07

PURPOSE: The purpose of this test was to screen test article extracts for potential toxic effects as a result of a single-dose systemic injection in mice.

TEST SAMPLE PREPARATION: A representative sample of the test article was cut into pieces, placed into test tubes and prepared at a ratio of 60cm^2 to 20 mL of extraction vehicle. The test article was extracted for 72 ± 2 hours at 37 ± 1°C. The test article consisted of clear silicone / rubber.

EXPERIMENTAL METHODS SUMMARY: Groups of five (5) Albino Swiss Mice (*Mus musculus*) were injected systemically with extracts of the test article or control vehicle at a dose rate of 50 mL extract to one kg body weight. The animals were observed for signs of toxicity immediately after injection and at 4 ± 0.75, 24 ± 2, 48 ± 2 and 72 ± 2 hours post-injection. The body weights were recorded prior to dosing, and at 24 ± 2, 48 ± 2 and 72 ± 2 hours post-injection. According to ISO Guidelines, the test is considered negative if none of the animals injected with the test article extract show a significantly greater biological reaction than the animals treated with the control vehicle extract. A significant biological reaction is interpreted as death in two or more mice or other toxic signs such as convulsions, prostration, or body weight loss greater than 10 % in three or more mice.

RESULTS:

DATA TABLE A: MORTALITY, CLINICAL SIGNS AND WEIGHT LOSS INCIDENCE

EXTRACT	FATALITIES		TOXICITY CLINICAL SIGNS		ANIMALS WITH >10% BODY WEIGHT LOSS	
	TEST	CONTROL	TEST	CONTROL	TEST	CONTROL
NS	0/5	0/5	0/5	0/5	0/5	0/5
CSO	0/5	0/5	0/5	0/5	0/5	0/5

STATISTICAL METHODS: Descriptive Statistics are presented in Data Table B.

CONCLUSION: TEST ARTICLE PASSES THE TEST.

Approval: Spencer Kubo, BS – Study Director Date: 10/1/07

TECHNICAL REFERENCES:

ISO 10993-11: 2006 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity

ISO 10993-12: 2002 Standard, Biological Evaluation of Medical Devices, Part 12-Sample Preparation and Reference Materials.

United States Pharmacopeia USP 30 (2007), Section 88, Biological Reactivity Test, *In Vivo*, Systemic Injection Test, page 116-117.

DATA TABLE B: ANIMAL WEIGHTS (g) AND STANDARD DEVIATION CALCULATIONS

Group	Animal #	Initial	24 Hrs	48 Hrs	72 Hrs	BW Change
Test NS	1	19.9	19.3	19.2	19.1	-0.8
	2	20.5	20.8	20.3	20.3	-0.2
	3	18.7	18.2	18.5	18.6	-0.1
	4	17.2	17.4	17.9	17.8	0.6
	5	18.9	17.8	18.0	18.1	-0.8
	Average Body Weight	**19.0**	**18.7**	**18.8**	**18.8**	**-0.3**
	Standard Deviation	**1.3**	**1.4**	**1.0**	**1.0**	**0.6**

Group	Animal #	Initial	24 Hrs	48 Hrs	72 Hrs	BW Change
Control NS	21	18.9	18.4	19.0	20.4	1.5
	22	17.1	17.0	17.7	18.9	1.8
	23	19.6	19.0	19.4	20.1	0.5
	24	17.7	17.3	17.9	18.7	1.0
	25	17.5	17.5	17.7	18.1	0.6
	Average Body Weight	**18.2**	**17.8**	**18.3**	**19.2**	**1.1**
	Standard Deviation	**1.0**	**0.8**	**0.8**	**1.0**	**0.6**

Group	Animal #	Initial	24 Hrs	48 Hrs	72 Hrs	BW Change
Test CSO	11	21.3	21.1	21.7	22.2	0.9
	12	19.2	19.3	18.9	19.5	0.3
	13	18.3	18.4	18.9	19.4	1.1
	14	19.1	19.0	19.4	19.6	0.5
	15	19.2	19.2	19.3	20.3	1.1
	Average Body Weight	**19.4**	**19.4**	**19.6**	**20.2**	**0.8**
	Standard Deviation	**1.1**	**1.0**	**1.2**	**1.2**	**0.4**

Group	Animal #	Initial	24 Hrs	48 Hrs	72 Hrs	BW Change
Control CSO	31	18.6	18.7	19.3	19.8	1.2
	32	19.3	19.1	19.5	20.0	0.7
	33	17.7	17.6	17.7	18.7	1.0
	34	17.7	17.5	17.6	18.4	0.7
	35	20.5	20.9	20.4	20.4	-0.1
	Average Body Weight	**18.8**	**18.8**	**18.9**	**19.5**	**0.7**
	Standard Deviation	**1.2**	**1.4**	**1.2**	**0.9**	**0.5**

NELSON LABORATORIES

Prepared For:
Dan Resnic
Strata Various Product Design
311 N. Robertson Blvd. #318
Beverly Hills, CA 90211

Submitted By:
Nelson Laboratories, Inc.
6280 S. Redwood Rd.
Salt Lake City, UT 84123-6600
801-290-7500

TEAR RESISTANCE OF PLASTICS AND FABRICS – FINAL REPORT

Laboratory Number:	391162
Procedure Number:	STP0067 REV 03
Standard Method:	ASTM D1004
Sample Source:	Strata Various Product Design
Sample Identification:	ORIGAMI SILICONE CONDOM-SVPD Lot #94 P.O. #SVPD-080207-002
Deviations:	Yes; refer to Table 1.
Statement of Uncertainty:	If applicable, available upon request
Method:	Die-cut
Sample Received Date:	23 Aug 2007
Lab Phase Start Date:	10 Sep 2007
Lab Phase Completion Date:	16 Oct 2007
Report Issue Date:	17 Oct 2007

RESULTS:

The results for tear resistance plastics are included in Tables 1-2.

Jennifer Gygi, B.S. SM(NRM)
Study Director

19 OCT 2007
Study Completion Date

lz/ad

NELSON LABORATORIES

TABLE 1. Results
ORIGAMI SILICONE CONDOM-SVPD

SPECIMEN NUMBER	MAXIMUM LOAD (lbf.)	MAXIMUM EXTENSION (in.)	AVERAGE THICKNESS (mm)
1	0.953	6.20	0.400
2	1.548	7.00	0.618
3	1.347	6.67	0.550
4	1.953	7.33	0.673
5	1.485	6.79	0.600
6	1.434	6.48	0.650
7	1.621	5.65	0.595
8	1.279	6.42	0.490
9	1.516	6.34	0.585
10	1.887	7.43	0.733
11	1.524	6.47	0.642
12	1.680	8.13	0.625
13	1.460	6.35	0.593
Mean	1.515	6.71	0.596
Standard Deviation	0.25	0.64	0.08

Note: The samples showed irregular thickness which exceeded the requirements as outlined in the standard which is a deviation from the standard test protocol (STP).

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TABLE 2. Results
Trojan Latex Condom

SPECIMEN NUMBER	MAXIMUM LOAD (lbf.)	MAXIMUM EXTENSION (in.)	AVERAGE THICKNESS (mm)
1	1.698	14.80	0.108

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FINAL REPORT

CONDOM BARRIER EVALUATION STUDY

PROTOCOL NO. 200702249 REV 01

LABORATORY NO. 391160

PREPARED FOR:

DAN RESNIC
STRATA VARIOUS PRODUCT DESIGN
311 N. ROBERTSON BLVD. #318
BEVERLY HILLS, CA 90211

SUBMITTED BY:

NELSON LABORATORIES, INC.
6280 S. REDWOOD RD.
SALT LAKE CITY, UT 84123-6600
801-290-7500

NELSON LABORATORIES

CONDOM BARRIER EVALUATION STUDY

LABORATORY NUMBER:	391160
PROTOCOL NUMBER:	200702249 REV 01
SAMPLE SOURCE:	STRATA VARIOUS PRODUCT DESIGN
SAMPLE IDENTIFICATION:	Refer to Table 2 P.O. #SVPD-080207-001
DEVIATIONS:	None
PROTOCOL APPROVAL DATE:	30 Aug 2007
SAMPLE RECEIVED DATE:	23 Aug 2007
LAB PHASE START DATE:	06 Sep 2007
LAB PHASE COMPLETION DATE:	02 Oct 2007
REPORT ISSUE DATE:	09 Oct 2007

ACCEPTANCE CRITERIA

Condoms which demonstrate no visual leakage and viral passage, after the time periods observed, pass. Any condom that demonstrates viral passage during the timed period fails. Any condom that shows a visual dye leakage and viral passage shall be considered to have failed the test. Dye visual leakage on the second cotton layer of the assembled condom is not a test failure. If this leakage occurs, another condom needs to be tested. The samples met the requirements of the acceptance criteria.

INTRODUCTION:

This study was performed to evaluate the viral barrier properties of condoms. Condoms were challenged by inoculating the inside of each condom with bacteriophage ΦX174, an icosahedral virus with a diameter of about 27 nanometers. The condoms were then immersed in sterile simulated serum, pressurized to 1.28 ± 0.02 pounds per square inch gauge (psig) and held for 30 minutes at 37 ± 2°C. Aliquots of the collection fluid were removed after 30 minutes. The virus particles present were quantified using standard plaque assay techniques.

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PROCEDURES:

Condom Preparation: All handling and testing of condoms was performed in a controlled area to limit the possibility of extraneous virus being introduced into the sterile test system. Test condoms were handled aseptically and tested as received. Each condom was removed from the package by a technician wearing sterile surgical gloves. The condom was then filled to approximately half way with buffered Tween® 80 (ΦXNBT) solution and massaged 10 times to rinse the inside. The condom was swirled 10 times and dipped 3 times into ΦXNBT to rinse the outside. This rinsing procedure was then repeated.

The condom was suspended on a polypropylene tube with an open end. Two sterile rubber bands were tightly fitted around the mouth of the condom on the tube superimposed. Also a strip of white cotton was placed between the condom and sleeve at the top of the condom and tightened with another sterile rubber band (used to detect leaks).

To achieve a constant positive pressure, the volume was held constant using a sterile, polyester organza "sock." The socks were cut to 130 ± 4 mm in diameter for the test condoms and the bottoms shaped to match the contour of the test sample. They were sewn using cotton thread in a surger with a security stitch. A sock was placed around the condom and held in place with a sterile rubber band tightly fitted around the top of the condom assembly on the tube (refer to Figure 1).

The condom/tube assembly was fitted snugly into a lid with silicon gasket. The lid was screwed onto the receiving vessel which was aseptically filled with 410 ± 1 mL of ΦXNBT for the test condom. Then another layer of cotton was placed on top of the top rubber band of the condom assembly. If this cotton got discolored, the sample was not counted in the results. This system provided isolation of the test fluids and prevented contamination of the collection fluid.

Challenge Preparation: *Escherichia coli* C600 ATCC #13706 was grown overnight at 37 ± 2°C with shaking in ΦX nutrient broth (ΦXNB). The *E. coli* culture was then diluted 1/100 using sterile ΦXNB and re-incubated at 37 ± 2°C with shaking until slightly turbid, then inoculated with ΦX174 virus (ATCC #13706-B1). The host bacteria/virus mixture was then incubated at 37 ± 2°C until the culture "cleared" or reduced significantly in turbidity (approximately 6 hours). The virus stock was centrifuged at 10,000 x G for 40 minutes. The centrifuged stock virus was filtered through a 0.45 micron then a 0.22 micron microporous membrane filter to remove any remaining host cells or bacterial debris. The stock was held at >1 x 10^9 plaque forming units (PFU)/mL.

Assay Procedure: The stock culture was diluted to achieve a challenge >2 x 10^8 PFU/mL. The inside of the condom was filled with challenge solution using a syringe. The inoculation area was separate from the test area. The challenge titer was tested with each run, either from the challenge stock or from inside of a test condom.

The condom assembly was attached to a screw-cap lid fitted with a hose barb connector suspended on a 6-gang pressure manifold coupled through a pressure gauge to a compressed air source (refer to Figure 1). The collection vessels were set into a circulating water bath and brought to a constant temperature of 37 ± 2°C.

The FDA guideline has recommended saline with 0.1% Triton X-100 to prevent adherence and still achieve an appropriate surface tension of less than 0.05 Newtons per meter (N/m). Tween® 80 (ΦXNBT) may be used for polyurethanes or other materials. These fluids simulate the surface tension of human body fluids.

Analyses using buffered Tween® 80 (ΦXNBT) are performed at 37 ± 2°C. The test may be performed at room temperature (20-25°C) when saline is used, as prescribed by the guideline. It is more important to have the temperature consistent from assay to assay rather than at any given temperature. The scientific literature contains little about the viral barrier properties of materials as a function of temperature.

Air pressure was applied to the condom via a compressed air tank, regulator and pressure gauge. A pressure of 1.28 ± 0.02 psig (90 cm water, 60 mm Hg) was applied and maintained for 30 minutes. The condom was carefully removed from the collection vessel, re-inserted 3 times to increase elution, allowed to drip into the collection vessel for 5-10 seconds, and then capped the collection vessel.

Plaque Assays: Viral challenges and test samples were assayed using standard plaque assay techniques. Assays were performed by adding 2 drops of *E. coli* to 2.5 mL of ΦX top agar (TOPAG), held molten at 44 ± 2°C. A 0.5 or 1 mL aliquot of the test fluid (or the appropriate dilution) was then added to the top agar and vortexed. The top agar was poured over ΦX bottom agar (BOTAG), swirled gently and allowed to solidify at room temperature. Plates were incubated at 37 ± 2°C for 14-24 hours, or until plaques were easily countable. Plaques were counted using manual colony counters. All plaque assays were performed with triplicate plates. Values reported are converted averages from three determinations.

Negative Controls: A sterility (negative) control was run for each condom type. The condom was assembled and tested as a normal run above, but without the addition of virus to the condom. The assay fluid was then assayed using quantitative procedures. An aliquot was removed at time 0 from random test vessels after the full assembly process and assayed as an additional negative control. *E. coli* controls were prepared using the plaque assay procedure without addition of test fluid to demonstrate adequate host organisms and the absence of plaque contamination from the assay procedure. Media negative controls were also performed with each run.

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Environmental Controls: To detect airborne virus particles, an environmental control was performed by opening a receiving vessel partially filled with ΦXNBT in the test area during the entire challenge run. Fallout plates were prepared by adding 100 µL of *E. coli* to 2.5 mL of TOPAG to BOTAG, swirled gently and allowed to solidify at room temperature. Fallout plates were left open during each run, normally one was placed at each end of the condom test apparatus. Fallout plates were incubated as with plaque assays above. Environmental control bottles were evaluated using the plaque assay procedure above.

Spike Neutralization Controls: The effectiveness of rinsing to eliminating inhibitory properties on the condoms was demonstrated. This may also be referred to as neutralization verification. Known numbers of virus (10^1-10^2 PFU/mL in bottle) were inoculated into the collection fluid with the condom at the beginning of a simulated test run. At time-0 aliquots were removed from the collection fluid to a sterile tube to be assayed. After 30 minutes the samples were plaque assayed. This control is to demonstrate if there is loss of virus titer during the run, which would necessitate an increased start titer to maintain the sensitivity of the assay.
Positive Controls: Positive control simulated condoms were prepared by piercing 0.12 mm holes on the bottom side of the condom with a sterile Seirin acupuncture needle. The complete test was performed on one of each condom type using same volumes and procedures as for test condoms.

RESULTS:

The titer of the viral challenge stock was > 2 x 10^8 PFU/mL and is reported in Tables 1-2. Results are reported using sequential numbers for each condom for simplicity. Plaque assay values are averages from 3 mL of sample, so the sensitivity of the assay is 1 PFU/mL as detailed in the FDA guideline. The tables include the predicted mL of fluid passing through the condom based on virus titers. It assumes no filtration effect and was calculated as follows:

$$\frac{\text{Total PFU Passage}}{\text{ln - Condom Titer (PFU/mL)}}$$

Where Total PFU Passage = Collect titer x volume

Results for the predicate condoms are found in Table 1. The results of the test condoms are found in Table 2. Twenty test condoms and twenty predicate condoms were evaluated. One of the predicate condoms had viral passage, while there were no failures from the twenty test condoms.

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CONTROL RESULTS:

All *E. coli* controls were confluent with no plaques, demonstrating adequate host organisms and the absence of contamination in the plaque assay procedure. Time zero controls from the collection vessels demonstrated no growth (8 were tested). The uninoculated condom control was also negative for virus, showing that the test process was aseptic. Media and culture controls from each reported run demonstrated proper growth and no contamination.

Positive controls all demonstrated passage. Positive control results are in Tables 1 and 2.

Environmental Controls: All fallout bottles were negative. Aerosol controls were negative (usually 2 plates to each side of the set-up).

In-Condom Controls: The in-condom challenge stability controls for 0 minutes and 30 minutes are reported in Table 3 for both condom brands. Table 3 demonstrates that no significant anti-viral effect resulted from the inside of the condoms, since in-condom titers did not decrease significantly and remained higher than the required titer throughout the assay.

Spike/Neutralization: Spike neutralization control results are found in Table 4 as calculated from triplicate plaque assays on triplicate samples. Results demonstrate no inhibitory effect from the condoms over time or as compared with media controls.

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

Hilda M. Fontanet, B.S.
Study Director

11 Oct 2007
Study Completion Date

HF/lxi

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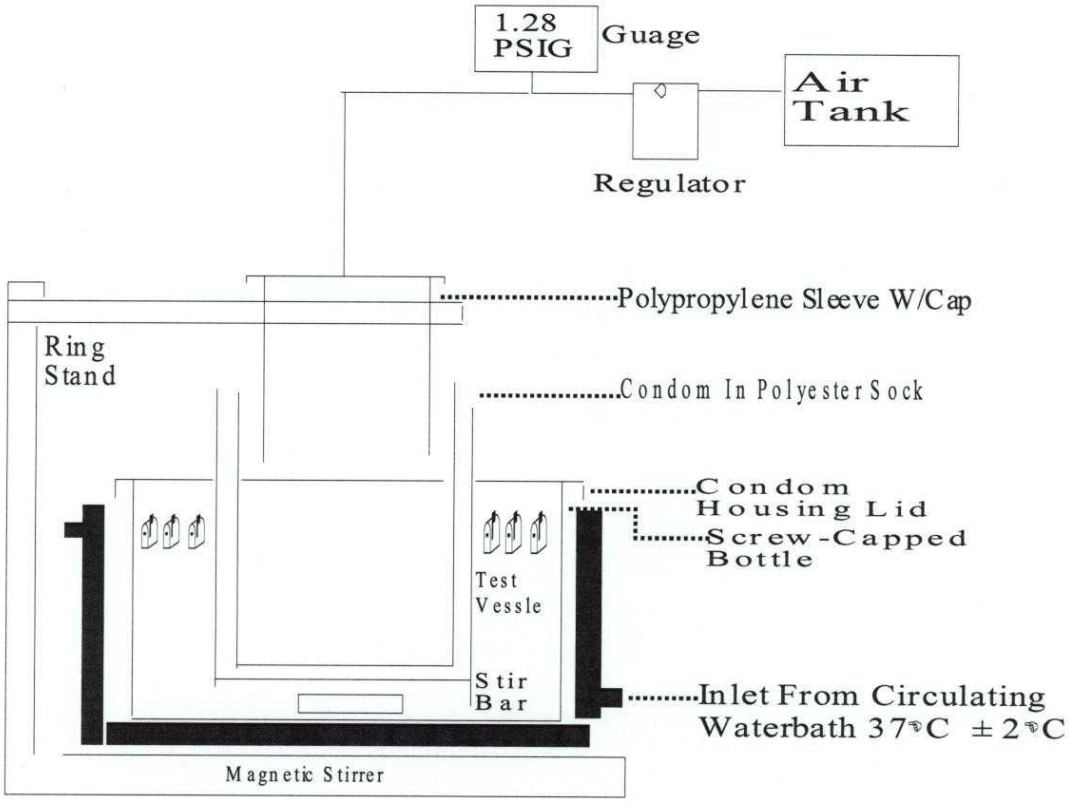

FIGURE 1. Test Apparatus Schematic

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TABLE 1. Virus Penetration Results
Predicate condoms: Trojan Latex, Non-Lubricated Condoms
Lot #TT7101BZ1, Exp. Apr 2012

SAMPLE NUMBER	CHALLENGE TITER (PFU/mL)	DETECT LIMIT (mL)	COLLECT FLUID (PFU)[a]	COLLECT TITER (PFU)[b]	VOLUME PASSAGE[c]
T1	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T2	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T3	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T4	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T5	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T6	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T7	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T8	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T9	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T10	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T11	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T12	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T13	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T14	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T15	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T16	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T17	2.0×10^{8}	2.1×10^{-6}	15	5.0	1.0×10^{-5}
T18	2.1×10^{8}	2.0×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T19	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
T20	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
NEG	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
POS	2.0×10^{8}	2.1×10^{-6}	<1	31000.0	6.4×10^{-2}

[a] Total raw number of PFU detected per 3 mL plaque assay.

[b] Average PFU/mL detected in collection vessel.

[c] Predicted mL of fluid passing through the condom= $\frac{\text{Total PFU Passage}}{\text{ln - Condom Titer (PFU/mL)}}$

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TABLE 2. Virus Penetration Results
Test condoms: Origami Silicone Condom-SVPD
Lot #94

SAMPLE NUMBER	CHALLENGE TITER (PFU/mL)	DETECT LIMIT (mL)	COLLECT FLUID (PFU)[a]	COLLECT TITER (PFU)[b]	VOLUME PASSAGE[c]
P1	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P2	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P3	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P4	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P5	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P6	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P7	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P8	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P9	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P10	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P11	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P12	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P13	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P14	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P15	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P16	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P17	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P18	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P19	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
P20	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
NEG	2.0×10^{8}	2.1×10^{-6}	<1	<0.3	$<6.8 \times 10^{-7}$
POS	2.0×10^{8}	2.1×10^{-6}	6	2.0	4.1×10^{-6}

[a] Total raw number of PFU detected per 3 mL plaque assay.
[b] Average PFU/mL detected in collection vessel.
[c] Predicted mL of fluid passing through the condom= $\frac{\text{Total PFU Passage}}{\text{In - Condom Titer (PFU/mL)}}$

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TABLE 3. Challenge Virus Stability In-condom Titers

REPLICATE	INITIAL (PFU/mL)	30 MINUTE (PFU/mL)	LOG_{10} COMPARISON
T 17	2.0×10^8	2.0×10^8	
T 18	2.0×10^8	2.0×10^8	
T 19	2.0×10^8	2.0×10^8	
T Average	2.0×10^8	2.0×10^8	0.00
C 17	2.0×10^8	2.0×10^8	
C 18	2.1×10^8	2.1×10^8	
C 19	2.0×10^8	2.0×10^8	
C Average	2.0×10^8	2.0×10^8	0.00

Note: Each value is the average of 3 plates reported in PFU/mL.

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TABLE 4. Spike Neutralization Controls

SAMPLE IDENTIFICATION	CALCULATED TITER TIME ZERO	CALCULATED TITER TIME 30
T 1	7	7
T 2	7	6
T Average	7	7
C 1	40	41
C 2	41	41
C Average	41	41

Note: Each value is the average of 3 plates reported in PFU/mL. No inhibition shown.

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RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix	* First Name	Middle Name	* Last Name	Suffix
Mr.	Daniel		Resnic	

Position/Title: Owner/CFO
Department: Product Design
Organization Name: Strata Various Product Design
Division: R&D
* Street1: 311 North Robertson Blvd
Street2: Suite 318
* City: Beverly Hills
County: Los Angeles
* State: CA: California
Province:
* Country: USA: UNITED STATES
* Zip / Postal Code: 90211

*Phone Number	Fax Number	* E-Mail
310-305-2984	440-508-2984	resnicpi@gmail.com

Credential, e.g., agency login: DANINDESERTPI

*** Project Role:** PD/PI
Other Project Role Category:

	File Name	Mime Type
***Attach Biographical Sketch**	4829--Biosketch_RESNIC.pdf	application/pdf
Attach Current & Pending Support		

PROFILE - Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix
Dr.	Pamina		Gorbach	

Position/Title: Associate Professor
Department: Dept. of Epidemiology
Organization Name: Regents of the University of California
Division: Research
* Street1: 1080 Wilshire Blvd
Street2: Suite 540
* City: Los Angeles
County: Los Angeles
* State: CA: California
Province:
* Country: USA: UNITED STATES
* Zip / Postal Code: 90095-7353

*Phone Number	Fax Number	* E-Mail
310-794-2555	310-794-2808	pgorbach@ucla.edu

Credential, e.g., agency login: GORBACH2

*** Project Role:** Other (Specify)
Other Project Role Category: co-Investigator

	File Name	Mime Type
***Attach Biographical Sketch**	9076-Biosketch-Gorbach.pdf	application/pdf
Attach Current & Pending Support		

PROFILE - Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix
Dr.	Alen		Voskanian	MD

Position/Title: Associate Physician Diplomate, UCLA
Department:
Organization Name: Regents of the University of California
Division: Research
* Street1: 2629 Main St.
Street2: Suite 110
* City: Santa Monica
County: Los Angeles
* State: CA: California
Province:

* Country: USA: UNITED STATES	* Zip / Postal Code: 90405	
*Phone Number 818-248-9574	Fax Number 310-584-1459	* E-Mail doctorav@hotmail.com
Credential, e.g., agency login:		
*** Project Role:** Consultant	**Other Project Role Category:**	
	File Name	Mime Type
***Attach Biographical Sketch**	6106-Biosketch-Voskanian.pdf	application/pdf
Attach Current & Pending Support		

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

Additional Senior/Key Person Form Attachments

When submitting senior/key persons in excess of 8 individuals, please attach additional senior/key person forms here. Each additional form attached here, will provide you with the ability to identify another 8 individuals, up to a maximum of 4 attachments (32 people).

The means to obtain a supplementary form is provided here on this form, by the button below. In order to extract, fill, and attach each additional form, simply follow these steps:

- Select the "Select to Extract the R&R Additional Senior/Key Person Form" button, which appears below.
- Save the file using a descriptive name, that will help you remember the content of the supplemental form that you are creating. When assigning a name to the file, please remember to give it the extension ".xfd" (for example, "My_Senior_Key.xfd"). If you do not name your file with the ".xfd" extension you will be unable to open it later, using your PureEdge viewer software.
- Using the "Open Form" tool on your PureEdge viewer, open the new form that you have just saved.
- Enter your additional Senior/Key Person information in this supplemental form. It is essentially the same as the Senior/Key person form that you see in the main body of your application.
- When you have completed entering information in the supplemental form, save it and close it.
- Return to this "Additional Senior/Key Person Form Attachments" page.
- Attach the saved supplemental form, that you just filled in, to one of the blocks provided on this "attachments" form.

Important: Please attach additional Senior/Key Person forms, using the blocks below. Please remember that the files you attach must be Senior/Key Person Pure Edge forms, which were previously extracted using the process outlined above. Attaching any other type of file may result in the inability to submit your application to Grants.gov.

1) Please attach Attachment 1	
2) Please attach Attachment 2	
3) Please attach Attachment 3	
4) Please attach Attachment 4	

ADDITIONAL SENIOR/KEY PERSON PROFILE(S)	**Filename** **MimeType**
Additional Biographical Sketch(es) (Senior/Key Person)	**Filename** **MimeType**
Additional Current and Pending Support(s)	**Filename** **MimeType**

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Daniel Resnic	Principal Investigator/Program Director

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Art Center College of Design - Los Angeles, CA	N/A	1973-1975	Graphic & Product Design
North Shore Community College - Beverly, MA	AS	1971-1973	Liberal Arts

A. Positions and Honors.

1995-Present **Strata Various Product Design**
Founder of product design firm. Presently the company has patented several medical devices and Resnic has served as Principal Investigator for an NIH funded Feasibility Study of the Origami Male Condom™, a non-latex silicone condom, with the CA Family Health Council, LA.

1989-1992 **President, Palos Verdes Fine Art, Inc.** - Redondo Beach, CA
Founder of art publishing company that produced limited-edition serigraphs by emerging artists. Supervised and art directed silk-screen printing of editions in Israel, produced company trade shows, directed advertising and promotion, and designed catalog. Managed staff of eight employees. Developed company to $3.4 million gross annual sales after the first 18 months in business.

1984-1986 **Publisher and Author of the Art Buyer's Index** (ISBN # 0-936183-00-4)
Authored and published the first art industry buyers' reference directory endorsed by the ALA (American Library Association).

1975-1982 **President, Gallery Prints, Inc**. - New Orleans, LA

Founder of publishing company that produced fine art posters and prints by emerging and well-known artists and photographers. Supervised four-color printing of prints and posters, produced company trade shows, directed advertising and promotion, and designed catalog. Managed staff of eleven employees. Published for world-renowned photographers Richard Avedon and Victor Skrebneski. The company became one of eight such companies in the art poster field worldwide.

1968-1971 **PFC, US Army Reserve; Infantry -** Fort Dix, NJ
Honorable Discharge

B. Selected peer-reviewed publications (in chronological order).

Not applicable

C. Research support and relevant experience

Daniel Resnic is the inventor of the Comfort Condom™. He is uniquely qualified with the vision and commitment to supervise product design and provide administrative support and direction to the entire project. His goal is to see the new condom through its fabrication, pre-clinical testing, and clinical trials. The device will be submitted for FDA approval, and Mr. Resnic will oversee its route to commercial manufacturing and worldwide marketing.

Mr. Resnic studied packaging and product design in the early 1970s at the Art Center College of Design in California. After his studies, he founded several successful design and publishing businesses. In 2001, Mr. Resnic directed his company's attention to condom design. He researched characteristics that have prevented condoms from being used as extensively and consistently as needed to curtail the current HIV epidemic. After a year-long investigation, he identified several key areas where design solutions could have a marked effect on consumer satisfaction:

- Creating a barrier that does not diminish sensitivity
- Improving fit and reducing constriction of the glans
- Making the condom easier and quicker to donn (less interruption of sexual activity)
- Reducing slippage by designing a means of securing the condom
- Reducing breakage by searching for a more durable alternative to latex and plastic
- Finding an alternative material that is acceptable to consumers with latex allergy (4% of population)

Mr. Resnic determined that latex formulations would never achieve the characteristics he was seeking. Consequently, he selected silicone as the candidate material. Silicone is an established material used in many medical devices and is biocompatible for internal contact with human tissue, having been successfully used for heart valves, implants, and surgical tools. In addition, silicone can stretch to 300% of its original size and feels like human tissue to the touch.

Mr. Resnic then addressed the other major design issues, creating viable solutions for each of them. To improve condom fit, manufacturers of standard latex condoms have experimented with looser condoms. Mr. Resnic, on the other hand, decided that the "super-stretch" properties and life-like feel of heavy gauge silicone would provide the solution - better fit and greater comfort than latex condoms.

To improve the problem of diminished sensation, the latex condom industry has traditionally opted for thinner materials. In contrast, Mr. Resnic designed a thick, heavy gauge condom with a "life-like" feel that could *create* the desired sensation instead of acting as a *barrier to* sensation. His heavy gauge design not only resolved diminished sensation, but at the same time, reduced the likelihood of condom breakage. Preliminary experiments with the new material required a pair of scissors to break the barrier.

The problem of slippage was resolved with a discreet scrotal band that would anchor the "soft" condom sheath during use by male consumers. The condom also features a radical, shape-retaining design that could provide faster and easier application that rolled latex condoms.

After producing hundreds of design iterations, Mr. Resnic filed for a U.S. patent for the novel device. Permission has also been granted for international patent filing. The new condom is designed to meet or exceed FDA performance standards. Family Health International and the American Society of Testing and Materials (ASTM) have invited Mr. Resnic to present the concept of this novel condom. One of the world's largest manufacturers of latex condom has expressed interest in a licensing option. Confidential talks are ongoing at this time.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Gorbach, Pamina M.	Associate Professor
eRA COMMONS USER NAME GORBACH2	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Brown University, Providence, RI	Honors B.A.	1987	Latin American Studies
Johns Hopkins University, Baltimore, MD	M.H.S.	1990	International Health
University of North Carolina, Chapel Hill, NC	Dr.P.H.	1995	MCH, & Health Behavior
University of Washington, Seattle, WA	Infectious Disease Fellow	1995-1999	STD/HIV Epidemiology

A. Positions:

7/2008 -	Associate Professor, Department of Epidemiology, School of Public Health
7/2005-7/2008	Associate Professor-In Residence, Department of Epidemiology, School of Public Health, and Division of Infectious Diseases, School of Medicine, University of California, LA
7/2001-6/2005	Assistant Professor-In-Residence, Department of Epidemiology. School of Public Health, University of California, Los Angeles
7/2001-7/2005	Director and Co-investigator, HIV Prevention Trials Network-Los Angeles
1999-2001	Assistant Professor, Graduate School of Public Health, San Diego State University
1997-1999	Senior Research Fellow, Center for AIDS & STD, Division of Infectious Diseases, University of Washington, Seattle WA.
1995-1997	Senior Research Fellow, The Department Health Services, University of Washington.
1992-1995	Predoctoral Trainee, The Carolina Population Center, University of North Carolina
1990-1991	Home Office Coordinator, The Papua New Guinea Child Survival Project and the Bangladesh Urban EPI Project, the International Division, John Snow, Inc.
1989-1990	Primary Health Care and Nutrition Advisor, CARE-Costa Rica

Honors

Best Oral Presentation Award - 2000 ASTA/MSSVD meeting STIs at the Millenium
National Institute of Allergy and Infectious Diseases – Research Scholar Development Award K22 1999-01.
National Institute of Allergy and Infectious Diseases **-** STD/AIDS Training Grant: Fellowship, 1997-99.
The Association of Health Services Research Postdoctoral Fellowship, University of Washington 1995-97.
The Andrew W. Mellon Foundation: Predoctoral Training at the Carolina Population Center, 1994-1995.
The Andrew W. Mellon & William and Flora Hewlett Foundations**:** Research Residency in Vietnam, 1994.
NICHD - Public Health Service Grant: Predoctoral Training, The Carolina Population Center, 1991-1993.
Odyssey Fellow**,** Ford Foundation. For undergraduate students to pursue research careers, 1987.
Prize for Academic Excellence in Latin American Studies: Brown University, 1987.

B. Selected peer-reviewed publications.

1. Gorbach PM, Manhart LE, Hess KL, Stoner BP, Martin DH, Holmes KK. Anal Intercourse among Young Heterosexuals in Three US STD Clinics. Sex Transm Dis, in press, July 2008.
2. Coly A and Gorbach PM. Microbicide Acceptability Research: Recent Findings and Context Evolution. Current Opinion in HIV and AIDS; Oct 2008, Vol. 3, No. 5: 581-586.
3. Gorbach, PM, Drumright LN, Javanbakht M, Pond SLK, Woelk CH, Daar ES, Little SJ. Antiretroviral drug resistance and risk behavior among recently HIV-infected men who have sex with men (MSM). J Acquir Immune Defic Synd, 2008 Apr 15;47(5):639-643.
4. Sharma A, Bukusi E, Gorbach, P, Cohen CR, Muga C, Kwena Z1, HolmesKK . Sexual Identity and risk of HIV/STI among men who have sex with men in Nairobi. Sex Trans Dis, April 2008, Vol. 35, No. 4, p.352–354.

5. Drumright LN, Gorbach, PM, Little SJ, Strathdee SA. Associations between Substance Use, Erectile Dysfunction Medication and Recent HIV Infection among Men Who have Sex with Men. AIDS & Behav, 2007 Dec 7.
6. Nelson SJ, Manhart LE, Gorbach PM, Martin DH, Stoner BP, Aral SO, Holmes KK. Measuring sex partner concurrency: it's what's missing that counts. Sex Transm Dis 2007, 30(6):
7. King WD, Larkins S, Hucks-Ortiz C, Wang J, Gorbach P, Veniegas R, Shoptaw S. Factors Associated with HIV Viral Load in a Respondent Driven Sample in Los Angeles, AIDS and Behavior, 2007 Dec 7..
8. Menza, TW; Colfax, G; Shoptaw, S; Fleming, M; Guzman, R; Klausner, JD; Gorbach, P; Golden, MR. Interest in a Methamphetamine Intervention Among Men Who Have Sex With Men. Sex Trans Dis 2007, 34 (4):209-214.
9. Drumright LN, Little SJ, Strathdee SA, Slymen DJ, Araneta MRG, Malcarne VL, Daar ES, Gorbach PM. Unprotected anal intercourse and substance use before and after HIV diagnosis among recently HIV infected men who have sex with men. Sex Trans Dis, 2007. Jun;34(6):401-7.
10. Smith DN, Drumright LN, Frost SDW, Susan Cheng WS, Espitia S, Daar ES, Little SJ, Gorbach PM. Characteristics of Recently HIV-Infected Men Who Use the Internet to Find Male Sex Partners and Sexual Practices with those Partners. J Acquir Immune Defic Synd, 2006, 43(5):582-587.
11. Gorbach PM; Sopheab, H, Chhorvann C, Weiss R, Vun MC. Changing Behaviors and Patterns Among Cambodian Sex Workers: 1997-03. J Acquir Immune Defic Synd, 2006, 42(2): 242-247.
12. Gorbach PM, Drumright LN, Daar ES, Little SJ. Transmission behaviors of recently HIV infected men who have sex with men. J Acquir Immune Defic Synd, 2006, 42(1): 80-85.
13. Drumright LN, Little SJ, Strathdee SA, Slymen DJ, Araneta MRG, Malcarne VL, Daar ES, Gorbach PM. Unprotected anal intercourse and substance use among men who have sex with men with recent HIV infection. J Acquir Immune Defic Synd. 2006, 43(3):344-50
14. Gorbach PM, Drumright LN, Holmes KK. Discord, Discordance & Concurrency: Comparing Individual and Partnership-Level Analyses of New Partnerships of Young Adults at Risk of STI. Sex Transm Dis, 2005 Jan, 32(1):7-12.
15. Gorbach PM, Galea J, Amani B, Shin A, Celum C, Kerndt P, Golden M. Don't ask, Don't Tell: Patterns of HIV Disclosure Among HIV Positive Men Who Have Sex with Men (MSM) with Recent STI Practicing High Risk Behavior In Los Angeles and Seattle. Sexually Transmitted Infections, 2004 December, 80(6):512-517.
16. Saphonn V, Sopheab H, Sun LP, Vun MC, Wantha SS, Gorbach PM, Detels R. Current HIV/AIDS/STI Epidemic: Intervention Programs in Cambodia, 1993-2003. AIDS Education and Prevention, 2004 (16) Supplement A: 64–77.
17. Drumright LN, Gorbach PM, Holmes KK Do People Really Know Their Sex Partners? Concurrency, Knowledge of Partner Behavior and Sexually Transmitted Diseases within Partnerships. Sex Transm Dis. 2004 Jul;31(7):437-42.
18. Gorbach PM and Holmes, KK. Transmission of STIs/HIV at the Partnership Level: Beyond Individual Level Analyses. J Urban Health. 2003 Dec;80 Suppl 3:III15-III25.
19. Sopheab H, Gorbach PM, Gloyd S, Leng HB. Rural Sex Work in Cambodia: Work Characteristics, Risk Behaviors, HIV, and Syphilis. Sexually Transm Inf, 2003, 79(4).
20. Gorbach PM; Ryan CG; Saphonn V; Detels R. The Impact of Social, Economic and Political Forces on Emerging HIV Epidemics. AIDS 2002, 16(suppl 4):S35-43.
21. Gorbach PM, Stoner BP, Aral SO, Coronado N, Connor S, Holmes KK. It Takes a Village: Understanding Concurrent Partnerships In Seattle, WA. Sex Transm Dis, 2002; 29(8): 453-462.
22. Baganizi E, MacLachlan E, Maiga O, Bougoudogo F, Castle S, Gorbach P, Parker K, Ryan C. The feasibility of integrated STI prevalence and behavioral surveys in developing countries. Sex Transm Infect 2002; 78:187-189.
23. Kurth A, Spielberg F, Gorbach PM, Goldbaum G, Branson BM. Moving from apprehension to action: HIV counseling and testing preferences in three at-risk populations. AIDS Educ Prev 2001 Dec;13(6):524-40.
24. Golden MR, Whittington WLH, Handsfield HH, Malinski C, Russell K, Boyd MA, Hughes J, Gorbach PM, Holmes KK, Partner notification and treatment for gonococcal and chlamydial infection: expansion of public health services to the private sector and expedited sex partner treatment through a public health partnership with commercial pharmacies. Sex Transm Dis 2001 Nov;28(11):658-665.
25. Gorbach PM, Sopheab H, Leng HB, Sutwantha S, Vunn MC, Saidel T. Sexual bridging among Cambodian males. International Journal of STD & AIDS. 2001; 12 (Suppl 2): 17.

26. Gorbach PM; Phalla T; Sopheab H; Leng HB; Mills S; Bennett T; Holmes KK. Sexual Bridging by Cambodian Men: Potential Importance for General Population Spread of STD/HIV Epidemics. Sex Transm Dis. 2000 Jul;27(6):320-6.
27. Gorbach PM, Aral SO, Celum C, Stoner BP, Whittington WL, Galea J, Coronado N, Connor S, Holmes KK. To Notify or Not To Notify: STD Patients' Perspectives of Partner Notification in Seattle. Sex Trans Dis 2000; 27(4): April.
28. Golden MR, Whittington WLH, Gorbach P, Coronado N, Boyd M, Holmes KK. Partner notification for chlamydial infections among private sector clinicians in Seattle-King county: a clinician and patient survey. Sex Transm Dis. 1999 Oct;26(9):543-7.
29. Phalla T; Leng HB; Mills S; Bennett A; Wienrawee P; Gorbach PM; Chin J. 1998. HIV and STD epidemiology , risk behaviors, and prevention and care response in Cambodia. AIDS 1998,12(suppl B): S11-S18.
30. Gorbach, PM; Hoa, TKD; Tsui, AO; and Nhan, VQ. Reproduction, Risk and Reality: Family Planning and Reproductive Health in Northern Vietnam. The Journal of Biosocial Science, 1998, July, (30): 393-409.
31. Ryan CA; Vathiny OV; Gorbach PM**;** Leng HB; Berlioz-Arthuad, A; Whittington WL; Holmes KK; 1998. Explosive Spread of HIV-1 and Sexually Transmitted Diseases in Cambodia. The Lancet. 1998. Vol. 351, No. 9110, P. 1175.
32. Gorbach, PM; Hoa, TKD; Tsui, AO; and Nhan, VQ. Contraception and Abortion in Two Vietnamese Communes. The American Journal of Public Health. 1998. April 88 (4).
33. Gorbach, PM.; Hoa, DTK.; Eng, E and Tsui, AO. The Meaning of RTI Symptoms to Women in Vietnam, A Qualitative Study of Illness Representation: Collaboration or Self Regulation? Health Education and Behavior. 1997. 24(6):773-785.

C. Research Support On-Going or Completed

ONGOING

1R01DA022116-01A1: (PI Gorbach) NIDA 04/01/07-03/31/12
Transmission Behavior in Partnerships of Newly HIV Infected Southern Californians (PI: Gorbach)
This study will measure how transmission risks and partnership dynamics change over time among recently HIV-infected individuals and their partners comparing their behavioral patterns with those with chronic HIV infection and no HIV infection. It will allow for partnership level analyses by actively recruiting sexual partners. Of special focus will be the role of drug use, especially methamphetamine, in affecting behaviors over time, and how partnership dynamics interact with drug use to allow for HIV transmission.

1 U01 AI068633-01 MTN (PI: Hillier; Gorbach subcontract PI) NIAID 08/01/06-08/31/13
Microbicide Trials Network
Co-investigator with subcontract to UCLA to be Chair of the Behavioral Research Committee. For the Microbicide Trials Network (MTN) are responsible for reviewing, designing, and analyzing acceptability, adherence and other behavioral data collected within clinical trials of the MTN. Develop ancillary behavioral studies to address contextual and related behavioral studies regarding microbicides within the network.

1 U19 AI060614:01/01R (PI: U19: Anton; PI: Gorbach - Project 3) NIH/NIAID 08/15/04 – 07/31/09
Rectal Health, Behaviors and Microbicide Acceptability
This study guides development of rectal microbicides by providing descriptive data on anal sex, anal health, and the acceptability of carrier methods for rectal microbicides. We will test hypotheses associating sexual behaviors (receptive anal intercourse) and anal health among 896 men and women including HIV positive and negative subjects in Los Angeles and Baltimore.

CH05-LA-608 (PI: Mitsuyasu; PI: Gorbach- Project 2) 07/01/05 – 06/30/09
Network for AIDS Research in Los Angeles (NARLA). Universitywide AIDS Research Program (UARP)
Project 2: Barriers to Enrollment in Research Registry for Microbicides Clinical Trials
This study will develop educational materials for men and women about rectal microbicides, assess the best format in which to deliver such information, and consider potential barriers to microbicide trial participation by analyzing factors that facilitate enrollment in a microbicide trial registry.

DA-03-01 (Shoptaw and Gorbach, Co-PIs) NIH/NIDA 10/10/03 - 09/30/08
HIV/AIDS Risk Behaviors in Methamphetamine User Networks

Co-principal investigator in a study of drug using men who have sex with men (MSM), drug using MSM/W, and non drug using MSM and their male and female sexual partners to examine the diffusion of HIV and STDs in drug users in LA to identify the individual-level, partnership-level, and environmental factors that promote the spread of these diseases.

DA-03-01 (Shoptaw and Gorbach, Co- PIs) NIH/NIDA 07/01/04 -09/30/08
HIV/AIDS Risk Behaviors in Methamphetamine User Networks (Supplement).
The supplement will describe the prevalence of anal human papillomavirus (HPV) among this ethnically diverse community sample of substance using MSM and their sexual partners and evaluate the extent to which prevalence of HPV may function as a biological co-factor with the incidence of HIV in this population.

UARP: (UCLA: Brown, ARA: Hezareh)
Women's Attitudes towards Microbicides and Clinical Trials
In a cohort of 200 ethnically diverse population of women in Los Angeles who will be interviewed and tested for STIs including HIV, and 30 women who participate in in-depth qualitative interviews we will investigate vaginal and rectal commercial lubricant use; cultural, interpersonal and individual issues that influence the practice of lubricant use; frequency and distribution of high risk sexual behaviors; feasibility of conducting a microbicide trial in this population as measured by the incidence of STIs and HIV, participant retention, and attitudes toward study related procedures.

COMPLETED

U01 A143638 (Gorbach, UCLA PI; Richman U01 PI.) 06/01/02-08/31/07
NIH/NIAID- The Southern California Primary Infections Program
PI of sub-contract to guide in development and analysis of behavioral epidemiology within the AIEDRP network. PI of a sub-study entitled "Partnership Types and Primary HIV Infection and Transmission." Responsible for guiding the behavioral epidemiology in this site. Co-investigator of the University of California, San Diego's (UCSD) site of the multi-site NIAID Acute HIV Infection and Early Disease Research Program (AIEDRP) program to develop a better understanding of HIV-1 disease pathogenesis in adults in Southern California. Sites included the UCSD HIV Treatment Center, Cedars-Sinai Hospital and Harbor-UCLA.

99000-P (Gorbach, PI of Part B; Kerndt, PI of Part A) 10/01/01 - 09/30/05
Centers for Disease Control
"Formative Research to Inform the Development of Educational Messages for Women with High Risk Human Papilloma Virus Infection and Their Partners"
Principal investigator of a study that collaborated with Los Angeles County Health Department's STD Program's support for monitoring prevalence of human papillomavirus infection among women attending facilities providing health services. Qualitative and quantitative research was conducted for the development of educational messages for women with high risk human papillomavirus infection and their sexual partners.

R03 TW05925 (PI: Gorbach) 09/01/01 - 08/31/04
NIH/Fogarty International Center
"Sexual Risk and HIV/STD in Vulnerable Cambodian Females"
This study was a cohort of HIV/AIDS risk and sexually transmitted diseases among vulnerable female populations including factory workers and indirect sex workers in Phnom Penh, Cambodia.

ID02-LA-033 (PI: Gorbach) 10/01/02 - 09/30/04
Universitywide AIDS Research Program (UARP)
"Developing Interventions for Men Who Have Sex Men with HIV and STDs in Los Angeles"
Qualitative interviews were conducted among HIV-positive men who have sex with men (MSM) with STDs to consider problems with current approaches to STD control, and to clarify how to best approach the structure and content of new interventions targeting HIV-positive MSM in STD clinics. The results from the research on partner notification were used to develop a computer-assisted self interview to elicit partner contact information for partner notification from HIV-positive MSM with syphilis in STD clinics. This was piloted to measure the acceptability of a computer-based interview for collecting contact tracing information for syphilis and HIV.

BIOGRAPHICAL SKETCH

NAME VOSKANIAN, ALEN M.D.	POSITION TITLE Director of High Resolution Anoscopy Clinic
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
University of California, Berkeley	B.A.	1994-1996	Molecular and Cell Biology and Neurobiology
University of California, Irvine	M.D.	1996-2000	College of Medicine
UCLA-Santa Monica	Residency	2000-2003	Resident in Family Medicine
AIDS Healthcare Foundation	Fellowship	2003-2004	Fellow in HIV Medicine

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A. Positions:

2007-Present — Associate Physician Diplomate, UCLA

2007-Present — Medical Director, Vitas Innovative Hospice Care

2007-Present — High Resolution Anoscopist, AIDS Research Alliance

2004-2007 — Director of High Resolution Anoscopy Clinic, AIDS Healthcare Foundation, Beverly Hills, CA

2005-Present — Lead Physician/Coordinator, Men's Wellness/STD clinic, Hollywood, CA

2003-2007 — Primary Investigator and Sub-Investigator, AIDS Healthcare Foundation Research Department, Beverly Hills, CA

2003-2007 — Attending Physician, AIDS Healthcare Foundation. Providing medical care for more than 350 HIV positive patients, Beverly Hills, CA

2004-2005 — Associate Director, Immune Suppressed Unit, Hollywood Presbyterian Medical Center, Hollywood, CA

Medical License: California (Active)

Board Certification:
2003 American Academy of HIV Medicine
2003 American Board of Family Medicine

Honors

Alpha Omega Alpha (AOA)
American Cancer Society Research Award 1996
American Heart Association Research Award 1994
Honors earned in Internal medicine, Surgery, Obstetrics and Gynecology, Psychiatry, Emergency Medicine
UC Berkeley Dean's Honor list, 1995 and 1996
California Academy of Family Physicians Preceptorship Award, 1997
Armenian Professional Society Graduate Student Award, 1997

B. Selected peer-reviewed publications.

Leung JM, **Voskanian A**, Bellows WH, Pastor D. "Automated Electrocardiogram ST Segment Trending Monitors: Accuracy in Detecting Myocardial Ischemia." Anesthesia and Analgesia 1998, July 87 (1):4-10.

Leung JM, **Voskanian A**, Bellows WH, Pastor D, Charles R. "Automated ST-Segment Trending Analysis System: Comparison with Holter Electrocardiogram in Detecting Myocardial Ischemia." Anesthesiology Vol 83, 3A (1995): A121

C. Research Support On-Going or Completed

Principal Investigator for A4001027. A multicenter, randomized, double-blind, placebo-controlled trial of a novel CCR5 antagonist, UK-427,857, in combination with optimized background therapy versus optimized background therapy alone for the treatment of antiretroviral-experienced HIV-1 infected subjects

Principal Investigator for GSK ABC107442. Hypersensitivity study for abacavir using patch testing.

Principal Investigator for SP01A-111-05. A Phase II, multi-center, placebo-controlled study designed to look at the dose response, efficacy, and safety of SP01A, given as a pill to be swallowed, in the treatment of HIV-infected subjects

Principal Investigator for Incyte 08721-204-A randomized, double-blind, phase II study comparing the anti-retroviral safety and efficacy of Dexelvucitabine (DFC) 200 mg once daily to Lamivudine(3TC) 300 mg once daily in addition to optimized background therapy in HIV-1 infected subjects who have failed and/or harbor HIV with resistance mutations to NRTIs, PIs, and NNRTIs

Sub-Investigator for AI266073: Phase IV, open-label, randomized, multicenter study evaluating efficacy and tolerability of single tablet regimen of Efavirenz//Emtricitabine/Tenofovir DF compared to unmodified HAART in HIV-1 infected subjects who have achieved virological suppression on their HAART regimen

Sub-Investigator for GS-US-164-0107. Combination of Efavirenz and Truvada (The COMET Study): A phase 4 evaluation of switching from twice daily Zidovudine and Lamivudine (Combivir®) to a simplified, once-daily regimen of co-formulated Emtricitabine and Tenofovir Disoproxil Fumarate (TruvadaTM), in virologically suppressed, HIV- infected patients taking Efavirenz

Sub-Investigator for TMC114-C202- A Phase II randomized, controlled, partially blinded, 48-week trial to investigate dose response of TMC114/RTV in 3-class-experienced, multi PI-experienced HIV-1 infected subjects

Sub-Investigator for Tibotec TMC114-C214-A randomized, controlled, open-label trial to compare the efficacy, safety and tolerability of TMC114/RTV versus LPV/RTV in treatment-experienced HIV-1 infected subjects

Sub-Investigator for TMC114-C215 An open label trial of TMC114/RTV in HIV-1 infected subjects who failed trial treatment in the sponsor selected trials with TMC114

Sub-Investigator for TMC125-C223: A randomized, controlled, partially blinded Phase IIb dose-finding trial of TMC125, in HIV-1 infected subjects with documented genotypic evidence of resistance currently available NNRTIs and with at least three primary PI mutations.

Sub-Investigator for TMC125-C223sub: A sub-study of TMC125-C223 to evaluate the pharmacokinetic profile at baseline and at week 4 of different doses of TMC125 b.i.d. on top of an individually optimized antiretroviral therapy

Sub-Investigator for TMC278-C204: A sub-study of TMC278-C204 to evaluate the pharmacokinetic profile of TMC278 at week 4, 24, and optionally (subject's decision) week 48 of different doses of TMC278 as an addition to an investigator-selected combination of 2 NRTIs.

Sub-Investigator for TMC278-C204: Protocol TMC278-C204: A phase IIb randomized, partially blinded, dose-finding trial of TMC278 in antiretroviral naive HIV-1 infected subjects

Sub-Investigator for TMC125-C229: An open-label trial with TMC125 in HIV-1 infected subjects, who were randomized to a TMC125 treatment arm in a sponsor-selected TMC125 trial and were treated for at least 48 weeks

Sub-Investigator for TMC114-C200: Open-label safety study of TMC114 in combination with low dose RTV and other ARVs in highly experienced HIV-1 infected patients with limited or no treatment options

Sub-Investigator for A4001029. A multicenter, randomized, double-blind, placebo-controlled trial of a novel CCR5 antagonist, UK-427,857, in combination with optimized background therapy versus optimized background therapy alone the treatment of antiretroviral-experienced, non CCR5-Tropic HIV-1 infected subjects

Sub-Investigator for A4001026. A multicenter, randomized, double-blind, comparative trial of a novel CCR5 antagonist, UK-427,857, in combination with Zidovudine/Lamivudine versus Efavirenz in combination with Zidovudine/Lamivudine for the treatment of antiretroviral-naïve HIV-1 infected subjects

Sub-Investigator for De-Escalate. Atazanavir or Atazanavir/Ritonavir substitution for Ritonavir boosted PI therapy in HIV-infected individuals experiencing ongoing HIV viremia and hyperlipidemia: A randomized controlled pilot study

American Cancer Society Research Award, 1996- Studied the mutation frequencies in mismatch repair genes and microsatellite instability in tumor tissues from hereditary nonpolyposis colon cancer cases under the supervision of Dr. Hoda Anton-Culver. U.C.Irvine, College of Medicine.

American Heart Association Research Award, 1994- Conducted a cardiovascular research project at UCSF under the supervision of Dr. Leung. The research aimed to investigate the utility and accuracy of automated ST-Segment trending analysis during operations.

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RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 7992129310000

*** Budget Type:** ● Project ○ Subaward/Consortium

Enter name of Organization: Strata Various Product Design

*** Start Date:** 07-01-2009 *** End Date:** 06-30-2010 **Budget Period: 1**

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Mr.	Daniel		Resnic		PD/PI	128,000.00	12.00			57,600.00	4,800.00	62,400.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **62,400.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	12.00			26,244.00	3,200.00	29,444.00
1	Project Co-Ordinator	6.00			38,410.00	6,200.00	44,610.00
1	R&D Project Manager	6.00			35,288.00	6,200.00	41,488.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**115,542.00**
					Total Salary, Wages and Fringe Benefits (A+B)		**177,942.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT00559879

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 7992129310000

*** Budget Type:** ● Project ○ Subaward/Consortium

Enter name of Organization: Strata Various Product Design

*** Start Date:** 07-01-2009 *** End Date:** 06-30-2010 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
1. Dedicated Project laptop- Mac format	2,900.00
2. 3-D software	2,200.00
3. Anatomical model	7,500.00

Total funds requested for all equipment listed in the attached file

Total Equipment **12,600.00**

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	5,860.00
2. Foreign Travel Costs	
Total Travel Cost	**5,860.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	

Number of Participants/Trainees **Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 7992129310000

*** Budget Type:** ● Project ○ Subaward/Consortium

Enter name of Organization: Strata Various Product Design

*** Start Date:** 07-01-2009 *** End Date:** 06-30-2010 **Budget Period: 1**

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	3,850.00
2. Publication Costs	3,700.00
3. Consultant Services	166,904.00
4. ADP/Computer Services	5,500.00
5. Subawards/Consortium/Contractual Costs	157,677.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Telephone, Postage, Courier	4,580.00
9. Liability Insurance, Staff Parking, mileage	12,280.00
10. Packaging (product study samples)	8,550.00
Total Other Direct Costs	**363,041.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**559,443.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. Multiple "Business Confidential" Rates used			25,045.00
		Total Indirect Costs	**25,045.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**584,488.00**

J. Fee	**Funds Requested ($)**
	40,912.00

K. * Budget Justification File Name: 269-1_BUDGET_JUSTIFICATION.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

* ORGANIZATIONAL DUNS: 7992129310000

*** Budget Type:** ● Project ○ Subaward/Consortium

Enter name of Organization: Strata Various Product Design

*** Start Date:** 07-01-2010 *** End Date:** 12-31-2010 **Budget Period: 2**

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Mr.	Daniel		Resnic		PD/PI	128,000.00	6.00			28,000.00	2,980.00	30,980.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **30,980.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	6.00			15,000.00	1,580.00	16,580.00
1	**Total Number Other Personnel**					**Total Other Personnel**	**16,580.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**47,560.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT00559879

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

* ORGANIZATIONAL DUNS: 7992129310000

*** Budget Type:** ● Project ○ Subaward/Consortium

Enter name of Organization: Strata Various Product Design

*** Start Date:** 07-01-2010 *** End Date:** 12-31-2010 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	2,600.00
2. Foreign Travel Costs	
Total Travel Cost	**2,600.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	

Number of Participants/Trainees **Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

* ORGANIZATIONAL DUNS: 7992129310000

*** Budget Type:** ● Project ○ Subaward/Consortium

Enter name of Organization: Strata Various Product Design

*** Start Date:** 07-01-2010 *** End Date:** 12-31-2010 **Budget Period: 2**

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	1,725.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	79,826.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	**81,551.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**131,711.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. Multiple "Business Confidential" Rates used		15,000.00	15,000.00
		Total Indirect Costs	**15,000.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**146,711.00**

J. Fee	**Funds Requested ($)**
	10,267.00

K. * Budget Justification File Name: 269-1_BUDGET_JUSTIFICATION.pdf Mime Type: application/pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

DETAIL BREAKDOWN AND BUDGET JUSTIFICATION

SENIOR/KEY PERSONNEL

Principal-Investigator
Daniel Resnic, PI (45% effort): Mr. Resnic will coordinate the efforts of the consortium and oversee all aspects of the project. He will also have a significant role in product development with Medco Products, Inc. (product fabricator) and BlueStar Silicones (silicone formulation). Although Mr. Resnic will contribute 45% effort to the 12 mo. project, he is requesting only **$78,750.** The remainder of his salary will be provided in-kind by Strata Various Product Design.

OTHER PERSONNEL

TBN/ Secretarial; Data Entry, organize travel arrangements, scheduling, handling shipping & receiving. A salary of **$29,444**., is requested. (includes medical insurance benefit)

Lonnie Sheinart, Project Coordinator: The Project Coordinator will lend support to Mr. Resnic for 6 months of the project, 40 hrs/wk, for the first six months of the project, to assist him with his dual project roles of PI and product designer. Lonnie will maintain records, organize, maintain and update the project calender, and manage project correspondence, quarterly grants reporting and accounts payable. A salary of **$38,410**., is requested. (includes medical insurance benefit).

Hank Greenberg, Project Manager/R&D: Hank will manage project activities, maintain deadlines, act as liaison to the fabricator, silicone supplier and the study site. A salary of **$35,888**., is requested. (includes pro-rated medical insurance benefit)

SUPPLIES and EXPENSES

Equipment
Strata Various Product Design has budgeted **$150.** for the purchase of 5 web cams for the consortium to use for web conferencing. This will reduce additional travel expenses.

Laptop Notebook;
Dedicated Mac 17" Notebook, 2.5GHz**, $2900.**

Anatomical Model: Strata Various Product Design has budgeted **$ 7,500.** for the purchase of 3-D anatomical models used for rectal imagery in the testing of prototype design and fit.

Software;
TBD/ 3-D; **$2,200.**

Travel
We are requesting funds in the amount of **$5,860.** to cover gas costs for R/T travel for the PI between Beverly Hills and Medco Products, in Anaheim, CA, R/T for Ventura, CA, to meet with Reeshemah Chattham, the silicone consultant and to the study site in Los Angeles. Although the PI will be in regular weekly contact with co-Investigators, Medco, and other members of the Consortium, he will visit their sites to discuss silicone R&D, CAD drawings, product modifications and packaging. Est. Cost: **$3,560.**

Liability Insurance, Staff parking, Mileage; $8,280.

Material & Supplies

Packaging Costs
Packaging design contributes significantly to consumer perceptions and acceptability. The studies will compare the ORIGAMI MALE CONDOM™. The PI is requesting funds in the amount of $8,550 for product packaging of the ORIGAMI MALE

CONDOMs™. When used in the comparison study with Trojan® latex condoms the project must use vapor & moisture barrier foil package design (to prevent lubrication dry out) and labeling created for the study. Est. Cost: **$8,550.**

Publication Costs

Strata Various Product Design is requesting **$3,700.** to cover the design and production costs of a condom-use brochure/DVD, to provide the study group with illustrated, easy to understand and consistent condom-use instructions.

Telecommunications

Telephone costs correspond to an average rate of $280./Month for telephone calls, web conferencing and faxes. Est. Cost: **$5,040.**

Postage/Courier

Strata Various Product Design has budgeted $1,620. for overnight shipping and postage costs for the duration of the project. Est. Cost: **$1,620.**

Office supplies,
Copying, etc;
Est. Cost: **$1,800.**

SUBAWARD/CONTRACTUAL COSTS

Dr. Pamina M. Gorbach and Dr. Robert Weiss will be co-Investigators, responsible for the overall scientific oversight of the project. UCLA will be responsible for the overall management of the user preference and acceptability studies phase of the proposed project at the research site, develop the study protocol, study procedures and provide input into the study instruments and the interpretation of results, interview study participants and facilitate the qualitative aspect of the research, tabulation of data collected, and will interface with the IRBs involved in this project and oversee the communication with the UCLA IRB and with the Project PI.

UCLA will oversee the development of the protocol, procedures and study instruments and the interpretation of findings analyzing the final quantitative data that will be collected, and they will advise on data interpretation. Est. Cost: **$247,715.**

Medco Products, Inc.; Dennis Bui will collaborate with the inventor to develop the molds and sample fabrication of the condom. Medco engineers and technicians will execute plan drawings; build molds to revised device specifications, produce first iteration prototypes, make necessary modifications and produce product samples for use in the pre-clinical and clinical studies. Est. cost: **$ 80,357.**

Nelson Laboratories, Inc. will conduct the pre-clinical testing (structural and biocompatibility; **$52,287.** of the finished product, including viral barrier evaluations of both silicone formulas, the ORIGAMI Elastomer™ and the ORIGAMI Elastomer-SL™ (self-lubricating formula). Nelson will subcontract animal testing to WuXi Apptec,Inc. (formerly Apptec Laboratories, Inc.) Est. cost: **$52,287.**

CONSULTANT SERVICES

Silicone Expert

Reehsemah Chatham (BlueStar Silicones): Reeshema is a Senior Scientist at BlueStar and one of the foremost authorities on medical grade silicone material in the United States. She will provide consultation on silicone formulation as needed. Est. cost: **$8,000.** (40 hours at $200 / hr).

Consumer Acceptability Constultants

Adam Glickman, (Condomania)

Adam Glickman, founder and CEO of Condomania, Inc., the world's original and largest retailer of condoms, is the foremost expert on consumer preferences and marketing trends. He will serve as project advisor/consultant. Adam will discuss proposed product modifications with the Consortium, the inventor and mechanical engineers from the consumers' preference perspective. Adam has over 21 years of experience with condom marketing. He has been consultant to the major condom manufacturers around the world. Est. cost: **$12,060.** (67 hours at $180. / hour).

Patent Consultant

Eric Hanscom (Law Firm of Eric Hanscom): Mr. Hanscom will provide consultation services to the project regarding prototype modifications as they relate to the inventor's existing patents. The SBIR funding mechanism provides up to $5K for 'patent consultations that are unrelated to patent filing'. We will consult with Mr. Hanscom on design modifications that could effect the patent. Additional legal costs are discussed under FEE, below. Est. cost: **$5,000.** (20 hours at $250 per hour).

Medical Device Illustrator

Kevin Comras (Kevin Comras Illustration): Kevin Comras will provide medical illustration of the prototypes and their subsequent revisions, which will enable Mr. Resnic, in his capacity as product designer, to communicate design matters easily and effectively with the various members of the consortium (i.e. fabricator, mechanical design engineers, patent consultant and clinical research team). Mr. Comras will also be responsible for producing CAD 3-D illustration/animation for on-line discussions between mechanical engineers, the inventor and key personnel. Est. cost: **$8,700.**

Mechanical Engineering Drawings/CAD Designer

Ed Gemma will provide mechanical engineering drawings and 3-D modeling to the fabricator for mold making. **$12,200.**

Project Web Site

TBN; A project web site will enable all project personnel to keep informed with a project calendar and to update their sector of the project. This will facilitate efficient project management by the PI. UCLA may also utilize this site for efficient questionnaire response with volunteers. Funds are requested in the amount of **$5,500.**

INDIRECT COSTS

The proposed Indirect Costs of **$40,045.,** included in the budget are based on several "Business Confidential" rates.

FEE

A 7% fee of $ 51,179. is requested by the applicant Small Business. Project complexities not addressed in other sections represent additional costs that will arise, such as discussions and interactions with the FDA and the US Patent & Trademark Office (USPTO). Although the novel device is patent pending, design modifications will need to be discussed and cleared with the USPTO. This procedure is, in part covered with consultant services by Eric Hanscom, however, one or two trips to Washington, DC will likely be needed to expedite and resolve time sensitive issues that inevitably arise with such design modifications. This has occurred with previous patent work by the inventor (Origami Male Condom™), which is not uncommon to the patent process. Mr. Resnic has met for preliminary discussions with the USPTO on April 22, 2008.

Additional unidentified business costs for the proposal, such as mold-making rush charges, weekend and holiday labor costs will need to be covered. Mold-makers have a long list of clients in Q waiting for their molds to be produced and most clients want it done 'yesterday'. It is often necessary to order the work on a rush/priority basis depending on the Mold-maker's workload, which can range from a turnaround of 2 weeks to 4 months.

Also, previous work on the Origami Male Condom™ required the fabricator to keep staff and the facilities operating overtime late in the evening, on Saturdays, Sundays, Thanksgiving and New Years Day. We anticipate similar requirements for this proposed project as well. Additional costs may also include a few overnight stays for the PI in Anaheim, CA to expedite the R&D.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		**93,380.00**
Section B, Other Personnel		**132,122.00**
Total Number Other Personnel	4	
Total Salary, Wages and Fringe Benefits (A+B)		**225,502.00**
Section C, Equipment		**12,600.00**
Section D, Travel		**8,460.00**
1. Domestic	8,460.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		**444,592.00**
1. Materials and Supplies	5,575.00	
2. Publication Costs	3,700.00	
3. Consultant Services	166,904.00	
4. ADP/Computer Services	5,500.00	
5. Subawards/Consortium/Contractual Costs	237,503.00	
6. Equipment or Facility Rental/User Fees	0.00	
7. Alterations and Renovations		
8. Other 1	4,580.00	
9. Other 2	12,280.00	
10. Other 3	8,550.00	
Section G, Direct Costs (A thru F)		**691,154.00**
Section H, Indirect Costs		**40,045.00**
Section I, Total Direct and Indirect Costs (G + H)		**731,199.00**
Section J, Fee		**51,179.00**

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0925303690000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Regents of the University of Califrnia

*** Start Date:** 07-01-2009 *** End Date:** 06-30-2010 **Budget Period: 1**

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Pamina		Gorbach	PhD	PD/PI	168,400.00	1.20			16,840.00	2,863.00	19,703.00
2.	Dr.	Robert		Weiss	PhD	Biostatistician	126,567.00	0.60			6,328.00	1,202.00	7,530.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **27,233.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
1	Graduate Students		2.20	3.00	19,579.00	587.00	20,166.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Clinical Research Coordinator	6.00			35,000.00	8,400.00	43,400.00
1	Program/IT	1.20			6,000.00	1,440.00	7,440.00
3	**Total Number Other Personnel**					**Total Other Personnel**	**71,006.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**98,239.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT00559879

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0925303690000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Regents of the University of Califrnia

*** Start Date:** 07-01-2009 *** End Date:** 06-30-2010 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0925303690000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Regents of the University of Califrnia

*** Start Date:** 07-01-2009 *** End Date:** 06-30-2010 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	2,700.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	10,500.00
7. Alterations and Renovations	
8. Communications	2,581.00
9. Other project expenses	15,285.00
Total Other Direct Costs	**31,066.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**129,305.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. Facilities & Administration Modified Direct Costs	26	109,123.00	28,372.00
		Total Indirect Costs	**28,372.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**157,677.00**

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 5214-Budject_Justification_UCLA.pdf	Mime Type: application/pdf
	(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0925303690000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Regents of the University of Califrnia

*** Start Date:** 07-01-2010 *** End Date:** 12-31-2010 **Budget Period: 2**

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Dr.	Pamina		Gorbach	PhD	PI/PD	176,820.00	1.20			17,682.00	3,360.00	21,042.00
2.	Dr.	Robert		Weiss	PhD	Biostatistician	132,895.00	0.60			6,645.00	1,263.00	7,908.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **28,950.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
1	Graduate Students		2.20	3.00	5,573.00	167.00	5,740.00
	Undergraduate Students						
	Secretarial/Clerical						
1	Clinical Research Study Coordinator	6.00			36,400.00	8,736.00	45,136.00
2	**Total Number Other Personnel**					**Total Other Personnel**	**50,876.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**79,826.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT00559879

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0925303690000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Regents of the University of Califrnia

*** Start Date:** 07-01-2010 *** End Date:** 12-31-2010 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0925303690000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: Regents of the University of Califrnia

*** Start Date:** 07-01-2010 *** End Date:** 12-31-2010 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	79,826.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
		Total Indirect Costs	

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	79,826.00

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 5214-Budject_Justification_UCLA.pdf	Mime Type: application/pdf
	(Only attach one file.)	

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		**56,183.00**
Section B, Other Personnel		**121,882.00**
Total Number Other Personnel	5	
Total Salary, Wages and Fringe Benefits (A+B)		**178,065.00**
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		**31,066.00**
1. Materials and Supplies	2,700.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees	10,500.00	
7. Alterations and Renovations		
8. Other 1	2,581.00	
9. Other 2	15,285.00	
10. Other 3		
Section G, Direct Costs (A thru F)		**209,131.00**
Section H, Indirect Costs		**28,372.00**
Section I, Total Direct and Indirect Costs (G + H)		**237,503.00**
Section J, Fee		

BUDGET JUSTIFICATION

Total Direct Cost: **$247,715.** While this exceeds the specified 33% of the total SBIR allowed for a sub-contract, we feel this is justified given the large scope of the activity to be conducted by UCLA including all subject recruitment, screening, follow-up, data collection and analysis for two acceptability studies. The budget represents 18 months of work, year 2 is assumed to have 6 months of effort. Total Support (including indirect costs): **$303,195.00.**

PERSONNEL

Pamina M. Gorbach, MHS, Dr.P.H. Principal Investigator of the UCLA subcontract – (1.2 calendar months (10%) effort in years 1 and 2). will be co-Investigators responsible for the overall scientific oversight of the project. Dr. Gorbach will be responsible for the overall management of the acceptability studies phase of the proposed project at the research site, develop the study protocol, study procedures and provide input into the study instruments and the interpretation of results, interview study participants and facilitate the quantitative and qualitative aspects of the research, tabulation of data collected, and will interface with the IRBs involved in this project and oversee the communication with the UCLA IRB and with the Project PI. Dr. Gorbach is an Associate Professor at UCLA in the Department of Epidemiology, School of Public Health and in the Division of Infectious Diseases, School of Medicine and trained at Johns Hopkins University, University of North Carolina, Chapel Hill, and the University of Washington. Dr. Gorbach's expertise is in behavioral epidemiology and her research is focused on the risk behaviors that expose individuals to sexually transmitted infections including HIV, understanding the types and dynamics of sexual partnerships and the social context of sexual health. She has been conducting clinical research on the acceptability of new methods of HIV prevention such as microbicides as part of the Microbicides Trials Network and leading research on the acceptability of rectal microbicides in the UCLA Microbicide Development Program (U19).

Robert Weiss, Ph.D., Biostatistician (0.6 calendar months (5%) effort in years 1 and 2) will serve as a biostatistician and will spend his effort on analysis of the survey data. Dr. Weiss will provide biostatistical support to Dr. Gorbach conducting analysis of this data. His effort reflects time required on the study during different phases such as early on during development of instruments and creation of datasets and codebooks, in the middle of the study when regular data reports are being produced, and then in the last year as reports and manuscripts are being written and presentations prepared. Dr. Weiss is Professor with tenure in the Department of Biostatistics in the UCLA School of Public Health and a fellow of the American Statistical Association. He is an expert in the analysis of regression and longitudinal data models. He has contributed extensively to the statistical literature in the areas of (1) model specification, selection, fitting, elaboration and checking; (2) data graphics; (3) influence and outlier diagnostics; (4) longitudinal data analysis and (5) Bayesian methodology. He specializes in the application of regression and longitudinal models to (1) secondary prevention trials for HIV, (2) medical, biological and social science applications, and (3) problems in HIV biology. He has been an associate editor for the Journal of Educational and Behavioral Statistics (JEBS) and for Evaluation Review. Dr. Weiss has supervised eight PhD/DrPh dissertations in Biostatistics and is currently supervising five more, in areas of longitudinal data analysis and hierarchical models. He regularly teaches courses on longitudinal models, Bayesian methods, statistical graphics and multivariate statistics. He is currently writing a textbook, Modeling Continuous Longitudinal Data, to be published by Springer-Verlag.

Edward Robbie, Clinical Research Coordinator – (6 calendar months (50% effort) in years 1-2). The clinical research study coordinator will be responsible for managing the recruitment, screening, and data collection in this study. He/she will be responsible for day to day operations of the research protocol at UCLA overseeing all aspects of data collection activities, developing and implementing study recruitment materials, programming the computer- assisted interview, creating and managing the interviewing and examination and biospecimen collection schedules, conducting qualitative interviews at the project site, and coordinating the laboratory shipment and processing for STI testing. He will also be responsible for enrolling every new subject in the study and will travel to the collaborating site for study enrollment of participants. He/she will also be responsible for data management for the study and will report directly to Dr. Gorbach. His duties include financial projection and management of the studies, maintaining Institutional Review Board applications, responses, and records, and assisting with study related activities.

Programmer/IT support staff (1.2 calendar months (10%) effort in year 1 and 0 calendar months (0%) effort in year 2). A staff person will provide support for programming the questionnaires for the Audio Computer Assisted Interview (ie web-based survey). He will maintain the study web server where data will be collected, managed and stored. This person will work with the study coordinator to insure that the study databases are secure and that the data is properly received and archived. Throughout the study he will maintain the computers at the sites used for the web-based data collection.

Graduate Research Assistant: (2.3 academic months (25%) plus 3 summer months (100%) effort in year 1 and 2.3 academic months (25%) effort in year 2): A graduate research assistant will support the Clinical Research Coordinator, focusing on recruitment, screening, consenting, and enrolling study participants.

SUPPLIES:

A laptop computer will be used by the study to enable participants to access the web-based survey online. $1500 is requested for this. Project-related supplies are requested for $1200 per year for items such as paper, computer disks, etc.

TRAVEL

For year 2, funds have been budgeted for Dr. Gorbach and the study coordinator to attend a scientific meeting at $1,500 for presentation of final results.

OTHER EXPENSES

Space rental costs – Year 1-2. The study will be housed in an off-campus location where rent will be covered at $6,000 in year 1 and $3,000 in year 2 and to the UCLA CARE clinic where participants will be enrolled in the study at $4,500 per year as these costs reflect burden and use of clinic space rather than rent.

Recruitment materials – Year 1 and Year 3. $2,000 is budgeted for production funds to be used to defray the costs of online advertising in places like Craigs List, buying print ads in popular local papers, printing of posters, palmcards, and flyers for participants. 30 men will be recruited in Year 1 and 24 couples will be recruited in Year 2.

Software for qualitative data analysis is Atlas Ti that is budgeted for purchase at $1800 in year 1 only. Dr. Gorbach's research group has a license for ACASI questionnaire software Sensus that needs annual renewal at $1200 per year.

Telecommunications expenses are $2000 per year for the UCLA office. UCLA also requires an annual technology infrastructure fee to support internet services of $587 in year 1 and $544 in year 2.

Participant incentives - $4500 in year 1 and $9,600 in year 2: Each new enrollment will be compensated $50 for each prototype of condom tested in User Preference Study for a total of $150 for each of the 30 participants, and each member of the 24 couples (48 individuals) will be compensated $200 for the three uses of the selected prototype during sex.

HIV testing expenses and STD testing expenses - $1,785 in year 1 and $10,146 in year 2: All individuals will be screened to insure they are HIV negative. The cost is $25 for a rapid HIV test, and $45 for a western blot confirmatory test (required by law in our state). We assume that 10% of our sample will test positive for HIV and require a confirmatory test. The cost of STD testing is $13 for syphilis test (and $33 for a confirmatory for the 10% requiring this), $30 for both gonorrhea and Chlamydia testing – for either urethral and rectal testing. For the User Preference 30 study participants will only be screened for rectal STIs (gonorrhea and Chlamydia) and HIV only at study screening. For the Couples Acceptability and Performance 48 study participants will be screened for HIV and urethral as well as rectal STIs at study screening and study exit.

Qualitative interview transcription ($3000 in year 1 and $2400 in year 2): The cost to transcribe each interview is $100 for 30 interviews in User Preference study and 24 interviews in Couples Acceptability study.

Website design & hosting support: ($1000 year 1 and $500 in year 2): The study will utilize Audio Computer Assisted Interviewing run off a study website hosted by the PI's server based in her research office. Support is for creation of the study website and updates and support for the server.

SBIR/STTR Information

OMB Number: 0925-0001
Expiration Date: 09/30/2007

*** Program Type (select only one)**

● SBIR ○ STTR

○ Both *(See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)*

*** SBIR/STTR Type (select only one)**

● Phase I ○ Phase II

○ Fast-Track *(See agency-specific instructions to determine whether a particular agency participates in Fast-Track)*

Questions 1-7 must be completed by all SBIR and STTR Applicants:

● Yes ○ No	* 1. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?
○ Yes ● No	* 2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies? * If yes, insert the names of the Federal laboratories/agencies:
○ Yes ● No	* 3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: http://www.sba.gov
● Yes ○ No	* 4. Will all research and development on the project be performed in its entirety in the United States? If no, provide an explanation in an attached file. * Explanation:
○ Yes ● No	* 5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work? * If yes, insert the names of the other Federal agencies:
○ Yes ● No	* 6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?
	* 7. Commercialization Plan: If you are submitting a Phase II or Phase I/Phase II Fast-Track Application, include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions. * Attach File:

SBIR/STTR Information

OMB Number: 0925-0001
Expiration Date: 09/30/2007

SBIR-Specific Questions:

Questions 8 and 9 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 8 and 9 blank and proceed to question 10.

○ Yes ● No	* 8. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment. * Attach File:
● Yes ○ No	* 9. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?

STTR-Specific Questions:

Questions 10 and 11 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 10 and 11 blank.

○ Yes ○ No	* 10. Please indicate whether the answer to BOTH of the following questions is TRUE: (1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND (2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?
○ Yes ○ No	* 11. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?

Attachments

NonDomesticPerformanceExplanation

File Name **Mime Type**

CommercializationPlan

File Name **Mime Type**

SBIR

File Name **Mime Type**

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 9/30/2007

1. Project Director / Principal Investigator (PD/PI)

Prefix: Mr.
* First Name: Daniel
Middle Name:
* Last Name: Resnic
Suffix:

* New Investigator? ● No ○ Yes

Degrees: AS

2. Human Subjects

Clinical Trial? ○ No ● Yes

* Agency-Defined Phase III Clinical Trial? ● No ○ Yes

3. Applicant Organization Contact

Person to be contacted on matters involving this application

Prefix: Mr.
* First Name: Daniel
Middle Name:
* Last Name: Resnic
Suffix:

* Phone Number: 310-305-2984
Fax Number: 440-508-2984
Email: resnicpi@gmail.com

* Title: Owner/CFO

* Street1: 311 North Robertson Blvd.
Street2: Suite 318
* City: Beverly Hills
County: Los Angeles
* State: CA: California
Province:
* Country: USA:
* Zip / Postal Code: 90211

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 9/30/2007

4. Human Embryonic Stem Cells

* Does the proposed project involve human embryonic stem cells? ●No ○Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/registry/index.asp . Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): ❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

OMB Number: 0925-0001
Expiration Date: 9/30/2007

PHS 398 Research Plan

1. Application Type:

From SF 424 (R&R) Cover Page and PHS398 Checklist. The responses provided on these pages, regarding the type of application being submitted, are repeated for your reference, as you attach the appropriate sections of the research plan.

*Type of Application:

● New ❍ Resubmission ❍ Renewal ❍ Continuation ❍ Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application (for RESUBMISSION or REVISION only)	
2. Specific Aims	4026-2_SPECIFIC_AIMS___.pdf
3. Background and Significance	3797-3__BACKGROUND__.pdf
4. Preliminary Studies / Progress Report	2836-4_PRELIMINARY_WORK___.pdf
5. Research Design and Methods	289-5_RESEARCH_DESIGN_and_METHODS___.pdf
6. Inclusion Enrollment Report	9365-6_Inclusion_Enrollment_Report.pdf
7. Progress Report Publication List	3760-7_Progress_Report_Publication_List.pdf

Human Subjects Sections

Attachments 8-11 apply only when you have answered "yes" to the question "are human subjects involved" on the R&R Other Project Information Form. In this case, attachments 8-11 may be required, and you are encouraged to consult the Application guide instructions and/or the specific Funding Opportunity Announcement to determine which sections must be submitted with this application.

8. Protection of Human Subjects	1108-8_PROTECTION_OF_HUMAN_SUBJECTS.pdf
9. Inclusion of Women and Minorities	615-9_Inclusion_of_Women_and_Minorities.pdf
10. Targeted/Planned Enrollment Table	7100-10_Targetted_Plan_Enrollment.pdf
11. Inclusion of Children	1161-11_Inclusion_of_Children.pdf

Other Research Plan Sections

12. Vertebrate Animals	7690-12_Vertebrate_Animals.pdf
13. Select Agent Research	5267-13_Select_Agent_Research.pdf
14. Multiple PI Leadership	4994-14_Multiple_PI-PD.pdf
15. Consortium/Contractual Arrangements	9928-15_Consortium-Contractual.pdf
16. Letters of Support	3223-16_Letters_of_Support.pdf
17. Resource Sharing Plan(s)	3055-17__Resource_Sharing_Plan.pdf

18. Appendix

Attachments

IntroductionToApplication_attDataGroup0

File Name	Mime Type

SpecificAims_attDataGroup0

File Name	Mime Type
4026-2_SPECIFIC_AIMS___.pdf	application/pdf

BackgroundSignificance_attDataGroup0

File Name	Mime Type
3797-3__BACKGROUND__.pdf	application/pdf

ProgressReport_attDataGroup0

File Name	Mime Type
2836-4_PRELIMINARY_WORK___.pdf	application/pdf

ResearchDesignMethods_attDataGroup0

File Name	Mime Type
289-5_RESEARCH_DESIGN_and_METHODS___.pdf	application/pdf

InclusionEnrollmentReport_attDataGroup0

File Name	Mime Type
9365-6_Inclusion_Enrollment_Report.pdf	application/pdf

ProgressReportPublicationList_attDataGroup0

File Name	Mime Type
3760-7_Progress_Report_Publication_List.pdf	application/pdf

ProtectionOfHumanSubjects_attDataGroup0

File Name	Mime Type
1108-8_PROTECTION_OF_HUMAN_SUBJECTS.pdf	application/pdf

InclusionOfWomenAndMinorities_attDataGroup0

File Name	Mime Type
615-9_Inclusion_of_Women_and_Minorities.pdf	application/pdf

TargetedPlannedEnrollmentTable_attDataGroup0

File Name	Mime Type
7100-10_Targetted_Plan_Enrollment.pdf	application/pdf

InclusionOfChildren_attDataGroup0

File Name	Mime Type
1161-11_Inclusion_of_Children.pdf	application/pdf

VertebrateAnimals_attDataGroup0

File Name	Mime Type
7690-12_Vertebrate_Animals.pdf	application/pdf

SelectAgentResearch_attDataGroup0

File Name	Mime Type
5267-13_Select_Agent_Research.pdf	application/pdf

MultiplePILeadershipPlan_attDataGroup0

File Name	Mime Type
4994-14_Multiple_PI-PD.pdf	application/pdf

ConsortiumContractualArrangements_attDataGroup0

File Name	Mime Type
9928-15_Consortium-Contractual.pdf	application/pdf

LettersOfSupport_attDataGroup0

File Name	Mime Type
3223-16_Letters_of_Support.pdf	application/pdf

ResourceSharingPlans_attDataGroup0

File Name	Mime Type
3055-17__Resource_Sharing_Plan.pdf	application/pdf

Appendix

File Name	Mime Type

Research Plan

2. Specific Aims

Absent from the landscape of HIV prevention strategies is a receptive anal intercourse (RAI) condom that is safe and approved for use during anal intercourse (AI). Given the large number of men and women who engage in AI, the high risk of spreading HIV infection through AI, and the lack of safe barrier methods to prevent HIV infection during RAI, there is a critical need for a safe, receptive-partner-controlled condom that men and women can insert anorectally and rely on to protect themselves from HIV infection when they practice RAI.

Currently, no condoms are made of Silicone, a widely accepted, biocompatible medical material (See Sec. 12.2.1) that resembles the feel of human tissue. The ORIGAMI RAI CONDOM™ will be made of the uniquely formulated, 100% biocompatible ORIGAMI ELASTOMER™ silicone, a material which has been verified to have 100% viral impermeability to virus smaller than HIV, compared to a 5% viral permeability of a leading brand of male latex condoms (See Viral Barrier Lab Report)[1] The ORIGAMI ELASTOMER™ silicone is a durable material that is not only impermeable to virus, but also has high tear and tensile strength properties, making it extremely strong and less prone to breakage than existing male latex condoms. The proposed ORIGAMI RAI CONDOM™ will be designed with a flat, tapered body intended to facilitate convenient rectal insertion.

Available latex and polyurethane male and female condoms are the main barrier method promoted for HIV prevention but labeled for use in penile-vaginal intercourse only and have never undergone FDA review for their effectiveness during AI. Research studies have reported usage problems with available male condoms, including breakage, slippage, difficulty with administration, and latex allergies. Because available male condoms are rolled onto the penis, they are under the control of the inserting partner, leaving the receptive partner no direct means to protect himself or herself. The proposed ORIGAMI RAI CONDOM™ will be under the control of the receptive partner, and will potentially provide options that increase both safety and pleasure simultaneously for individuals who practice AI/RAI, to help prevent HIV and STI transmission.

Specific Aims

1. Prototype fabrication: Produce up to three (3) RAI condom prototypes made of ORIGAMI ELASTOMER™ silicones, using liquid injection molding (LIM) (See Sec. 2.2.2).
2. Pre-clinical testing: Conduct pre-clinical condom laboratory testing of the RAI condom prototypes, consistent with testing guidance from the FDA, the ISO and the American Society for Testing and Materials (ASTM), which includes biocompatibility testing (toxicity, sensitization, irritation) and structural testing (tensile properties, leakage, viral barrier evaluation, airburst test, accelerated aging and reusability tests).
3. User Preference Study: To identify the preferred prototype by comparing measures of user preference among the three final prototypes including: ease of insertion and removal, attractiveness, feel, strength, shape, fit, and comfort of the three selected ORIGAMI RAI CONDOM™ prototypes among 30 Volunteers, in a non-coital context.
4. Couples Acceptability & Perfomance Study: Measure acceptability of the preferred ORIGAMI RAI CONDOM™ prototype identified in Specific Aim 3, among 24 male couples who engage in AI. Subjects will be asked about comfort, sexual pleasure, ease of insertion and removal, fit, lubrication, sensation, breakage, slippage, and disposal. Each partner will also be asked to provide an overall preference between the ORIGAMI RAI CONDOM™ and the commercially available Male Latex condom. (See Sec 5.4)

Pre-clinical testing will be conducted according to FDA and ASTM guidelines. The condoms will undergo pre-clinical testing (Specific Aim 2) before proceeding to the User Preference Study (Specific Aim 3), and the most successful prototype will proceed to the Couples Acceptability & Performance Study (Specific Aim 4). For study procedures and data analysis (see Section 5.0 - 5.15.1).

2.1 Project Timeline, Coordination, and Budget: **Start Date: July 2009.** It is anticipated that it will take 18 months to complete this project. Below, is a timeline (Table 4) for the completion of each specific task. Information regarding staff and subcontractor coordination, communication, and facilitation of data exchange is provided below. Furthermore, the budget for the human volunteer testing portion of the Research Plan has been considered to allow for the possibility of repeating the User Preference Study, if the prototypes require further modification after the first study (see Specific Aim 3).

The principal investigator will be responsible for coordinating all project activities and will ensure that they remain on schedule. He will be in regular contact with consortium members through e-mail, PDA, phone conferences, Web-based videoconferencing, and in-person meetings. In addition, a Web site with an online project calendar and Web conferencing system will be utilized to enhance consortium/contractor interactivity.

Table 1. Project Timeline **Month**

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Prototype fabrication for pre-clinical testing	X	X	X															
Preclinical Testing; (structural and biocompatibility)				X	X													
Design questionnaires, interview guides, prepare interview format, train interview staff, IRB submission; study protocol, informed consent form, instructional materials, data collection instruments, and any advertisements	X	X	X	X														
Recruitment for User Preference Study					X													
Conduct User Preference Study					X	X	X											
Modifications to prototype design and Fabrication of modified prototype Samples								X	X									
Fabrication of Samples (for Couples Acceptability & Performance (CAP) Study)										X	X							
Modify questionnaires and interview guides; IRB approval											X	X	X					
Recruitment of volunteers for CAP Study													X	X	X			
CAP Study (24 Couples)														X	X	X		
Data analysis and report writing																	X	X

2.2 Technological Innovation

The novel device will feature the following technological innovations:

1. An advanced formula, biocompatible, non-toxic, non-allergenic, silicone developed specifically for this device.
2. Unique, shape-retaining memory and biomorphic design.
3. Pre-tested, viral-impermeable, non-toxic, hypo-allergenic, ORIGAMI Elastomer™ silicone material.
4. Excellent elongation, tear-resistance and tensile strength.
5. A unique patented reservoir designed to help minimize backflow/spillage.
6. A unique patented retention feature designed to secure the condom comfortably in the rectum.
7. Injection moulding rather than dip moulding maximizes innovative structural design options.

2.2.1 Condom Material: At present, there are no commercial condoms made of silicone. The ORIGAMI RAI CONDOM™ is composed of a biocompatible, non-toxic, non-allergenic, USP Class VI medical grade silicone. Class VI products meet the ISO (International Organization for Standardization) requirements for surface devices with "limited" (<24 hours) or "prolonged" (1 to 30 days) contact duration. [2]

Silicone is a widely accepted biocompatible material that resembles the feel of human tissue and is highly robust and stretchable. The silicone material used in the ORIGAMI RAI CONDOM™ is intended to facilitate a pleasurable AI sexual experience with sensation that simulates sex without a condom. It provides maximum protection against breakage, slippage, and viral permeability.

Silicone has many unique advantages over latex and other polymers for medical device applications. ORIGAMI Elastomer™ is preferred for its unique biocompatibility, resistance to heat (up to 425°F), extended shelf life, high tensile and tear strengths (660 psi), resistance to various chemicals and oils, and its excellent elongation modulus (1100%), all of which are considered by experts to be superior to latex. Other Silicones are utilized in medical applications throughout the human body. It is used to construct heart valves; as a tissue expander; as an injected cosmetic agent; in the genital tract, including penile prostheses; and in many other applications.[2] In addition, silicone is used in a number of contraceptive devices, including two FDA-approved cervical caps (FemCap™, Lea's Shield™), and demonstrates superiority to latex, which produces allergic reaction in about 2%-6% of the general population (17%-30% of health care workers).[2-7] Silicone produces no such reactions [6,7] and is also more durable. Latex condoms degrade in UV light and at over 100°F; silicone is unaffected by UV light and can withstand temperatures over 100°F.[6-8] The shelf life of an unwrapped FemCap™ is 2 years[6-9]. The shelf-life of an unwrapped latex condom can be measured in hours.[6]

With regards to properties such as tensile strength, tear strength, elongation, resiliency, elastic modulus, and permeability, silicone is superior to latex.[2-9] The thickness of the proposed ORIGAMI RAI CONDOM™ will also contribute to its durability. It will have a thickness of **0.8 – 1.4** mm, which is 10 times thicker than the thickest commercial male condom and 100 times thicker than the thinnest one. Silicone's impermeability to pathogens is supported by recent testing of the ORIGAMI MALE CONDOM™, which was verified with 100 % viral impermeability of virus smaller than HIV, compared to a 5% failure of a leading brand of male latex condoms.[1] The viral impermeability of silicone is additionally supported by silicone devices such as the diaphragm portion of the Ameda™ Breast Pump.[10] Rigorous testing resulted in zero viral penetration through the silicone barrier in either direction. The diaphragm served as a viral barrier not only to HIV, but also to the Phi-X174 bacteriophage, one of the smallest known viruses.

Unlike latex products that can produce sensitization and allergic reaction in 2% of the population (17% among medical professionals), silicone typically does not produce sensitive reactions.[6,7] In addition, silicone's tensile strength, tear strength, elongation, resiliency, elastic modulus, and viral impermeability, is consistently superior to latex.[6-10]

. The following contains proprietary/privileged information that Strata Various Product Design .
requests not be released to persons outside the Government, except for purposes of review and evaluation.

2.2.1 Condom Design: The design of the ORIGAMI RAI CONDOM™ addresses several key problems that can occur with conventional male condoms such as discomfort, improper fit, difficult donning procedure, and various product shortcomings and failures, detailed in (Table 2, Sec. 3.5).

- To deal with the issue of diminished sensation, a male condom is made of thin latex or polyurethane designed to facilitate the transfer of sensation through the barrier. In contrast, the ORIGAMI RAI CONDOM™ features thicker, heavy gauge material with a soft "life-like" feel of human tissue that can *create* sensation through direct penile contact with the inside surface of the condom instead of acting as a filter against sensation, as with indirect penile contact or transferred sensation with thin latex, and could also reduce breakage.
- The ORIGAMI RAI CONDOM™ also contains discreet ribs (Fig 3) in its shape-retaining form to facilitate easy insertion with no fumbling. The soft, resilient, odorless and tasteless material has high elongation that can resolve issues about improper fit.
- Another distinction is the flat, shape-retaining design. Unlike the thin, limp latex condoms, this device is ready to use in its shape-retaining form and thus should be easier to manage and insert into the rectum.
- Also, the ORIGAMI RAI CONDOM™ contains a unique, patented reservoir in its tip (Fig 1), which introduces a one-way valve (Fig 1) that is intended to help minimize backflow to reduce or possibly eliminating spillage. The dome-shaped reservoir has a concave membrane with a centered entry hole to allow collection of semen during ejaculation. (Fig 1)

Fig 1

Fig 2

Fig 3

3. BACKGROUND, SIGNIFICANCE, and RELATED R & D

3.1 Lack of safe barrier methods to prevent HIV infection during anal intercourse (AI) : Absent from the landscape of HIV prevention strategies is a condom that is safe and approved for use during receptive anal intercourse (RAI), which is the riskiest sex act that can lead to HIV infection and is commonly practiced by men and women around the world. Male condoms, the only available method to prevent the sexual transmission of HIV, have been tested and labeled for use in penile-vaginal intercourse only and have not undergone testing by the FDA for their use during AI, during which more strain is put on the condom. Statistical data (2002-2005) at the CDC [30] indicate that among adults 25–44 years of age, 40 percent of men and 35 percent of women have had anal intercourse with an opposite-sex partner. About 20.8 million men and 18.5 million women in the U.S. have AI with opposite-sex partners and 2.3 million men have AI with same-sex partners.[30] Similar estimates have been reported in other parts of the world; approximately 50% of sexually-active Brazilian adults, 44% of male and 32% of female college students in Puerto Rico, 29% of Danish women, 12% of college students in Togo, 7% of British men, 6% of French men, and 5% of South African youth report regularly having heterosexual AI.[30] Given the large number of men and women who engage in AI, the high risk of spreading HIV infection through AI, and the lack of safe barrier methods to prevent HIV infection during AI, there is a critical need for a safe, user-controlled condom that men and women can insert rectally to protect themselves from HIV infection when they practice AI. Failure to acknowledge AI as a common sexual practice and to address reasonable solutions perpetuates the HIV crisis for millions of men and women worldwide.

3.2 ORIGAMI ELASTOMER™ silicone facilitates a safer, more pleasurable, receptive-partner-controlled condom: Until vaccines or microbicides are available, there is an immediate and urgent need for functional, receptive-partner-controlled barrier methods specifically for use during RAI. We propose to take an unconventional approach to this serious problem by developing a unique insertable RAI condom that can be used safely during AI and that will be under the control of the receptive partner. Our condom is designed to insert into the rectum, not put onto the penis, giving the receptive partner more control over a decision to use a condom.

3.3 Unconventional pioneering HIV prevention strategy; An RAI condom inserted into the rectum: The ORIGAMI RAI CONDOM™ is an unconventional approach with structural priorities and design objectives that have not been considered until now. Male condom design has focused primarily on safety features with less attention to sensory issues, which has created near-universal dissatisfaction with traditional rolled latex condoms and has marked the history of condom usage since its introduction in 1918. Available latex and polyurethane male and female condoms are the main barrier method promoted for HIV prevention but labeled for use in penile-vaginal intercourse only and have not yet undergone FDA testing for their effectiveness during AI. Research studies have reported usage problems for available male condoms, including breakage (up to 2.3% for vaginal intercourse compared to up to 7.4% during AI), slippage, and latex allergies.

The ORIGAMI RAI CONDOM™ varies from current approach in that it will be made of 100% biocompatible ORIGAMI ELASTOMER™ silicone, a material which has been verified to have zero viral permeability to virus smaller than HIV, compared to a 5% viral permeability of a leading brand of male latex condoms.[1] The ORIGAMI ELASTOMER™ is a durable material that is not only impermeable to virus, but also has high tear and tensile strength properties, making it extremely strong and less prone to breakage than existing male condoms. Moreover, the ORIGAMI ELASTOMER™ silicone can withstand a wider range of temperatures, up to 425°F, and is more resistant to many other adverse conditions than latex. The ORIGAMI ELASTOMER™ is also tasteless, odorless, 100% biocompatible with the body, non-allergenic and has the feel of human tissue to improve sensation.

There are no injection-moulded condoms made of silicone, other than the male counterpart, the ORIGAMI MALE CONDOM™. The ORIGAMI RAI CONDOM™ is made of USP Class VI medical grade silicone, which meets the ISO requirements for surface devices with less than 24 hours contact duration (limited contact) or (1 to 30 days) contact duration (prolonged contact).

3.4 Societal Benefits: Potential role of AI condom in HIV prevention: The introduction of an RAI condom will provide a new receptive-partner-controlled HIV prevention strategy. As addressed by the Global Campaign for Microbicides, “The escalating numbers of new HIV and STI infections resulting from unprotected AI testify to the fact that having one prevention tool, [male latex] condoms, just isn't enough. It is time for receptive partners of both genders to have prevention methods they can control.” In 1996, President Clinton's Presidential Advisory Council on HIV/AIDS issued a call for studies on anal condom use and stated in its report that, "…studies should be funded to assess potential safety and efficacy of anal usage of insertive condoms." To date, none has been investigated.

In addition, the RAI condom may be inserted in advance of intercourse to avoid disrupting intimacy. RAI Condoms could bridge an existing gap in global HIV prevention strategies. Commercially available Male and Female condoms are neither designed nor

FDA approved for AI/RAI use, although RAI is the riskiest sex act that can lead to HIV infection and is commonly practiced by both heterosexual and homosexual men and women around the world. The insertable, ORIGAMI RAI CONDOM™ is a potentially safer, receptive-partner-controlled, more pleasurable means of protecting both partners during RAI than with male latex condoms.

3.5 Commercial Application: The ORIGAMI RAI CONDOM™ is intended to increase the acceptability of condoms among consumers at risk of HIV transmission through AI and to encourage consistent and correct use. Worldwide, people use 6 -to 9 billion male condoms annually, however, it is conservatively estimated that 24 billion condoms are needed - 15 billion more than are currently used.[13] The ORIGAMI RAI CONDOM™ is intended to appeal to the countless consumers who are currently at risk of HIV transmission because they have rejected male or female condoms or use them inconsistently. It is specifically designed to increase the acceptability of condoms by addressing consumer concerns about sensitivity, performance, comfort, and ease of use, in addition to its many new safety features, which are not possible with the Male condom. The numerous innovative features of the ORIGAMI RAI CONDOM™ are discussed in detail above and specifically designed to increase condom acceptability by addressing consumer concerns regarding function, sensitivity, performance, comfort, safety and ease of use, in addition to its many new structural features designed to optimize its RAI use (Table 2 below & "Technological Innovation", Sec. 2.2).

The preliminary production cost estimates for the ORIGAMI RAI CONDOM™ is between $0.43 to $0.56 USD. Cost is reduced considerably when considered in larger volumes of 5M and 10M units.

The high risk of spreading HIV infection through AI/RAI, and the lack of safe barrier methods to prevent HIV infection during RAI, speaks to a critical and urgent need for a safe, receptive-partner-controlled condom that men and women can insert rectally to protect themselves from HIV infection when they practice RAI.

Eleven key areas are identified where design solutions could have a marked effect on performance and consumer satisfaction:

Table 2 Existing Male Latex Condom *vs* Proposed RAI Silicone Condom Solutions

EXISTING PROBLEMS with LATEX CONDOMS for AI Use	PROPOSED SOLUTIONS RAI CONDOM
1. Diminished sensitivity: sexual sensation does not adequately transfer through a thin barrier for the active male user.	1. Enhanced sensitivity: sensation is created by the condom interior surface, which feels like human tissue for the active male user, a pivotal determinant for consumer acceptability.
2. Donning the male latex condom can present unrolling difficulties, snagging the skin, disruption of intimacy and potential risk of tearing.	2. Simple, instant insertion procedure: a soft, semi-rigid, self-piloting, RAI condom with shape-retaining memory that easily inserts anorectally, with no internal ring mechanism. Could be easily inserted in advance of intercourse without discomfort or irritation.
3. Improper fit; the latex or polyurethane sheath of the existing MC has issues regarding proper size/fit.	3. A one-size-fits-all condom with high elongation that can insert small and expand during use.
4. Slippage	4. A means of retaining the condom anorectally.
5. Breakage	5. Condoms made of extremely durable silicone.
6. Deterioration of latex by UV light, air, heat, and oils.	6. Silicone is resistant to UV light, air exposure and heat up to 425°F.
7. Allergy to latex (2.3% of population)	7. Silicone is non-toxic, biocompatible and non-allergenic.
8. Limited shelf-life: maximum of 1 yr under ideal conditions at room temp.	8. Extended shelf life: 2 years or longer at high heat temperatures.
9. Dip molding: limited fabrication method does not allow for varied structural design features. Material is either coated onto a mold or welded together with flat sheets of polyurethane.	9. Injection molding fabrication permits unlimited internal/external design features and controls.
10. Spillage/backflow; the MC provides a 'reservoir' that cannot retain semen, which can lead to spillage.	10. A unique, patented, one-way valve reservoir is designed help prevent backflow and spillage.
11. 5% or greater viral permeability	11. ORIGAMI ELASTOMER™ has tested at Zero viral permeability.

THE ORIGAMI ELASTOMER™ silicone has many significant advantages over existing materials such as latex and polyurethane. Silicone is more controllable, transmits heat better to facilitate greater sensitivity, and can be molded into any shape and size. The novel device is currently patent pending in the U.S. A European patent was approved in April 2008 and permission was granted for additional international patent application.

Mr. Resnic chose to produce the novel device using Liquid Injection Molding (LIM), a production process that is highly efficient, and offers a low unit cost. In addition, LIM can be processed anywhere there is electricity in a facility as small as 15'x20', compared with a latex condom plant, typically the size of a football field and requires proximity to a rubber source, such as in Thailand or Malaysia.

3.6 Relationship to longer-term Phase II objectives: The two human volunteer studies outlined in this protocol will accomplish a number of goals. The first, a User Preference Study, will allow us to identify which prototype of the ORIGAMI RAI CONDOM™ is most comfortable and acceptable to subjects to insert/ remove and wear. The Couples Acceptability & Performance Study will compare the performance and acceptability of the ORIGAMI RAI CONDOM™ with a commercial Latex Male condom, anal intercourse among the study participants.

Taken together, the results from the pre-clinical testing and user Preference/Acceptability Studies proposed here, will allow us to ascertain whether it is feasible and acceptable to use the ORIGAMI RAI CONDOM™, and to determine the optimal product design.

Table 3. Comparison of Condom Types

LEADING BRAND Male Latex Condom		**ORIGAMI RAI CONDOM™** Patented	
	**.01- .09** mm **W** 52 mm **L** 170-190 mm		**0.8–1.4** mm **W** 50 mm **L** 130-380 mm

Subsequently, if successful (as determined by criteria outlined in Sections 5.9, 8.4 we intend to conduct a Phase II, 12-week slippage & breakage and acceptability trial involving 200 couples and a minimum of 2400 (1200 uses of each condom type) condom-use events to evaluate acceptability and functional performance during intercourse of the final prototype compared with a Male Latex condom. That study will evaluate the breakage, slippage and safety of the ORIGAMI RAI CONDOM™ for both partners in comparison to the male latex condom. In addition, any episode of anal or genital irritation with product use would be promptly reported and symptomatic individuals will be evaluated. Adverse events and acceptability data would be collected.

Summary: The ORIGAMI RAI CONDOM™ varies from current approaches due to the biocompatible silicone material that it will be made of, which allows for improved sensation by simulating soft, natural human tissue and improved safety because of its greater strength and viral-impermeability. The ORIGAMI RAI CONDOM™ will also give the anal-receptive partner a method that is under his or her control, and it may be inserted in advance of intercourse to avoid disrupting intimacy.
as quotations that represent the themes – by subgroups.

4. Preliminary work done by the Key Investigators

4.1 Related R & D

ORIGAMI MALE CONDOM™

Thickness: 1.1 mm

W 45 mm

L 160 mm

The inventor, Daniel Resnic (PI of this proposed study), developed the ORIGAMI ELASTOMER™ silicone for the ORIGAMI MALE CONDOM™ (< LEFT) in 2006. The biocompatible silicone combined a high-tensile strength (660 psi), a low derometer (as low as 5 Duro), high elongation (1100-1350%) and unsurpassed tear strength while it created the soft feel of human tissue.

The "Origami Male Condom™ performed very well in a Phase I clinical trial ; no clinical breaks and only one slip off among approximately 100 uses. In addition, one-third of participants preferred the Origami Male Condom™ to the "TrojanEnz™" latex control condom, a best selling commercial condom. (See Attachment)

4.2. Acceptability Research Experience: The UCLA team lead by Dr. Pamina Gorbach has previous experience conducting acceptability research in clinical trials. Dr. Gorbach is a member of the Behavioral Research Working Group of the Microbicide Trials Network in which she conducts acceptability research. Additionally, she is the PI in the UCLA Microbicide Development Program (U19) on an acceptability study testing three types of rectal applicators entitled: Rectal Health, Behaviors and Microbicide Acceptability. This study just received full approval and site activation, which will occur January-March 2008. We propose the same study coordinator and site for the proposed study as was used for the rectal applicator acceptability study.

5. Research Design and Methods

5.1. Prototype Production: The PI, Daniel Resnic, inventor of the ORIGAMI RAI CONDOM™, will also serve as advisor and fabrication manager with product design engineers at Medco Products, Inc. to fabricate a first-iteration prototype mold using computer-aided design (CAD). The CAD model will be based on detailed patent drawings, latex models, 3-D animation, and detailed engineering specifications. The condom prototypes will be manufactured using liquid injection molding (LIM) with a two-part steel mold. The original mold cavity may be re-tooled and re-shaped for certain modifications. The use of LIM and a 2-part steel mold provides maximum flexibility and economy for design alterations that may be required in subsequent iterations. Samples will be made with pre-tested, biocompatible, high-strength ORIGAMI ELASTOMER™ silicone. Successful first-iteration prototypes will be readily produced. The sponsor has already invested a considerable amount of manufacturing research time and expense to develop the ORIGAMI ELASTOMER™ silicone, CAD resources, and computer animation. Three prototypes of the condom will be produced for pre-clinical testing, subject to pre-clinical testing outcomes of the proposed silicone materials (See Table 4 below).

The condom material, ORIGAMI ELASTOMER™, is a biocompatible, medical grade silicone. Previous silicones have been widely used in medical device applications for their extreme reliability and competitive unit costs, biocompatibility and it can be easily injected into a closed LIM mold system. The advantages of this manufacturing process include (1) cost-effectiveness due to the efficiency of the process, (2) fully automated closed-loop controls that reduce process variability and increase output reproducibility, (3) inherent cleanliness because material preparation is not required, (4) faster cycle times that allow higher production volumes, and (5) a wide range of design options for internal and external product design features not possible with latex dipping.

Table 4. Characteristics of the ORIGAMI RAI CONDOM™ Prototypes

PROTOTYPES	MATERIAL	SILICONE THICKNESS:	CONDOM BODY DUROMETER:	CONDOM COLLAR DUROMETER:
Prototype 1	ORIGAMI ELASTOMER-0134™	1.1 mm	10 Duro	20 Duro
Prototype 2	ORIGAMI ELASTOMER-8034™	1.2 mm	08 Duro	15 Duro
Prototype 3	ORIGAMI ELASTOMER-5034™	1.4 mm	05 Duro	10 Duro

Prior to testing, the prototypes will undergo the same fabrication procedures (solvent rinsing etc.) that the final, marketable condom will undergo to ensure that test results will reflect the true nature of the finished device.

5.2 Pre-Clinical Biocompatibility Testing: Biocompatibility testing is designed to predict how the body will react to product contact. The most recognized guideline for this type of testing is the ISO 10993-1 standard 18, developed for medical devices and dental materials by the International Organization for Standardization,[23,24] a worldwide federation of national standards.

The ORIGAMI RAI CONDOM™ will be manufactured using USP Class VI medical grade ORIGAMI ELASTOMER™ silicone. Class VI products meet the requirements defined in ISO 10993-1 for Surface Devices with "limited" (<24 hours) or "prolonged" (1 to 30 days) contact duration. [19,23,24] Class VI requires the most stringent testing of the six classes available.

The proposed testing is in accordance with ASTM and FDA guidelines for condom testing, as outlined in the blue book memorandum G95-1: Required Bio-compatibility Training and Toxicology Profiles for Evaluation of Medical Devices. [21] The guidelines require various tests depending on the device contact type, contact duration, and its clinical use. We anticipate a Non-Significant Risk (NSR) study determination by the UCLA IRB, because the low risk study population, previous biocompatibility testing and repeated pre-clinical testing proposed.

Although USP Class VI testing is widely used and accepted in the medical products industry, some view it as the minimum requirement a raw material must meet to be considered for use in health care applications. For this reason, additional biocompatibility testing will be conducted on samples cut from completely manufactured Origami Female Condom™ prototypes.

The proposed testing is in accordance with ASTM and FDA guidelines for condom testing, as outlined in the blue book memorandum G95-1: Required Bio-compatibility Training and Toxicology Profiles for Evaluation of Medical Devices.[40] The guidelines require various tests depending on the device contact type, contact duration, and its clinical use. We plan to do a pre-Investigational Device Exemption (IDE) submission to the FDA and make a request for a Non-Significant Risk (NSR) study determination, because the two studies proposed here are "design and preference" studies. Phase 1 results of the Origami Male Condom Feasibility Study (Section 4.1 and Attachment) report approximately 32% of consumer preference over the Trojan latex condom, of both men and women, with zero reported breakage .[31]

Specific pre-clinical toxicity tests [19] for this proposed project are as follows:

- The **MEM Elution** method will be used to test for **cytotoxicity**. This test demonstrates the cytotoxic effect of a material using mammalian cell culture media (MEM).

- **Local Lymph Node Assay** will be used to estimate the potential for contact sensitization.
- An **Intracutaneous Reactivity Test** will be used to assess the potential for irritation. In this test, an extract of the test article is injected intracutaneously (in rabbits). A control is also injected. The injection sites are observed and evaluated immediately after injection and at 24, 48, and 72 hours.

Acute systemic toxicity will be evaluated using systemic injection and a material-mediated pyrogen test. Systemic injection is used to evaluate systemic responses to leachables extracted from the test article following an intravenous or intraperitoneal injection into mice. Five mice will be injected intravenously or intraperitoneally with an extract of the test article. Similarly, five mice will be injected with a control. The material-mediated pyrogen test is designed to estimate the risk of a pyrogenic reaction as a result of parenteral (not digested) exposure to the material components. Three rabbits are injected in an ear vein with the test extract.

5.2.1 Preclinical Structural Testing: All three prototypes will undergo preclinical structural testing. Structural testing will be conducted by Nelson Labs in accordance with the American Society for Testing and Material's (ASTM) standard testing methods for rubber contraceptives/condoms (ASTM D3492-03)[23] and for male condoms made from synthetic materials (ASTM D6324-99A).[24] Tensile properties, leakage, permeability, and airburst volume and pressure will be evaluated. Additional structural testing will be conducted to determine potential failure points and of the device, providing information otherwise not determinable with conventional latex condom testing.

- **The tensile properties test** [23,24] evaluates the following parameters: dimensions, tensile strength, elongation, and tear resistance. To evaluate the **dimensions**, the condom specimens are put over a mandrel, and the length is measured in millimeters. The width is measured in millimeters at a specific distance from the open end. The thickness is measured in millimeters at three specific points measured from the two ends. To evaluate **tensile strength** and **elongation** [both at 25°C and 37°C], a ring specimen is cut from a specific place on the condom. The thickness at three equidistant points around the rim is measured and the median of the measurements is recorded. The minimum breaking force, the tensile strength, and the ultimate elongation are recorded. To evaluate **tear resistance**, samples of the silicone condom material are cut using the ASTM D624 C die, and the average of several thickness measurements is reported.
- In the **leakage test**, the condom is filled with a specific volume of water and is inspected for evidence of leakage. The **permeability test,** or **condom viral barrier evaluation,** is conducted for evaluation of the barrier properties of the condom. The evaluation consists of placing a suspension of Phi-X174 bacteriophage into the test condom and suspending the condom in sterile simulated serum. The external liquid will be assayed for the challenge virus (Phi-X174) using plaque assay techniques at time intervals of 0 and 30 minutes. The **airburst test** is used to determine the condom's strength and is performed by pressurizing the condom until it bursts. The results for the burst test include the burst pressure data and a description of where the seal failure occurred to provide a better idea of where the stress points are located.

5.3 User Preference Study *(Specific Aim 3):* After completion of prototype fabrication and pre-clinical testing (Specific Aims 1 & 2), we propose to conduct a User Preference Study* to identify the preferred prototype by comparing measures of user preference among the three prototypes including: ease of insertion and removal, attractiveness, feel, strength, shape, fit, and comfort of the three selected ORIGAMI RAI CONDOM™ prototypes among 30 Volunteers who practice RAI, in a non-coital context, who will practice insertion and removal (unrelated to coitus) of each ORIGAMI RAI CONDOM™ two times, either manually or by using a dildo. Subjects will be randomly assigned the order of trying the 3 different RAI prototypes. The study will consist of a telephone pre-screening, and 2 visits, 2 weeks apart: Screening Visit and Enrollment visit. **The criteria that will be used to determine that feasibility is demonstrated are outlined in Section 5.3.3.*

5.3.1 Study Design (User Preference Study)

We propose a randomized crossover study among 30 MSM participants who report a history of RAI. The cross-over design will allow direct comparison of preferences for the three silicone ORIGAMI RAI CONDOM™ prototypes. All eligible participants (Section 5.3.3 Eligibility Criteria) will be randomized to a sequence of three different ORIGAMI RAI CONDOM™ prototypes. Participants will be given two condoms of each prototype, and instructed to use each type of prototype at the Study Site (unrelated to coitus).

Because silicone has been FDA approved for medical devices, human implants and several contraceptive devices, such as cervical caps (FemCap™[11] & Lea's Shield™[12]) the likelihood of a serious adverse event is very small. However, in order to ensure the safety of study participants, we will instruct participants to contact the study staff by telephone and provide participants with a 24-hour telephone number if they feel any discomfort or pain beyond what is usual for them. If any participant requires medical attention, study staff will arrange for a medical examination by an appropriate licensed clinician. Our consultant Dr. Raphy Landovitz, is a physician present at the study site, who will be available if there is need for clinical intervention during use of

a RAI condom. He can also refer to the emergency room if necessary. A detailed list of eligibility criteria, (Section 5.3.3) has been previously reviewed by the FDA and used in dozens of Male and Female condom studies.

5.3.3 Eligibility Criteria (User Preference Study):

Subjects must meet all of the following Inclusion criteria to be eligible for the User Preference study:

- Aged minimum of 18 years.
- Able to speak, read and write in English.
- At least 3 acts of RAI sex with a man in the past month.
- In general good health, as assessed by self-reported medical history, with no acute or chronic illnesses that would interfere with study participation.
- Willing to not use non-study intra-rectal medication/device 24 hours prior to and throughout the study.
- Willing to not wear genital jewelry while using study condoms.

Subjects who meet any of the following Exclusion criteria will NOT be eligible for the study:

- Positive test for a rectal sexually transmitted infection at time of screening.
- Any other condition or reason that, in the opinion of the investigator, would make the patient unsuitable for the study or unable to comply with study requirements, such as, current or recent history of severe, progressive, renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, neurological, or cerebral disease.
- Allergy to silicone, latex, mineral oil or glycerin-based lubricants.
- History of anorectal herpes outbreak within 30 days of screening or enrollment.
- Report of anorectal pain or bleeding at screening or enrollment.

5.3.4 Recruitment and Telephone Pre-Screening (User Preference): In order to ensure timely recruitment of volunteers, we will implement a number of strategies that have been successfully used for previous research. Prospective participants will be recruited using the UCLA HIV Prevention Research Registry of which Dr. Gorbach is PI, advertisements in community media outlets (e.g. newspaper and internet classified listings). In addition, flyers will be designed to target eligible men and will be distributed in hard copy at HIV/AIDS service organizations, health clinics, community-based organizations, HIV testing sites, and community events. Interested participants will be pre-screened over the telephone for study eligibility. While on the phone, prospective participants will be given a description of the study. If they are interested, the interviewer will then proceed to schedule a screening visit. Study staff will maintain a database of all screening contacts.

5.3.5 Screening Visit (User Preference Study): Potential subjects will first be asked to provide written informed consent for screening procedures. Subjects will complete a baseline audio computer self-administered interview (ACASI) (20 minutes) about their sexual history and current anorectal symptoms.

5.3.6. STI tests. At study screening all potential participants will be tested for anorectal STIs via collection of anorectal specimens. Testing for *Neisseria gonorrhoeae and Chlamydia trachomatis* will be performed at a local laboratory where the PI has existing contracts for her other studies using the BD ProbeTech Strand Displacement Amplification System(SDA).

5.3.7. Collection of rectal swabs for *C. trachomatis* (CT), and *N. gonorrhoeae* (NG) testing. At screening, self-obtained anorectal swabs will be collected for NAAT testing for *C. trachomatis* and *N. gonorrhoeae*. Potential study subjects will be instructed to collect a anorectal specimens (one pink BD ProbeTec ET collection device) by inserting a swab 4 cm into the anorectal canal, placing it on the sides of the canal, and rotating. Upon collection, the pink BD ProbeTec ET collection device will be refrigerated and sent to the local for subsequent CT/NG testing. *Chlamydia trachomatis and Neisseria gonorrhoeae* will be detected rectal specimens using a BD ProbeTech Stand Displacement Amplification test that has been validated at the local laboratory for their detection in anorectal swabs.

5.3.8. Management of STI results: All participants will be contacted to be informed of the results of their tests for Gonorrhea, Chlamydia and all those with positive STI tests will be referred for treatment to a local STD clinic that provides free STI treatment according to their standard of care and STD Treatment Guidelines. As Gonorrhea and Chlamydia are reportable diseases all positives results of these tests must be reported to the LAC STDP. The laboratory conducting the analysis will automatically file a report and the participants will be referred to the Partner Notification program of LACSTDP.

5.3.9 HIV testing: This study is using a rapid HIV test, thus results are available within 20 minutes. The general structure of the HIV rapid testing session will be follows: Pre-test counseling and informed consent; HIV prevention/risk reduction counseling (in the clinical setting (risk reduction may be provided as part of pre-test counseling or by referral to a dedicated counselor or health educator); disclosure of the test result. After the study staff person completes the biological sample collection, s/he will take the participant to meet with a trained HIV counselor. In a private room, pre-test counseling will proceed. All participants will receive the result of their HIV

test, whether positive of negative, during the screening visit (i.e., post-test counseling). Post-test counseling will be conducted with all participants regardless of their results. Results will be disclosed in a private and confidential manner to the participant and the meaning of the result will be fully explained. Participants with a negative result will be eligible for study enrollment. Participants with a positive test result will be informed they are not eligible for the study. In cases where the HIV Rapid Test is positive and the participant originally reported that his/her last HIV test was negative or unknown, a blood sample will be sent to the local laboratory for Western Blot confirmation per federal and local regulations. The study staff person will also assist participants testing positive to get HIV medical care by referrals to local agencies.

5.3.10 Enrollment Visit (User Preference Study) – Acceptability testing and questionnaires: Within two weeks of the screening visit if all STI tests were negative potential participants will return to the clinic for the enrollment visit. Full informed consent for the study will then be obtained. Following the informed consent process, subjects will then be given a demonstration on the use of ORIGAMI RAI CONDOM™ by the study coordinator. In this demonstration, participants will be presented with the three prototypes. The study staff member will give an insertion demonstration on a translucent model. Subjects will be asked to visually and physically examine the ORIGAMI RAI CONDOM™. Each participant will receive a numbered packet of each of the three prototype ORIGAMI RAI CONDOMS™, for a total of six. The number on the packet will indicate the sequence of use randomly assigned for each participant, using computer-generated random sequence. Volunteers will be instructed to insert each condom prototype manually, wear it for up ten minutes, then remove and dispose of the condom. They will be asked to also insert with a dildo and then remove to determine the effect on the condom of removal with an object inside. Participants will be given a scorecard for each condom prototype use.

After trying each of the 3 prototypes twice, participants will complete a short, self-administered questionnaire to assess their preferences for each ORIGAMI RAI CONDOM™ design, comfort (inserting, removing, wearing), texture, odor, etc. This brief questionnaire will be administered via an Audio Self-Administered Interview (ACASI) and will last 5 minutes for each ORIGAMI RAI CONDOM™ donned at the clinic. The definition of acceptability used in this protocol is user satisfaction and preferences. The participants will be asked to rate up to 10 characteristics (e.g. ease of insertion, comfort while inserted) of each product after using it. Each individual measure makes up an aspect of acceptability, and the overall sum of the response to each item will produce an overall acceptability score per product. Finally, at the end of using all products the participants will be asked to rate them in order of preference and this will produce a measure of acceptability between the three tested products.

The participant will also have a short open-ended discussion (mini-qualitative interview) with the counselor after each try, and the exact words of his experience and opinions will be tape recorded. These tapes will be later transcribed verbatim and analyzed contextually (see analysis section). The study visit will take approximately 1.5 hours.

5.4 Couples *Acceptability & Performance Study (CAP Study):* After completion of the User Preference Study (Specific Aim 3) and refinement, if needed, of the preferred ORIGAMI RAI CONDOM™, we will conduct the Couples Acceptability & Perfomance Study (Specific Aim 4) to measure feasibility in terms of; functional performance variables, fit, safety, and acceptability during sex. Twenty four (24) HIV-negative male couples (minimum 3 month relationship) who practice anal intercourse, will participate in this study. Each couple will use the ORIGAMI RAI CONDOM™ that had the highest acceptability rating in the User Preference Study during a two week period. At the end of the two weeks, all couples will fill out an ACASI interview such as the one described above in which they will then be asked to rate various subjective features of the condom and report on any problems or challenges with using the product. They will also be asked to compare it to their experiences with using a latex condom during AI. This interview can be conducted via the web or the participants can come to the clinic to fill it out on a study computer. Then the couples will be supplied with latex condoms and asked to use these during at least 3 anal intercourse events over a two week period. At the end of this the two weeks, all couples will fill out an ACASI interview such as the one described above in which they will then be asked to rate various subjective features of the condom and report on any problems or challenges with using the product. They will also be asked to compare it to their experiences with using the ORIGAMI RAI CONDOM™ during AI. The CAP Study will consist of a telephone pre-screening, a screening visit, an enrollment visit, an ACASI interview after 2 weeks of use of product with each partner, a two week latex condom testing period, an ACASI interview, and a dyadic open-ended interview with both couple partners together, which will be taped and transcribed for qualitative analysis.

**The criteria that will be used to determine that feasibility is demonstrated are outlined in Section 5.5.7.*

Schema for Couples Acceptability & Performance Study *(CAP Study)*

Preferred Condom : 3 uses

	Visit 1	**Visit 2**	**Study**	**Study**	**Visit 3**
Telephone Pre-Screening	Screening Visit	Enrollment.	Each Couple will use 3 RAI condoms for RAI	Each couple will use 3 latex condoms for AI	Condom use Exit Visit .interview

over two weeks. over 2 weeks.

0 Wks . 1 Wk . 3 Wks 2 Wks 2 wks 1 Wks

5.4.1 Study Design (CAP Study)

We propose to conduct an open-label, study to measure the acceptability and performance of the preferred ORIGAMI RAI CONDOM™ prototype. The design will allow couples to directly assess the acceptability & performance of the ORIGAMI RAI CONDOM™ during AI with their partner. Each Subject will be interviewed separately.

5.4.2 Eligibility Criteria (CAP Study))

The eligibility criteria for Subjects will be identical to those for the User Preference Study (Section 5.3.4, above) with the addition of the requirement to agree to be monogamous during the month period when they are testing the condoms.

5.4.3 Recruitment and Telephone Pre-Screening (CAP Study)

The recruitment and screening procedures are the same as the User Preference Study (Section 5.3.8, above).

5.4.4 Screening Visit (CAP Study) : The screening visit will be the same procedures as the User Preference Study described above with the addition of urethral screening for STIs in addition to the rectal screening and HIV testing described above. At screening 30 mls of first void urine will be collected in addition to the self-obtained anorectal swabs for NAAT testing for *C. trachomatis* and *N. gonorrhoeae*. Subjects will be instructed to refrain from urinating for a least one hour before urine specimens are obtained and to provide 20-30 mL of first catch urine in the 4 oz urine specimen cup (Kendall) provided. Urine specimens of 4 mls will be immediately aliquoted into a Pink ProbeET collection devise (for CT/NG testing. The CT/NG BD tube will placed in the refrigerator (within one hour of collection) and maintained refrigerated until it is sent to the local laboratory (on ice) for CT/NG testing. Study subjects will be instructed to collect a anorectal specimens (one pink BD ProbeTec ET collection device) by inserting a swab 4 cm into the anorectal canal, placing it on the sides of the canal, and rotating. Upon collection, the pink BD ProbeTec ET collection device will be refrigerated and sent to the local for subsequent CT/NG testing. *Chlamydia trachomatis and Neisseria gonorrhoeae* will be detected in urine and rectal specimens using a BD ProbeTech Stand Displacement Amplification test that is FDA-approved to detect the organisms in urine and evaluated at a laboratory in anorectal swabs.

5.4.5 Management of STI Results: *These will be the same as described above for the User Preference Study (5,3,8).*

5.4.6 HIV Testing: *These will be the same as described above for the User Preference Study (5,3,9).*

5.4.7 Enrollment Visit: (CAP Study): All individuals who screened as eligible will come in with their partner to discuss the project with the Clinical Research Coordinator or Research Assistant, and those who confirm willingness to participate will undergo written informed consent (for each partner done separately). Then subjects will complete an ACASI questionnaire about their sexual history. Each participant will be asked about their prior use of male and female condoms, use of lubricants (commercial and otherwise) during sex, as well as their preferences and attitudes about these methods. Participants will also be asked to report any current anal symptoms.

The Clinical Research Coordinator or research assistant will then give the health education and condom demonstration session (13.3.5) and the preferred ORIGAMI RAI CONDOM™ will be demonstrated. Participants will be asked to privately practice inserting and removing the ORIGAMI RAI CONDOM™ while at the study site. Each couple will receive a packet that will contain three of the preferred ORIGAMI RAI CONDOMS™. Couples will be asked to use the three condoms during anal intercourse at home over the subsequent 2 weeks. Participants will be given a sheet with instructions on how to use the condom, including use of lubricant, and reminded to contact the study staff if they experience any trouble with condom use. Participants will use score cards for each condom use. Couples will also be asked to use latex condoms for 2 weeks following their trial period with the ORIGAMI RAI CONDOM™; and at the end of that 2 week period complete a ACASI interview. Participants will be instructed to contact research staff immediately if they encounter any problems or concerns related to the study, or experience any symptoms that are unusual for them. (Section 8.2.2)

5.4.8 Exit Visit (CAP Study): At the end of the two weeks, each participant (both members of each couple) will separately complete an ACASI questionnaire either by web or by coming to the study site to use the study computer, to assess the design, comfort and sexual pleasure aspects of use, and explore practical and feasibility issues such as ease of insertion, ease of removal, and disposal. Participants will be asked to return to the clinic together for their exit visit at the conclusion of 4 weeks of condom testing (2 with the ORIGAMI RAI CONDOM™ and 2 weeks with the latex condom) for a dyadic qualitative interview with a trained interviewer to provide in their own words their experiences and opinions about the condoms they used. These interviews will be tape-recorded and

transcribed verbatim. Finally, at the exit interview each member of the couple will be tested for STIs to assure that if one was acquired during the course of the study, it would be detected and any positive participant referred to an STI clinic for treatment. As the couples are encouraged to be monogamous during the study, we anticipate low risk for STI acquisition.

The *Couples Acceptability & Performance Questionnaire* will assess physical attributes, context, and use and performance attributes of the condom. Additional questions on the form at the exit visit will be asked about the new ORIGAMI RAI CONDOM™, such as design, fit, lubrication, sensation, comfort, and sexual pleasure (Table 3). Each Participant will also be asked to state an overall opinion of the ORIGAMI RAI CONDOM™ from the AI and RAI perspectives. The same acceptability assessment described above for the User Preference Study will be used for the ACASI questionnaire with the addition of items specifically about use during AI and the conditions around the AI event. Each individual measure makes up an aspect of acceptability, and the overall sum of the response to each item will produce an overall acceptability score per product.

Table 5 Key Measures to Assess Acceptability and Performance of ORIGAMI RAI CONDOMS™

Background characteristics*	Physical Attributes*	Context and Use Attributes	Performance Attributes
Previous MC experience	Appearance	Comfort, ease of use*	Breakage*
Attitudes toward FC/ MC	Insertion / Removal method	Interference with sex act	Slippage*
Lubricant use during AI	Lubrication	Noise	Semen backflow
	Fit	Mood/arousal level	

**Will also be measured during User Preference Study*

5.4.9 Objectives (CAP Study): The overall research objectives of this Feasibility & Acceptability Study are to investigate a safe, acceptable, insertable, RAI condom that is made of silicone. As such, we propose to produce three (3) ORIGAMI RAI CONDOM™ prototypes and conduct pre-clinical testing of those prototypes (See 5.2). Upon completion of pre-clinical testing we will identify safe and biocompatible prototypes, conduct a User Preference Study to identify which prototype is most preferred by men and women in a non-coital context, and refine the prototypes as needed (Specific Aim 3). Upon identification and refinement of the preferred ORIGAMI RAI CONDOM™ prototype, we will conduct a simulated sex Acceptability & Perfomance Study to measure the RAI acceptability of the ORIGAMI RAI CONDOM™ (Specific Aim 4).

Functional Performance & Fit: Examine the functional performance variables of the ORIGAMI RAI CONDOM™ prototypes during RAI.

Safety: Examine the effect of 3 separate condom uses during simulated RAI of the preferred ORIGAMI RAI CONDOM™ on symptoms of anal/rectal irritation associated in time with simulated RAI condom use for male Subjects.

Acceptability: Examine the acceptability of each condom use through the completion of a Study Questionnaire and open-ended interview after 3 uses after 3 RAI uses of each condom sample. Key items will be identified prior to analysis.

5.5 Data Collection and Statistical Analysis

5.5.1 Study population: (UPS Study and CAP Study): A total of 30 sexually active, HIV uninfected, males will be enrolled in the UPS study. They will be recruited from advertising and from the UCLA Research Registry. Participants will be selected according to the inclusion criteria. There was no formal sample size calculation for the User Preference Study and the Couples Acceptability & Performance Study because these are feasibility studies and some of the data is qualitative. However, the proposed sample sizes for each study will yield sufficient information to guide further research of the ORIGAMI RAI CONDOM™ in Phase II and evidence of this for UPS is provided below. We may, however, not have adequate power to identify statistically significant differences by group. The User Preference Study will involve 30 male participants. The Couples Acceptability & Performance Study will involve 24 Couples.

The ACASI questionnaires will be entered on a secure UCLA server where it will be available for data processing by UCLA research staff. Data coding, editing, verification and analysis will be performed at UCLA. ACCESS™ or comparable software will be used to structure and maintain data files. SAS and STATA software will be used to prepare tables and for statistical analyses.

5.5.2 Sample size (UPS Study): There was no formal sample size calculation for the Couples Acceptability & Performance Study because it is a feasibility study only. However, the proposed sample sizes will yield sufficient information to guide further research of the ORIGAMI RAI CONDOM™ in a subsequent Phase I and/or Phase II study. We may, however, not have adequate power to identify statistically significant differences. We calculate required sample size to carry out the primary objective of a paired comparison for the UPS. The sample size of 30 was chosen to ensure that we would be able to detect a difference of 1 unit or greater in acceptability score between the 3 condoms to be tested. We assume we are comparing the result of a Likert 1-5 scaled item or sum of several Likert 1-5 scale items and we conservatively assume that the within-person variance ^{2} (variance of a single person's ratings on repeated trials of condoms which have equal underlying true ratings) equals the between person variance D equals 1 for a total variance of D + ^{2} = 2. In a paired comparison, the between participant variance component D goes away, leaving the within participant

variance. The difference between two observations has sampling variance equal to 2 ^{2}. For a sample size of 20, we can detect a difference of 1.15 or .99 for 95% and 80% power respectively, giving us adequate power for the larger sample of 30. If we reduce to a more probable, but no longer conservative total variance of D+ ^{2} =1 equally split between within (variance ^{2} = .5) and between variance components (variance D = .5), then at 95% (80%) power for n=20, we can detect a difference of .57 (45). We conclude that we can detect a larger difference in a range of .50 to 1.1. Therefore, the sample sizes for both studies are adequate for analysis to detect differences in acceptability.

5.5.3 Sample size (CAP Study): There was no formal sample size calculated on this study as the goal is exploratory and descriptive about couples experiences using this condom during sex. As they are not comparing between different prototypes, and only provide gross comparisons to a latex condom, we feel the findings will provide excellent preliminary data for a future study.

5.5.4 Overview of Data Collection and Statistical Analysis: For the User Preference Study the design and preferences for the three prototypes of the ORIGAMI RAI CONDOM™ will be determined (Specific Aim 3). To assess acceptability, ratings of various subjective features; ease of insertion and removal, attractiveness, feel, strength, shape, fit, and comfort will be compared to determine overall preference for prototype #1, #2 or #3. There is a single major outcome: overall acceptability. It is the average of the constituent variables evaluating each of three condom prototypes. Average ratings will be plotted and broken out by participant covariates in profile plots (plotting ratings or averages on the y axis against applicator type 1, 2, or 3 on the x-axis or product sequence (temporal order of trial), connecting the dots within participant or within specific groups) for initial exploratory analysis. The product ratings from Likert response scales and sum of Likert scales using normal random intercept models will be modeled. Each participant will be assumed to have a person-specific random effect, and each product will have its own fixed effect. *Let y_{ij} be the i-th participant's response to the j-th condom. Let b_i be the random intercept for the i-th participant, and let m_j be the mean for the j-th product. We model- $y_{ij} = m_j + b_i + e_I$ with univariate $b_i \sim N(0,D)$ and $e_i \sim N(0, \ ^2)$. We will check to see if there is an order effect– mainly we anticipate that the first condom rating may be different (either high or low) compared to later condoms.* These models will be fit in SAS Proc Mixed (SAS Institute, Cary NC). Our primary interest is in identifying which prototype condom receives the highest average rating and whether it is better than the next highest rated condom. In exploratory analyses, person covariates will be included in the model to estimate differences in satisfaction between different groups (for example regular condom users versus non-regular users). For binary condom ratings, the model becomes a logistic random effects model which can be fit with SAS Proc Glimmix. Person specific covariates will be added to the models to determine what groups have higher satisfaction with the condoms.

For the Couples Acceptability & Perfomance Study (Specific Aim 4), the breakage, slippage, and failure rates for the ORIGAMI RAI CONDOM™ will be considered in RAI. To assess acceptability, ratings of various subjective features, such as comfort, sexual pleasure, ease of insertion and removal, fit, lubrication, sensation, breakage, slippage, and disposal of the preferred ORIGAMI RAI CONDOM™ will be evaluated. We will assess if there are differences in the acceptability rating by demographic differences in participants such as age and ethnicity and by behavioral differences such as previous condom experience and lubricant use.

5.5.5 Data Collection Instruments, Data Entry and Data Management: We will create all data collection instruments, including the questionnaires, forms, and IDI interview guides. Study staff will be trained by Dr. Gorbach in how to complete and to make corrections to data collection instruments. The study coordinator or designee will verify that data was entered on the ACASI questionnaires and they will have built-in checks for completeness. All questionnaires will be written in English. Completed documents will be kept in Participant folders (one folder per participant) in locked files at the study site and accessible online through the secure study website. These files can be accessed by study staff only. Information collected on study forms will be checked three times: by staff completing the forms at the study visit, when the Subject is still present; by the study coordinator or designee at the end of each day; by the data verifier at the time of data entry. ACCESS™ or comparable software will be used to structure and maintain data files. SAS software will be used to prepare tables and perform statistical analyses.

5.5.6 Data Analysis: In the User Preference Study, key outcomes will be (a) prototype preference and (b) non-clinical performance. Preference will be tabulated, and results will be stratified by demographic and behavioral characteristics, such as previous male condom use. Performance between the various condom prototypes will be assessed on the following characteristics: non-clinical breakage rate, slippage or breakage while in situ and misdirection Table 3 (Sec 3.6). Although the sample will be too small to make any conclusions based on these performance characteristics, they will be important considerations to inform design modifications. Preferences for key design criteria will be summarized.

In the Couples Acceptability and Performance Study, key outcomes will be (a) acceptability score described above for each of 3 condom uses, and (c) performance level (total clinical failures). Data will be tabulated and cross-tabulated to summarize group data, and separately for Subjects:

- Product preference will be assessed by asking participants to rate the three uses of the preferred condom.

- Product Acceptability will include for each condom use, a general question (overall, how much did you like condom X? rated on a 1-10 point scale), as well as specific questions regarding physical attributes, context, and use Table 3 (Sec 3.6). We will also assess product compliance and use, and ask participants for recommendations to improve design characteristics of the RAI CONDOM.
- We will describe (for each sample) the performance indicators[28] in Table 3 (Sec 3.6). For each condom sample, we will analyze the proportion of participants who experience a given outcome and the proportion of events over the total number of condoms used.

Men's experiences by age, previous condom use experience, and lubrication use will be compared, and results will be examined in relation to key contextual, behavioral, and demographic characteristics, as appropriate. For example, at each receptive anal intercourse act, data will be collected on alcohol use, timing of sex, and the location of sex. Results will be stratified by these contextual variables.

5.5.7 User Preference Testing: The prototypes tested in the User Preference Study may or may not be appropriate for further testing without modification. There will be data for 180 uses per prototype (30 volunteers x 3 prototypes x 2 uses each).

The following criteria will be used to determine the feasibility of proceeding to the Acceptability & Performance Study :

- No more than five condoms (of 180 total uses) break during anal intercourse or withdrawal (≤5%).
- No more than five condoms (of 180 total uses) completely slid out during intercourse or withdrawal (≤5%).
- Receptive Participant wears condom throughout RAI for at least 2 uses.
- Fewer than 20% of condom uses result in anal discomfort.
- Fewer than 20% of condom uses result in male penile discomfort.
- At least 50% of Subjects report that they would be willing to use the ORIGAMI RAI CONDOM™.

These criteria are based on dozens of earlier Male and Female condom studies conducted, where they were found highly typical.[28] If all 3 prototypes meet the criteria above, a preferred prototype will proceed to an Acceptability & Performance Study.

If none of the prototypes meets all the criteria, the best one will be improved through design modifications. Subsequently, we will enroll a second pilot group in a User Preference Study, which will compare three modified versions of the ORIGAMI RAI CONDOM™ before proceeding to the Acceptability & Performance Study.

5.5.8 Couples Acceptability & Performance Testing: If the preferred version of the ORIGAMI RAI CONDOM™ prototype tested in the Acceptability & Performance Study does not meet all of the above criteria, the condom design will be modified to correct any deficiencies before continuing with future testing plans for a *Phase II Couples Acceptability & Performance Study*.

There will be data for 180 uses of the ORIGAMI RAI CONDOM™ and 30 uses of the male latex condom. The following criteria will be used to determine the feasibility of proceeding to Phase II R&D studies:

- Fewer than 20% of condom uses of the ORIGAMI RAI CONDOM™ result in anal discomfort.
- Fewer than 20% of condom uses of the ORIGAMI RAI CONDOM™ result in male penile discomfort.
- At least 50% of Subjects report that they would be willing to use the RAI condom.
- The clinical failure rate of the ORIGAMI RAI CONDOM™ is no higher than that of the male latex condom
- The total failure rate of the ORIGAMI RAI CONDOM™ is no higher than that of the male latex condom
- At least 25% of Participants prefer the ORIGAMI RAI CONDOM™ to the male latex condom

Other than the issues discussed above, the sponsor and UCLA do not anticipate any other difficulties in conducting the proposed studies. The Investigators have successfully conducted both studies and clinical clinical research for over a decade. In previous and ongoing studies, the Investigators have not had difficulties with participant recruitment or retention. In fact, the lost to follow-up for their studies has historically been below 10%. Therefore, we do not expect problems with recruitment and retention for the proposed studies. In the unlikely event that such problems arise, advertising and follow-up efforts will be increased accordingly.

5.5.9 In depth Interviews (IDI)s: At the end of the visit for the *User Performance Study* and the Couples Acceptability & Performance Study, individuals will be interviewed using an open-ended interview guide by a trained interviewer (the interviews will be with the couples together for the latter study). Male interviewers will be trained in interview techniques such as probing, framing, summarizing, and checking. An interviewer manual and interview guide will be developed by the study investigators (Gorbach and Resnic) to insure the consistency of the data. Participants will be asked to describe in their own words their experiences with the condoms and opinions and impressions about each prototype or each sexual event for the CAP study. Each episode where they used the condom will be asked about in detail so that other influences will be described (such as the individuals general feelings such as being tired, irritated, highly aroused, ect.). All tape recorded interviews will be transcribed verbatim into Word documents for text analysis.

It is anticipated that quantitative and qualitative results from the pilot User Preference Study will lead to clear preferences and modification recommendations that will be taken directly to the design studio for the revisions of one ORIGAMI RAI CONDOM™ model for testing in the Acceptability & Performance Study. The measurement criteria used to select the best ORIGAMI RAI CONDOM™

prototype are described in detail in Table 3 (Sec 3.6), above. However, if the study does not yield clear preferences, it may be necessary to complete an additional round of the user preference study with additional participants.

5.6. Analysis for IDIs: For the analysis, all interviews will be tape recorded and transcribed verbatim. The response text will be searched, labeled, extracted, and categorized for each topic of interest using content analysis. The labels, also known as codes, will be derived from the project's research questions. To identify themes, interview segments with the same label will be grouped and analyzed for similarities and differences. The first set of interviews will be independently coded by two individuals and discrepancies compared to standardize code definitions. Throughout the proposed study all coded interview transcripts will be reviewed by Gorbach to provide oversight to the coding process. The text from the interviews will be analyzed in ATLAS.ti, a software package for text analyses that will be used to extract and sort interview text into single file statements with the same code from all interviews. Matrices will be developed for each of the codes to note common threads and contrasts found in the statements. Once themes have been identified, described and summarized, survey questions will be developed to form the basis of the questionnaire described below. We will report findings by the proportion of various sub-groups interviewed, including ethnicity and age, giving their reasons under each category, the apparent strength with which certain attitudes are held, or issues on which there is substantial difference of opinion.

5.7 Potential Pitfalls, Alternatives, and Solutions: Potential difficulties have been minimized with previous research for the ORIGAMI MALE CONDOM™ made of ORIGAMI ELASTOMER-0134™ silicone. Solutions to molding issues have been extensively discussed and resolved with Medco Products. Silicone development has been extensively explored with the assistance of BlueStar Silicones, the foremost international supplier source of medical grade silicone. Proper fit and condom retention are of primary focus and we have included consultants to expedite the design process.

5.8 Final Study Report: The final study report will contain pre-clinical testing reports, descriptive statistics on the study population, a tabular presentation of findings, and the results of the analyses. Narrative descriptions of all results and methods of analysis will be included. The final report will also include recommendations for product revisions.

Pre-clinical testing reports for the ORIGAMI RAI CONDOM™, independently prepared by Nelson Laboratories, are summarized (Attachments). Complete reports are available on request. Product labeling for this investigational device is as follows;

RESEARCH CONDOM CAUTION:
Investigational Device. Limited by law to investigational use only. This product may fail during use and must **not** be used for contraception or STD/HIV prevention. This product contains silicone and mineral oil, which are not known to cause allergic reactions.
Participants must return unopened condoms to study site at the end of the study.
DISTRIBUTED BY: Strata Various Product Design, USA

5.9 The prototypes tested in the User Preference & Acceptability Study may or may not be appropriate for further testing without modification. There will be data for 180 uses of the ORIGAMI RAI CONDOM™ prototypes (30 volunteers x 3 prototypes x 2 uses each). The following criteria will be used to determine the feasibility of proceeding with a preferred prototype to the Acceptability & Performance Study:

- No more than five condoms (of 180 total uses) break during anal insertion or removal (≤5%).
- No more than five condoms (of 180 total uses) completely slid out during simulated intercourse or withdrawal (≤5%).
- Receptive AI partner wears condom throughout intercourse for at least 2 uses.
- Fewer than 20% of condom uses result in female anal discomfort.
- Fewer than 20% of condom uses result in male anal discomfort.
- At least 25% of Subjects report that they would be willing to use the ORIGAMI RAI CONDOM™ for RAI in the future.
- The clinical failure rate of the ORIGAMI RAI CONDOM™ is no higher than that of the male latex condom statistics.
- The total failure rate of the ORIGAMI RAI CONDOM™ is no higher than that of male latex condom statistics.

5.10 Overview of Data Collection and Statistical Analysis: Our research staff will review all questionnaires and forms for completeness and accuracy and return them to the central research office for processing. Data coding, editing, entry, verification, and analysis will be performed there as well. There is no formal sample size calculation for the User Preference Study, as it is not a hypothesis-driven study. The proposed sample size of 30 for the User Preference Study and its results concerning measures of user preference (by most number of votes) among the three prototypes including: ease of insertion and removal, attractiveness, feel, strength, shape, fit, and comfort should yield enough information for further refinement and, if needed, design modification before proceeding to the Couples Acceptability & Performance Study.

In each study, the following information will be collected for each condom type:

a. number of packages opened
b. number of condoms used for anal intercourse
c. number of condoms broken prior to anal intercourse while opening package or inserting condom
d. number of condoms broken during anal intercourse or withdrawal from rectum (breakage)
e. number of condoms that slid/pulled out completely during anal intercourse (slippage)
f. number of condoms that slid out completely during withdrawal causing semen to spill into rectum
g. number of condoms that involved penile misdirection
h. number of condoms that could not be used for other reasons (e.g. defective, would not unfold)
i. identification and number of any other performance problems (e.g. partial slippage)

From the data listed above, we will calculate the following rates:

Total breakage rate (c + d)/a, Clinical breakage rate (d/b), Total slippage rate (e + f)/b, Other failure rate (g/a), Total failure rate (c + d + e + f + g + h)/a and Clinical failure rate (d + e + f)/b

The final report will contain: descriptive statistics on the study population, a tabular presentation of findings, and the results of analysis, recommendations for condom improvements / testing (if needed) and Narrative descriptions of results and methods of analysis. Verbatim quotations from the IDIs will be entered into matrices and an analysis of themes conducted. The final report will include a report of the themes as well as quotations that represent the themes – by subgroups.

6. Inclusion Enrollment Report

Not applicable.

7. Progress Report Publication List

Not applicable.

8. PROTECTION OF HUMAN SUBJECTS

8.1 Risks to the Subjects

Human Subjects Involvement and Characteristics

UCLA conducts studies involving human subjects after the UCLA Institutional Review Board has approved the research, including the study protocol, informed consent form, instructional materials, data collection instruments, and any advertisements. UCLA has over 10 years of experience in the design, execution, administration and analysis of Phase I, II, III, AIDS-prevention studies. The proposed research will be conducted in compliance with UCLA Research Division institutional policies, requirements of the UCLA IRB, and Title 45 Code of Federal Regulations, Part 46, Protection of Human Subjects, FWA00004642.

In the User Preference Study, the preferences of three prototypes of the ORIGAMI RAI CONDOM™ will be evaluated. UCLA will recruit 30 volunteers to test two condoms of each of three prototypes (180 total) in a non-coital context and, for each condom type, complete a structured questionnaire inquiring about ease of application, ease of removal, appearance, fit and comfort. MSM Subjects will be between the ages of 18 and 45 (inclusive). Please see Section 5.3.3 for a full list of eligibility criteria.

In the Couples Acceptability & Performance Study, subjects (24 couples – 24 individuals will use an ORIGAMI RAI CONDOM™ prototypes. Subjects must meet all of the eligibility criteria (Section 5.3.3 and 5.4.2), including to not be allergic to silicone, latex or mineral oil.

A detailed description of study involvement is provided in Sections 4.0 and 5.0 of the Research Plan.

Sources of Materials

Data is collected through interaction with research subjects specifically for research purposes. Subjects complete questionnaires, condom use reports, and submit comments/suggestions. A detailed description of the information to be collected is presented in Sections 4.0 and 5.0 of the Research Plan.

Potential Risks

Minor side effects related to condom use may include irritation, rash, itching, swelling and redness of the rectal/anal area. These side effects are expected to be self-limiting. Potential risks to privacy and confidentiality also exist. There are no known serious risks associated with silicone, lubricants or any of the procedures employed in the study.

8.2 Adequacy of Protection against Risks

8.2.1 Recruitment and Informed Consent: All subjects will be recruited from print media advertisements placed in a variety of community newspapers and Internet classifieds / web blogs to assure a diverse, representative study population. Any advertisements to recruit subjects will be submitted to the IRB for review and implemented only after their review and approval.

The purpose and requirements of the study will be explained before prospective subjects are presented with an informed consent. Subjects will also be advised that more detailed information about sexual activity will be collected than is typical of most family planning visits. Subjects will be given an opportunity to ask questions about the study and/or the content of the informed consent. All volunteers will be required to provide written informed consent before they are enrolled in the study. All subjects will receive a copy of their signed informed consent form. Informed consent is sought from each Subject in accordance with Code of Federal Regulations, Title 45, Part 46, paragraph 46.116.

8.2.2 Protection against Risk: Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk. Subjects are required to use the study products at the study site in non-coital context of simulated RAI sex and are not at any risk of contracting a sexually transmitted disease. All members of the research staff are required to complete NIH's internet-based Protection of Human Research Subjects training course.

To assure subject confidentiality, personal identifiers will be deleted from all the data forms. All data records will be identified by number only and will not contain any name, social security number, or address.

The Institutional Review Board will assess measures to make sure subject's safety, privacy, and confidentiality are maximized.

8.3 Potential Benefits of the Proposed Research to the Subjects and Others: There are no benefits to subjects associated with study Subject. All supplies, including condoms, will be provided free-of-charge to subjects. Potential benefit to others is the development of a new RAI condom that might help combat the HIV/AIDS crisis.

Although not considered a benefit, each Subject in the User Preference Study will be compensated $50 for trying each ORIGAMI RAI CONDOM™ prototype for a total of $150. For the Couples Acceptability & Performance Study will be compensated $200 for completing all study visits and forms and using the ORIGAMI RAI CONDOM™ and the male latex condom during sexual intercourse over a period of two weeks.

Risks to subjects are reasonable in relation to anticipated benefits. The IRB will review the research proposal to determine whether: the research design is scientifically sound and will not unnecessarily expose subjects to risk; risks to subjects are reasonable in relation to anticipated benefits; Subject selection is equitable; and safeguards are included for subjects likely to be vulnerable to undue influence.

8.4 Importance of the Knowledge Gained: With at least 32 million people currently living with HIV/AIDS and another 5 million acquiring the disease annually, slowing the spread of this deadly disease is a major public health priority.[15,16] For sexually active couples who engage in RAI sex, male latex condoms are the most widely used method to reduce the risk of transmitting HIV and other sexually transmitted infections (STI). Unfortunately, many individuals are unwilling or unable to use male condoms. Reasons for non-use and discontinuation include such factors as perceived lack of product quality, breakage, access and availability, cost, difficulty and discomfort with use, diminished sensitivity, allergy to latex, and social and cultural beliefs. The development of a new RAI condom for both women and men is an urgently needed component in combating the HIV/AIDS crisis.

The primary objective of this grant is to refine a prototype of the ORIGAMI RAI CONDOM™: an RAI silicone condom that is intended to help prevent HIV/STD/STI transmission. The two clinical studies outlined in this protocol will accomplish a number of goals. The User Preference Study will allow us to identify which prototype of the ORIGAMI RAI CONDOM™ is most preferred and provide a basis for product modification and improvement. The Couples Acceptability & Performance Study will allow us to compare the acceptability and performance of the ORIGAMI RAI CONDOM ™ to a commercially available Male Latex condom.

The data obtained in the Phase I evaluation will allow us to finalize the product design and ascertain whether the product is feasible and sufficiently safe and acceptable for human subjects to use, which is necessary before proceeding with a Phase II Study. If successful in Phase I, we intend to conduct a Phase II Study involving 300 subjects and a minimum of 1,080 condom uses to evaluate the functional performance, breakage/slippage (B/S) rates, safety, and overall acceptability of the final prototype. The Phase II Study will allow us to establish whether we have a sufficiently acceptable and safe product and if that product needs to be modified.

9. Inclusion of Women and Minorities in Clinical Research: UCLA adheres to the NIH policy of including women and members of minority groups and their sub-populations in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate. The rectal condom will likely target men who have sex with men (MSM) first, and then if it proves acceptable, it would also be tested by women. Therefore, in this first acceptability study of the ORIGAMI RAI CONDOM™ only MSM who practice AI on a regular basis will be included.

UCLA has a proven track record of including racially and ethnically diverse subjects in all of its phase I, II, and III studies of contraceptives. UCLA has clinic locations in different geographic locations in Los Angeles, and they use broad-based multimedia advertising campaigns to ensure that subjects are racially and ethnically diverse. UCLA will recruit 24 Couples for the CAP study.

Principal Investigator/Program Director (Last, First, Middle): Resnic, Daniel

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: RAI Condom; User Acceptability Study and Couples Acceptabilty Study

Total Planned Enrollment: 78 participants: (30 individuals, 24 couples of 48 individuals);

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	15	15
Not Hispanic or Latino	0	63	63
Ethnic Category: Total of All Subjects *	0	78	78
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	4	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	8	8
White	0	66	66
Racial Categories: Total of All Subjects *	0	78	78

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

11. Inclusion of Children: UCLA recognizes that it is the policy of NIH to include children in all human subjects research unless there are compelling reasons not to include them, and we understand that the NIH considers individuals under 21 as "children." At UCLA, research involving children is reviewed by the IRB under 45 CFR 46 Subpart D, which allows adolescents under the age of 18 to participate in research studies in limited circumstances; however, this study has been limited to individuals aged 18 and over because the target population of the study product is sexually active MSM and their partners.

12. Vertebrate Animals

Vertebrate animals will be used for pre-clinical testing by WuXi-Apptec Laboratory Services Inc. (subcontractor of Nelson Laboratories). WuXi-Apptec will use approximately 12 rabbits and 20 mice. The rabbits will be New Zealand White strain male or female adults. The mice will be 8-12 week old females of the CBA/J or CBA/Ca stAIn.

The use of animals in this study (including the species and numbers proposed) is in accordance with biocompatibility testing guidelines established by International Standard ISO 10993-10 and 10993-5 (1998), the Federal Hazardous Substances Act (FHSA), and AAMI Standards & Recommended Practices (1997).[2, 5]

The rabbits will be housed individually at 16-22˚C and 20% relative humidity. They will be fed approximately 200 grams of Laboratory Rabbit Diet per day and tap water ad libitum. The mice will be housed in groups of ≤5 at 18-26˚C and 20% relative humidity. They will be fed Laboratory Rodent Diet and water *ad libidum.*

WuXi-Apptec Inc. Laboratory Services, located in St. Paul, MN, is a sub-contractor of Nelson Laboratories. They will conduct all necessary irritation and other animal testing. There are 22 animal rooms in the WuXi-Apptec facility and 6 rooms at the Veteran's Hospital controlled by WuXi-Apptec. The vivarium area at WuXi-Apptec is divided among quarantine and general housing dedicated to rodents. WuXi-Apptec has a separate BSL-2 rodent suite, and an expansion area to accommodate additional animal housing for both rodents and non-rodents. All air supply is certified air exchanges. WuXi-Apptec's design allows for ample support areas, including clean rooms, sample prep areas, a new cage rack pass-through washer and a separate clean cage storage room. WuXi-Apptec also has a histology lab, tissue processing area, locker/change rooms, and offices for the In Vivo Services department with further room to expand as necessary.

The Veteran's Hospital also is divided similarly among quarantine, general housing, and surgical suites for non-rodent and larger animal studies such as rabbits and dogs. There are separate areas for offices, cage washing and storage.

WuXi-Apptec Inc. Laboratory Services was issued a renewal of their Animal Welfare Assurance certification, No. 41-R-0061, and expires on September 28, 2010.

13. Select Agent Research

Not applicable.

14. Multiple PI/PD Leadership Plan

Not applicable.

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15. Consortium/Contractual Arrangements

15.11 Regulatory: UCLA maintains a registered IRB in full compliance with all current FDA, OHRP and NIH guidelines which meets regularly to review and approve all UCLA research projects. All IRB members (as well as all UCLA research staff) have completed required NIH computer-based training in the protection of research subjects. Prior to the onset of a clinical research study, the study protocol, instructional materials, data collection instruments, and informed consent are reviewed and approved by the UCLA IRB.

The UCLA Research team proposes the support of a clinical research coordinator who will be responsible for developing and updating all Research Division Standard Operating Procedures (SOP's) and maintaining all research records in accordance with current FDA regulations and International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines.

UCLA has a current Federalwide Assurance , FWA00004642, the OHRP, as required to conduct federally-funded research. The UCLA IRB is registered with the OHRP. The UCLA research staff report all serious adverse events to the IRB and the study sponsor as required by law and as stipulated by study protocols.

UCLA maintains an active cohort of appropriate participants, and a research clinic in Los Angeles , that will be used for this study. The UCLA co-Investigators, Dr. Pamina M. Gorbach and Dr. Robert Weiss, will design the study instruments, and be the key liaison with the UCLA IRB and the study site.

15.2 Medco Products, Inc. (Anaheim, CA)

As a member of the consortium, Medco will be responsible for the formulation, specification and fabrication of the ORIGAMI RAI CONDOM™. Medco has facilities for prototyping and mass production of medical device components produced in LIM silicone. Medco is a custom injection molder of precision silicone products. The company provides innovative, leading-edge design and development of prototype and production products, which has enabled it to build a successful organization capitalizing on years of molding experience.

Medco has been serving the needs of the medical device industry since 1997, operating from a 5,000-square ft facility, housing liquid injection molding machines ranging from 21 ton up to 225 ton for both silicone and thermoplastic. All components are GMP manufactured in a Class 100,000 Cleanroom with two shifts daily to maintain quality and on-time delivery. Medco provides cost savings and on-time delivery in tooling with the comprehensive tooling designers and mold-building equipment in-house.

15.3 Nelson Laboratories, Inc. (Salt Lake City, UT)

As a member of the consortium, Nelson Laboratories, Inc. will conduct the pre-clinical biocompatibility testing. Nelson Laboratories has a 62,000 sq. ft., FDA-registered facility. They maintain 80 labs, a custom-built 3,000 sq. ft. Cleanroom, and employ more than 170 scientists and staff. Among their more than 75 degreed scientists are 25+ registered and specialist microbiologists (National Registry of Microbiologists). In January of 1996, Nelson Laboratories was certified to ISO 9001 standards by BSI Quality Assurance (ISO 9001:2000 certificate of registration), surpassing all of the auditors' expectations. Also, in March of 1997, Nelson Laboratories was certified to EN 45001/IEC/ISO 17025 standards (ISO 17025 certificate of registration) by Amtac Certification Services Limited, (Certificate No. 123) FDA Registered (Registration Number 1721109). Nelson Laboratories offers more than 400 microbiological and analytical tests and extensive condom testing experience.

15.4 WuXi-Apptec Inc. Laboratory Services (St. Paul, MN)

WuXi-AppTec Laboratory Services located in St. Paul, MN is a sub-contractor of Nelson Laboratories. They will conduct all necessary irritation and other animal testing. There are 22 animal rooms in the WuXi-AppTec facility and 6 rooms at the Veteran's Hospital controlled by WuXi-AppTec. The vivarium area at WuXi-AppTec is divided among quarantine and general housing dedicated to rodents. WuXi-AppTec has a separate BSL-2 rodent suite, and an expansion area to accommodate additional animal housing for both rodents and non-rodents. All air supply is certified air exchanges. WuXi-AppTec's design allows for ample support areas, including clean rooms, sample prep areas, a new cage rack pass-through washer and a separate clean cage storage room. WuXi-AppTec also has a histology lab, tissue processing area, locker/change rooms, and offices for the In Vivo Services department with further room to expand as necessary.

The Veteran's Hospital also is divided similarly among quarantine, general housing, and surgical suites for non-rodent and larger animal studies such as rabbits and dogs. There are separate areas for offices, cage washing and storage.

WuXi-AppTec was issued a renewal of their Animal Welfare Assurance certification, No. 41-R-0061, which expires on September 28, 2010.

15.5 Silicone Developer; BlueStar Silicones

BlueStar Silicones is one of the foremost, fully integrated silicone manufacturers in the world. With over 50 years of silicone expertise, BlueStar Silicones offers a comprehensive range of silicones products in the sectors of release coatings, engineering elastomers, healthcare products, specialty fluids, emulsions and resins.

BlueStar Silicones, a first rate contact for manufacturers in all health care application sectors, offers the Consortium the opportunity to take full advantage of its research, expertise and broad commercial experience in silicone technology.

BlueStar Silicones' commitment to service in the fields of dentistry and health care treatments, also means: a perfect grasp of silicone chemistry by its research laboratory teams bringing original solutions to the problems being faced, specialists in materials ready to provide rapid, reliable and expert technical assistance, technical datasheets and samples on request, assistance with any questions related to regulations concerning the use of silicones provided by their experts in toxicology and regulatory matters, a commercial BlueStar Silicones' network in more than 140 countries, constantly responding to customer needs.

Extensive toxicology testing on BlueStar Silicone products has demonstrated their adequate biocompatibility and suitability for the recommended applications. Our evaluations according to EN/ISO 10993 showed that silicone products are non skin-irritating nor skin-sensitizing materials. They satisfy regulatory requirements in several countries, in particular those of class I medical devices as in 93/42/CEE European Directive, or those of US Pharmacopeia Class VI. Toxicological summaries, statements and specific regulatory status are available upon request from Bluestar Silicones.

BlueStar Silicones offers a wide range of two component silicone elastomers of both silanol cure and addition cure type that fully meet the increasing requirements of the medical device industries. BlueStar Silicones is committed to a sustainable development policy based on health, safety, the environment, transport, substances and regulations related to manufactured products.

16. Letters of Support

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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SANTA BARBARA • SANTA CRUZ

DEPARTMENT OF EPIDEMIOLOGY
SCHOOL OF PUBLIC HEALTH
BOX 951772
LOS ANGELES, CALIFORNIA 90095-1772

January 4, 2009

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd, Suite 318
Beverly Hills, CA 90211

RE: Origami RAI Condom Study

Dear Dan,

It is my pleasure to collaborate on your proposed Phase I study of the Origami RAI Condom™ for receptive anal intercourse (RAI). The Origami RAI Condom™ is innovative and potentially acceptable for AI use, considering the durable, heavy gauge silicone material they are made of. It could offer a viable alternative to latex condoms that may be more compatible with AI, and therefore, provide a much needed other method of HIV prevention.

My research team is experienced in conducting acceptability research on new methods of HIV prevention. As a member of the Behavioral Working Group of the Microbicides Trials Network I have been actively involved in the design of acceptability component of clinical trials of microbicides. Furthermore, at the University of California, Los Angeles, I am the team leader of Project 3 (Rectal Health and Behaviors and Acceptability of Rectal Applicators) of the Microbicide Development Program a U19 to develop rectal microbicides. My study involves acceptability research on rectal applicators. The same research team is proposed to conduct the Phase I acceptability research for the Origami RAI Condom™.

Several other researchers here at UCLA are interested in discussing these research projects further with you and we hope we can provide some support for these innovative projects. If funded, I look forward to working with you to conduct the acceptability research on the Origami RAI Condom™ at UCLA.

Sincerely,

Pamina M. Gorbach, MHS, DrPH - Associate Professor

Department of Epidemiology, School of Public Health and
Division of Infectious Diseases, David Geffen School of Medicine,
University of California, Los Angeles

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On-Campus Mailcode: 140607

www.research.ucla.edu/eipa

December 19, 2008

Daniel Resnic
Strata Various Project Design
311 North Robertson Blvd #318
Beverly Hills, CA 90211

SUBJECT: UCLA SBIR Subaward Proposal Entitled: RAI Condom: Feasibility & Acceptability Study, Phase 1 Pilot Research Program

Dear Mr. Resnic:

On behalf of the Regents of the University of California, I am enclosing an SBIR subcontract proposal entitled: "RAI Condom: Feasibility and Acceptability Study, Phase 1 Pilot Research Program." The research will be supervised by Pamina Gorbach M.H.S, Dr.P.H. The amount of funding requested is $303,195.00 (including direct costs) for the period of July 1, 2009 through December 31, 2010.

UCLA's final acceptance of this award will be contingent upon approval from the UCLA Conflict of Interest Review Committee and execution of an appropriate subcontract agreement. Please note that UCLA cannot enter into a subcontract that incorporates terms and conditions inconsistent with UCLA's status as a public, educational, non-profit institution. In addition, UCLA must be able to publish the results of the research without restriction and retain title to any UCLA-developed intellectual property.

We look forward to the opportunity to contribute our expertise and knowledge to this project.

Sincerely,

Karla Zepeda
Industry Contract Officer
Industry Sponsored Research
kzepeda@research.ucla.edu
(T) 310-206-5202

DAVID GEFFEN SCHOOL OF MEDICINE
UCLA CARE CENTER
1309 Roxbury Drive, Suite 100
Los Angeles, California 90035

ALEN VOSKANIAN, M.D.
ASSOCIATE PHYSICIAN DIPLOMATE
Phone: 310-557-2273
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Prescription line: 310-557-9691
Page Operator: 310-825-6301

December 30, 2008

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd
Suite 318
Beverly Hills, CA 90211

RE: Origami RAI Condom Study

Dear Dan,

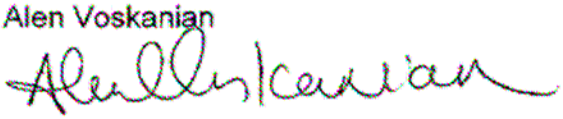
I am happy to be included as a consultant for your Phase I proposal of the Origami RAI Condom, a unique condom concept specific for AI use. It has the potential to provide an improved option for AI than the traditional latex condom, which is not designed or FDA approved for AI use.

I will provide assistance relevant to product development and design surrounding potential issues of condom retention in the rectum. As a specialist in rectal anatomy and health, my background has involved research in many areas of HIV prevention strategies, including performing high resolution anoscopies for various research projects including AMC-025 and U-19. AMC-025. These projects included evaluation of efficacy of Gardisil vaccine in HPV prevention in HIV infected patients, development of rectal microbicides, and evaluation of various new HIV medications.

I look forward to providing technical and anatomical scientific support for this innovative project. Please feel free to include this letter of support with your grant applications.

Sincerely,

Dr. Alen Voskanian



UCLA
Center for
Prevention Research
CPR
Strategic Interventions Against HIV

David Geffen School of Medicine at UCLA
Department of Medicine
Division of Digestive Diseases

10940 Wilshire Boulevard, Suite 1250
Los Angeles, CA 90024

October 24, 2008

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd, Suite 318
Beverly Hills, CA 90211

RE: Origami Condom Study

Dear Dan,

It was good talking with you in detail about your proposed Phase I study of the Origami Male Condom for AI use. The Origami Male Condom and the Origami RAI Condom are innovative and potentially more acceptable for AI use, considering the durable, heavy gauge silicone material they are made of. These could offer a viable alternative to latex condoms that may be more compatible with AI.

In particular, with our vaccine and microbicide studies and clinical trials, we have routinely heard from our participants about the need for less offensive, more sensitive condoms. Our particular group, with expertise in mucosal immune responses and topical toxicity, may be of help in the panning and design of future pre-Phase 1/Phase 1 trials. If so, we'd be glad to be of assistance.

Several researchers here at UCLA are interested in discussing these research projects further with you and we hope we can provide some support for these innovative projects. Please feel free to include this letter of support with your grant applications.

Sincerely,

Peter A. Anton, MD
Professor of Medicine
Director, Center for HIV Prevention Research
David Geffen School of Medicine at UCLA
MRL 2734, 675 Charles E. Young Dr. South
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January 2, 2009

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd
Suite 318
Beverly Hills, CA 90211

RE: Origami RAI Condom Study

Dear Dan,

I am pleased to be part of your proposed Phase I study of the Origami RAI Condom, an innovative condom specific for AI use. This new concept has the potential to provide a viable, more compatible option for AI than the male latex condom.

I will be happy to provide safety support in the CARE clinic and make appropriate referrals to the ER if necessary. My background has involved research in many areas of HIV prevention strategies, including rectal microbicides, pre- and post-exposure prophylaxis, and vaccine trials. Your work is innovative and much needed, and I am excited to be a part of your multidisciplinary team. As you know, I have collaborated with one of your other co-investigators, Dr. Pamina Gorbach on a number of other NIH and local studies, projects, and grant applications.

I look forward to providing technical and scientific support for this innovative project. Please feel free to include this letter of support with your grant applications.

Sincerely,

Raphael J. Landovitz, MD
Assistant Professor of Medicine
Center for Clinical AIDS Research & Education
David Geffen School of Medicine at UCLA

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January 5, 2009

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd
Suite 318
Beverly Hills, CA 90211

RE: The ORIGAMI RAI Condom™; Phase I Study

Dear Dan,

Congratulations on the successful Phase I study results for the ORIGAMI RAI Condom™ using the ORIGAMI Elastomer™ Silicone we helped develop for you.

As we've discussed, latex sensitization and allergies have been a public concern for years, especially for health care workers and atopic individuals. With an estimated 1.3% of the US population being sensitized by latex products (balloons, toys, adhesive tapes and bandages, gloves, condoms, etc.), much work has been invested in finding alternative chemistries that will provide similar, if not better, performance characteristics without the health risks.

We have been committed to the support of your projects since early 2007, when you contacted the Healthcare Division of BlueStar Silicones Corporation, to discuss the use of a liquid silicone rubber (LSR) as the replacement material of latex and polyurethane for your patented Origami Condoms™. At the time, you had a good idea of what you would need to meet both the physical performance and sensory requirements of the product. By bringing together early in the project the technical staff at BlueStar Silicones and the silicone molding expertise of Medco, you've formed a working team that could address and provide solutions to any of the project's challenges.

Your efficient management of the various tasks and communication within the team helps to keep everyone focused and the end goal clearly defined for the team. Few people have the skills required to not only formulate the idea for the invention, but to also effectively manage each phase of taking a product from concept to commercialization. You've proven your ability to be the effective manager required for a successful project team.

During the early discussion of the material construction needs, we determined quickly that although BlueStar Silicones' had a product to meet the physical requirements of a condom, we did not have a commercial product in our portfolio that would offer the skin-like feel that the Origami RAI Condom™ design required. BlueStar Silicones was tasked with developing your low durometer LSR that would be soft to the touch when molded in a thin layer but remain strong and resilient. After several months of lab work and molding trials, the formulation was finalized.

In my 17 years in a technical or marketing role, I have seen few projects move as quickly and smoothly as this project has moved. As the silicone manufacturer, the timely evaluation and feedback from the molder (Medco) and the end user (Strata Various Product Design) has been critical to optimizing our silicone formulation. The silicone condoms that are now part of your Study and biocompatibility testing, have a high degree of elongation, high tear strength, and low stiffness. Each of these physical characteristics is critical to making a condom that will be durable yet comfortable. The unique design of the silicone condom addresses the issue of slippage currently experienced with female condoms. The innovative design of your silicone female condoms combined with the strength of the Origami Elastomer™ Silicones, offer an alternative to latex that will likely reduce the failure rate of female condoms and possibly increase their use.

We have developed your new experimental material, the ORIGAMI SL Silicone™, which has lubricant imbedded in the silicone formula. This continuous supply of lubrication could be an attractive feature for ORIGAMI Condoms in the future. If pre-clinical testing is as successful as the Non-SL 0134 Silicone, used for the ORIGAMI RAI Condom™ you could have a unique product to offer to consumers. We look forward to seeing pre-clinical test results for ORGIAMI SL Silicone™ when you conduct your lubricant study.

Given the condom design / material construction, your initiative, project management and communication skills, I have no doubts that within a couple of years we will see the ORIGAMI RAI Condoms™ in the marketplace and having a positive impact on prevention strategies and contraception in the US and throughout the world.

BlueStar Silicones feels that your development of the ORIGAMI RAI Condom is a viable and resource-worthy project for our company.

Please feel free to include this letter of support with your NIH grant applications.

Sincerely,

Reeshemah B. Chatham

Reeshemah B. Chatham
Senior Scientist
Technical Service Department

Medco Products, Inc.
3863 East Eagle Drive, Anaheim, CA 92807
Tel: 714.630.1920 Fax: 714.630.7022
dennis@medcoproducts.com
www.medcoproducts.com

January 2, 2009

Mr. Daniel Resnic
Strata Various Product Design
311 North Robertson Blvd Suite #318
Beverly Hills, CA 90211

RE : ORIGAMI RAI Condom™, ORIGAMI Elastomers™

Dear Dan,

I am happy to provide a Quote for your fabrication work of the ORIGAMI RAI Condom™, and our continued support of your company's product development goals.

Medco Products has been a leader in the industry of silicone injection molding. As you are aware, we have been serving your company's needs since 2005, and the needs of the medical device industry since 1997, including prototyping and mass manufacturing of medical device components.

After discussing the design specs for the ORIGAMI RAI Condom™, with you in detail, I believe we can expect similar success to the work we've done to develop the Origami Male Condom. We will produce the condom using liquid injection molding and I have provided below our rationale regarding production of the ORIGAMI RAI Condom™. Please let me know if you have any further questions.

Liquid Injection Molding of ORIGAMI Elastomer-0134™

As you know from our previous projects, when product engineers are faced with a need for an elastomer to solve a unique design or functional requirements, they usually turn to specialized silicone molding. The success of Medco Products is due to our unparalleled knowledge of high performance elastomer materials with an exceptional amount of expertise in silicone technology and injection molding. Prototyping of liquid silicone rubber parts using Medco's innovative tooling technology is one of the fastest and economical methods for producing simple medical device parts.

Silicone Formulation & Properties
Your product will be fabricated in the ORIGAMI Elastomers™, your custom formulated USP Class VI silicone material, in the range of 5-20 durometer. This material complies with established ASTM testing standards, as recommended by USP and accepted by the FDA.

As you are aware from your pre-clinical testing of the male condom made of ORIGAMI Elastome-0134™, it is superior to latex in almost every aspect of its strength (tensile strength, elongation, tear strength) and its biocompatibility. Hospitals worldwide have been working towards a latex-free environment for many years.

The prototype that we've discussed will be a variable thickness of **0.8 – 1.2** mm. The male and female condoms on the market in the US are much thinner. The difference in thickness, in conjunction with the other advantageous properties offered by the ORIGAMI Elastomers™, has exponentially increased its softness, elongation, tensile and tear strength.

Cost

Mold and fabrication costs have increased since our last project. The final unit price of the proposed ORIGAMI RAI Condom™ will be based on the volume of silicone used per unit (and waste material). We project an estimated mass production unit cost between .43 and .56 USD when produced in large 10M unit volumes.

The increasing use of silicone materials and your development of the ORIGAMI Elastomer™ for healthcare/medical applications is not surprising considering silicone's long history of safe and beneficial use.

In closing, I along with the staff at Medco Products, are committed to providing our high quality molding and full support for the development of the ORIGAMI RAI Condom™. In addition, we are confident your new product will be successful in the market. Following FDA and/or WHO approval, we are prepared to assist you with your pilot program and provide you with a no-cost production run of up to 10K units, using the final mold and your own ORIGAMI Elastomer™ Silicone, which BlueStar Silicone is donating to the project.

You may include my letter with your NIH grant application.

Sincerely,

Dennis Bui
Engineer/Owner

E. GEMMA
INDUSTRIAL DESIGNER

Structural Packaging Design
Display and Exhibit Design
Concept Visualization
Product Design
CAD Services
Ideation
Identity

January 5, 2009

Mr. Daniel Resnic
STRATA VARIOUS PRODUCT DESIGN
311 North Robertson Blvd Suite #318
Beverly Hills, CA 90211
resnicpi@gmail.com

RE: Engineering Drawing Proposal; ORIGAMI RAI Condom™; Feasibility Study:
3-D product drawings and alterations (3 revisions).
Develop related 3-D mechanical engineering drawings for product molds.

Dear Mr. Resnic,

Thank you for the opportunity to provide your Phase 1 Feasibility Study of the ORIGAMI RAI Condom™; Study with mechanical engineering drawings. I am glad to provide support for your research.

In addition to creating engineering drawings based on your design concepts, I will be using a 3-D surfacing program to generate the final geometry for your product. This will enable you and your team to see very detailed images of the product from many angles before time and money is spent on making a prototype. This will allow better assessment of the design.

Additionally, I will provide three-dimensional data files (.iges files) that allow your molder to generate his tooling more rapidly and accurately than with more traditional two-dimensional drawings and manual processes. This is because your molder will be able to process and use this data to automatically run his machines for making tooling parts.

Please feel free to include this letter with your grant application to the NIH.

Sincerely,

Edward Gemma,
E. Gemma, Industrial Designer

P.O. BOX 3258 • MILFORD, CT 06460 • TEL & FAX: 203-877-8547 • EMAIL: EG_IND_DESIGN@YAHOO.COM

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adam@condomania.com

December 29, 2008

Daniel Resnic
Strata Various Product Design
311 N. Robertson Blvd, Suite 318
Beverly Hills, CA 90211

RE: ORIGAMI RAI Condom™; Feasibility Studies

Dear Dan,

Thank you for the presentation of the new ORIGAMI RAI Condom™. We were impressed with both the design and the new condom concept. We believe that the Origami RAI Condom™ would be an excellent fit for Condomania® and consistent with our corporate goals. As the leading international condom retailer we are prepared to support your brand and help you introduce this new condom concept to address the unmet needs of consumers, worldwide.

Consumer demand from both women and men who engage in AI has been extremely high for a better alternative to the latex condom with fewer performance issues during AI use. The added benefit of a receptive-partner-controlled device would be especially attractive to consumers as it would facilitate the option of inserting the device in advance of sexual intercourse. We welcome this unique opportunity to help introduce a new condom concept to a global market.

Since 1991, Condomania® has been at the forefront of condom marketing on a global scale. Our chain of retail stores pioneered the new image of condoms at the start of the AIDS epidemic, making them more acceptable to include in daily conversation. Although this has translated over the years into more widespread condom use there are many unresolved design matters that consumers still require.

The Origami Condoms™ have addressed several of the most important design challenges that could not otherwise be resolved with the rolled latex condom. The viral impermeable ORIGAMI ELASTOMER™ material you've developed is unmatched in the condom industry anywhere in the world. I have also reviewed your pre-clinical testing data for the Origami Male Condom™, conducted by Nelson Labs, and its impermeability to virus smaller than HIV is highly significant, especially when considered in context with the simultaneous comparison tests they conducted with the Trojan® latex condom that validates 5% failure in its viral barrier evaluation.

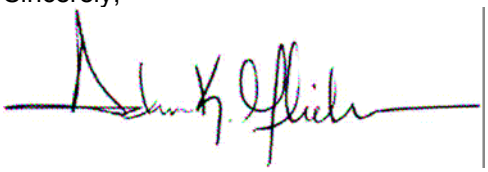
The robust material appears not only extremely durable but also it appears potentially reusable, pending your Phase II testing. I have reviewed your preliminary data for this unique ORIGAMI ELASTOMER™ material, which verifies its tolerance of temperatures up to 425°F, making its extended shelf life highly probable. It's resistance to chemicals such as bleach and oils, is also a significant structural innovation that is not possible with traditional latex or polyurethane condoms. Also, the unique reservoir will introduce a much safer product with reduced potential of semen backflow.

We would like to commit the expertise and marketing resources of Condomania® for your Phase I-III research plans to support you with successful product development and commercialization. In my 20+ years as a leader in condom marketing, I have seen many proposals of new ideas. I have been hired as a marketing consultant by Arm & Hammer's Church & Dwight subsidiary, the world's largest condom manufacturer. Many innovations have been discussed with my company over the years, from industry-changing new shapes and designs (Pleasure Plus & Inspiral condoms) to expansive new ranges of condom sizes (TheyFit® Sized-to-Fit condoms). I have the professional confidence in your products to tell you that the Origami RAI innovations address more consumer issues than anything that has been presented to me before.

I would like to discuss pricing with you further, however, my market experience indicates that US consumers will spend more money for unique products that offer greater sensitivity and improved safety features, such as the Naturalamb, a lamb skin condom that sells for up to $5./condom. We are confident that we can help position the ORIGAMI RAI Condom™ competitively in the condom industry.

Please feel free to include this letter of support with your NIH grant applications.

Sincerely,



Adam Glickman, CEO

Eric A. Hanscom, Attorney at Law

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Offices in Hong Kong and Bangkok

December 28, 2008

Mr. Daniel Resnic
Strata Various Product Design
ORIGAMI CONDOMS™
311 North Robertson Blvd. Suite 318
Beverly Hills, CA 90211

RE: ORIGAMI RAI Condom™; Phase I Feasibility Study

Dear Dan:

The Law Offices of Eric Hanscom will be happy to consult for your study of the ORIGAMI RAI Condom™. As you are aware from our previous work, variations from your original patent application will likely require some discussion before you proceed with any significant modifications.

In that regard we would like to offer advice to your study in the capacity of legal consultant. Our fees are at the rate of $250./ Hr. Based on our earlier conversations you may expect to utilize approximately 20 hours of consultation time. This is for consultation only and will not cover any actual patent work, CITs research or filings.

We are happy to be a part of your continued success with these important projects. Please include this letter of support in your grant application to the National Institutes of Health.

Sincerely,

Eric Hanscom

17. Resource Sharing Plan(s)

Not applicable.

PHS 398 Checklist

OMB Number: 0925-0001
Expiration Date: 9/30/2007

1. Application Type:

From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:

● New ❍ Resubmission ❍ Renewal ❍ Continuation ❍ Revision

Federal Identifier: 1R43HD050805-01A1

2. Change of Investigator / Change of Institution Questions

❑ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:
* First Name:
Middle Name:
* Last Name:
Suffix:

❑ Change of Grantee Institution

* Name of former institution:

3. Inventions and Patents (For renewal applications only)

* Inventions and Patents: Yes ❍ No ❍

If the answer is "Yes" then please answer the following:

* Previously Reported: Yes ❍ No ❍

OMB Number. 0925-0001
Expiration Date: 9/30/2007

4. * Program Income

Is program income anticipated during the periods for which the grant support is requested?

○Yes ●No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

5. Assurances/Certifications (see instructions)

In agreeing to the assurances/certification section 18 on the SF424 (R&R) form, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the agency's application guide, when applicable. Descriptions of individual assurances/certifications are provided at: http://grants.nih.gov/grants/funding/424

If unable to certify compliance, where applicable, provide an explanation and attach below.

Explanation:

Attachments

CertificationExplanation_attDataGroup0

File Name	Mime Type