

18-039 87-E

April 12, 2018

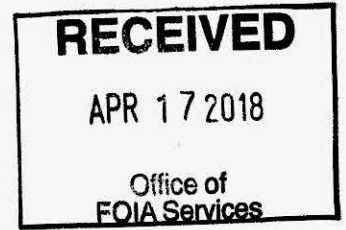
Dear SEC FOIA Office:

I am requesting a copy of  
Exhibit 10.1 Form 10-Q filed by Targeted Genetics Corp /WA/ on 11/14/2002.  
I am willing to pay up to \$61.00.

Thank you,

Diane Martin

**AUS Consultants Inc.**  
155 Gaither Dr, Suite A  
Mt. Laurel  
NJ 08054  
856.234.9200





UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
STATION PLACE  
100 F STREET, NE  
WASHINGTON, DC 20549-2465

Office of FOIA Services

May 10, 2018

Ms. Diane Martin  
AUS Consultants, Inc.  
155 Gaither Dr., Suite A  
Mt. Laurel, NJ 08054

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-03987-E

Dear Ms. Martin:

This letter is in response to your request, dated April 12, 2018, and received in this office on April 17, 2018, for Exhibit 10.1 to the Form 10-Q filed by Targeted Genetics Corp. /WA/ on November 14, 2002.

Your request is granted in full. The 30-page exhibit is enclosed with this letter. Because this exhibit was released in response to a previous FOIA request, no processing fees have been assessed.

If you have any questions, please contact me at [Gbenoua@sec.gov](mailto:Gbenoua@sec.gov) or (202) 551-5327. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Jeffery Ovall as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or [Archives.gov](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

*Amy Gbenou*

Amy Gbenou  
FOIA Research Specialist

Enclosure

NOV 15 2002

**CONFIDENTIAL TREATMENT  
REQUESTED**

**INDUSTRIAL COLLABORATION AGREEMENT**

COLLABORATION AGREEMENT effective as of February 1, 2000 (the "Effective Date"), by and among INTERNATIONAL AIDS VACCINE INITIATIVE, a not-for-profit corporation with its principal offices at 810 Seventh Avenue, New York, New York 10019 (hereinafter referred to as "IAVI"), CHILDREN'S RESEARCH INSTITUTE, a not-for-profit corporation with its principal offices at 700 Children's Drive, Columbus, Ohio 43205 (hereinafter referred to as "Children's"), and TARGETED GENETICS CORPORATION, a Washington corporation with its principal offices at 1100 Olive Way, Suite 100, Seattle, WA 98101 (hereinafter referred to as "TGC").

WHEREAS, IAVI has, as one of its principal objectives, the acceleration of development of vaccines against HIV for use and distribution in Developing Countries (as defined below); and

WHEREAS, Children's and its personnel have certain skills and own rights to certain technology, primarily relating to vaccine design, and TGC possesses certain skills and owns or has license rights to certain technology, primarily relating to vaccine development, which can aid IAVI in its objectives; and

WHEREAS, the Research and Development Program (as defined below) contemplated by this Agreement is of mutual interest and benefit to Children's, TGC and IAVI, and will further the objectives of IAVI in a manner consistent with its status as a not-for-profit, tax-exempt, institution;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. DEFINITIONS. For purposes hereof, the following terms shall have the meanings specified below:

(a) "Affiliate" of a party means the entities that, directly or indirectly, own or control the voting of at least 50% of the voting capital interests of such party ("Parent"), or at least 50% of the voting capital interests (or equivalent control) of which are, directly or indirectly, owned, or the voting of which are controlled, by such party, its Parent, or an Affiliate of such party.

(b) "Background Technology" shall mean: (i) the rights to make, use, sell, offer for sale, and import the TGC-Controlled Inventions; (ii) all inventions (whether or not patented or patentable), know-how, techniques, cell lines, data, studies and results of studies and other proprietary information in the possession or control of Children's at the Effective Date and at any time thereafter during the period in which Children's remains a direct participant in the Research and Development Program, to the extent bearing upon the Program Vaccines, the TGC-Controlled Inventions, the Program Inventions, or any of them within the Program Field (as and to the extent the Program Field exists during the period of such direct participation by Children's); and (iii) know-how and other proprietary information in the possession or control of TGC at the Effective Date and at any time thereafter during the period in which TGC remains a direct participant in the Research and Development Program, to the extent useful for the practice

of the TGC-Controlled Inventions within the Program Field (as and to the extent the Program Field exists during the period of such direct participation by TGC).

(c) "Collaboration Payments" shall mean the cash payments to be made (subject to Sections 6(b) and 6(e)(i)) by IAVI to Children's and by Children's to TGC under this Agreement as awards in support of the Research and Development Program.

(d) "Developing Countries" shall mean those countries defined from time to time by the World Bank on a mutually-acceptable public listing as having "low-income economies" or "middle-income economies" (whether lower-middle or upper-middle) (or a mutually acceptable equivalent list of countries, if such World Bank country lists are discontinued). A list of all such Developing Countries as of the Effective Date is set forth in Attachment A annexed hereto. Notwithstanding the foregoing, no country which is at the relevant time under a trade embargo imposed by U.S. law or regulation or any other applicable export restriction imposed by law or regulation affecting the Program Vaccines, any Background Technology or any Program Inventions will be considered part of the Developing Countries for purposes of the section(s) of this Agreement that would constitute, call for, or facilitate any violation of such embargo or restriction, unless and to the extent that IAVI establishes to TGC's reasonable satisfaction in each instance that IAVI has at its own risk and expense received (for itself and for TGC, to the extent applicable to the transactions under this Agreement) an exemption, export license, or other governmental authorization removing all such embargoes and restrictions as to that country, as applicable to such section(s) hereof. If IAVI so requests, Children's and TGC will make available reasonable assistance to IAVI in support of its application for any such exemption, license or authorization.

(e) "Follow-On Project(s)" shall mean any project in whole or in part to be conducted under the auspices of, or with funding from, IAVI or any of its affiliates or contractors to conduct further work on or with respect to the Program Inventions (or any of them) or other results of the Research and Development Program, whether involving TGC (i.e., under a separate agreement) and/or any third party; provided, however, that those supplemental testing and subcontracting projects that are designated to be conducted by or for IAVI under the Work Plan and Budget by contractors other than Children's and TGC shall not be considered Follow-On Projects.

(f) "Marketing Approval Application" shall mean an application to the relevant health regulatory agency in a country seeking formal approval for the marketing and sale of a product for use in humans for prophylactic or therapeutic purposes. As an example, the current term for a Marketing Approval Application made to the US Food and Drug Administration is "BLA" (Biological License Application), and the term shall be applied to similar sorts of applications in other nations. An initial application for clinical testing (called an IND in the US) would not be a Marketing Approval Application as the term is used herein.

(g) "Net Sales" shall mean the gross sales (i.e., gross invoice prices of Program Vaccine billed by TGC and/or Children's or their respective Affiliates and sublicensees to non-Affiliate third party customers) less: (a) actual credited allowances to such customers for spoiled, damaged, outdated and returned Program Vaccine and for retroactive price reductions; (b) the amounts of actual trade and cash discounts and rebates, including Medicaid (and

equivalent programs outside the United States of America) rebates, given that were not already credited to such customers in the invoice; (c) all transportation, shipping, and third-party handling charges invoiced in accordance with industry norms, sales taxes, excise taxes and import/export duties and rebates (including rebates to third party payors) actually paid; and (d) other reasonable and customary allowances and adjustments actually credited to customers, whether during a specific royalty period or not. Sales among any combination of TGC, its Affiliates, and any of its or their sublicensees for resale will not be part of the Net Sales hereunder. Sales to Affiliates or sublicensees for end use will be treated for purposes of the calculation of Net Sales as if sold at the average price in the month of sale by the party to unrelated parties.

(h) "Program Field" shall mean the manufacture of one or more of the Program Vaccines through the use of the particular combination of Program Inventions and Background Technology as implemented by Children's and TGC under this Agreement during and in the course of the Research and Development Program (as the same may be supplemented or improved by or for IAVI with other inventions or technology from sources other than Children's or TGC), solely for distribution in the Public Sector, and the use, sale, offer for sale, and import of such Program Vaccines so manufactured in and to the Public Sector. IAVI understands that Children's and/or TGC may also engage, outside the Research and Development Program but contemporaneously with it, in other activities, programs or collaborations using and/or improving upon the Background Technology or other technology that may be useful in connection with one or more vaccines, and that Children's and/or TGC may continue, after the end of the Research and Development Program, to improve the Background Technology and to make other inventions or to develop other know-how which may be useful in connection with one or more vaccines, including without limitation by improving concentration levels, purity, scale of manufacture, efficiency of manufacture, clinical effectiveness, safety, and/or quality of the results. Unless otherwise agreed by Children's or TGC, in its discretion and as applicable to it respectively, under subsequent agreement(s), the Program Field will not include the use or exploitation of any such improvements, inventions or know-how so developed or obtained by or for Children's or TGC outside or after the Research and Development Program.

(i) "Program Inventions" shall mean inventions, discoveries, and improvements, patentable or unpatentable, first conceived or reduced to practice by Children's, TGC, IAVI, or the subcontractors of any of them during and in the course of work under the Research and Development Program, inclusive of any cell lines or other materials first developed in the course of such work under the Research and Development Program.

(j) "Program Vaccines" shall mean any AAV (adeno-associated virus) particle-based vector that contains an HIV-1 gene in the recombinant vector genome and that can act as a prophylactic vaccine against HIV-1.

(k) "Proprietary Technology" shall mean any Background Technology to the extent it has not previously been disclosed in an issued patent or a published patent application.

(l) "Public Sector" shall mean governmental health agencies of Developing Countries and shall also include IAVI, the World Health Organization, UNICEF and other non-

profit agencies, to the extent, as to each of the foregoing, that it purchases or manufactures Program Vaccines for delivery and/or sale solely on a non-profit basis for use within Developing Countries.

(m) "Qualified Bidder" shall mean a company or governmental entity: (i) with the demonstrated and existing resources and capability to manufacture Program Vaccines for use by humans, assuming such company or entity were provided with the necessary license rights and access to the necessary Proprietary Technology in order to do so; and (ii) that certifies and otherwise reasonably establishes that it desires to submit a bona fide bid to engage in the business of manufacturing the Program Vaccines for use by humans in the particular relevant Developing Country(ies).

(n) "Reasonable Public Sector Profit" means a profit margin (which may vary from Developing Country to Developing Country) that takes into account the practicalities of the market in the Public Sector in the relevant Developing Country and similarly-situated Developing Countries, including without limitation profit margins then being realized by manufacturers on the sale of other pharmaceutical products in the Public Sector and other considerations that distinguish such markets from other markets, such as the impoverished nature of such countries and the potential international public benefits that may be furthered by widespread availability of the Program Vaccines in such Developing Countries. It is anticipated that a Reasonable Public Sector Profit in most Developing Countries will be substantially less than the profit levels contemporaneously being realized outside the Developing Countries on the same or similar pharmaceuticals.

(o) "Research and Development Program" shall mean the program described in the Work Plan and Budget, as conducted during the term of this Agreement and with the IAVI funding provided under this Agreement. "Year 1" of the Research and Development Program will start as of the Effective Date and will end on January 31, 2001. "Year 2" will run from February 1, 2001 through January 31, 2002. "Year 3" will run from February 1, 2002 through January 31, 2003. Each year of the Research and Development Program will be divided into four quarters of three months each ("Program Quarter(s)").

(p) "TGC-Controlled Inventions" shall mean the inventions disclosed in the United States patents and foreign equivalents and United States and foreign patent applications listed in Attachment B and all divisions, continuations, continuations in part, reissues, or extensions thereof, any periods of marketing exclusivity relating thereto, and any letters patent that issue thereon. It is understood that certain of the TGC-Controlled Inventions (the "Licensed Children's Rights") are owned by Children's and are covered by one or more exclusive licenses or sublicenses to TGC, directly or indirectly.

(q) "TGC Withdrawal Date" shall mean the effective date of a termination of this Agreement pursuant to Section 6(a), Section 6(c)(ii), or Section 6(f)(i).

(r) "Work Plan and Budget" shall mean the set of tasks, procedures, protocols, standards, budgets, and target time frames set forth in Attachment C hereto, as such Attachment may be amended or supplemented by mutual written agreement of the parties from time to time.

2. STATEMENT OF WORK. (a) Each of Children's and TGC agrees to perform the work designated in the Work Plan and Budget to be performed by it, respectively, in the course of the Research and Development Program substantially within the time frames designated in the Work Plan and Budget. TGC will act as the primary Vaccine Developer under the Work Plan and Budget. Children's and TGC will be entitled to involve one or more subcontractors in the performance of such work, provided that each such subcontractor is approved in writing for such purpose by all parties to this Agreement, which approval shall not be unreasonably withheld or delayed. IAVI acknowledges that later steps and phases of work in the Research and Development Program, and the time frames therefor, will depend in part upon the results achieved in earlier steps and phases. The responsibility of Children's and TGC hereunder shall be satisfied by their devotion to the Research and Development Program of the efforts called for from them, respectively, in the Work Plan and Budget; neither of Children's nor TGC warrants or commits that it will achieve successful or timely results in the conduct of the Research and Development Program.

(b) The initial Work Plan and Budget attached hereto as of the Effective Date describes Children's and TGC's respective work for year 1 of the Research and Development Program. On or before the end of the ninth month of year 1 of the Research and Development Program, Children's and TGC will jointly prepare and provide in draft form to IAVI a proposed amendment to the Work Plan and Budget, containing a statement of Children's and TGC's work for year 2 of the Research and Development Program, and of the amounts of Collaboration Payments to be made with respect to that period, and the parties will in good faith come to agreement on or before the end of the eleventh month of year 1, on the final form of such an amendment. Similarly, on or before the end of the ninth month of year 2, Children's and TGC will jointly prepare and provide in draft form to IAVI a proposed amendment to the Work Plan and Budget, containing a statement of Children's and TGC's work for year 3 of the Research and Development Program, and of the amounts of Collaboration Payments to be made with respect to that period, and the parties will in good faith come to agreement on or before the end of the eleventh month of year 2, on the final form of such an amendment. The amounts of Collaboration Payments to be made with respect to year 2 and year 3 will be prepared and agreed upon on the basis of similar cost principles used in the preparation and agreement upon the Collaboration Payments to be made with respect to year 1. Such amendments to the Work Plan and Budget will be prepared and agreed upon in light of the progress made to that time in the course of the Research and Development Program, and no party will unreasonably withhold or delay its agreement to any such amendment.

(c) Throughout the Research and Development Program, each of Children's and TGC agrees to consult with IAVI and its authorized representatives concerning its respective progress and developments in connection with the Research and Development Program. Children's and TGC acknowledge that IAVI may appoint one or more advisory committees with respect to this Agreement and the conduct of the Research and Development Program, including outside experts. IAVI agrees to consult with Children's and TGC and to take into reasonable account their views concerning the members of such committee(s), and, where reasonably so instructed by Children's or TGC, to prevent the disclosure of any confidential information of Children's and/or TGC to specific members of such committee(s). On a quarterly basis, Children's and TGC shall jointly provide IAVI with detailed written scientific reports concerning the progress of research and development conducted by them as part of the Research and

Development Program. Such written reports shall be supplemented and updated by verbal reports provided by Children's and/or TGC to IAVI on at least a monthly basis. Children's and TGC shall jointly provide IAVI with a final written report concerning the Research and Development Program within three (3) months after the completion of the Research and Development Program.

(d) In connection with the Research and Development Program, each of Children's and TGC agrees that it will 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 its respective role in the Research and Development Program (including, without limitation, any laws, statutes, rules, regulations or guidelines concerning animal or human use or testing) and will give IAVI immediate written notice of any breach, violation or deviation (or threatened or alleged breach, violation or deviation) from any such laws, statutes, rules, regulations or guidelines or of the institution or threatened institution of any action, suit or proceeding related thereto. During the Research and Development Program, Children's and TGC will comply with all biohazard or other safeguards as may be required by any applicable law, statute, rule, regulation or guideline.

(e) A Project Management Committee shall be established within thirty (30) days after the Effective Date and shall be maintained throughout the period of the Research and Development Program and in accordance with the Work Plan and Budget. The Project Management Committee shall consist of three (3) members, one (1) appointed by each party hereto, and shall be chaired by the member appointed by IAVI. The Project Management Committee shall be responsible for regular coordination and monitoring of activities hereunder and 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 Project Management Committee will be held at the call of any member, upon at least five days prior notice to the others. Meetings may be held by conference telephone call in which all members can hear the others and be heard by them.

(f) In recognition of IAVI's contacts and position in and with respect to the Developing Countries, IAVI shall, whether as part of the Research and Development Program or as part of any Follow-On Project involving TGC, exert all reasonable efforts to make available IAVI resources, contacts and cooperation to facilitate design of, contracting for, and conduct of, Phase I, Phase II and/or Phase III clinical trials of the relevant Program Vaccines, to the extent such trials will be conducted in any of the Developing Countries.

3. VACCINE DESIGNER. All research conducted by Children's in connection with the Research and Development Program will be supervised by Dr. Philip R. Johnson (hereinafter referred to as the "Vaccine Designer") who shall have the duties and authority customarily associated with being the principal investigator for such research and who, by his signature below, agrees to perform such services. If, for any reason, Dr. Johnson is unable or unwilling to continue to serve as Vaccine Designer for the Research and Development Program (of which Children's agrees to notify TGC and IAVI promptly), Children's will within thirty (30) days nominate a successor Vaccine Designer at Children's, subject to the approval of TGC and IAVI, which approval shall not be unreasonably withheld or delayed. If a successor Vaccine Designer at Children's and acceptable to TGC and IAVI cannot be determined by the



parties within ninety (90) days from the date Dr. Johnson ceases to serve as Vaccine Designer for the Research and Development Program: (i) IAVI may terminate this Agreement immediately upon written notice to Children's and TGC; or (ii) if IAVI does not so terminate this Agreement as of the end of such 90-day period, TGC and/or IAVI may terminate Children's direct involvement in the Research and Development Program, clause (i) of Section 6(b) shall apply, and TGC and IAVI shall determine a replacement Vaccine Designer with approval from Children's as a continuing licensor of rights hereunder, which approval shall not be unreasonably withheld or delayed. The foregoing provisions shall apply to any replacement or successor Vaccine Designer selected by IAVI, Children's and TGC in accordance with the terms of this Agreement.

4. **PERIOD OF PERFORMANCE.** The Research and Development Program shall be conducted during the period from the Effective Date through the end of year 3 of the Research and Development Program, and will be subject to renewal by mutual agreement (in writing) of the parties.

5. **PAYMENTS.** (a) In consideration of the services to be provided and rights granted by Children's and TGC hereunder during year 1 of the Research and Development Program, IAVI agrees to pay the Collaboration Payments with respect to year 1 of the Research and Development Program to Children's, as more fully described in the Work Plan and Budget. IAVI agrees to pay a one-time, forward-funded payment with respect to the period through the end of the sixth month of the Research and Development Program, payable within ten business days after the date this Agreement has been signed by all parties. The purpose of this is to expedite the start-up costs associated with the program, and to enable Children's and TGC to immediately begin addressing project related tasks. Thereafter, Collaboration Payments will be made to Children's with respect to each Program Quarter on or before the first day of such Program Quarter. In the event of a significant delay or acceleration in the Work Plan and Budget for year 1, the payment schedule may be amended by mutual written agreement of the parties.

(b) Payments shall be made by IAVI on the condition that the funds will be administered by Children's and TGC in accordance with the terms and conditions of this Agreement, the Work Plan and Budget for the applicable year, and the Research and Development Program. Children's and TGC shall provide to IAVI summary quarterly reports no less than thirty (30) days after the end of each Program Quarter for which funding hereunder was obtained from IAVI documenting, on a basis consistent with Children's or TGC's (as the case may be) internal, generally-applicable cost accounting methods, that all such funds were utilized for the Research and Development Program in accordance with the foregoing.

(c) Children's shall, within ten (10) business days following its receipt of each and every Collaboration Payment hereunder, remit the entire amount of the Collaboration Payment to TGC, less the portion of the Collaboration Payments attributable under the Work Plan and Budget to Children's for the work of the Vaccine Designer in the Research and Development Program (the "Vaccine Designer's Portion"), and Children's reasonable overhead charges (as more fully described in the Work Plan and Budget) with respect solely to the Vaccine Designer's Portion. Children's will not charge for or impose on its role or activities hereunder, nor deduct from the Collaboration Payments, any other overhead, processing, administrative or other fees of any sort.

(d) Other than the Collaboration Payments set forth above, all costs and expenses incurred by Children's in connection with the rendition of its services hereunder shall be borne exclusively by Children's without further reimbursement or compensation directly or indirectly by IAVI or TGC. Other than the Collaboration Payments set forth above, all costs and expenses incurred by TGC in connection with the rendition of its services hereunder shall be borne exclusively by TGC without further reimbursement or compensation directly or indirectly by IAVI or Children's.

6. TERMINATION. (a) TGC may terminate this Agreement at any time, without cause, by giving at least ninety (90) days' notice in writing to Children's and IAVI.

(b) Children's may terminate its direct involvement in the Research and Development Program at any time, without cause, by giving at least ninety (90) days' notice in writing to TGC and IAVI. In that event: (i) IAVI and TGC will cooperate reasonably in the institution by them of alternative procedures whereby the Collaboration Payments (including the Vaccine Designer's Portion) will from that point forward be paid directly by IAVI to TGC; (ii) unless alternative arrangements reasonably satisfactory to TGC and IAVI are made for the continuation of Dr. Johnson as the Vaccine Designer after the termination of Children's involvement hereunder, a replacement Vaccine Designer acceptable to TGC and IAVI shall be substituted (with approval from Children's as a continuing licensor of rights hereunder, which approval shall not be unreasonably withheld or delayed), it being agreed that if a substitute Vaccine Designer reasonably acceptable to IAVI cannot be agreed upon within ninety (90) days following the end of such involvement by Children's, then IAVI may terminate this Agreement immediately upon written notice to TGC.

(c) IAVI may terminate this Agreement without cause, effective at any time following the end of year 1 of the Research and Development Program, by giving at least ninety (90) days' notice in writing to Children's and TGC.

(d) If the parties fail to reach a mutual agreement on an amendment to the Work Plan and Budget for the coming year of the Research and Development Program, on or before the dates specified in Section 2(b) or such later date as they may mutually agree, this Agreement may be terminated by any party upon notice to the other parties effective ninety (90) days following such date (or such later date, as may be agreed upon in writing by the parties).

(e) In addition to the foregoing:

(i) in the event that Children's shall breach any of the terms, conditions and agreements contained in this Agreement to be kept, observed or performed by it, then either IAVI or TGC may at its option and without prejudice to any of its other legal and equitable rights and remedies terminate the direct involvement of Children's in the Research and Development Program by giving Children's thirty (30) days' notice in writing, particularly specifying the breach, unless Children's within such thirty (30) day period shall have rectified the breach. If the involvement of Children's is so terminated, IAVI and TGC will cooperate reasonably in the institution by them of alternative procedures whereby the Collaboration Payments (including the Vaccine Designer's Portion) will from that point forward be paid directly by IAVI to TGC (unless

alternative arrangements are made with Dr. Johnson or a successor); and, unless alternative arrangements reasonably satisfactory to TGC and IAVI are made for the continuation of Dr. Johnson as the Vaccine Designer after the termination of Children's involvement hereunder, a replacement Vaccine Designer acceptable to TGC and IAVI shall be substituted (without the need for approval from Children's, notwithstanding Children's role as a continuing licensor of rights hereunder), it being agreed that if a substitute Vaccine Designer reasonably acceptable to IAVI cannot be agreed upon within ninety (90) days, then IAVI may terminate this Agreement immediately upon written notice to TGC;

(ii) in the event that TGC shall breach any of the terms, conditions and agreements contained in this Agreement to be kept, observed or performed by it, then IAVI may at its option and without prejudice to any of its other legal and equitable rights and remedies terminate this Agreement by giving TGC and Children's thirty (30) days' notice in writing, particularly specifying the breach, unless TGC within such thirty (30) day period shall have rectified the breach; and

(iii) in the event that IAVI shall breach any of the terms, conditions and agreements contained in this Agreement to be kept, observed or performed by it, then TGC may at its option and without prejudice to any of its other legal and equitable rights and remedies terminate this Agreement by giving Children's and IAVI thirty (30) days' notice in writing, particularly specifying the breach, unless IAVI within such thirty (30) day period shall have rectified the breach.

(f) In addition to the foregoing:

(i) in the event TGC shall become insolvent or shall suspend its business or shall file a voluntary petition or an answer admitting the jurisdiction of the court in the material allegations of, or shall consent to, an involuntary petition pursuant to any reorganization or insolvency law of any jurisdiction, or shall make an assignment for the benefit of creditors, or shall apply or consent to the appointment of a receiver or trustee of a substantial part of its property, then IAVI may thereafter immediately terminate this Agreement by giving written notice of termination to TGC; and

(ii) in the event Children's shall become insolvent or shall suspend its business or shall file a voluntary petition or an answer admitting the jurisdiction of the court in the material allegations of, or shall consent to, an involuntary petition pursuant to any reorganization or insolvency law of any jurisdiction, or shall make an assignment for the benefit of creditors, or shall apply or consent to the appointment of a receiver or trustee of a substantial part of its property, then either IAVI or TGC may thereafter immediately terminate Children's direct involvement in the Research and Development Program by giving written notice thereof to the other and to Children's and the provisions of clauses (i) and (ii) of Section 6(b) shall apply.

(g) If this Agreement is terminated by TGC at its election pursuant to Section 6(a) or due to an uncured breach by TGC as described in clause 6(e)(ii), the unexpended and uncommitted balance of any Collaboration Payments made to Children's (including those

portions retained by it and those paid by it to TGC) shall be promptly returned to IAVI by Children's and by TGC, as appropriate. If this Agreement is terminated by IAVI at its election pursuant to clause (b) of this section, or due to a failure of the parties to reach agreement as described in clause (c) of this section, or due to a failure to agree upon a replacement Vaccine Designer as described in Sections 3 or 6(b) or clause 6(e)(i), all Collaboration Payments paid or payable to Children's and TGC prior to the effective date of the termination shall be retained by Children's and TGC, respectively.

(h) The provisions of Sections 6 through 24 of this Agreement shall survive the termination or expiration of this Agreement; provided, however, that to the extent any such provision(s) would by their nature not be applicable to post-term periods, or where they state that they are applicable during the term of this Agreement or during the Research and Development Period, or for a stated period or under stated conditions thereafter, such provisions will not survive such termination or expiration, such stated period, or in the absence of such conditions, as applicable in each instance.

7. PUBLICATIONS. TGC and/or Children's will be free to publish the results of research performed under this Agreement after providing IAVI with a thirty (30) day period in which to review each publication for patent purposes and to identify and correct any inadvertent disclosure of IAVI's proprietary information or use of IAVI's name which IAVI, in its sole discretion, considers inappropriate. In any such publication, IAVI's funding collaboration shall be acknowledged by TGC and/or Children's, as shall the respective roles of TGC and Children's hereunder. TGC and Children's further agrees to promptly publish, at IAVI's request or to allow IAVI to publish, following sufficient time for filing of patent applications, those results of the Research and Development Program that, in TGC's and Children's reasonable judgment, may be published without disclosing significant trade secrets of TGC or of Children's.

8. PROPRIETARY INFORMATION. A party may disclose to one or more of the other parties its proprietary information which the disclosing party considers necessary to the performance or interpretation of the results of the Research and Development Program and to any subsequent development of the technology of the Research and Development Program. The disclosing party shall be obligated to identify the proprietary nature of the information promptly in writing. The receiving party(ies) agree(s) to retain such information in confidence and use its (or their) best efforts to prevent its disclosure to third parties, other than to another party to this Agreement, which shall not be considered a third party under this clause to the extent any disclosures to it of information obtained from the disclosing party are made solely in support of the Research and Development Program. The receiving party shall be relieved of this obligation only when this information becomes publicly available through no fault of the receiving party or is independently developed without utilization of such proprietary information.

9. RELEASE OF INFORMATION. Any press release, public statement or public release or disclosure of any information not previously disclosed publicly with respect to the Research and Development Program (including, without limitation, any release of information in connection with any scientific and medical conference) that is not mandated by law shall be subject to the mutual approval of IAVI, Children's and TGC, which approval shall not be unreasonably withheld or delayed. In any such press release, public statement or public

release or disclosure of information, IAVI's funding collaboration and the respective roles of Children's and TGC hereunder shall be acknowledged. Notice of any such press release, public statement or public release or disclosure which is mandated by law shall be furnished to the other parties as far in advance as is reasonably possible and their input shall be taken into account with respect thereto to the extent not inconsistent with such legal obligation.

10. INTELLECTUAL PROPERTY. (a) Each of Children's and TGC shall disclose to each other and to IAVI in writing, at the earliest practical time, all Program Inventions. IAVI and each of Children's and TGC shall retain all such disclosures in confidence and use its best efforts to prevent their disclosure to other third parties. The party receiving such a disclosure shall be relieved of this obligation only when this information becomes publicly available through no fault of such party, or as published or otherwise publicly disclosed in accordance with the terms of this Agreement. Each of TGC and Children's agrees to notify the other parties immediately of any decision to apply for letters patent with respect to any Program Invention. TGC and Children's shall provide the other parties with the opportunity to review and comment on all such patent applications prepared by it hereunder and it shall consider the other parties' comments seriously and in good faith.

(b) Subject to the provisions of this Agreement, as among the parties to this Agreement:

(i) TGC shall retain all of its rights and properties (whether as title holder, licensee or sublicensee) in and to the TGC-Controlled Inventions and the other Background Technology of TGC. TGC hereby grants to Children's and its Affiliates a ~~nonexclusive, worldwide and royalty-free right and license, for research purposes only and without any purpose to commercialize, to make and use TGC-Controlled Inventions and the other Background Technology of TGC (to the extent TGC has the right to permit the use of the same for such purpose(s))~~ solely during and within the scope of and directly in support of Children's activities and work under the Research and Development Program. Where TGC believes that there are restrictions on its right to permit the use of any Background Technology for purposes of such license, it shall promptly so inform Children's and IAVI and the parties will consult as to the proper course of action under the circumstances, it being agreed that TGC will not unreasonably refuse to exert reasonable efforts to remove such restrictions where IAVI and/or Children's bears all material costs, fees, and risks of such efforts and such removal;

(ii) Children's shall retain all of its rights and properties (whether as title holder, licensee or sublicensee) in and to the Background Technology of Children's (inclusive of its title in the Licensed Children's Rights, subject to the applicable licenses granted thereon). Children's hereby grants to TGC and its Affiliates an ~~irrevocable, worldwide right and license, with right to sublicense, to make, use, sell, offer for sale, and import Program Vaccines under the Background Technology of Children's (to the extent Children's has the right to permit the use of the same for such purpose(s)),~~ whether such making, use, sales, offers, or importation occurs during or after the term of this Agreement, and specifically including without limitation within the scope of and in support of all grants (contingent or otherwise) by TGC to IAVI hereunder and of any activities by or for TGC or its licensees or contractors as described in clauses (i) and (ii)

of Section 11(e) or in Section 11(i). To the extent any such Background Technology of Children's is part of the Licensed Children's Rights, such license under this clause shall be ~~exclusive and royalty-bearing~~ as provided in those existing license and sublicense agreements. Otherwise, such license to TGC hereunder shall be ~~exclusive to TGC~~ (except with respect to use by Children's within the scope of the research rights of Children's described in clause (vi) below); shall be ~~royalty-free within the Public Sector~~; and shall bear royalties outside the Public Sector at reasonable royalty rates to be determined but not in any event to exceed the sales-based royalty rates specified in the now-existing agreements to be payable to Children's by its licensee (and TGC's sublicensee) under the Licensed Children's Rights. To the extent the sale of any Program Vaccine would for any reason generate a royalty obligation owed by TGC to Children's licensee under the agreements relating to the Licensed Children's Rights, such sale shall not, notwithstanding any other provision hereof, generate any additional royalty obligation to Children's hereunder. Where Children's believes that there are restrictions on its right to permit the use of any Background Technology for purposes of such license, it shall promptly so inform TGC and IAVI and the parties will consult as to the proper course of action under the circumstances, it being agreed that Children's will not unreasonably refuse to exert reasonable efforts to remove such restrictions where IAVI and/or TGC bears all material costs, fees, and risks of such efforts and such removal;

(iii) Title to any and all Program Inventions that are invented solely by TGC personnel shall be and remain the property of TGC;

(iv) Title to any and all Program Inventions that are invented jointly by TGC personnel and Children's personnel shall be and remain co-owned by TGC and Children's;

(v) TGC will control all patent matters with respect to all Program Inventions that are invented either solely by TGC personnel or jointly by TGC personnel and Children's personnel and may file patents on any such Program Invention at its sole cost and expense;

(vi) TGC hereby grants to Children's and its Affiliates an ~~irrevocable, nonexclusive, worldwide and royalty-free right and license, for non-commercial research purposes only and without any purpose to commercialize; to make, use, sell, offer for sale and import all Program Inventions other than those that are invented solely by TGC personnel, provided that Children's shall not without the prior written consent of TGC commercialize, attempt to commercialize; or purport to authorize or assist any third party to commercialize, any of such Program Inventions for any purpose whatsoever;~~

(vii) Title to any and all Program Inventions that are invented solely by Children's personnel shall be and remain the property of Children's;

(viii) Children's hereby grants to TGC and its Affiliates an irrevocable, worldwide right and license, with right to sublicense, to make, use, sell, offer for sale and import Program Vaccines under all Program Inventions that are invented solely by Children's or jointly by Children's and TGC, whether such making, use, sales, offers, or

importation occurs during or after the term hereof, and specifically including without limitation within the scope of and in support of all grants (contingent or otherwise) by TGC to IAVI hereunder and of any activities by or for TGC or its licensees or contractors as described in clauses (i) and (ii) of Section 11(e) or in Section 11(i). To the extent any such Program Inventions would be automatically included in the Licensed Children's Rights pursuant to the terms of the existing license and sublicense agreements with respect to the Licensed Children's Rights, such license under this clause shall be exclusive and royalty-bearing as provided in those existing license and sublicense agreements. Otherwise, such license by Children's to TGC hereunder shall be exclusive (except with respect to use by Children's within the scope of the research rights of Children's described in clause (vi) above) and royalty-free within the Public Sector and shall be exclusive and will bear royalties outside the Public Sector at reasonable royalty rates to be determined but not in any event to exceed the rates specified in Section 11(i) hereof. To the extent the sale of any Program Vaccine would for any reason generate a royalty obligation owed by TGC to Children's licensee under the agreements relating to the Licensed Children's Rights, such sale shall not, notwithstanding any other provision hereof, generate any additional royalty obligation to Children's hereunder.

(ix) Except to the extent the applicable Program Invention is among the Licensed Children's Rights and the existing license and sublicense agreements with respect thereto provide otherwise, Children's will control all patent matters with respect to all Program Inventions that are invented solely by Children's personnel and may file patents on any such Program Invention at its sole cost and expense. Children's agrees to notify TGC and IAVI immediately of Children's decision to apply for letters patent with respect to any such Program Inventions. Children's shall provide TGC and IAVI with the opportunity to review and comment on all such patent applications prepared by Children's hereunder and Children's shall consider TGC's and IAVI's comments seriously and in good faith; and

(x) In the event TGC intends to sell any products or services covered by the foregoing licenses to other than the Public Sector, Children's and TGC agree to enter into a formal royalty agreement which shall include terms governing the payment of the applicable royalties (including, without limitation, the definition of net sales; frequency of royalty payments; audit rights and maintenance of books and records by TGC). Children's and TGC do not intend that the clauses hereof calling for royalties to Children's will be applied cumulatively. Accordingly, where any royalties would be payable to Children's under more than one clause hereof with respect to the same product or service, the clause that provides for the higher or highest royalty rate will be the only clause that will be effective as to that product or service.

11. CERTAIN AGREEMENTS. (a) For IAVI to achieve its goal of accelerating the development of the most promising candidate vaccines for large-scale clinical trials in the developing world, it is likely that IAVI will need to conduct head to head comparative studies of different vaccines in early stage preclinical and clinical testing. Subject to IAVI's obligations under Section 8 hereof, each of Children's and TGC agrees to make available to IAVI without additional cost during the term of the Research and Development Program sufficient quantities of the Program Vaccine(s), reagents and/or blood samples

associated with preclinical and clinical development of the Program Vaccine(s) solely for such comparative studies and independent analyses. IAVI's rights to obtain quantities of the Program Vaccine(s), reagents and/or blood samples associated with preclinical and clinical development of the Program Vaccine(s) for such comparative studies and independent analyses after termination or expiration of this Agreement will require that IAVI purchase the same from Children's and/or TGC in return for Children's and TGC's respective costs, plus a reasonable profit for TGC, to be determined, and such right shall not survive for more than three years following such termination or expiration.

(b) TGC and Children's hereby acknowledge that IAVI may at any time conduct or start to conduct, or enter into any agreement to fund the conduct by any third party, of any supplemental or other research provided that the same either (i) is entered and performed pursuant to Section 11(c), 11(d), or 11(e) or (ii) does not constitute a Follow-On Project and does not involve any use or exploitation of any Background Technology or Program Inventions (except as and to the extent licensed hereunder to IAVI).

(c) IAVI shall not enter, nor commence or continue to negotiate or seek to enter, into any Follow-On Projects not involving TGC prior to the earlier of the TGC Withdrawal Date or the expiration of 30 full calendar months starting on or after the Effective Date (the "30-Month Point"). If, following the TGC Withdrawal Date or such 30-Month Point, IAVI notifies TGC that IAVI desires to fund one or more Follow-On Projects that do not involve TGC as the principal vaccine developer, then the following shall apply:

(i) IAVI shall first notify TGC of its intent to fund any such Follow-On Project, including a description of the contemplated scope and goals likely to be involved;

(ii) IAVI shall exert reasonable commercial efforts, through good faith negotiations over a period of at least 120 days, to reach agreement with TGC whereby TGC would receive the funding for, and would conduct, such Follow-On Project as the principal vaccine developer, unless TGC waives this section in writing or fails to negotiate in good faith; and

(iii) to the extent that no agreement is reached pursuant to clause (ii) above, IAVI must give TGC at least 60 days' prior written notice of the terms of any proposed agreement with any third party with respect to such Follow-On Project, if IAVI is willing to extend to such third party any material terms that are in any respect more favorable for such third party than the terms that IAVI had offered to extend to TGC in the course of the negotiations under clause (ii), and afford TGC the opportunity during such notice period to accept and agree to such agreement on such terms in lieu of such third party;

provided, however, that if IAVI establishes (and notifies TGC in writing of the grounds therefor and the facts that so establish), following the notification by IAVI under clause (i) as to any proposed Follow-On Project, that TGC's participation in such Follow-On Project in lieu of a specific third party would be materially detrimental to the likelihood for successful technical, scientific or clinical results from such Follow-On Project, and that such third party's



participation would not suffer from similar detrimental factors, nor from any others at least as serious, then clauses (ii) and (iii) will not apply to that Follow-On Project (although all of clauses (i) - (iii) will nevertheless apply to any other Follow-On Projects). If, after satisfaction of the foregoing, IAVI enters into such a Follow-On Project with another party as the principal vaccine developer (which shall be the "Other Developer" in that situation), it shall have, and TGC and Children's hereby grant, a license permitting IAVI to make, use, sell, offer for sale and import the Program Vaccines under the Program Inventions and the Background Technology (to the extent Children's and/or TGC, as applicable, has the right to permit the use of the same for such purpose(s)), other than the Proprietary Technology, for research purposes only, within the Program Field and only for and within the scope of such Follow-On Project. Subject to Section 11(f), such license will be royalty-free and sublicensable only to such Other Developer.

(d) If, following the earlier of the TGC Withdrawal Date or the last to occur of:

(i) the expiration of 36 full calendar months starting on or after the Effective Date;

(ii) three months after the end of the last-to-expire of all Research and Development Programs under this Agreement and under any Follow-On Project(s) involving TGC; or

(iii) (A) with respect to any Program Vaccine for which TGC or any of its licensees is then conducting a Commercially Reasonable Program utilizing Program Inventions, three months after the filing by TGC in the United States or any country in the European Union of the first Marketing Approval Application with respect to such Program Vaccine utilizing any Program Invention(s); or

(B) with respect to any Program Vaccine for which none of TGC or its licensees is then conducting a Commercially Reasonable Program utilizing Program Inventions, this clause (iii) shall not be applicable;

(C) as used in this clause (iii), a "Commercially Reasonable Program" means a substantially continuous program of development and clinical testing involving efforts as would normally be devoted to such a program by commercial parties with similar resources to those of the applicable entity (where such resources of the applicable entity are for such purpose deemed to be no less than those available to it as of the Effective Date), where such parties are highly motivated to achieve the milestone of submitting a Marketing Approval Application in at least one of the United States or any of the countries in the European Union. The conduct of a Commercially Reasonable Program will not require that the entity devote thereto efforts or resources beyond those that a prudent commercial enterprise would devote, even though remaining motivated to do so as described above,

TGC or its licensees have not filed any Marketing Approval Application in a particular Developing Country, and IAVI notifies TGC that one or more Other Developers (who shall be

named by IAVI in such notice) desires to pursue an active program or application to seek such regulatory approval for the sale of such Program Vaccine to the Public Sector in that Developing Country, then IAVI shall exert reasonable commercial efforts, through good faith negotiations over a period of at least 120 days, to reach agreement with TGC whereby TGC will agree to pursue such an active program and to make such an application in such Developing Country. To the extent that no such agreement is reached in that time frame, IAVI must give TGC at least 60 days prior written notice of the terms of any proposed agreement with such Other Developer if IAVI is willing to extend to such Other Developer any material terms that are in any respect more favorable for such Other Developer than the terms that IAVI had offered to extend to TGC in the course of the negotiations during such 120-day period, and afford TGC the opportunity during such notice period to accept and agree to such agreement on such terms in lieu of such Other Developer. Otherwise, IAVI will be entitled to enter such agreement with such Other Developer and TGC and Children's hereby grant a license permitting IAVI to make, use, sell, offer for sale and import the Program Vaccines and otherwise to practice the Program Inventions and the Background Technology (to the extent Children's and/or TGC, as applicable, has the right to permit the use of the same for such purpose(s)), other than Proprietary Technology not bearing on clinical testing and test data, only within the Program Field and only as necessary to seek such regulatory approval within such Developing Country. Such license will not entitle IAVI or the Other Developer to manufacture the Program Vaccine for purposes of commercial sale, it being understood that commercial sale rights shall be governed by Section 11(c) below. Subject to Section 11(f), such license will be royalty-free and sublicensable only to such Other Developer.

(e) Following the grant of all regulatory approvals for the sale of a Program Vaccine for use in humans pursuant to a Marketing Approval Application in a particular Developing Country, either TGC shall manufacture and supply such Program Vaccine for commercial sale in the Public Sector in such Developing Country or IAVI or the Other Developer (if any) shall have the right to do so, to be determined as follows:

(i) If no more than three months have passed since the grant of such regulatory approval, or, thereafter, if TGC or its licensees or distributors are making such Program Vaccine regularly available to the Public Sector in such Developing Country in quantities reasonably proportionate to the needs in the Public Sector of such Developing Country and at prices that do not, in IAVI's independent assessment after consultation with TGC, exceed TGC's or such licensees' or distributors' fully-burdened costs of production (inclusive, without limitation, of research and development costs and facilities costs not otherwise funded by grants or awards from IAVI or other not-for-profit sources, amortized using TGC's current generally-applicable accounting methods) plus a Reasonable Public Sector Profit, then the provisions of clauses (ii), (iii), and (iv) of this Section 11(e) will not be applicable to that Developing Country;

(ii) Subject to clause (i) above, IAVI may solicit good faith bids from Qualified Bidders with respect to the Developing Country no more than once per year. Upon it being demonstrated to TGC that each such listed entity is a bona fide Qualified Bidder, TGC shall provide each such Qualified Bidder with a disclosure of what information TGC has that is part of the applicable Proprietary Technology to the extent it is necessary for the preparation by such Qualified Bidder of a bid to manufacture the

Program Vaccine for the Public Sector in such Developing Country. TGC does not and will not warrant that such disclosure or information will be fully understood or useful to such Qualified Bidder for the preparation of such a bid or for the successful production of the Program Vaccine(s) or otherwise. TGC may condition any disclosure of any Proprietary Technology on the execution and performance of one or more reasonable confidentiality agreements from the recipients (whether individuals or entities) and on the establishment of other protections reasonable in the circumstances for the protection of TGC's confidential information, but TGC will not unreasonably refuse to provide, or delay the provision of, such confidential information.

(iii) If a Qualified Bidder submits a bid whereby such Qualified Bidder would manufacture and sell Program Vaccines in the Public Sector of the Developing Country at a price that is less than 90% of the price then being charged by TGC, then LAVI may require that TGC (at TGC's option among such alternatives) either accept the result described in clause (iv) below or that TGC do either or both of the following:

(A) that TGC reduces the price it is then charging in the Public Sector of the Developing Country to be equal or less expensive than the bid submitted by such Qualified Bidder, or to be equal to such other price (higher than such bid but less than the price previously being charged by TGC) as may be mutually agreed by LAVI and TGC in recognition of non-price factors that may make TGC the more desirable manufacturer; or (B) that TGC will engage that Qualified Bidder to produce the Program Vaccines for distribution in the Public Sector of such Developing Country such that the Program Vaccines will be made available in the Public Sector of the Developing Country at a price that satisfies the criteria stated in subclause (A) of this clause (iii); and

(iv) If TGC does not take either or both of the alternatives in subclauses (A) and (B) of clause (iii) within a reasonable time, TGC and Children's hereby grant a license permitting such Qualified Bidder to make, use, sell, offer for sale and import the Program Vaccines and otherwise to practice the Program Inventions and the Background Technology (to the extent Children's and/or TGC, as applicable, has the right to permit the use of the same for such purpose(s)) only within the Program Field within such Developing Country, using, on a strictly confidential basis, the applicable Proprietary Technology so disclosed by TGC to such Qualified Bidder, solely within the scope of the license under this Section 11(e). If such license under this clause (iv) is applicable, TGC shall provide the Qualified Bidder with a disclosure of additional information TGC has that is part of the applicable Proprietary Technology (if any such information in addition to that already provided under clause (ii) is necessary for manufacture of the Program Vaccine by the Qualified Bidder). TGC does not and will not warrant that such disclosure or information will be fully understood or useful to such Qualified Bidder for the successful production of the Program Vaccine(s) or otherwise. TGC may condition any disclosure of any such Proprietary Technology on the execution and performance of one or more reasonable confidentiality agreements from the Qualified Bidder and on the establishment of other protections reasonable in the circumstances for the protection of TGC's confidential information, but TGC will not unreasonably refuse to provide, or delay the provision of, such confidential information.

(f)

(i) All licenses to Background Technology under this Section 11 shall be subject to any pre-existing obligations TGC has made to third parties, inclusive of any royalty obligations and other amounts payable by TGC to its licensors, sublicensees, or suppliers with respect to such licensing or use of the Background Technology and any audit rights and other terms and conditions required to be imposed on sublicensees; and

(ii) Where either of TGC or Children's believes that there are restrictions on its right to permit the use of any Background Technology for purposes of such license, it shall promptly so inform the other and IAVI and the parties will consult as to the proper course of action under the circumstances, it being agreed that neither TGC nor Children's will unreasonably refuse to exert reasonable efforts to remove such restrictions where IAVI (and/or the other of Children's and TGC) bears all material costs, fees, and risks of such efforts and such removal.

(g) Neither Children's nor TGC grants, or shall grant, to IAVI any implied licenses or other rights to use any other rights, know-how, or technologies (whether or not available to Children's or TGC) other than the Program Inventions and the Background Technology as stated in this Section, nor in any way outside of the Program Field.

(h) IAVI shall not be entitled to any license under this Section 11 if the Research and Development Program is not fully funded by IAVI (at an aggregate level, for the entire Research and Development Program of at least twice the total budget stated herein for year 1 of the Research and Development Program) over at least three years (other than where this Agreement is terminated prior to that time at TGC's election, TGC's insolvency as described in Section 6(f), or due to the uncured breach of TGC).

(i) TGC agrees that it shall pay to IAVI an aggregate royalty of one percent (1.0%) of the Net Sales by TGC or any of its sublicensees of any Program Vaccine to other than the Public Sector which falls under an issued patent on a Program Invention in the country in which the Program Vaccine is manufactured or sold. TGC agrees that it shall pay to IAVI an aggregate royalty of one-half of one percent (0.5%) of the Net Sales by TGC or any of its sublicensees of any Program Vaccine to other than the Public Sector, when such Program Vaccine does not fall under the preceding sentence, but was nonetheless developed in whole or in material part under the Research and Development Program and is sold prior to the tenth anniversary of the first approval for commercial sale of such Program Vaccine pursuant to a Marketing Approval Application in that jurisdiction.

(j) On or before the 60th day after the end of each calendar quarter following the first approval for commercial sale of a Program Vaccine pursuant to a Marketing Approval Application, TGC shall furnish to IAVI, on such form as is reasonably acceptable to IAVI, accurate statements showing the number, description, gross sales price, itemized deductions from gross sales price and Net Sales price, specified by product and customer (including the full name and address of each customer), together with any returns made, and simultaneously therewith shall make all payments to IAVI required by such statement. Such statements shall be furnished to IAVI whether or not they reflect any sales. Further, within sixty (60) days after the

completion of TGC's annual financial reports, it will furnish LAVI with a statement from an officer, certified as correct thereby, that all royalty payments made during the annual period conform to this Agreement. If TGC regularly engages a certified public accountant for its own or other purposes to prepare such information, then such statement shall be certified as correct by such accountant. All information so furnished shall be treated as confidential by LAVI. Receipt or acceptance by LAVI of any of the statements furnished pursuant to this Agreement or of any sums paid hereunder shall not preclude LAVI from questioning the correctness thereof.

(k) TGC agrees to keep accurate books of account and records covering all sales referred to in Paragraph 11(i) and LAVI and its duly authorized representatives shall have the right at reasonable times (but not more than once per year, and not more than once as to any accounting period) during regular business hours on reasonable notice to examine such books of account and records and all other documents and material in their possession or under its control with respect to the subject matter and terms of this Agreement, and shall have free and full access for such purposes and for the purpose of making extracts therefrom. In the event of an underpayment in excess of five percent (5%) of the royalties actually due, TGC shall promptly pay to LAVI the reasonable cost of the audit. TGC shall maintain the books and records in connection until the later of three (3) years after the end of the calendar year in which the revenues or expenses therein were received or incurred or the resolution of any question raised with respect thereto. TGC further agree to take such steps as are reasonably appropriate in order to facilitate inspection by LAVI or its nominee of its books and records with respect to amounts due LAVI and that all billings by TGC to its customers shall be kept by it for inspection as provided hereunder.

12. INDEMNIFICATION. (a) TGC agrees to indemnify and hold Children's, LAVI and their respective affiliates, officers, directors, employees, agents, licensees and sublicensees (collectively, the "Indemnitees" under this subsection) harmless from and against any and all losses, claims, demands, suits, damages, liabilities and related costs and expenses (including reasonable attorneys' fees) incurred by or asserted against any Indemnitee which may arise as a result of the activities of TGC (or any of its affiliates, officers, directors, employees and agents) in connection with this Agreement unless such losses, claims, demands, suits, damages, liabilities and related costs and expenses (including reasonable attorneys' fees) shall be due to the gross negligence or willful misconduct of any Indemnitee.

(b) Children's agrees to indemnify and hold TGC, LAVI and their respective affiliates, officers, directors, employees, agents, licensees and sublicensees (collectively, the "Indemnitees" under this subsection) harmless from and against any and all losses, claims, demands, suits, damages, liabilities and related costs and expenses (including reasonable attorneys' fees) incurred by or asserted against any Indemnitee which may arise as a result of the activities of Children's (or any of its affiliates, officers, directors, employees and agents) in connection with this Agreement unless such losses, claims, demands, suits, damages, liabilities and related costs and expenses (including reasonable attorneys' fees) shall be due to the gross negligence or willful misconduct of any Indemnitee.

13. INSURANCE. TGC shall maintain general liability or similar insurance concerning TGC's activities in connection with the Research and Development Program with general aggregate limits of at least \$2,000,000 during the Research and Development Program

(prior to any commercial launch of a Program Vaccine as to which royalties would be payable to IAVI hereunder) and of at least \$10,000,000 following any commercial launch of such a Program Vaccine, and during the period such Program Vaccine remains on the market and subject to a royalty obligation hereunder. Children's shall maintain general liability or similar insurance concerning Children's activities in connection with the Research and Development Program with limits of at least \$1,000,000 (occurrence)/\$2,000,000 (aggregate) during the Research and Development Program and following any commercial launch of a Program Vaccine, during the period such Program Vaccine remains on the market and subject to a royalty obligation hereunder. Each of Children's and TGC shall provide the other, and IAVI, with a certificate of insurance evidencing such coverage and such certificate of insurance shall provide that the insurance coverage may not be terminated or amended without at least thirty (30) days' prior written notice to such other, and to IAVI.

14. REPRESENTATIONS AND WARRANTIES. Each of the parties warrants and represents to each of the others that: (i) it has the power and authority to enter into this Agreement and perform its responsibilities and obligations herein and the execution and delivery of this Agreement has been duly authorized; (ii) it has the power to carry out its obligations under this Agreement; and (iii) nothing in this Agreement or in the execution or performance thereof shall constitute a breach, violation or default of any provision contained in such party's certificate or articles of incorporation or other organizing instruments nor violate any contract or other commitment made by such party.

15. NO AGENCY OR JOINT VENTURE. Nothing in this Agreement shall be deemed to create an agency relationship or joint venture among the parties. Each party shall be responsible for all taxes, benefits, withholding, worker's compensation, unemployment insurance and similar requirements of its own employees and no party's employees shall be deemed agents or employees of any other party.

16. BOOKS AND RECORDS. Children's and TGC shall each keep complete and accurate records pertaining to the Research and Development Program and its respective expenditures in connection therewith. Subject to the confidentiality provisions hereof, such books and records shall be available to each of the parties to this Agreement for inspection on reasonable prior notice at mutually convenient times, such inspections to occur no more often than twice a year, no more than once as to any period, and no more than three years after the end of the period to which the respective records apply.

17. USE OF NAMES. No party will use the name of any other party in any advertising or other form of publicity without the written permission of such other party.

18. NOTICES. Any notices required to be given or which shall be given under this Agreement shall be in writing delivered by first class mail (air mail if not domestic), certified or registered mail, or facsimile in which an electronic confirmation of receipt is transmitted, addressed to the parties as shown below and shall be deemed to have been given or made as of the date received:

TARGETED GENETICS CORPORATION  
1100 Olive Way, Suite 100  
Seattle, WA 98101  
Attention: Chief Executive Officer  
FAX: 206-623-7064

with a copy to:  
Perkins Coie LLP  
411 – 108th Avenue NE  
Bellevue, WA 98004  
Attention: Roger M. Tolbert  
FAX: 425-453-7350

INTERNATIONAL AIDS VACCINE  
INITIATIVE  
810 Seventh Avenue, 31st Floor  
New York, New York 10019  
Attention: Wayne Koff  
FAX: 212-843-0480

with a copy to:  
Gilbert, Segall and Young LLP  
430 Park Avenue  
New York, New York 10022  
Attention: Neal N. Beaton  
FAX: 212-644-4051

CHILDREN'S RESEARCH INSTITUTE  
700 Children's Drive  
Columbus, Ohio 43205  
Attention: Philip Johnson, M.D.  
CEO, Children's Research  
Institute  
FAX: 614-722-3273

with a copy to:  
Director of Legal Services  
Children's Hospital  
700 Children's Drive  
Columbus, Ohio 43205  
Attn: Martha Johnson  
FAX: 614-722-3945

19. ASSIGNMENT. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Except for one or more assignments of all of a party's rights and obligations hereunder in connection with a corporate reorganization, a merger, consolidation or exchange, or an acquisition in which substantially all of the assets of such party that relate to this Agreement and the performance hereof by such party are also assigned, this Agreement shall not be assignable by any party without the prior written consent of each of the other parties. Any attempted assignment in contravention of the foregoing shall be void and of no force or effect.

20. GOVERNING LAW. The validity and interpretation of this Agreement and the legal relationship of the parties to it shall be governed by the laws of the State of New York and the United States.

21. ARBITRATION. In the event of any dispute, controversy or misunderstanding between or among the parties or any of them arising out of or related to this Agreement or any breach thereof, such dispute, controversy or misunderstanding shall be submitted to binding arbitration conducted by the American Arbitration Association ("AAA") in New York, New York in accordance with then applicable AAA rules. Any award or judgment rendered by such arbitrator(s) may be entered by either party in any court having jurisdiction thereof. Each party hereby consents to the personal jurisdiction of the state and federal courts of New York.

22. GOVERNING LANGUAGE. In the event that a translation of this Agreement is prepared and signed by the parties for the convenience of LAVI, this English

language version shall be the official version and shall govern if there is a conflict between the two.

23. **FORCE MAJEURE.** Neither Children's nor TGC shall be responsible to the other or to IAVI for failure to perform any of the obligations imposed by this Agreement, provided such failure shall be occasioned by fire, flood, explosion, lightning, windstorm, earthquake, subsidence of soil, failure or destruction, in whole or in part, of machinery or equipment or failure of supply of materials, discontinuity in the supply of power, governmental interference, civil commotion, riot, war, strikes, labor disturbance, transportation difficulties, labor shortage or any cause, whether similar or dissimilar to the foregoing, beyond the reasonable control of Children's or TGC, respectively.

24. **ENTIRE AGREEMENT.** This Agreement embodies the entire understanding and agreement among Children's, TGC and IAVI with respect to the subject matter contained herein, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or changes to this Agreement shall be effective unless made in writing and signed and delivered by authorized representatives of all of the parties.

\* \* \* \* \*



TARGETED GENETICS CORPORATION

INTERNATIONAL AIDS VACCINE  
INITIATIVE

By: /s/ H. Stewart Parker

Name: H. Stewart Parker

Title: Pres. & CEO

By: /s/ Seth Berkley

Name: Dr. Seth Berkley

Title: President

CHILDREN'S RESEARCH INSTITUTE

By: [signature illegible]

Name:

Title:

Acknowledged with respect to  
The first sentence of Section 3

/s/ Philip R. Johnson

Dr. Philip R. Johnson

**ATTACHMENT A**  
**DEVELOPING COUNTRIES AS OF THE EFFECTIVE DATE**  
 (Subject to the penultimate sentence of the definition in Section 1(d))

**Countries with Low-income economies:**

Afghanistan	Ghana	Nepal
Angola	Guinea	Nicaragua
Armenia	Guinea-Bissau	Niger
Azerbaijan	Haiti	Nigeria
Bangladesh	Honduras	Pakistan
Benin	India	Rwanda
Bhutan	Indonesia	Sao Tome and Principe
Burkina Faso	Kenya	Senegal
Burundi	Korea, Dem Rep.	Sierra Leone
Cambodia	Kyrgyz Republic	Solomon Islands
Cameroon	Lao PDR	Somalia
Central African Republic	Lesotho	Sudan
Chad	Liberia	Tajikistan
China	Madagascar	Tanzania
Comoros	Malawi	Togo
Congo, Dem Rep.	Mali	Turkmenistan
Congo, Rep.	Mauritania	Uganda
Côte d'Ivoire	Moldova	Vietnam
Eritrea	Mongolia	Yemen, Rep.
Ethiopia	Mozambique	Zambia
Gambia, The	Myanmar	Zimbabwe

**Countries with Lower-middle-income economies**

Albania	Georgia	Peru
Algeria	Guatemala	Philippines
Belarus	Guyana	Romania
Belize	Iran, Islamic Rep.	Russian Federation
Belivia	Iraq	Samoa
Bosnia and Herzegovina	Jamaica	South Africa
Bulgaria	Jordan	Sri Lanka
Cape Verde	Kazakhstan	St. Vincent and the Grenadines
Colombia	Kiribati	Suriname
Costa Rica	Latvia	Swaziland
Cuba	Lithuania	Syrian Arab Republic
Djibouti	Macedonia, FYR	Thailand
Dominica	Maldives	Tonga
Dominican Republic	Marshall Islands	Tunisia
Ecuador	Micronesia, Fed. Sts.	Ukraine
Egypt, Arab Rep.	Morocco	Uzbekistan
El Salvador	Namibia	Vanuatu
Equatorial Guinea	Papua New Guinea	West Bank and Gaza

Fiji

Paraguay

Yugoslavia, FR (Serbia/Montenegro)

Countries with Upper-middle-income economies

American Samoa

Antigua and Barbuda

Argentina

Bahrain

Barbados

Botswana

Brazil

Chile

Croatia

Czech Republic

Estonia

Gabon

Grenada

Guadeloupe

Hungary

Isle of Man

Korea, Rep.

Lebanon

Libya

Malaysia

Mauritius

Mayotte

Mexico

Oman

Palau

Panama

Poland

Puerto Rico

Saudi Arabia

Seychelles

Slovak Republic

St. Kitts and Nevis

St. Lucia

Trinidad and Tobago

Turkey

Uruguay

Venezuela

**ATTACHMENT B  
TGC-CONTROLLED INVENTIONS**

US Application 98/18600

US Application 09/142474

US Application 99/20524

US Patent 5858775

AU Application 31243/95

CA Application 2192215

EP Application 95927113.1

JP Application 8-802305

US Application 09/292703

US Patent 5786211

US Patent 5658785

US Application 60/123685

US Patent 5139941

**ATTACHMENT C  
WORK PLAN AND BUDGET**

Workplan for the Development and Testing of a  
Adeno-associated Virus Vector Prophylactic Vaccine against HIV-1

YEAR 1

Jointly authored and agreed to by:

Children's Research Institute and Targeted Genetics Corporation, January 26, 2000

**A. Definition of Vaccine Antigens.**

Vaccine antigens will be defined as soon as possible with direct input from IAVI personnel. It is anticipated that the first antigens to be incorporated will be gag genes from HIV-1 clades A and C. Antigen definition must be completed within 30 days of initiation of project. Any delays will impact all downstream activities.

**B. Generation of producer cell lines.**

Two producer cell lines, each containing an AAV-HIV(X) vector by no later than end of Program Q3.

B.1. Molecular construction of two plasmids each containing a specific HIV sequence pAAV-HIV(X); sequences to be synthetically derived and codon optimized

B.2. Restriction map and sequence verification for the two pAAV-HIV(X) plasmids

B.3. Verification of expression from both pAAV-HIV(X) plasmids

B.4. Generation and analysis of clones capable of producing rAAV-HIV(X) vectors

B.5. Selection of at least one candidate producer clone for each rAAV-HIV(X) vector based on specific productivity, vector integrity, vector copy number, vector infectivity and absence of rcAAV production

**C. Biodistribution Study.**

A biodistribution study in rabbits and non-human primates initiated no later than Program Q3 and completed by Program Q4-Q5.

The in-life portion of the rabbit study to be conducted at Children's. The in-life portion requires 6 months to complete. The non-human primate study will have three primates injected with the highest dose and data will be acquired at one time-point to evaluate S1 site rearrangement, to be also done at Children's.

C.1. Provide  $5 \times 10^{14}$  DRPs of rAAV-HIV(X) to Children's. This lot of rAAV-HIV(X) will be used for approximately 60 rabbits and 3 non-human primate study. For the rabbit study

there are four proposed doses -  $2 \times 10^{10}$  DRPs /animal;  $2 \times 10^{11}$  DRPs/animal;  $2 \times 10^{12}$  DRPs/animal and possibly  $2 \times 10^{13}$  DRPs/animal. Each group will have 4 animals (two from each gender) and animals will be sacrificed at three time-points 5 weeks, 90 days & 180 days. Control rabbits will be included. The study will soon be finalized pending call with the FDA on February 10, 2000.

- C.2. Develop an assay to measure integration of rAAV in host genome
- C.3. Develop a quantitative PCR assay for measuring rAAV in distal sites
- C.4. Test tissues by PCR and integration assay from rabbit biodistribution study

**D. Process Development.**

Process development for at least one rAAV-HIV(X) producer cell line complete no later than Program Q4-Q5.

- D.1. Test lot at small scale
- D.2. Test runs at medium scale
- D.3. Scale-up, purification development
- D.4. Testing of scale up lots

**E. Analytical Development.**

Analytical development complete by early Program Q4.

- E.1. Vector specific assays for process and product characterization,
- E.2. Generation of vector specific reference standards and controls
- E.3. Assay(s) for determining expression of HIV(X) sequence
- E.4. Verification analysis of standard battery of assays in the context of specific rAAV-HIV(X) product
- E.5. Assays to test product change over in cGMP suite
- E.6. Documentation

**F. Master and Working Cell Banks.**

Master and working cell banks for the two producer cell lines complete no later than Program Q4-Q5 .

- F.1. Testing of pre-banks for each candidate producer clone

F.2. Batch records

F.3. Cell Banking

F.4. Testing of cell banks

**G. Induction Study.**

Induction of the cell banks (FDA request) to be performed by outside vendor. This study to be finalized pending call with the FDA.

**H. Development Lots.**

Development lots for at least one vector done at scale, tested and released no later than Program Q4-Q5.

H.1. Technology transfer from Process development group, training for Manufacturing and Batch record generation

H.2. Development lots done in Manufacturing suites

H.3. Process and product characterization of development lots

**I. GMP Set-up.**

GMP set-up includes product changeover complete no later than Program Q4.

I.1. Execution

I.2. Analysis

★ Confidential Treatment  
Requested

## YEAR 1 BUDGET IS ON THE FOLLOWING SPREADSHEET

Targeted Genetics  
 IAVI Budgeting  
 Summary of Deliverables - Cost Breakdown (in thousands)  
 As of January 25, 2000

<u>Deliverable</u>	Q1	Q2	Q3	Q4	<u>Total Price</u>
<u>Labor Components</u>					
Two Producer Cell Lines	44	115	106	-	265
PD for Producer Cell Lines	-	-	135	86	221
Analytical Development	-	-	80	25	105
Master and Working Cell Banks	-	-	29	71	100
Development Lots	-	-	7	303	310
Biodistribution	90	104	153	26	373
GMP Change Over	-	-	15	13	28
Labor Components Subtotal	135	219	525	524	1,402
<u>Non-Labor Components</u>					
Raw Materials, Outside Services, Travel, License Costs	21	12	49	171	253
TGC Subsubtotal					1,655
<u>Induction study by outside vendor</u>					150
TGC Subtotal					1,805
<u>Children's Research Institute</u>					
Personnel	26	26	26	26	104
Gene construction	50	-	-	-	50
Rabbit cages	25	-	-	-	25
Rabbit purchase	-	4	-	-	4
Rabbit per diem	-	13	13	13	39
Macaque cage	-	10	-	-	10
Macaque purchase	-	16	-	-	16
Macaque per diem	-	3	3	3	9
Biological reagents	5	5	5	5	20
Travel	-	2	-	2	4
Admin fee	10	10	10	10	40
CRI subtotal	116	89	57	59	321
Quarterly Totals	271	319	631	754	1,976
Induction study contracted by TGC, earliest Q4				150	150
TGC subtotal					1,805
CRI subtotal					321
Project Total					2,126