Exhibit 10.67

[***]Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

RESEARCH COLLABORATION AGREEMENT

This Research Collaboration Agreement (the **Agreement**) is dated as of July 1, 2009 (the **Effective Date**), between:

(1) **INTERNATIONAL AIDS VACCINE INITIATIVE**, a not-for-profit corporation with its principal offices located at 110 William Street, Floor 27, New York, NY 10038 (**IAVI**); and

(2) **THERACLONE SCIENCES, INC.** a biotechnology company with its principal offices located at 1124 Columbia Street, Suite 300, Seattle, WA 98104 (Theraclone).

IAVI and Theraclone, each a **Party** and together the **Parties**.

RECITALS

WHEREAS, IAVI is a global organization working to ensure the development of safe, effective, accessible, preventative HIV vaccines for use throughout the world.

WHEREAS, Theraclone is a biotechnology company focused on the development of novel therapeutic antibodies for the treatment of infectious disease and inflammation.

WHEREAS, IAVI and Theraclone have previously entered into a grant letter agreement dated as of February 1, 2008, as amended, which was funded by IAVI's Innovation Fund (the **Prior Agreement**) and successfully completed by Theraclone.

WHEREAS, IAVI and Theraclone now wish to enter into a further agreement to expand their collaboration so that Theraclone will use its technology to identify and rescue additional HIV neutralizing antibodies and generate quantities of HIV neutralizing antibodies for vaccine research to be conducted at IAVI or by IAVI collaborators, subject to the terms of this Agreement.

IT IS AGREED AS FOLLOWS:

1. Discovery Program

Each Party agrees to use its commercial best efforts to perform the research discovery program (the **Discovery Program**) set forth in the scope of work in Attachment I annexed hereto (the **Scope of Work**) within the time frame designated herein.

IAVI will also conduct and fund additional activities supportive of, and related to, the Discovery Program, including collection of donor samples, assay development and assay testing at Monogram Biosciences, activities related to the Program Team (as defined below), and the characterization of the Final MAbs (as defined in the Scope of Work).

2. Term

This Agreement will commence as of the Effective Date and will continue in full force and effect until all of the deliverables set forth in the Scope of Work (the **Deliverables**) have been delivered unless otherwise terminated in accordance with Section 8 (Expiration or Termination) below.

3. Fixed Price and Payment

(a) The total fixed price for the performance of activities covered in the Scope of Work by Theraclone is [***] (the **Total Fixed Price**).

(b) Subject to paragraph (c) below, the Total Fixed Price will be payable in the following, non-refundable installments:

(i) [***] on each of the Effective Date, [***]; and

(ii) [***].

If the delivery of all of the Deliverables occurs prior to [***], then all remaining installments shall become due and payable to Theraclone within thirty (30) days of such delivery.

(c) The payment of each installment of the Total Fixed Price (after the initial payment on the Effective Date) is guaranteed subject to (i) the receipt by IAVI of an invoice for such payment and (ii) the delivery of the quarterly report for such quarter (as referenced in Section 6 below) reflecting acceptable performance of the Scope of Work for such quarterly period, each on the following dates:

(i) [***]; and

(ii) [***].

In the event that IAVI is not satisfied with the performance of the Scope of Work for any quarterly period, then IAVI must notify Theraclone within 15 days of receipt of such quarterly report and provide reasonably detailed reasons for its lack of satisfaction. In the event that IAVI does not so notify Theraclone within such 15 day period, then IAVI will be deemed to be satisfied.

(d) All payments made by IAVI under this Agreement will be made in US Dollars by bank wire transfer to the following account:

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Bank Name: Silicon Valley Bank
ABA:
Account #:
Account Name: Theraclone Sciences, Inc.
Bank Address:

or any other account the details of which Theraclone provides to IAVI with five (5) days' notice.

(e) Any additional Deliverables requested from Theraclone which are mutually agreed to by the Parties will be subject to the terms and conditions of this Agreement, and paid by IAVI under a separate budget and payment plan.

4. Program Management

(a) A Joint Steering Committee (the **JSC**) shall be established within thirty (30) days after the Effective Date and shall be maintained throughout the term of this Agreement to provide oversight on the progress of the Discovery Program. The JSC shall consist of three (3) IAVI employees appointed by IAVI from time to time and three (3) Theraclone employees appointed by Theraclone from time to time, and shall be chaired by a member appointed by IAVI. It shall only act through the unanimous consent of its members, either at a meeting in which all members are in attendance or by a signed written consent in lieu of a meeting. Meetings of the JSC will be held quarterly. Meetings may be held by conference telephone call in which the members can hear the other members and be heard by them.

(b) The JSC shall appoint a Program Team of IAVI and Theraclone employees to collaborate on the isolation and characterization activities set forth in the Scope of Work and any patent filings with respect to the Discovery Program (the **Program Team**). The Program Team shall develop a detailed work plan and timetable for the isolation and characterization activities set forth in the Scope of Work. The Program Team will update the JSC at the JSC's quarterly meetings on the progress of the Scope of Work.

5. Records and Audit

(a) Theraclone shall maintain records of the results of the Discovery Program, including raw data and methods, in experimental notebooks that contain such information as shall be mutually agreed upon by IAVI and Theraclone.

(b) Theraclone agrees to permit IAVI, during normal business hours and with reasonable advance written notice, to audit and examine all records, including but not limited to, any documents, notes and financial accounts of Theraclone that relate to the Discovery Program and this Agreement, upon reasonable notice, at IAVI's expense. IAVI shall have the right to conduct such an audit once each calendar year.

6. Reporting

Each Party shall provide the other with quarterly written reports of the activities, progress, and results of the Discovery Program in a format and detail level that is mutually acceptable to each of the Parties on the dates set forth in section 3(c) above. Each Party shall provide a comprehensive final written report to the other on their respective contributions to the Discovery Program upon the delivery of the final Deliverables.

7. Compliance

(a) Theraclone agrees to comply with all laws, statutes, rules, regulations, and guidelines promulgated by any governmental agency, instrumentality, authority, or regulatory body having jurisdiction over any matters relating to the Discovery Program, including those related to studies involving micro-organisms, animals, or human subjects.

(b) Theraclone acknowledges that it is familiar with the U.S. Executive Orders and laws that prohibit the provision of resources and support to individuals and organizations associated with terrorism and the terrorist related lists promulgated by the U.S. Government. Theraclone will use reasonable efforts to ensure that it does not support or promote violence, terrorist activity or related training, or money laundering.

(c) IAVI anticipates that it will fund a portion of the Scope of Work with monies from the United States Agency for International Development (USAID). Therefore, this Agreement will be administered in accordance with the USAID Standard Provisions incorporated as Attachment II to this Agreement, with the exception of the following provisions which do not apply to this Agreement as currently executed: 2, 3, 4, 12, 13, 14, 19, 20, 21, 24, 26 and 29. In the event the scope/nature of this Agreement changes, this exception may be modified as deemed required by the Parties.

(d) In the event that IAVI utilizes monies originating from restricted sources other than USAID to fund the Scope of Work, IAVI shall notify Theraclone and provide Theraclone with copies of any rules, regulations, and grant requirements applicable to the Scope of Work funded with such monies. Restricted monies compliance provisions will be incorporated as an amendment to this Agreement's terms and conditions only after IAVI and Theraclone discuss them in good faith and mutually agree upon the use of such funds for the Scope of Work. IAVI agrees that it shall inform Theraclone of any such restrictions that present the potential for material breach of this Agreement as soon as possible.

(e) For the avoidance of doubt, due to restrictions contained in the informed consents used to obtain the new biological specimens provided to Theraclone under this Agreement, those biological specimens can only be used for the field of HIV, i.e., prophylactic and/or therapeutic HIV/AIDS vaccines, related diagnostic tools and HIV/AIDS treatment. In compliance with US Department of Health and Human Services/Office of Human Research Protection guidance, IAVI will not under any circumstances provide Theraclone personal identifying information or the key to decipher the code for any biological specimen to reveal the identity of the donor.

(f) If Theraclone uses subcontractors to assist in the completion of the Scope of Work. Theraclone is responsible for ensuring that any such subcontractor complies with the terms and conditions of this Agreement and the Scope of Work.

8. Expiration or Termination

(a) IAVI may terminate this Agreement immediately after providing Theraclone with sixty (60) days prior written notice if (i) IAVI is not reasonably satisfied with Theraclone's diligence in performing the Scope of Work or (ii) Theraclone fails to comply with any material term or condition of this Agreement, provided that such failure in performance or non-compliance is not cured within such sixty (60) day period. IAVI also reserves the right to withhold funds or terminate this Agreement if significant changes in scientific stalling at Theraclone occur that IAVI believes may jeopardize the Discovery Program.

(b) Theraclone may terminate this Agreement immediately after providing IAVI with sixty (60) days prior written notice of such failure to comply with any material term or condition of this Agreement, provided that such non-compliance is not cured within such sixty (60) day period.

(c) Upon expiration or termination of this Agreement, and upon (i) IAVI's request, Theraclone shall either destroy or return to IAVI all IAVI Materials, and (ii) Theraclone's request, IAVI shall either destroy or return to Theraclone all Theraclone Materials (for clarification, Theraclone Materials do not include Program Inventions and Program Deliverables (as set forth in the Scope of Work)).

(d) Upon the termination of this Agreement, Sections 6, and 8(b) through 17 shall survive any termination.

9. Materials

(a) The Parties anticipate that under this Agreement it may be necessary for either Party to transfer to the other material(s) of a proprietary nature, including but not limited to cell lines, vectors, nucleic acid sequences, sera, processes, samples and reagents (**Program Materials**). Program Materials provided by IAVI on a non-exclusive basis to Theraclone, whether owned by IAVI or by other third parties shall be, for purposes of this Agreement, owned by IAVI and controlled by the licenses granted by this Agreement (**IAVI Materials**). IAVI Materials are human biospecimens of freshly cryopreserved lymphocytes from HIV-infected volunteers, and include any cellular progeny, compositions and formulations of such materials, and any mixtures or combinations of such materials. Program Materials provided by Theraclone to IAVI, IAVI's collaborators, or IAVI's contractors shall be owned by Theraclone and controlled by the licenses granted by this Agreement (**Theraclone Materials**). Theraclone Materials include B-cell supernatants, any replicates, progeny, compositions, formulations, and derivatives therefrom (including, without limitation, antibodies derived from any of the foregoing), and any mixtures or combinations of such materials. The Parties agree that other Party's Program Materials may not be distributed to any other Party for any purpose except those covered by the licenses granted by this Agreement.

(b) THERACLONE AND IAVI DISCLAIM AND MAKE NO REPRESENTATIONS NOR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AS TO ANY MATTER, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, PATENTABILITY OR THAT THE USE OF PROGRAM MATERIALS OR DISCOVERY PROGRAM RESULTS WILL NOT INFRINGE ANY PATENTS, COPYRIGHTS, TRADEMARKS OR OTHER RIGHTS OF THIRD PARTIES. Notwithstanding the foregoing, IAVI hereby represents, warrants, and covenants to Theraclone that the IAVI Materials have been or will be collected under IRB-approved and appropriately consented protocols in which the subjects from which the IAVI Materials were sourced have released any and all claims to economic and intellectual property rights with respect to any potential future products derived from such materials and that such appropriately consented protocols allow for unencumbered product development related to the field of HIV.

10. Intellectual Property

(a) The Parties anticipate that it may be necessary for either Party to use its preexisting intellectual property in the performance of the Scope of Work (**Preexisting Inventions**). Each Party retains title and ownership to its Preexisting Inventions.

(b) Inventions conceived or first reduced to practice by either Party or jointly by the parties during and in the performance of the Scope of Work shall be determined in accordance with US Patent laws (**Program Inventions**). Ownership of Program Inventions shall follow inventorship. Program Inventions made by Theraclone shall be owned by Theraclone and defined as (**Theraclone Inventions**), Program Inventions made by IAVI shall be owned by IAVI and defined as (**IAVI Inventions**), and Program Inventions made jointly by IAVI and Theraclone shall be jointly owned and defined as (**Joint Inventions**). Notwithstanding anything in this Agreement to the contrary, if any B cell cultures or lysates (post B-cell activation) are transferred from Theraclone to IAVI, and antibodies are derived from such B cell cultures or lysates (post B-cell activation) at any time in the future, then such antibodies shall be regarded as and treated as Program Inventions under this Agreement. Regardless of inventorship or ownership of Program Inventions, the Parties agree to coordinate the characterization of the Final MAbs and the related data to maximize the potential utility of the Final MAbs. Prior to the filing of an initial U.S. provisional patent application relating to any Final MAbs, any transfer of such Final MAbs to any third party shall be reviewed and approved by the Program Team prior to such transfer. The Parties also agree that each Party shall promptly share Final MAbs characterization data with the other.

(c) Each Party agrees to secure assignments from its employees and execute any necessary assignments of Program Inventions to the other Party.

(d) For Theraclone Inventions, Theraclone will be responsible for deciding whether to prepare, file or prosecute (as the case may be) any patent applications and maintain, defend or enforce (as the case may be) any patents for Theraclone. For IAVI Inventions, IAVI will be responsible for deciding whether to prepare, file or prosecute (as the case may be) any patent applications and maintain, defend or enforce (as the case may be) any patents for IAVI. For Joint Inventions, Theraclone, after consultation with IAVI, shall prepare, file or prosecute (as the case may be) any patent applications, and maintain, defend or enforce (as the case may be) any patents. The Parties will also agree on coordinating the prosecution of patents for Joint Inventions and the appropriate sharing of patent related costs. Such sharing shall be allocated evenly between the Parties.

11. Licenses

(a) Under this Agreement the definition of licensed fields shall be defined as:

(i) "**IAVI Licensed Fields**" means use of any anti-HIV antibody or derivatives thereof derived from Program Materials and Program Inventions (A) as a tool to design HIV vaccines, (B) as part of any HIV vaccine (1) that is for prophylactic use, and (2) that is co-formulated with an immunogenic, bona fide HIV vaccine antigen or part of a vector expressing a protein, or (C) as part of any HIV diagnostic products; and

(ii) "**Theraclone Licensed Fields**" means use of an antibody or derivatives thereof derived from Program Materials and Program Inventions used (A) to treat (excluding vaccines) HIV, or (B) for an assay to pre-screen HIV- positive human patients to determine eligibility for a therapeutic treatment that incorporates an antibody proprietary to Theraclone, or for an assay to monitor HIV-positive human patients receiving such therapeutic treatment either during clinical development or following commercialization thereof.

(b) All licenses granted by this Agreement shall be for a "**Territory**" and Territory means the entire world.

(c) Licenses:

(i) IAVI hereby grants to Theraclone, under all of IAVI's intellectual property and proprietary rights in, to, and under the IAVI Materials and the Program Inventions, an irrevocable, perpetual, exclusive, sublicensable (through multiple tiers of sublicenses), fully paid-up, royalty-free right and license in the Territory to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, or import any and all antibodies related to or from the IAVI Materials and Program Inventions in the Theraclone Licensed Fields, with the understanding that Theraclone shall ensure that any commercial program for HIV treatment products will incorporate the principles of prompt dissemination of data and licensed access to products or enabling reagents at affordable prices in reasonable quantities for Developing Countries. As used herein the term "Developing Countries" shall mean all countries in the Territory except for the USA, Canada, the countries of the European Union (Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom), Switzerland, Iceland, Japan, Australia, and New Zealand. Notwithstanding the foregoing, any license with respect to Section 1(a)(ii)(B) shall be non-exclusive.

(ii) Theraclone hereby grants to IAVI, under all of Theraclone's intellectual property and proprietary rights in, to and under Theraclone Materials and the Program Inventions, an irrevocable, perpetual, exclusive, sublicensable (through multiple tiers of sublicenses), fully paid-up, royalty-free right and license in the Territory to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, or import any and all antibodies related to or from the Theraclone Materials and Program Inventions in the IAVI Licensed Fields with the understanding that IAVI shall ensure that any commercial program will incorporate the principles of prompt dissemination of data and access to products at affordable prices in Developing Countries.

(d) Each Party hereby reserves all rights in and to all its respective materials and inventions not expressly granted in this Agreement and there are no implied rights or licenses under this Agreement.

12. Confidentiality

(a) **Confidential Information** shall mean any proprietary information disclosed by either Party to the other Party, in connection with this Agreement, or any data relating to, or generated in the Program (the Confidential Information). For the avoidance of doubt, any information related to the source of any biological samples provided by IAVI to Theraclone shall be considered Confidential Information of IAVI. The receiving Party agrees not to disclose the Confidential Information to its employees, directors or other advisors or representatives, except on a need to know basis to persons subject to confidentiality obligations (or with the consent of the disclosing Party), not to use the Confidential Information except for purposes contemplated by this Agreement and to use its reasonable commercial efforts to prevent its disclosure to third parties.

(b) These obligations of nondisclosure and nonuse do not apply to any Confidential Information which the receiving Party can demonstrate by reliable written evidence:

(i) was generally available to the public at the time of disclosure to the receiving Party;

(ii) was already in the possession of the receiving Party at the time of the disclosure, other than pursuant to a confidential disclosure agreement between the Parties, and not due to any unauthorized act by the receiving Party;

(iii) becomes lawfully known to it by disclosure from a third party who is legally entitled to so disclose without being made subject to an obligation of confidence by a third party;

(iv) was independently developed by an agent or employee of that receiving Party who at no time had any knowledge of or access to that Confidential Information;

(v) the receiving Party is required by law to disclose; or

(vi) is necessary for IAVI, its agents or its donors for the purpose of auditing this Agreement.

(c) Each Party acknowledges that the other Party would not have any adequate remedy at law for the breach by it of any one or more of its obligations contained in this Section 12 and agrees that, notwithstanding Section 15 (Dispute Resolution) below, in the event of any such actual or potential breach, the non-breaching Party may, in addition to the other remedies which may be available to it, file a suit in equity, to enforce such obligations by appropriate injunctive relief.

(d) Upon termination or expiration of this Agreement, each Party will, at the request of the other Party, either promptly return all Confidential Information of the other Party, and any copies thereof, in its possession or control, or certify in writing that all tangible Confidential Information has been destroyed. Notwithstanding the foregoing, each Party may retain, solely for the purpose of determining the scope of its obligations under this Agreement, one (1) copy of such Confidential Information.

13. Publications and Public Announcements

(a) All reports and papers of research and other activities conducted under the Discovery Program may be published by IAVI or Theraclone in accordance with academic standards. Authorship shall be determined in accordance with academic standards. Any such reports or papers shall reference the fact that the Discovery Program was conducted pursuant to funding from IAVI and shall acknowledge IAVI's source of funds. The Party wishing to publish agrees to submit an advance draft of any proposed publication or presentation of results to the other Party for review prior to publication. Within thirty (30) days of its receipt or fifteen (15) days in the case of oral presentations, the non-publishing Party shall advise the publishing Party in writing of any proprietary or patentable information contained therein and may, as necessary, formally request to delay the disclosure of the information. The publishing Party agrees to refrain from publishing any such information categorized by the non-publishing Party as proprietary or patentable for a period not to exceed thirty (30) days from the date of such written request, to enable the non-publishing Party to appropriately coordinate with the publishing Party to file for the protection of any intellectual property or proprietary property interests.

(b) IAVI may include information on this Agreement in its periodic public reports and may make information about this Agreement public at any time on its web page and as part of press releases, public reports, speeches, newsletters, and other public documents. If Theraclone wishes to issue a press release, report, article or other announcement or other publication associated with, or referencing this Agreement or the Scope of Work (whether at its inception or at any time during the term of the Scope of Work), or otherwise use IAVI's name or logo, Theraclone must contact IAVI to obtain advance written approval from IAVI which approval will not be unreasonably withheld or delayed. In any such report, article, announcement or publication, IAVI's funding of the Discovery Program and IAVI's source of funds will be acknowledged. Theraclone may reference information content from prior approved announcements or releases without the need for consent from IAVI on each occasion if the information is already in the public domain.

(c) Theraclone has been selected to collaborate in the Discovery Program and Theraclone may not make any statement or otherwise imply to the media, the general public or any other donor or investor that Theraclone, its operations, or its collaboration in this program is supported by any organization other than IAVI unless Theraclone has directly received funds from the other organization.

(d) Neither Party shall prevent the other from publishing on their respective technologies provided that the publication does not disclose any Confidential Information of the other Party.

(e) The Parties will agree on procedures and rules for data handling and use of each Party's name in public disclosures including for the use of information related to donor samples and their collection sites. The Parties shall also agree on procedures and rules for trademarks and branding with the basic goal of acknowledging both Parties' contributions to the Discovery Program.

14. Indemnification

To the extent allowable under the law, each Party agrees to indemnify, defend and hold the other Party and its respective officers, agents, employees, subgrantees, contractors, and subcontractors harmless from and against any and all liability, loss, and expense (including reasonable attorneys' fees) or claims for injury or damages arising out of or resulting from, or that are alleged to arise out of or result from, the actions or omissions by such Party or of any of its officers, agents, employees, subgrantees, contractors or subcontractors with respect to this Agreement.

15. Dispute Resolution

Prior to engaging in any formal dispute resolution with respect to any dispute, controversy or claim arising out of or in relation to this Agreement, or the breach, termination or invalidity hereof (each, a "**Dispute**"), the Chief Executive Officers of the Parties or their designees shall attempt over a period of not more than thirty (30) days to resolve such Dispute. In the case of Disputes that the Chief Executive Officers cannot resolve within such thirty (30) day period, such a Dispute shall be finally settled by binding arbitration in accordance with the arbitration rules of the American Arbitration Association ("**AAA**") in force at that time. If the Parties cannot agree upon an arbitrator within ten (10) days after demand by either of them, either or both Parties may request the AAA to name a panel of five (5) arbitrators. IAVI shall then strike the names of two (2) on this list, and Theraclone shall then strike two (2) names, and the remaining name shall be the arbitrator. The place of the arbitration shall be in Seattle, Washington, if initiated by IAVI and in New York, New York if initiated by Theraclone. The arbitrator's award rendered shall be final and binding upon the parties. Judgment upon the award may be entered in any court having jurisdiction, or application may be made to such court for judicial acceptance of the award and/or an order of enforcement, as the case may be. The expense of the arbitrator shall be shared equally by the parties. In any action brought to enforce or interpret the provisions of this Agreement, the prevailing Party will be entitled to reasonable legal and attorneys' fees as determined by the arbitrator or court in the same action.

16. Notices

(a) Any consent, notice or report permitted or required pursuant to this Agreement must be in writing and, unless otherwise stated, may be given in person, by first- class mail, fax or email as follows (or to any other address the details of which a Party provides to the other with five (5) days' notice):

(i) if to IAVI, to:

Address:	International AIDS Vaccine Initiative 110 William Street, 27th Floor New York, NY 10038
Fax No.:	001 212 847 1132
Attention:	- Elisha Manning (emanning@iavi.org), for all invoices - Ruchey Sharma (rsharma@iavi.org), in connection with contract administration or amendment under this Agreement - Steve Fling (sfling@iavi.org), in connection with any other communication, including technical and operational, under this Agreement; and

(ii) if to Theraclone, to:

Address:	1124 Columbia Street Suite 300 Seattle, WA 98104
Fax No.:	206-805-1699
Attention:	David Fanning

(b) Any communication in connection with this Agreement will be deemed to be Oven at the time of delivery, if delivered in person; three (3) business days after being placed in the mail, if sent by first-class mail, or when received if sent by fax or email.

17. Other Terms

(a) Nothing, in this Agreement will be deemed to create an agency, joint venture or partnership between the Parties. Each Party will be responsible for all taxes and benefits of their own employees and neither Party's employees will be deemed agents or employees of the other Party.

(b) This Agreement is binding upon and shall inure to the benefit of the Parties hereto, and their respective representatives, successors and assigns. No failure or successive failures on the part of either Party, its successors or assigns, to enforce any covenant or agreement, and no waiver or successive waivers on its or their part of any condition of this Agreement, shall operate as a discharge of such covenant, agreement or condition, or render the same invalid, or impair the right of either Party, its successors and assigns to enforce the same in the event of any subsequent breach or breaches by the other Party, its successors or assigns.

(c) This Agreement will be governed by and construed in accordance with the laws of the State of New York, without giving effect to principles of conflicts of laws.

(d) This Agreement including its attachments constitute the entire agreement and understanding between IAVI and Theraclone with regard to the transactions contemplated by this Agreement, and supersede any prior verbal or written contracts, agreements and/or obligations between the Parties. Any amendments to this Agreement including its attachments are subject to prior written approval of IAVI and Theraclone.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed by their authorized representatives.

International AIDS Vaccine Initiative

By: /s/ Seth Berkley
Name: Seth Berkley
Title: President & CEO
Date: June 24, 2009

Theraclone Sciences, Inc.

By: /s/ David Fanning
Name: David Fanning
Title: President & CEO
Date: June 23, 2009

ATTACHMENT I

SCOPE OF WORK

[***]

***Confidential Treatement Requested.**

ATTACHMENT II

Supplementary Provisions:
Standard USAID Requirements

Contractor shall comply with the standard USAID requirements specified in this Appendix. The term "Contractor' shall also mean "Recipient" or "Grantee" and the term "Agreement" shall also mean "Contract", "Award" or "Grant" for the purposes of these requirements.

1. Applicability of 22 CFR Part 226
2. Reimbursable Costs
3. Indirect Costs
4. Accounting Systems and Records
5. Payment Advances and Refunds
6. Debarment
7. Probity
8. Nonliability and Disclaimers
9. Procurement and Eligibility Rules of Goods and Services
10. Capital Expenditures
11. Travel and Transportation
12. Human Subjects Research
13. Animal Welfare
14. Worker's Compensation Insurance
15. Nondiscrimination
16. Real Property
17. Clean/Air Water
18. Publications and Media Releases
19. Investment Promotion
20. Organizations Eligible for Assistance
21. Condoms
22. Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking
23. Equal Protection of the Laws for Faith-Based and Community Organizations
24. Voluntary Population Planning Activities - Mandatory Requirements
25. Participant Training
26. Reporting of Foreign Taxes
27. Drug Free Workplace
28. USAID Disability Policy
29 Foreign Government Delegations to International Conferences
30. Marking under USAID Funded Assistance

The following are the principal standard federal requirements applicable to the performance of both parties' responsibilities under this Agreement (in addition and without prejudice to the other provisions of this Agreement):

(1) Applicability of 22 CFR Part 226. *This provision is only applicable to agreements and subagreements awarded to U.S. organizations.* All provisions of 22 CFR Part 226 are applicable to this Agreement.

(2) Reimbursable Costs. *This Provision is Only applicable to cost reimbursement contracts.* To be reimbursable under this Agreement, costs must comply with the applicable cost principles. For educational institutions, use OMB Circular A-21; for all other non-profit organizations, use OMB Circular A-122; and for profit making fines, use Federal Acquisition Regulation 31.2 (see below). Requirements include the following, without limitation: direct costs must be necessary and incurred specifically for the Services; verifiable from the books and records of Contractor, as applicable, and supported by source documentation; allocable to this Agreement; reasonable in nature and amount; and allowable (i.e. conform to the provisions and limitations of this Agreement). To facilitate monitoring of charges under this Agreement, once each year. IAVI may provide Contractor with a USAID compliance form which Contractor agrees to fill out completely and accurately and return promptly to IAVI for review and consultation as appropriate.

(3) Indirect Costs. *This Provision is only applicable to cost reimbursement contracts.* Unless predetermined indirect cost rates are included in the approved budget for this Agreement (or each Task Order, when applicable), funding from USAID will only be used for reimbursable direct costs.

(4) Accounting Systems, Records and Audits. *This Provision is only applicable to cost reimbursement contracts.* Contractor shall maintain books, records, documents and other evidence in accordance with generally accepted and recognized accounting procedures. Contractor shall preserve and make available its accounting records and documents for examination and audit by IAVI, USAID and the Comptroller General of the United States, or any of their duly authorized representatives: (a) until the expiration of three years from the termination of this Agreement; (b) for such longer period, if any, as is required to complete an audit to resolve all questions concerning expenditures unless written approval has been obtained from USAID to dispose of the records; and (c) if any litigation, claim, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved. Contractor agrees to make available any further information requested by either IAVI or USAID with respect to any questions arising as a result of the aforementioned audit. U.S. organizations are also subject to the audit requirements of 22 CFR 226.26 (Non-Federal Audits). Non-U.S. organizations may be subject to annual audit in accordance with the "Guidelines for Financial Audits Contracted by Foreign Recipients" issued by the USAID Inspector General.

(5) Payment Advances and Refunds. If Contractor receives advance payments under this Agreement, Contractor shall maintain advances in interest hearing accounts unless: 1) Contractor receives less than [***] in U.S. Government awards per year; or 2) the best interest bearing account would not be expected to earn more than [***] in interest each year; or 3) the bank would require an unreasonable average or minimum balance so as to make it impractical to do so. Interest earned in excess of [***] per year must be refunded to IAVI. In addition, funds advanced to Contractor but not expended by the end of this Agreement or not expended in accordance with the terms of this Agreement must be refunded to IAVI.

(6) Debarment. Contractor certifies that neither it nor its principals is presently excluded or disqualified or proposed for exclusion or disqualification from participation in this Agreement by any U.S. Federal department or agency (see the U.S. Governments Excluded Parties List at http://epls.arnet.gov). Furthermore, Contractor agrees that it will not knowingly enter into a subcontract or subaward with a disqualified or excluded party on this list. Contractor agrees to notify IAVI immediately upon learning that it or any of its principals: 1) are presently excluded or disqualified from covered transactions by any Federal department or agency; 2) have been indicted or otherwise criminally or civilly charged, convicted of or had a civil judgment rendered against them for commission of any of the acts listed in the USAID Standard Provision entitled "Debarment, Suspension, and other Responsibility Matters"; or 3) have had one or more public transactions (with local, State or the Federal governments) terminated for cause or default within the preceding three years. Contractor shall include this provision in any subcontracts or subawards under this Agreement.

***Confidential Treatement Requested.**

(7) Probity. (a) Contractor represents and warrants that (i) to the best of its knowledge and belief, no IAVI employee, officer, or agent, or member of his/her immediate family, his or her partner, or an organization which is about to employ any of the foregoing, has a financial interest in Contractor; and (ii) no officer, employee or agent of IAVI has solicited or accepted gratuities, favors, or anything of monetary value from Contractor.

(b) U.S. Executive Orders and U.S. law prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of Contractor to ensure compliance with these Executive Orders and laws in the conduct of its own activities. Contractor is required to obtain the updated lists at the time of procurement of goods or services. The updated lists are available at: http://treasury.gov/offices/enforcement/ofac/sanctions/terrorism.htm and http://www.un.org/Docs/sc/committees/1267. This provision must be included in all contracts, subcontracts or subawards awarded hereunder.

(8) Nonliability and Disclaimers. Contractor agrees that USAID will not assume liability for third party claims for damages arising out of this Agreement and that Contractor will have no relationship with USAID solely because of this Agreement.

(9) Procurement and Eligibility Rules of Goods and Services. (a) Procurements of goods and services pursuant to this Agreement shall be conducted in accordance with sound commercial practices and the USAID Standard Provisions "USAID Eligibility Rules for Goods and Services (April 1998)" and shall be supported by original invoices or other appropriate supporting documentation. Furthermore, procurement by U.S. organizations should be in accordance with the procurement procedures outlined in 22 CFR 226.44, and procurement by non-U.S. organizations should be in accordance with the Standard Provisions for Non-U.S. Organizations entitled 'Procurement of Goods and Services (October 1998)". The text of these policies is available on USAID's website (see below).

(b) Goods on USAJD's list of ineligible items (military equipment, surveillance equipment, equipment to support police or law enforcement activities, abortion equipment, luxury goods, gambling equipment, and weather modification equipment) may not be financed. Goods on USAID's list of restricted items (agricultural equipment, pesticides, fertilizers. U.S. government-owned excess property, used equipment, pharmaceuticals, including HIV Test kits, motor vehicles and motor bikes) may only be financed with IAVI's written approval.

(c) Other Goods and services may be procured from any country except the following Foreign Policy Restricted Countries: Cuba, Iran, Laos, North Korea, or Syria. Goods may not be procured from firms on the U.S. government's Excluded Parties List (see "http://epls.arnet.gov"). For purposes of the preceding sentence, "procured from" includes supplier nationality (for goods and services) and the source and origin of the goods.

(10) Capital Expenditures.

(a) Unless indicated otherwise in the schedule of this Agreement, title to all equipment purchased with funds provided hereunder shall belong to IAVI.

(b) Contractor must obtain IAVI's prior written approval before: (i) purchasing capital equipment or (ii) incurring costs for renovations or other material improvements to land, buildings or equipment, if such equipment or costs is/are not included in the approved budget.

(11) Travel and Transportation. *This provision is applicable when international travel is authorized under this Agreement.* Unless included in the approved budget for this Agreement, no funds may be expended for international travel without IAVI's written approval. Expenditures of hinds provided under this Agreement (i) for transportation of goods or travel of personnel overseas shall be subject to the USAID Standard Provision, "International Air Travel and Transportation (JUNE 1999)," and (ii) for shipments of goods by sea shall be subject to the USAID Standard Provision, "Ocean Shipment of Goods (JUNE 1999)." U.S. flag carriers must be used to the extent service by such carriers is available. The text of these provisions is available on USAID's website (see below). This provision will be included in all subawards and contracts hereunder which require international travel and transportation.

(12) Human Subjects Research. *This provision is applicable when human subjects research is conducted pursuant to this Agreement.* Contractor agrees to comply with USAID policies. to the extent applicable, including without limitation the Common Federal Policy for the Protection of Human Subjects (implemented by USAID at 22 CFR Part 225); the "Procedures for Protection of Human Subjects in Research Supported by USAID"; and the USAID Standard Provision entitled "Protection of the Individual as a Research Subject (APRIL 1998)." The texts of these policies are available on USAID's website (see below.)

(13) Animal Welfare. *This provision is applicable when research involving laboratory animals is conducted pursuant to this Agreement.* Contractor agrees to work with IAVI to ensure compliance with USAID policies to the extent applicable, as referenced in the USAID Standard Provision entitled "Care of Laboratory Animals (MARCH 2004)". The text of this policy is available on USAID's website (see below).

(14) Worker's Compensation Insurance. *The provision is applicable to U.S. based contractors who will perform work hereunder outside the United States.* Pursuant to 22 CFR Part 226, Appendix A, Contractor agrees to provide worker's compensation insurance to all persons employed outside the U.S. who are U.S. citizens or residents. Contractor agrees to provide insurance required by applicable law to all persons employed outside the U.S. who are not U.S. citizens or residents

(15) Nondiscrimination. *This provision is applicable when work under this Agreement will be performed in the United States or when employees are recruited in the United States.* No U.S. citizen or legal resident of the United States will be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any activity funded under this Agreement on the basis of race, color, national origin, age, handicap or sex.

(16) Real Property. Funding may not be used under this Agreement to construct, alter, repair or improve real property without IAVI's advance written approval, which [approval] may be subject to additional USAID requirements.

(17) Clean Air/Water. *This provision is applicable to contracts in excess of $100,000 to be performed in the United States.* Contractor agrees to comply with all applicable standards, orders or regulations pursuant to the Clean Air Act (42 U.S.C. 7401 et seq.) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.) Violations are to be reported to IAVI.

(18) Publications and Media Releases. (a) Contractor shall provide to IAVI, for submission to USAID, one hard copy and one electronic copy in PDF form, if available, of all published works developed under this Agreement. Each document submitted should contain essential bibliographic elements such as 1) descriptive title; 2) author(s) name; 3) date of publication: 4) and a statement that this publication was funded in whole or in part by the International AIDS Vaccine Initiative under Cooperative Agreement No. GPO-A-00-06-00006-00 awarded by the U.S. Agency for International Development (Office of Health/AIDS, Bureau of Global Health, S.O. 936-004).

(b) In the event funds provided under this Agreement are used to fund the cost of publishing, any related profits or royalties realized by Contractor (up to the amount of these publishing costs) should be credited back to this Agreement.

(c) Except as otherwise provided elsewhere in this Agreement, the author or Contractor is free to copyright any books, publications or copyrightable materials development under this Agreement; however USAID reserves a royalty-free nonexclusive and revocable right to reproduce, publish, or otherwise use, and to authorize others to use, the work for U.S. government purposes.

(d) Any "public communications", as defined in 22 CFR 226.2, funded under this Agreement in which the content has not been approved by USAID, must contain the following disclaimer:

> *"This study/report/audio/visual/other information/media project is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert Contractor's name] and do not necessarily reflect the views of USAID or the United States Government".*

(19) Investment Promotion. Except as may be specifically set forth in this Agreement or as IAVI may otherwise approve in advance, no funds or other support provided under this Agreement may be used by Contractor for an activity that involves investment promotion in a foreign country. The Contractor must ensure that its employees and subrecipients and contractors providing investment promotion services are made aware of these restrictions and include this clause in all subagreements and contracts.

(20) Organizations Eligible for Assistance. If Contractor is otherwise eligible to receive funds under this Agreement to prevent, treat, or monitor HIV/AIDS, Contractor shall not be required to endorse or utilize a multisectoral approach to combatting HIV/AIDS or to endorse, utilize, or participate in a prevention method or treatment program to which Contractor has a religious or moral objection. The Contractor shall include this provision in any subcontracts or subawards under this Agreement.

(21) Condoms. If information is provided under this Agreement about the use of condoms, the information shall be medically accurate and shall include the public health benefits and failure rates of such use and shall be consistent with USAID's fact sheet entitled "USAID: HIV/STI Prevention and Condoms". This fact sheet may be accessed at: http://www.usaid.gov/our_work/global_health/aids/TechAreas/prevention/condomfactsheet.html."

(22) Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking. None of the funds made available under this Agreement may be used by Contractor to promote or advocate the legalization or practice of prostitution or sex trafficking. The funds made available under this Agreement may be used by Contractor to provide palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides, if applicable under this Agreement. For the purposes of this provision, "sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. The Contractor shall include this provision in any subcontracts or subawards under this Agreement.

(23) Equal Protection of the Laws for Faith-Based and Community Organizations. (a) In providing services supported by this Agreement or in its outreach activities related to these services, Contractor may not discriminate against any beneficiary or potential beneficiary on the basis of religion or religious belief.

(b) If Contractor engages in inherently religious activities, these activities must occur at a different time and/or location from any programs or services funded by this Agreement.

(c) In awarding subagreements or contracts under this Agreement, Contractor should not discriminate against a faith-based organization in selecting qualified organizations.

(24) Voluntary Population Planning Activities — Mandatory Requirements. (a) No funds under this Agreement may be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

(b) No funds under this Agreement made be used to finance, support or be attributed to any activities whatsoever related to the performance of abortion as a method of family planning, including paying incentives to coerce or motive individuals to have abortions. The term "motivate" as it relates to family planning assistance shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

c) No funds under this Agreement may be used for biomedical research which relates in whole or in part to the methods or performance of abortions or involuntary sterilization as a means of family planning. This does not preclude epidemiological or descriptive research to assess the incidence, extent or consequences of abortions.

(25) Participant Training. *This provision is applicable to this Agreement if training will be provided to any non-U.S. individual outside of that individual 's home county.* Participant training under this Agreement shall comply with the policies established in USAID ADS Chapter 253.

(26) Reporting of Foreign Taxes. Quarterly financial reports or other requests for reimbursement in accordance with the payment terms of this Agreement should include the amount of any value added tax (VAT) and custom duties paid to the foreign government of the country receiving assistance hereunder on commodity purchase transactions valued at $500 or more financed under this Agreement as well as any reimbursements of such taxes that may be received during the period of this Agreement. "Commodity" means any material, article, supply, goods or equipment.

(27) Drug Free Workplace. Within 30 days after either the effective date of this Agreement, if awarded after July 11, 2006 or of the effective date of the amendment incorporating this provision if this Agreement was awarded prior to July 11, 2006. Contractor agrees to publish a drug-free workplace statement and provide a copy to each employee who will be engaged in performance of this Agreement. The statement must be in accordance with the USAID Standard Provision entitled "Drug-Free Workplace (JAN 2004)". Contractor agrees to both immediately notify IAVI if an employee working hereunder is convicted of a drug violation in the workplace and to either terminate the employee or take other appropriate action in accordance with the above-referenced Standard Provision.

(28) USAID Disability Policy. Contractor shall not discriminate against people with disabilities in the implementation of the program funded by this Agreement and shall make every effort to comply with the objectives of the USAID Disability Policy to the extent that it can do so within the scope of the program. The full text of the policy can be found at http://www.usaid.gov/about/disability/DISABPOL.FIN.html.

(29) Foreign Government Delegations to International Conferences. Funds in this Agreement may not be used to finance any travel costs or conferences fees for any member of a foreign government's delegation to an international conference sponsored by a public international organization, except as provided in USAID ADS Mandatory Reference "Guidance on Funding Foreign Government Delegations to International Conferences" or as approved by USAID.

(30) Marking under USAID Funded Assistance. As a condition of receipt of this Agreement, Contractor must mark all overseas programs, projects, activities, public communications and commodities in accordance with the attached IAVI Marking Plan. In doing so, marking with either the IAVI logo or the USAID logo (as stipulated) should be of a size and prominence equivalent to or greater than the logos of Contractor, Contractor's other donors, or third parties.

The text of the Standard Provisions and other regulations that are referenced above is available at the following websites. IAVI will provide a copy upon request.

22 CFR Part 226 - http://www.access.gpo.gov/nara/cfr/waisidx_02/22cfr226_02.html
OMB Circular A-122 - http://www.whitehouse.gov/omb/circulars/a122/a122_2004.html
OMB Circular A-21 - http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html
FAR Part 31.2 - http://www.arnet.gov/far/current/html/Subpart%2031_2.html#wp1095552
USAID Standard Provisions for U.S. Organizations - http://www.usaid.gov/policy/ads/300/303maa.pdf
USAID Standard Provisions for non-U.S. Organizations - http://www.usaid.eov/policy/ads/300/303mab.pdf

IAVI Marking Plan
under USAID Cooperative Agreement GPO-A-00-06-00006-00

As an international organization, IAVI's continued success in accelerating the development of promising HIV vaccine candidates relies upon long-term engagement with our diverse portfolio of contributors and other stakeholders. This fact is reflected in our Marking Plan. Under this Plan, IAVI had developed a multi-donor logo which acknowledges all of IAVI's governmental and largest private sector donors. This logo will be applied universally, both domestically and outside the U.S., to mark items such as physical infrastructure, workshops, and program communications; however, the USAID-logo sticker by itself will be used to mark equipment procured entirely with USAID funds. For example, when appropriate, items would be marked as follows:

- Publications and other public communications marked with IAVI multi-donor logo in a visible location such as the front or back cover
- Invitation letterhead, report or cover marked with IAVI multi-donor logo in a visible location such as in the body text or footnoted
- Equipment marked with a USAID logo sticker in a visible location
- Infrastructure marked with a IAVI multi-donor plaque in a visible location

Marking with either the IAVI logo or the USAID logo (as stipulated above) should be of a size and prominence equivalent to or greater than the logos of the contractor/recipient, other donors, or other third parties. The Marking Plan Table which follows indicates the items and activities to be marked and those which are exempt from marking.

The USAID logo stickers (for equipment) can be either obtained from IAVI or ordered directly from vendors listed on the USAID website (http://www.usaid.gov/branding/suppliers.html). An electronic file of the IAVI multi-donor logo below will be sent by IAVI to each contractor/recipient.

IAVI MARKING TABLE

ACTIVITY	TO BE MARKED	NOT TO BE MARKED (EXEMPT)*
External Publications	Informational, educational and communication materials for use by staff, partners and other stakeholders on AIDS vaccines and related topics (includes leaflets & brochures)	Reports and publications done in partnership with governments
	Research working papers, policy briefs, and discussion papers	
Tools and Operational Documents	Tool kit for needs assessment/program planning for community involvement	
	Community advisory board(s) guidance documents	
Reports	Reports of select social science research projects on issues relevant to clinical research in developing countries or reports from needs assessment and monitoring and evaluation efforts	Reports on programs involving governmental policies and programs
Workshops, technical meetings, training programs, seminars, consultations	Invitation letters, informational handouts, briefs, reports, and meeting signage	Invitation letters, informational handouts, briefs, reports, and meeting signage for Policy Makers Workshops covering national policy issues
		Meetings and trainings implemented in partnership with the Government of India
Core Laboratory (Imperial College; trial sites and laboratories in Africa and India; biotechnology firms and pharmaceuticals outside the U.S.)	Buildings/facilities	Internal Documents (e.g. Good Clinical Laboratory Practice guidelines, standard operating procedures guidelines, audits, validation study reports, clinical trial study reports, etc.)
	Laboratory and office equipment unless item is too small or marking would impair functionality	Consumables and laboratory supplies such as scissors, forceps, test tubes, vaccine vials, pipettes
	Shipping containers packed with equipment or supplies to the Africa or India IAVI sites unless marking would jeopardize the integrity of the contents	Shipping clinical samples from site to London or Johannesburg core labs

* If IAVI determines that these items/activities are no longer exempt, IAVI will notify the subawardee or contractor in writing that these items/activities should also be marked with the IAVI multi-donor logo (or the USAID logo for equipment).

June 25, 2009

International AIDS
Vaccine Initiative

110 William Street
New York, NY
10038-3901 USA
www.iavi.org
info@iavi.org
tel:212.847.1111
fax:212.847.1112

David Fanning
President and CEO
Theraclone Sciences, Inc.
1124 Columbia Street, Suite 300
Seattle, WA 98104

Dear Mr. Fanning,

I am enclosing an original copy of the Research Collaboration Agreement between IAVI and Theraclone. If you have any questions, please feel free to contact me.

Best regards,

Rachel Belt
Executive Assistant, Office of the General Counsel
International AIDS Vaccine Initiative
Tel.: 212.847.1109
Fax: 212.847.1112

Exhibit 10.68

[***]Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

AMENDMENT NO. 1
TO RESEARCH COLLABORATION AGREEMENT

This Amendment No. 1 to the Research Collaboration Agreement (this **Amendment**) is dated as of November 30, 2010 (the **Effective Date**), between:

(1) **INTERNATIONAL AIDS VACCINE INITIATIVE**, a not-for-profit corporation with its principal offices located at 110 William Street, Floor 27, New York, NY 10038 (**IAVI**); and

(2) **THERACLONE SCIENCES, INC.** a biotechnology company with its principal offices located at 1124 Columbia Street, Suite 300, Seattle, WA 98104 (**Theraclone**).

IAVI and Theraclone are each a **Party** and together the **Parties**.

RECITALS

WHEREAS, IAVI and Theraclone entered into a Research Collaboration Agreement dated July 1, 2009 (the **Agreement**); and

WHEREAS, the Parties wish to amend the payments due and the Scope of Work under the Agreement.

IT IS AGREED AS FOLLOWS:

1. Definitions

Unless otherwise provided herein, all defined terms used in this Amendment No. 1 will have the same meaning as in the Agreement.

2. Amendment of Section 3 (Fixed Price and Payment)

Sections 3(a), (b) and (c) (Fixed Price and Payment) of the Agreement are hereby deleted and replaced as follows:

"(a) The total fixed price for the performance of activities covered in the Scope of Work by Theraclone is [***] (the **Total Fixed Price**).

***Confidential Treatment Requested.**

(b) Subject to paragraph (c) below, the Total Fixed Price will be payable in the following, non-refundable installments:

(i) [***] on each of the Effective Date, [***]; and

(ii) [***] on or before [***]; and

(iii) [***] on or before [***].

(c) The payment of each installment of the Total Fixed Price (after the initial payment on the Effective Date) is guaranteed subject to (i) the receipt by IAVI of an invoice for such payment and (ii) the delivery of the quarterly report for such quarter (as referenced in Section 6 below) reflecting acceptable performance of the Scope of Work for such quarterly period, each on the following dates: [***].

In the event that IAVI is not satisfied with the performance of the Scope of Work for any quarterly period, then IAVI must notify Theraclone within 15 days of receipt of such quarterly report and provide reasonably detailed reasons for its lack of satisfaction. In the event that IAVI does not so notify Theraclone within such 15 day period, then IAVI will be deemed to be satisfied."

3. Amendment of the Scope of Work

The Scope of Work attached to the Agreement is hereby deleted and replaced with the Scope of Work in Attachment I annexed hereto.

4. Full Force and Effect

Except as specifically modified or amended in this Amendment, the Agreement will remain in full force and effect. No oral promise, covenant or representation of any character or nature has been made to induce either Party to enter into this Amendment. No provision of this Amendment may be modified or amended except expressly in a writing signed by both Parties nor will any term be waived except expressly in a writing signed by the party charged therewith.

5. Counterparts

This Amendment may be executed in one or more counterparts, each of which together will be deemed original but all of which together will constitute one and the same document. A photocopy of the original signature of an authorized representative of a party will have the same validity as an original signature for the purpose of this Agreement.

***Confidential Treatment Requested.**

6. Governing Law

This Amendment will be governed by and construed in accordance with the laws of the State of New York, without giving effect to principles of conflicts of laws.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their authorized representatives.

International AIDS Vaccine Initiative

By /s/ Wayne Koff
Name: Wayne Koff
Title: Senior Vice President & CSO
Date: 12/6/10

Theraclone Sciences, Inc.

By /s/ Russ Hawkinson
Name: Russ Hawkinson
Title: CFO
Date: 11/30/2010

ATTACHMENT I

SCOPE OF WORK

[***]

***Confidential Treatment Requested.**

Exhibit 10.69

[***]Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

AMENDMENT NO. 2
TO RESEARCH COLLABORATION AGREEMENT

This Amendment No. 2 to the Research Collaboration Agreement (this **Amendment**) is dated as of December 3, 2012 (the **Effective Date**), between:

(1) **INTERNATIONAL AIDS VACCINE INITIATIVE**, a not-for-profit corporation with its new principal offices located at 125 Broad Street, Floor 9, New York, NY 10004 (**IAVI**); and

(2) **THERACLONE SCIENCES, INC.** a biotechnology company with its principal offices located at 1124 Columbia Street, Suite 300, Seattle, WA 98104 (**Theraclone**).

IAVI and Theraclone are each a **Party** and together the **Parties**.

RECITALS

WHEREAS, IAVI and Theraclone entered into a Research Collaboration Agreement dated July 1, 2009, and Amendment No.1 dated November 24, 2010 (the **Agreement**); and

WHEREAS, the Parties wish to amend the Total Fixed Price of the Agreement and the Scope of Work in this Amendment No. 2.

IT IS AGREED AS FOLLOWS:

1. Definitions

Unless otherwise provided herein, all defined terms used in this Amendment No. 2 will have the same meaning as in the Agreement.

2. Amendment of Section 3 (Fixed Price and Payment)

Sections 3 is amended to include the following modified or new language:

"(a) The total fixed price for the performance of activities covered in the Scope of Work by Theraclone through Amendment No.1 is [***] (the **Total Fixed Price**).

(f) Theraclone acknowledges that IAVI has fully paid for the completion of the original and Amendment No. 1 Scope of Work which included a 6th Protocol G donor deliverables which have not been delivered because of the absence of the an acceptable donor sample to initiate the work.

*** Confidential Treatment Requested.**

(g) The Parties agree to further modify the Agreement under this Amendment No. 2 to address a new Scope of Work as defined in the revised Attachment 1.

(h) The Fixed Price Amount for the revised Scope of Work for this Amendment No, 2 is [***]. Payment of the non-refundable, non-creditable amount of [***] will be made upon activation of the first donor sample as contemplated in Attachment 1 to this Amendment.

3. Amendment of Compliance

Section 7 of the Agreement are hereby deleted and replaced as follows:

"(a) Theraclone agrees to comply with all laws, statutes, rules, regulations, and guidelines promulgated by any governmental agency, instrumentality, authority, or regulatory body having jurisdiction over any matters relating to the Discovery Program, including those related to studies involving micro-organisms, animals, or human subjects.

(b) Theraclone acknowledges that it is familiar with the U.S. Executive Orders and laws that prohibit the provision of resources and support to individuals and organizations associated with terrorism and the terrorist related lists promulgated by the U.S. Government. Theraclone will use reasonable efforts to ensure that it does not support or promote violence, terrorist activity or related training, or money laundering.

(c) IAVI funded a portion of the original and Amendment No.1 Scope of Work with monies from the United States Agency for International Development (**USAID**). Therefore, the original and a portion of Amendment No.1 and a portion of Amendment No, 2 Scopes of Work will be administered in accordance with the USAID Standard Provisions incorporated as Attachment II to the Agreement, with the exception of the following provisions which do not apply to this Agreement as currently executed: 2, 3, 4, 12, 13, 14, 19, 20, 21, 24, 26 and 29. In the event the scope/nature of this Agreement changes, this exception may be modified as deemed required by the Parties. Effective September 13, 2011 IAVI will fund the Project Activities from the United States Agency for International Development (**USAID**) Cooperative Agreement No. AID-OAA-A-11-00020 and therefore, this Agreement will be administered in accordance with the USAID Standard Provisions incorporated as Attachment III to this Agreement, with the exception of the following provisions which do not apply to this Agreement as currently executed: 2, 3, 4, 12, 13, 14, 19, 20, 21, 24, 26 and 29. In the event the scope/nature of this Agreement changes, this exception may be modified as deemed required by the Parties."

(d) IAVI anticipates that it will fund a portion of the Scope of Work for, the Protocol C Donor Sample SOW in Attachment 1, for Amendment No. 2 with monies from a National Institute of Health (**NIH**) grant. Therefore, the Scope of Work for Amendment No. 2 will be administered in accordance with the NIH grant standard provisions, including reporting of inventions, incorporated as Attachment IV with the exception of the following provision which to not apply to this agreement as currently executed: 3,4,5,6, 16, 27.

***Confidential Treatment Requested**

(e) In the event that IAVI utilizes monies originating from restricted sources other than USAID or an NIH grant to fund the Scope of Work, IAVI shall notify Theraclone and provide Theraclone with copies of any rules, regulations, and grant requirements applicable to the Scope of Work funded with such monies. Restricted monies compliance provisions will be incorporated as an amendment to this Agreement's terms and conditions only after IAVI and Theraclone discuss them in good faith and mutually agree upon the use of such funds for the Scope of Work. IAVI agrees that it shall inform Theraelone of any such restrictions that present the potential for material breach of this Agreement as soon as possible.

(f) For the avoidance of doubt, due to restrictions contained in the informed consents used to obtain the new biological specimens provided to Theraclone under this Agreement, those biological specimens can only be used for the field of HIV, i.e., prophylactic and/or therapeutic HIV/AIDS vaccines, related diagnostic tools and HIV/AIDS treatment. In compliance with US Department of Health and Human Services/Office of Human Research Protection guidance, IAVI will not under any circumstances provide Theraclone personal identifying information or the key to decipher the code for any biological specimen to reveal the identity of the donor.

(g) If Theraelone uses subcontractors to assist in the completion of the Scope of Work, Theraclone is responsible for ensuring that any such subcontractor complies with the terms and conditions of this Agreement and the Scope of Work."

4. <u>Amendment of Expiration or Termination</u>

Section 8 of the Agreement is hereby deleted and replaced as follows:

"(a) IAVI may terminate this Agreement immediately after providing Theraclone with sixty (60) days prior written notice if (i) IAVI is not reasonably satisfied with Theraclone's diligence in performing the Scope of Work, or (ii) Theraclone fails to comply with any material term or condition of this Agreement, provided that such failure in performance or non-compliance is not cured within such sixty (60) day period. IAVI also reserves the right to withhold funds or terminate this Agreement if significant changes in scientific staffing at Theraclone occur that IAVI believes may jeopardize the Discovery Program.

(b) Theraclone may terminate this Agreement immediately after providing IAVI with sixty (60) days prior written notice of such failure to comply with any material term or condition of this Agreement, provided that such non-compliance is not cured within such sixty (60) day period.

(c) Upon expiration or termination of this Agreement, and upon (i) IAVI's request, Theraclone shall either destroy or return to IAVI all IAVI Materials, and (ii) Theraclone's request, IAVI shall either destroy or return to Theraclone all Theraclone Materials (for clarification, Theraclone Materials do not include Program Inventions and Program Deliverables (as set forth in the Scope of Work)).

(d) Upon the termination of the Agreement, Sections 6, and 8(c) through 17 shall survive any termination.

5. Amendment of the Scope of Work

The Scope of Work as amended in Amendment No. 1 shall be amended to include Attachment 1 which is attached to this Amendment.

6. Full Force and Effect

Except as specifically modified or amended in this Amendment, the Agreement will remain in full force and effect. No oral promise, covenant or representation of any character or nature has been made to induce either Party to enter into this Amendment. No provision of this Amendment may be modified or amended except expressly in a writing signed by both Parties nor will any term be waived except expressly in a writing signed by the party charged therewith.

7. Counterparts

This Amendment may be executed in one or more counterparts, each of which together will be deemed original but all of which together will constitute one and the same document. A photocopy of the original signature of an authorized representative of a party will have the same validity as an original signature for the purpose of this Agreement.

8. Governing Law

This Amendment will be governed by and construed in accordance with the laws of the State of New York, without giving effect to principles of conflicts of laws.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed by their authorized representatives.

International AIDS Vaccine Initiative

By /s/ Wayne Koff
Name: Wayne Koff
Title: Senior Vice President & CSO
Date: 12-3-12

Theraclone Sciences, Inc.

By /s/ Russ Hawkinson
Name: Russ Hawkinson
Title: CFO
Date: 12/11/12

ATTACHMENT 1 – Amendment No. 2

SCOPE OF WORK

[***]

***Confidential Treatment Requested**

ATTACHMENT III
Supplementary Provisions:
Standard USAID Requirements

Contractor shall comply with the standard USAID requirements specified in this Appendix. The term "Contractor" shall also mean "Recipient" or "Grantee" and the term "Agreement" shall also mean "Contract", "Award" or "Grant" for the purposes of these requirements.

1. Applicability of 22 CFR 226
2. Reimbursable Costs
3. Indirect Costs
4. Accounting Systems and Records
5. Payment Advances and Refunds
6. Debarment
7. Probity
8. Nonliability and Disclaimers
9. Procurement and Eligibility Rules of Goods and Services
10. Capital Expenditures
11. Travel and Transportation
12. Human Subjects Research
13. Animal Welfare
14. Worker's Compensation Insurance
15. Nondiscrimination
16. Real Property
17. Clean Air/Water
18. Publications and Media Releases
19. Investment Promotion
20. Organizations Eligible for Assistance
21. Condoms
22. Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking
23. Equal Protection of the Laws for Faith-Based and Community Organizations
24. Voluntary Population Planning Activities
25. Participant Training
26. Reporting of Foreign Taxes
27. Drug Free Workplace
28. USAID Disability Policy
29. Foreign Government Delegations to International Conferences
30. Marking under USAID Funded Assistance
31. Universal Identifier
32. Reporting Sub-Awards and Executive Compensation
33. Trafficking in Persons
34. Prohibition of Assistance to Drug Traffickers
35. Byrd Anti-Lobbying Amendment

The following are the principal standard federal requirements applicable to the performance of both parties' responsibilities under this Agreement (in addition and without prejudice to the other provisions of this Agreement):

(1) Applicability of 22 CFR Part 226. *This provision is only applicable to agreements and subagreements awarded to U.S. organizations.* All provisions of 22 CFR Part 226 are applicable to this Agreement.

(2) Reimbursable Costs. *This Provision is only applicable to cost reimbursement contracts.* To be reimbursable under this Agreement, costs must comply with the applicable cost principles. For educational institutions, use OMB Circular A-21; for all other non-profit organizations, use OMB Circular A-122; and for profit making firms, use Federal Acquisition Regulation 31.2 (see below). Requirements include the following, without limitation: direct costs must be necessary and incurred specifically for the Services; verifiable from the books and records of Contractor, as applicable, and supported by source documentation; allocable to this Agreement; reasonable in nature and amount; and allowable (i.e. conform to the provisions and limitations of this Agreement). To facilitate monitoring of charges under this Agreement, once each year, IAVI may provide Contractor with a USAID compliance form which Contractor agrees to fill out completely and accurately and return promptly to IAVI for review and consultation as appropriate.

(3) Indirect Costs. *This Provision is only applicable to cost reimbursement contracts.* Unless predetermined indirect cost rates are included in the approved budget for this Agreement (or each Task Order, when applicable), funding from USAID will only be used for reimbursable direct costs.

(4) Accounting Systems, Records and Audits. *This Provision is only applicable to cost reimbursement contracts.* Contractor shall maintain books, records, documents and other evidence in accordance with generally accepted and recognized accounting procedures. Contractor shall preserve and make available its accounting records and documents for examination and audit by IAVI, USAID and the Comptroller General of the United States, or any of their duly authorized representatives: (a) until the expiration of three years from the termination of this Agreement; (b) for such longer period, if any, as is required to complete an audit to resolve all questions concerning expenditures unless written approval has been obtained from USAID to dispose of the records; and (c) if any litigation, claim, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved. Contractor agrees to make available any further information requested by either IAVI or USAID with respect to any questions arising as a result of the aforementioned audit. U.S. organizations are also subject to the audit requirements of 22 CFR 226.26 (Non-Federal Audits). Non-U.S. organizations may be subject to annual audit in accordance with the "Guidelines for Financial Audits Contracted by Foreign Recipients" issued by the USAID Inspector General.

(5) Payment Advances and Refunds. If Contractor receives advance payments under this Agreement, Contractor shall maintain advances in interest bearing accounts unless: 1) Contractor receives less than $120,000 in U.S. Government awards per year; or 2) the best interest bearing account would not be expected to earn more than $250 in interest each year; or 3) the bank would require an unreasonable average or minimum balance so as to make it impractical to do so. Interest earned in excess of $250 per year must be refunded to IAVI. In addition, funds advanced to Contractor but not expended by the end of this Agreement or not expended in accordance with the terms of this Agreement must be refunded to IAVI.

(6) Debarment. Contractor certifies that neither it nor its principals is presently excluded or disqualified or proposed for exclusion or disqualification from participation in this Agreement by any U.S. Federal department or agency (see the U.S. Government's Excluded Parties List at http://epls.arnet.gov). Furthermore, Contractor agrees that it will not knowingly enter into a subcontract or subaward with a disqualified or excluded party on this list. Contractor agrees to notify IAVI immediately upon learning that it or any of its principals: 1) are presently excluded or disqualified from covered transactions by any Federal department or agency; 2) have been indicted or otherwise criminally or civilly charged, convicted of or had a civil judgment rendered against them for commission of any of the acts listed in the USAID Standard Provision entitled "Debarment, Suspension, and other Responsibility Matters"; or 3) have had one or more public transactions (with local, State or the Federal governments) terminated for cause or default within the preceding three years. Contractor shall include this provision in any subcontracts or subawards under this Agreement.

(7) Probity. Contractor represents and warrants that (i) to the best of its knowledge and belief, no IAVI employee, officer, or agent, or member of his/her immediate family, his or her partner, or an organization which is about to employ any of the foregoing, has a financial interest in Contractor; and (ii) no officer, employee or agent of IAVI has solicited or accepted gratuities, favors, or anything of monetary value from Contractor.

(b) U.S. Executive Orders and U.S. law prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of Contractor to ensure compliance with these Executive Orders and laws in the conduct of its own activities. Contractor is required to obtain the updated lists at the time of procurement of goods or services. The updated lists are available at: http://www.treas.gov/offices/enforcement/ofac/sdn/t11sdn.pdf and http://www.un.org/sc/committees/1267/consolist.shtml. This provision must be included in all contracts, subcontracts or subawards awarded hereunder.

(8) Nonliability and Disclaimers. Contractor agrees that USAID will not assume liability for third party claims for damages arising out of this Agreement and that Contractor will have no relationship with USAID solely because of this Agreement.

(9) Procurement and Eligibility Rules of Goods and Services. (a) Procurements of goods and services pursuant to this Agreement shall be conducted in accordance with sound commercial practices and the USAID Standard Provisions "USAID Eligibility Rules for Goods and Services (April 1998)" and shall be supported by original invoices or other appropriate supporting documentation. Furthermore, procurement by U.S. organizations should be in accordance with the procurement procedures outlined in 22 CFR 226.44, and procurement by non-U.S. organizations should be in accordance with the Standard Provisions for Non-U.S. Organizations entitled "Procurement of Goods and Services (October 1998)". The text of these policies is available on USAID's website (see below).

(b) Goods on USAID's list of ineligible items (military equipment, surveillance equipment, equipment to support police or law enforcement activities, abortion equipment, luxury goods, gambling equipment, and weather modification equipment) may not be financed. Goods on USAID's list of restricted items (agricultural equipment, pesticides, fertilizers, U.S. government-owned excess property, used equipment, pharmaceuticals, including HIV Test kits, motor vehicles and motor bikes) may only be financed with IAVI's prior written approval.

(c) Other Goods and services may be procured from any country except the following Foreign Policy Restricted Countries: Cuba, Iran, Iraq, Laos, North Korea, or Syria. Goods may not be procured from firms on the U.S. government's Excluded Parties List (see "http://epls.arnet.gov"). For purposes of the preceding sentence, "procured from" includes supplier nationality (for goods and services) and the source and origin of the goods.

(10) Capital Expenditures.

(a) Unless indicated otherwise in the schedule of this Agreement, title to all equipment purchased with funds provided hereunder shall belong to IAVI.

(b) Contractor must obtain IAVI's prior written approval before: (i) purchasing capital equipment or (ii) incurring costs for renovations or other material improvements to land, buildings or equipment.

(11) Travel and Transportation. *This provision is applicable when international travel is authorized under this Agreement.* Unless included in the approved budget for this Agreement, no funds may be expended for international travel without IAVI's written approval. Expenditures of funds provided under this Agreement (i) for transportation of goods or travel of personnel overseas shall be subject to the USAID Standard Provision, "International Air Travel and Transportation (JUNE 1999)," and (ii) for shipments of goods by sea shall be subject to the USAID Standard Provision, "Ocean Shipment of Goods (JUNE 1999)." U.S. flag carriers must be used to the extent service by such carriers is available. The text of these provisions is available on USAID's website (see below). This provision will be included in all subawards and contracts hereunder which require international travel and transportation.

(12) Human Subjects Research. *This provision is applicable when human subjects research is conducted pursuant to this Agreement.* Contractor agrees to comply with USAID policies, to the extent applicable, including without limitation the Common Federal Policy for the Protection of Human Subjects (implemented by USAID at 22 CFR Part 225); the "Procedures for Protection of Human Subjects in Research Supported by USAID"; and the USAID Standard Provision entitled "Protection of the Individual as a Research Subject (APRIL 1998)." The texts of these policies are available on USAID's website (see below.)

(13) Animal Welfare. *This provision is applicable when research involving laboratory animals is conducted pursuant to this Agreement.* Contractor agrees to work with IAVI to ensure compliance with USAID policies to the extent applicable, as referenced in the USAID Standard Provision entitled "Care of Laboratory Animals (MARCH 2004)". The text of this policy is available on USAID's website (see below).

(14) Worker's Compensation Insurance. *The provision is applicable to U.S. based contractors who will perform work hereunder outside the United States.* Pursuant to 22 CFR Part 226, Appendix A, Contractor agrees to provide worker's compensation insurance to all persons employed outside the U.S. who are U.S. citizens or residents. Contractor agrees to provide insurance required by applicable law to all persons employed outside the U.S. who are not U.S. citizens or residents

(15) Nondiscrimination. *This provision is applicable when work under this Agreement will be performed in the United States or when employees are recruited in the United States.* No U.S. citizen or legal resident of the United States will be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any activity funded under this Agreement on the basis of race, color, national origin, age, handicap or sex. Contractor will comply with E.O. 11246, "Equal Employment Opportunity," as amended by E.O. 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and as supplemented by regulations at 41 CFR Chapter 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor," to the extent required by the foregoing.

(16) Real Property. Funding may not be used under this Agreement to construct, alter, repair or improve real property without IAVI's advance written approval, which [approval] may be subject to additional USAID requirements.

(17) Clean Air/Water. *This provision is applicable to contracts in excess of $100,000 to be performed in the United States.* Contractor agrees to comply with all applicable standards, orders or regulations pursuant to the Clean Air Act (42 U.S.C. 7401 et seq.) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.) Violations are to be reported to IAVI.

(18) Publications and Media Releases. (a) Contractor shall provide to IAVI, for submission to USAID, one hard copy and one electronic copy in PDF form, if available, of all published works developed under this Agreement. Each document submitted should contain essential bibliographic elements such as 1) descriptive title; 2) author(s) name; 3) date of publication; 4) and a statement that this publication was funded in whole or in part by the International AIDS Vaccine Initiative under Cooperative Agreement No. AID-OAA-A-11-00020 awarded by the U.S. Agency for International Development (Office of Health/AIDS, Bureau of Global Health, S.O. 4100201).

(b) In the event funds provided under this Agreement are used to fund the cost of publishing, any related profits or royalties realized by Contractor (up to the amount of these publishing costs) should be credited back to this Agreement.

(c) Except as otherwise provided elsewhere in this Agreement, the author or Contractor is free to copyright any books, publications or copyrightable materials development under this Agreement; however USAID reserves a royalty-free nonexclusive and revocable right to reproduce, publish, or otherwise use, and to authorize others to use, the work for U.S. government purposes.

(d) Any "public communications", as defined in 22 CFR 226.2, funded under this Agreement in which the content has not been approved by USAID, must contain the following disclaimer:

> *"This study/report/audio/visual/other information/media project is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert Contractor's name] and do not necessarily reflect the views of USAID or the United States Government".*

(19) Investment Promotion. Except as may be specifically set forth in this Agreement or as IAVI may otherwise approve in advance, no funds or other support provided under this Agreement may be used by Contractor for an activity that involves investment promotion in a foreign country. The Contractor must ensure that its employees and subrecipients and contractors providing investment promotion services are made aware of these restrictions and include this clause in all subagreements and contracts.

(20) Organizations Eligible for Assistance. If Contractor is otherwise eligible to receive funds under this Agreement to prevent, treat, or monitor HIV/AIDS, Contractor shall not be required to endorse or utilize a multisectoral approach to combatting HIV/AIDS or to endorse, utilize, or participate in a prevention method or treatment program to which Contractor has a religious or moral objection. The Contractor shall include this provision in any subcontracts or subawards under this Agreement.

(21) Condoms. If information is provided under this Agreement about the use of condoms, the information shall be medically accurate and shall include the public health benefits and failure rates of such use and shall be consistent with USAID's fact sheet entitled "USAID: HIV/STI Prevention and Condoms". This fact sheet may be accessed at: http://www.usaid.gov/our work/global health/aids/TechAreas/prevention/condomfactshe et.html."

(22) Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking. None of the funds made available under this Agreement may be used by Contractor to promote or advocate the legalization or practice of prostitution or sex trafficking. The funds made available under this Agreement may be used by Contractor to provide palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides, if applicable under this Agreement. For the purposes of this provision, "sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act; "commercial sex act" means any sex act on account of which anything of value is given to or received by any person and; "prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning. The Contractor shall include this provision in any subcontracts or subawards under this Agreement.

(23) Equal Protection of the Laws for Faith-Based and Community Organizations. (a) In providing services supported by this Agreement or in its outreach activities related to these services, Contractor may not discriminate against any beneficiary or potential beneficiary on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

(b) If Contractor engages in inherently religious activities, these activities must occur at a different time and/or location from any programs or services funded by this Agreement and participation by beneficiaries in any such inherently religious activities must be voluntary. The Contractor must not engage in any inherently religious activities, such as worship, religious instruction or proselytization as part of the programs or services funded under this Agreement.

(c) In awarding subagreements or contracts under this Agreement, Contractor should not discriminate against a faith-based organization in selecting qualified organizations or impose additional requirements when awarding to a religious organization.

(d) When Contractor is a religious organization, Contractor:

(1) Retains its independence and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use funds from this Agreement to support any inherently religious activities, such as worship, religious instruction, or proselytization.

(2) Retains its authority over its internal governance and may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.

(3) Retains its exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of 1964, 42 U.S.C. 2000e-1.

(4) May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols.

(24) Voluntary Population Planning Activities — Mandatory Requirements. (a) No funds under this Agreement may be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

(b) No funds under this Agreement made be used to finance, support or be attributed to any activities whatsoever related to the performance of abortion as a method of family planning, including paying incentives to coerce or motive individuals to have abortions. The term "motivate" as it relates to family planning assistance shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

(c) No funds under this Agreement may be used for biomedical research which relates in whole or in part to the methods or performance of abortions or involuntary sterilizations as a means of family planning. This does not preclude epidemiological or descriptive research to assess the incidence, extent or consequences of abortions.

(d) When giving guidance and information regarding family planning the Contractor shall provide a broad range of family planning methods and services available in the country in which the activity is conducted or shall provide information to such individuals regarding where such methods and services may be obtained. The Contractor shall notify IAVI immediately if it learns about an alleged violation of the terms of this Provision 24(d).

(25) Participant Training. *This provision is applicable to this Agreement if training will be provided to any non-U.S. individual outside of that individual's home country.* Participant training under this Agreement shall comply with the policies established in USAID ADS Chapter 253.

(26) Reporting of Foreign Taxes. Quarterly financial reports or other requests for reimbursement in accordance with the payment terms of this Agreement should include the amount of any value added tax (VAT) and custom duties paid to the foreign government of the country receiving assistance hereunder on commodity purchase transactions valued at $500 or more financed under this Agreement as well as any reimbursements of such taxes that may be received during the period of this Agreement. “Commodity” means any material, article, supply, goods or equipment.

(27) Drug Free Workplace. Within 30 days after either the effective date of this Agreement, if awarded after September 13, 2011 or of the effective date of the amendment incorporating this provision if this Agreement was awarded prior to September 13, 2011, Contractor agrees to publish a drug-free workplace statement and provide a copy to each employee who will be engaged in performance of this Agreement. The statement must be in accordance with the USAID Standard Provision entitled “Drug-Free Workplace (JAN 2004)”. Contractor agrees to both immediately notify IAVI if an employee working hereunder is convicted of a drug violation in the workplace and to either terminate the employee or take other appropriate action in accordance with the above- referenced Standard Provision.

(28) USAID Disability Policy. Contractor shall not discriminate against people with disabilities in the implementation of the program funded by this Agreement and shall make every effort to comply with the objectives of the USAID Disability Policy to the extent that it can do so within the scope of the program. The full text of the policy can be found at http://www.usaid.gov/about/disability/DISABPOL.FIN.html.

(29) Foreign Government Delegations to International Conferences. Funds in this Agreement may not be used to finance any travel costs or conferences fees for any member of a foreign government’s delegation to an international conference sponsored by a public international organization, except as provided in USAID ADS Mandatory Reference “Guidance on Funding Foreign Government Delegations to International Conferences” or as approved by USAID.

(30) Marking under USAID Funded Assistance. As a condition of receipt of this Agreement,. Contractor must mark all overseas programs, projects, activities, public communications and commodities in accordance with the attached IAVI Marking Plan. In doing so, marking with either the IAVI logo or the USAID logo (as stipulated) should be of a size and prominence equivalent to or greater than the logos of Contractor, Contractor’s other donors, or third parties.

(31) Universal Identifier. *This Provision is only applicable to sub-awards. If applicable, Contractor will be requested to provide this information prior to the award of an agreement.* The Contractor is required to have a Data Universal Numbering System (DUNS) Number prior to the award of an Agreement by IAVI. A Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (currently 866-705-5711) or the Internet (currently at http://fedgov.dnb.com/webform). IAVI is not authorized to enter into an Agreement with any Contractor that has not provided IAVI with the Contractor’s DUNS Number.

(32) Reporting Sub-Awards and Executive Compensation. *This Provision is only applicable to sub-awards. If applicable, Contractor will be requested to provide this information prior to the award of an agreement.* This provision is only applicable to agreements equal to [***] or more. IAVI must report agreements in excess of [***] on the Federal Funding Accountability and Transparency Act (FFATA) Sub-Award Reporting System (FSRS). The information that must be reported for each agreement includes information regarding the Contractor's five most highly compensated executives. As a result the Contractor must report the names, title and compensation of its five most highly compensated executives to IAVI, if (i) in the Contractor's preceding fiscal year the Contractor received: (a) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and (b) [***] or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and (ii) the public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a),78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm). The Contractor will be requested to provide this information to IAVI by completing a FFATA Sub-Award Reporting Certification Form.

(33) Trafficking in Persons. The Contractor and the Contractor's employees, subcontractors and the subcontractor's employees may not: (a) Engage in severe forms of trafficking in persons during the period of time that the Agreement is in effect; (b) Procure a commercial sex act during the period of time that the Agreement is in effect; and (c) Use forced labor in the performance of the Agreement. IAVI shall have the right to unilaterally terminate this Agreement if the Contractor, the Contractor's employees, subcontractors or subcontractor's employees is determined to have violated any of the prohibitions of this Provision. The Contractor must inform IAVI immediately of any information the Contractor receives from any source alleging a violation of any prohibitions of this Provision. The Contractor shall include this provision in any subcontracts or subawards under this Agreement.

Definitions: (a) "Employee" means either: (i) An individual employed by you or a subrecipient who is engaged in the performance of the Agreement; or (ii) Another person engaged in the performance of the Agreement and not compensated by you including, but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing or matching requirements; (b) "Forced labor" means labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery; (c) "Severe forms of trafficking in persons,'" "commercial sex act," and "coercion" have the meanings given at section 103 of the TVPA, as amended (22 U.S.C. 7102).

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(34) Prohibition of Assistance to Drug Traffickers. IAVI reserves the right to terminate this Agreement or take other appropriate measures if the Contractor or a key individual of the Contractor is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defied in 22 CFR 140.

(35) Byrd Anti-Lobbying Amendment. Pursuant to 22 CFR Part 227, Contractor agrees to: (a) sign and submit to IAVI (i) upon signing of this Agreement, the required certification that it has not used and will not use federal appropriated funds to influence various government officials in making certain federal awards, using the "Certification Regarding Lobbying" form, and (ii) the "Disclosure of Lobbying Activities Form", if it uses or has agreed to use funds other than federal appropriated funds for this purpose; (b) sign and submit to IAVI at the end of each calendar quarter the Standard Form LLL, Disclosure of Lobbying Activities Form, if (i) it uses or has agreed to use funds other than federal appropriated funds and/or (ii) an event occurs that materially affects (as defined in 22 CFR Part 227) the accuracy of any information contained in any Disclosure Form previously submitted by the Contractor to IAVI. This provision must be included in all contracts, subcontracts or sub-awards exceeding $100,000 awarded hereunder.

The text of the Standard Provisions and other regulations that are referenced above is available at the following websites. IAVI will provide a copy upon request.

22 CFR Part 226 - http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title22/22cfr226_main_02.tpl
OMB Circular A-122 - http ://www.whitehouse.gov/omb/circulars/a122/a122_2004.html
OMB Circular A-21 - http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html
FAR Part 31.2 - https://www.acquisition.gov/far/html/Subpart%2031_2.html
USAID Standard Provisions for U.S. Organizations - http://www.usaid.gov/policy/ads/300/303maa.pdf
USAID Standard Provisions for non-U.S. Organizations - http://www.usaid.gov/policy/ads/300/303mab.pdf

IAVI Marking Plan
under USAID Cooperative Agreement AID-OAA-A-11-00020

As an international organization, IAVI's continued success in accelerating the development of promising HIV vaccine candidates relies upon long-term engagement with our diverse portfolio of contributors and other stakeholders. This fact is reflected in our Marking Plan. Under this Plan, IAVI had developed a multi-donor logo which acknowledges all of IAVI's governmental and largest private sector donors. This logo will be applied universally, both domestically and outside the U.S., to mark items such as physical infrastructure, workshops, and program communications; however, the USAID-logo sticker by itself will be used to mark equipment procured entirely with USAID funds. For example, when appropriate, items would be marked as follows:

- Publications and other public communications marked with IAVI multi-donor logo in a visible location such as the front or back cover
- Invitation letterhead, report or cover marked with IAVI multi-donor logo in a visible location such as in the body text or footnoted
- Equipment marked with a USAID logo sticker in a visible location
- Infrastructure marked with a IAVI multi-donor plaque in a visible location

Marking with either the IAVI logo or the USAID logo (as stipulated above) should be of a size and prominence equivalent to or greater than the logos of the contractor/recipient, other donors, or other third parties. The Marking Plan Table which follows indicates the items and activities to be marked and those which are exempt from marking.

The USA ID logo stickers (for equipment) can be either obtained from IAVI or ordered directly from vendors listed on the USAID website (http://www.usaid.gov/branding/suppliers.html). Three versions of the logo below are available to allow for flexibility of usage. Upon request, an electronic file of all three versions of the IAVI multi-donor logo will be sent by IAVI to the contractor/recipient.

IAVI MARKING TABLE

ACTIVITY	TO BE MARKED	NOT TO BE MARKED (EXEMPT)*
External Publications	Informational, educational and communication materials for use by staff, partners and other stakeholders on AIDS vaccines and related topics (includes leaflets & brochures)	Reports and publications done in partnership with governments
	Research working papers, policy briefs, and discussion papers	
Tools and Operational Documents	Tool kit for needs assessment/program planning for community involvement	
	Community advisory board(s) guidance documents	
Reports	Reports of select social science research projects on issues relevant to clinical research in developing countries or reports from needs assessment and monitoring and evaluation efforts	Reports on programs involving governmental policies and programs
Workshops, technical meetings, training programs, seminars, consultations	Invitation letters, informational handouts, briefs, reports, and meeting signage	Invitation letters, informational handouts, briefs, reports, and meeting signage for Policy Makers Workshops covering national policy issues
		Meetings and trainings implemented in partnership with the Government of India
Human Immunology Laboratory (Imperial College; trial sites and laboratories in Africa and India; biotechnology firms and pharmaceuticals outside the U.S.)	Buildings/facilities	Internal Documents (e.g. Good Clinical Laboratory Practice guidelines, standard operating procedures guidelines, audits, validation study reports, clinical trial study reports, etc.)
	Laboratory and office equipment unless item is too small or marking would impair functionality	Consumables and laboratory supplies such as scissors, forceps, test tubes, vaccine vials, pipettes
	Shipping containers packed with equipment or supplies to the Africa or India IAVI sites unless marking would jeopardize the integrity of the contents	Shipping clinical samples from site to London or Johannesburg core labs

* If IAVI determines that these items/activities are no longer exempt, IAVI will notify the subawardee or contractor in writing that these items/activities should also be marked with the IAVI multi-donor logo (or the USAID logo for equipment).

ATTACHMENT IV

NIH Standard Provisions

Theraclone shall comply with the standard NIH requirements specified in this Attachment. Throughout these provisions, Theraclone shall be defined as Subawardee.

1. General Provisions

   This Agreement is subject to the terms and conditions incorporated either directly or by reference in the following:

   a. 45 CFR Part 74; and

   b. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

2. Prior Approval

   As outlined in the administrative requirements of the NIH Grants Policy Statement, NIH prior written approval may be required before IAVI makes certain budget modifications or undertakes particular activities. As a result, Subawardee agrees to obtain written prior approval from IAVI for the following activities and/or expenditures under this Agreement:

   - Change in scope
   - Change in key personnel
   - Carryover of unobligated balances
   - Deviation from Agreement terms and conditions
   - Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement
   - Change in the specific aims approved at the time of award
   - Substitution of one animal model for another
   - Any change from the approved use of animals or human subjects
   - Shift of the research emphasis from one disease area to another
   - A clinical hold by FDA under a study involving an IND or an IDE
   - Application of a new technology, e.g., changing assays from those approved to a different type of assay
   - Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements.
   - Incurrence of research patient care costs if costs in that category were not previously approved by NTH or if a grantee desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category

3. Reimbursable Costs

   a. To be reimbursable under this Agreement, costs must comply with the applicable cost principles. For state, local or federally-recognized Indian tribal governments use OMB Circular A-87; for institutions of higher education, use OMB Circular A-21; for non-profit organizations, use OMB Circular A-122; for hospitals, use Appendix E of 45 CFR Part 74; and for profit making firms, Federal Acquisition Regulation (FAR) at 48 CFR part 31, except that independent research and development costs are unallowable.

   b. Requirements include the following, without limitation: direct costs must be necessary and incurred specifically for the Project Activities; verifiable from the books and records of Subawardee, as applicable, and supported by source documentation; allocable to this Agreement; reasonable in nature and amount; and allowable (i.e. conform to the provisions and limitations of this Agreement).

4. Accounting Systems, Records and Audits

   Subawardee shall maintain books, records, documents and other evidence in accordance with generally accepted accounting procedures. Subawardee shall preserve and make available its accounting records and documents for examination and audit by, NIH or the Comptroller General of the United States, or any of their duly authorized representatives: (a) until the expiration of three years from the termination of this Agreement; (b) for such longer period, if any, as is required to complete an audit to resolve all questions concerning expenditures unless written approval has been obtained from NTH to dispose of the records; and (c) if any litigation, claim, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved. Subawardee agrees to make available any further information requested by either IAVI or NIH with respect to any questions arising as a result of the aforementioned audit. Such audit shall be at no cost to Theraclone.

5. Procurement

   Procurements of goods and services pursuant to this Agreement shall be conducted in accordance with sound commercial practices and 45 CFR Part 74 or 45 CFR Part 92 (as applicable) and the NIH Grants Policy Statement and shall be supported by original invoices or other appropriate supporting documentation.

6. Equipment

   Subawardee must obtain IAVI's prior written approval before: (i) purchasing equipment or (ii) incurring costs for renovations or other material improvements to land, buildings or equipment. Title to any equipment purchased by the Subawardee under this Agreement will be, unless otherwise agreed in writing by IAV1, held by IAVI subject to the conditions of 45 CFR Part 74.34. The Equipment will be used as determined by the Parties under the terms of the SOW during the term of this Agreement and thereafter as determined by IAVI. Upon the termination or expiration of this Agreement, IAVI may, at its sole discretion, grant Subawardee title to, or retain title to, any Equipment and if IAVI does not grant Subawardee title, Subawardee will promptly return such Equipment (at IAVI's expense) to IAVI. Subawardee will be responsible for the proper use and maintenance of any Equipment during the term of this Agreement.

7. Real Property

Funding may not be used under this Agreement to construct, alter, repair or improve real property without IAVI's advance written approval. This approval is subject to 45 CFR Part 74.32.

8. Publications and Media Releases

Subawardee will make the results and accomplishments of the Project Activities available to the research community and to the public at large. Subawardee shall provide to IAVI, for submission to NIH, one hard copy and one electronic copy in PDF form, if available, of all published works developed under this Agreement. Each publication, press release or other document that cites results from activities funded under this Agreement must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number U19A1090970 from the National Institute of Allergy and Infectious Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Allergy and Infectious Diseases or the National Institutes of Health."

The Subawardee is required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (AMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

9. Copyright

a. Subawardee shall own the rights in data it generates from the Project Activities and any publications, data, or other copyrightable works developed under this Agreement may be copyrighted without NIH approval. Subawardee hereby grants NIH a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes.

b. The disposition of royalties and other income earned from a copyrighted work is addressed on the NIH website http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_part8.htm under "Administrative Requirements - Management Systems and Procedures - Program Income."

10. Sharing of Research Data

Subawardee will ensure the timely release and sharing of final research data from the Project Activities for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. Data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

11. Sharing of Unique Research Resources

Subawardee will share any unique research resources developed under this Agreement in accordance with the *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999), which is available on the NIH website (http://www.ott.nih.gov/policy/rt_guide_final.html). Upon the request of the NIH awarding office, Subawardee must also provide a copy of documents or a sample of any material developed under this Agreement to NIH. Subawardee will submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community.

12. Rights to Inventions

Rights to inventions made under this Agreement shall be determined in accordance with the standard Patent Rights clauses as specified in 37 CFR Part 401. The provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404) shall apply. [Need to Discuss]

13. Standards of Conduct

Subawardee must establish safeguards reflected in written standards of conduct, consistent with State and local laws, to prevent employees, consultants, members of governing bodies, and others who may be involved in Project Activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties, which cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas as political participation and bribery. A copy of these general standards of conduct must be made available to each of its officers, each of its employees and consultants working on the Project Activities, each member of the governing board, if applicable, and, upon request, to IAVI and the NIH. The NIH website http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm#_Toc54600064 provides additional information.

14. Financial Conflict of Interest

Subawardee must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Subawardee must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of this process, the Investigators' responsibilities, as well as provide Investigator training on this process. Prior to expenditure of the funds awarded under this Agreement, the Subawardee must report to IAVI the existence of a conflicting interest and within 30 days of any new conflicting interests identified after the initial report. Subawardee must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this Agreement. The NIH website http://grants.nih.gov/grants/policy/coi/index.htm provides additional information. If Subawardee or any subgrantee, contractor, or collaborator engaged by the Subawardee under this Agreement does not have a Financial Conflict of Interest Policy in place that complies with 42 CFR Part 50, Subpart F, such Subawardee, subgrantee, contractor, or collaborator must follow IAVI's Research Conflict of Interest Policy for Investigators Involved in PHS Funded Research.

15. Research Misconduct

The Subawardee will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct. Subawardee agrees to comply with 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science." The Subawardee certifies that it has established administrative policies as required by 42 CFR 50, Subpart A, and will comply with those policies and the requirements of the regulations. The regulations are available from the ORI on its home page (www.ori.dhhs.gov). The Subawardee will report promptly to IAVI any incident of alleged or apparent research misconduct that it judges as warranting investigation and must advise IAVI of any decision to initiate an investigation. The Subawardee agrees to promptly report issues involving potential criminal violations, such as misappropriation of funds awarded under this Agreement, to IAVI.

16. Human Subjects Research

a. Subawardee agrees to conduct human subjects research under this Agreement in compliance with 45 CFR Part 46 and the Standards for Privacy of Individually Identifiable Health Information outlined in the NIH Grants Policy Statement.

b. Subawardee certifies that it has an appropriate OHRP-approved assurance and IRB approval of the research consistent with 45 CFR Part 46 and that it will comply with NIH prior-approval requirements related to the addition of sites not included in the approved application. Subawardee certifies that all key personnel performing Project Activities under this Agreement have received training in the protection of human subjects.

17. Data and Safety Monitoring

    Subawardee agrees to comply with NIH requirements for data and safety monitoring outlined in the NIH Grants Policy Statement.

18. Investigational New Drug Applications/Investigational Device Exceptions

    If Project Activities under this Agreement involve INDs, drugs approved for a different indication, or experimental combinations of drugs, Subawardee agrees to comply with FDA's IND regulations, FDA's human subjects' protection requirements, and HHS's human subjects' requirements. As provided in the FDA regulations, an IND or IDE also may apply to biologics or devices. The FDA regulations are published in 21 CFR Parts 50 and 312.

19. Requirements for Inclusiveness in Research Design

    In accordance with the NIH Grants Policy Statement, Subawardee agrees that Project Activities under this Agreement will be as inclusive in design as possible to extend the validity of research findings and allow for enhancement of the health status of all population groups.

20. Inclusion of Women and Minorities as Subjects in Clinical Research

    Subawardee certifies that Project Activities under this Agreement involving human subjects of any age will comply with the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, implementing section 492B of the PHS Act. These guidelines require that women and members of minority groups and their subpopulations be included in Project Activities under this Agreement involving human subjects, unless a clear and compelling rationale and justification establishes, to the satisfaction of the NIH IC Director, that inclusion is inappropriate with respect to the health of the subjects, the purpose of the research, or other circumstances. Cost is not an acceptable reason for exclusion, except when the research would duplicate data already available from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. The guidelines should be reviewed for policy concerning inclusion of these groups in all NIH-supported clinical trials. This policy applies to subjects of all ages.

21. Inclusion of Children as Subjects in Clinical Research

    a. Subawardee certifies that Project Activities under this Agreement involving human subjects will be performed in compliance with the NIH Policy Statement and this research must include children in the research design unless there are scientific or ethical reasons not to include them. For the purpose of addressing the NIH policy requirement for inclusion, a child is defined as an individual under the age of 21 years.

b. The inclusion of children as subjects in Project Activities under this Agreement must comply with all applicable provisions of pertinent Federal laws and regulations, including 45 CFR Part 46. Regulatory requirements in 45 CFR 46 Subpart D address HHS protections for children who participate in research. These requirements must be addressed when "children" (persons who, under the applicable law of the jurisdiction in which the research will be conducted, have not attained the legal age for consent to treatments or procedures involved in the research) are involved as subjects in research.

22. Human Embryo Research, Cloning, and Transplantation

a. Ban on Human Embryo Research and Cloning: In accordance with NIB policy, funds awarded under this Agreement may not be used to support human embryo research. Funds awarded under this Agreement may not be used for the creation of a human embryo for research purposes or for research in which a human embryo is destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204 and 46.207 and subsection 498(b) of the PHS Act. The term "human embryo" includes any organism not protected as a human subject under 45 CFR 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

b. In addition to the statutory restrictions on human fetal research under subsection 498 (b) of the PHS Act, by Presidential memorandum of March 4, 1997, Subawardee is prohibited from using funds awarded under this Agreement for cloning of human beings.

c. Research on Human Fetal Tissue: Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable State and local laws as well as the following NIH guidance - NIH guidance for grantees conducting research on human fetal tissue and other information on the governing Federal statute, sections 498A and 498B of the PHS Act, 42 U.S.C. 289g-1 and 298g-2, is available on the NIH website at http://grants.nih.gov/grants/guide/notice-files/not93-235.html.

d. Research on Transplantation of Fetal Tissue: Subawardee will make available for audit by the HHS Secretary or designee, the physician statements and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the Subawardee. This requirement is in addition to the requirements concerning human subjects in research.

e. In addition, FDA issued a letter on November 30, 2000, indicating that it has jurisdiction over fetal cells and tissues intended for use in humans. FDA is requesting that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm105857.htm

23. Research Using Human Embryonic Stem Cells

Subawardee certifies that research using human embryonic germ cells derived from fetal tissue will be performed in compliance with NIH guidelines outlined in the NIH Grants Policy Statement.

24. Select Agent Research

Subawardee agrees to comply with the NTH Guidelines for Research Involving DNA Molecules. The NIH Guidelines are available at http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm.

25. Health and Safety Regulations and Guidelines

a. Subawardee is responsible for meeting Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to this Agreement. Subawardee agrees to comply with the following regulations:

b. 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910. These regulations are available at http://www.osha.gov/comp-links.html.

c. Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

26. Limitation on Use of Funds

Subawardee is prohibited from using funds awarded under this Agreement to support the promotion of the legalization of any drug or other substance included in Schedule I of the schedule of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812, to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug or for an abortion.

27. Animal Welfare

The Subawardee is responsible for the humane care and treatment of animals in activities funded under this Agreement. Subawardees are required to establish appropriate policies and procedures for the humane care and use of animals, based on the Office of Laboratory Animal Welfare Guide for the Care and Use of Laboratory Animals, and to comply with the Animal Welfare Act and its implementing regulations. This includes appointing an IACUC with specified responsibilities.

28. U.S. Executive Orders

U.S. Executive Orders and U.S. law prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of Subawardee to ensure compliance with these Executive Orders and laws in the conduct of its own activities. Subawardee is required to obtain the updated lists at the time of procurement of goods or services. The updated lists are available at: http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx and http://www.un.org/Docs/sc/committees/1267. This provision must be included in all contracts, subcontracts or subawards awarded hereunder.

29. Debarment and Suspension

In accordance with 45 CFR Part 74.13 and 45 CFR Part 76, the Subawardee certifies that neither it nor its principals is presently excluded or disqualified or proposed for exclusion or disqualification from participation in this Agreement by any U.S. Federal department or agency (see the General Services Administration's "Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with E.O.s 12549 and 12689, "Debarment and Suspension" at www.epls.gov). Furthermore, Subawardee agrees that it will not knowingly enter into a subcontract or subaward with a disqualified or excluded party on this list.

30. Nondelinquency on Federal Debt

The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. The Subawardee certifies that Subawardee is not delinquent in repaying any Federal debt, has not been judged to be in default on a Federal debt and Subawardee does not have a judgment lien filed against it.

31. Nonliability and Disclaimers

Subawardee agrees that NIH will not assume liability for third party claims for damages arising out of this Agreement and that Subawardee will have no relationship with NIH solely because of this Agreement.

32. Equal Employment Opportunity

Subawardee is required to comply with E.O. 11246, “Equal Employment Opportunity,” as amended by E.O. 11375, “Amending Executive Order 11246 Relating to Equal Employment Opportunity,” and as supplemented by regulations at 41 CFR part 60, “Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor. No U.S. citizen or legal resident of the United States will be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any activity funded under this Agreement on the basis of race, color, national origin, age, handicap or sex.

33. Clean Air/Water

Subawardee agrees to comply with all applicable standards, orders or regulations pursuant to the Clean Air Act (42 U.S.C. 7401 et seq.) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.) Violations are to be reported to 1AVI.

34. Drug Free Workplace

Subawardee agrees that it will provide a drug-free workplace and will comply with the requirements of the Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) and 45 CFR Part 76. Subawardee will notify lAVI if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment.

35. Lobbying

Subawardee agrees to comply with restrictions on lobbying in accordance with 45 CFR Part 93. Subawardee certifies that it will not and has not used funds awarded under this Agreement to pay any person or organization for influencing or attempting to influence an officer or employee of any Federal agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352.

36. Civil Rights

Subawardee certifies that it is incompliance with and has on file with OCR an Assurance of Compliance with the statutes described below:

- Age Discrimination Act of 1975
- Civil Rights Act of 1964
- Education Amendments of 1972
- Rehabilitation Act of 1973
- Limited English Proficiency

For reference:

Code of Federal Regulations (CFR) - www.gpoaccess.gov/cfr/
OMB Circulars - www.whitehouse.gov/omb/circulars
NIH Grants Policy Statement - http://grants.nih.gov/grants/policy/policy.htm