

PUBLIC HEALTH SERVICE
INTERINSTITUTIONAL AGREEMENT

This Agreement is entered into by and between the University of Utah ("THE INSTITUTION"), having an address at 210 Park Building, Salt Lake City, Utah 84112 and the PUBLIC HEALTH SERVICE ("PHS"), as represented by the Office of Technology Transfer, having an address at National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804.

1. BACKGROUND

1.1 In the course of research programs of the PHS, at THE INSTITUTION, funded in part under Department of Health and Human Services (DHHS) funding agreements (Grant/Contract Nos. CA-48711 and CA-55914), and at Myriad Genetics, Inc. ("Myriad"), P. Andrew Futreal, David E. Goldgar, Keith D. Harshman, Alexander Kamb, Yoshio Miki, Donna Shatuck-Eidens, Mark H. Skolnick, Jeff J. Swensen, Sean Tavtigian and Roger W. Wiseman ("Inventors") made or reduced to practice certain inventions which are included within the INVENTIONS, as defined in paragraph 2.1 below.

1.2 It is the mutual desire of THE INSTITUTION and the PHS that their respective undivided interests in said INVENTIONS be administered in a manner to ensure the rapid commercialization of the INVENTIONS and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10, PHS is granting an exclusive license to PHS's rights in the INVENTIONS to THE INSTITUTION under the conditions set forth herein.

2. DEFINITIONS

2.1 "INVENTIONS" means:

a) U.S. patent applications

1) USSN #08/249.602, filed on May 20, 1994, and entitled "Breast Cancer Gene,"

2) USSN #08/289,221 (CIP of 08/249,602), filed on August 12, 1994, and entitled, "17q-Linked Breast and Ovarian Cancer Susceptibility Gene,"

3) USSN #08/300,266 (CIP of 08/289,221), filed on September 9, 1994, and entitled, "17q-Linked Breast and Ovarian Cancer Susceptibility Gene,"

4) USSN #08/308,104 (CIP of 08/300,266), filed on September 16, 1994, and entitled, "17q-Linked Breast and Ovarian Cancer Susceptibility Gene,"

5) USSN #08/319,511, filed on October 6, 1994, and entitled "Isolation of BRCA1 Gene and its Involvement in Sporadic Breast and Ovarian Cancer," and

all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

- b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: *i)* continuations-in-part of a) above; *ii)* all divisions and continuations of these continuations-in-part; *iii)* all patents issuing from such continuations-in-part, divisions, and continuations; and *iv)* any reissues, reexaminations, and extensions of all such patents; and
- c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: all counterpart foreign applications and patents to a) and b) above.

INVENTIONS shall *not* include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in a) above.

2.2 "Net Revenues" means any and all consideration received,
by THE INSTITUTION from the licensing of said
INVENTIONS pursuant to this Agreement,

2.3 "Expenses" means all reasonable and actual out-of-pocket costs incurred by THE INSTITUTION for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of resulting patents, exclusive of any salaries, administrative, or other indirect costs.

2.4 "Recoverable Costs" means of Expenses incurred by THE INSTITUTION from its management of INVENTIONS pursuant to this Agreement, excluding costs reimbursed by third parties.

3. GRANT AND RESERVATION OF RIGHTS

3.1 PHS hereby grants and THE INSTITUTION accepts, subject to the terms and conditions of this Agreement, an exclusive worldwide license including the right to sublicense, under the INVENTIONS to make and have made, to use and have used, to sell and have sold, and to import and have imported as permitted by applicable law any tangible embodiment of the INVENTIONS and to practice and to have practiced any processes and methods included within INVENTIONS.

3.2 The government of the United States shall have the irrevocable, royalty-free right worldwide to practice and have practiced the INVENTIONS for or on behalf of the United States and on behalf of any foreign government or not for profit international organization under any existing or future treaty or agreement with the United States. Any license granted by THE INSTITUTION under the terms of this Agreement shall be subject to this right of the Government.

4. PATENT PROSECUTION AND PROTECTION

4.1 THE INSTITUTION shall, directly or through its licensees or sublicensees, file, prosecute, and maintain patent application(s) pertaining to INVENTIONS and shall promptly provide to PHS all serial numbers and filing dates, together with copies of all such applications, including copies of all patent office actions, responses, and all other patent office communications. In addition, upon PHS' request, PHS will be granted a revocable Power of Attorney for all such patent applications. THE INSTITUTION shall consult with PHS, when so requested, prior to communicating with the U.S. Patent and Trademark Office with respect to the INVENTIONS.

4.2 On or before June 12, 1995, THE INSTITUTION, after consultation with PHS, shall either decide that no foreign applications are to be filed with respect to the INVENTIONS or designate the foreign countries in which applications are to be filed. If any foreign patent applications are filed, THE INSTITUTION shall promptly provide to PHS all serial numbers and filing dates. THE INSTITUTION also shall provide to PHS copies of foreign patent applications and patent office actions. THE INSTITUTION shall consult with PHS, when so requested, prior to communication with any patent office with respect to the INVENTIONS.

4.3 THE INSTITUTION shall promptly record Assignments of domestic patent rights with respect to the INVENTIONS in the Patent and Trademark Office and shall promptly provide PHS with a photocopy of each recorded Assignment.

4.4 Notwithstanding any other provision of this Agreement, THE INSTITUTION shall not abandon the prosecution of any patent application (except for purposes of filing continuation application) or the maintenance of any patent contemplated by this Agreement without prior written notice to PHS. Upon receiving such written notice, PHS may, at its sole option, take over the prosecution of any such patent application, or the maintenance of any such patent.

4.5 THE INSTITUTION shall promptly provide to PHS copies of all issued patents under this Agreement.

4.6 In the event that THE INSTITUTION anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, THE INSTITUTION shall provide PHS with all relevant information and such extraordinary expenditures shall be included as Expenses only upon written agreement of PHS.

5. LICENSING

5.1 THE INSTITUTION shall diligently seek licensee(s) for the commercial development of said INVENTIONS and shall administer the INVENTIONS for the mutual benefit of the parties and in the public interest. THE INSTITUTION will ensure that any license granted on INVENTIONS is subject to the provisions of 37 CFR Part 401 and the rights retained by the government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.

5.2 **THE INSTITUTION** shall not issue any royalty free or paid-up licenses or assign patent rights to any third party, notwithstanding any other provision of this Agreement, without the prior written consent of **PHS**.

5.3 **THE INSTITUTION** shall promptly provide to **PHS** copies of all licenses and sublicenses issued on **INVENTIONS**.

6. ROYALTIES AND EXPENSES

6.1 **THE INSTITUTION** shall distribute Net Revenues to **PHS** concurrently with distributions it makes under **THE INSTITUTION**'s patent policy, but in any case not later than April 1 for the preceding calendar year, on the following basis: (a) _____ of the Net Revenues to **THE INSTITUTION** and (b) _____ of the Net Revenues as a royalty to **PHS**. All payments to **PHS** required under this Agreement shall be in U.S. Dollars and shall be made by check or bank draft drawn on a United States bank and made payable to "NIH/Patent Licensing." All such payments shall be sent to the following address: NIH, P.O. Box 360120, Pittsburgh, Pennsylvania, 15251-6120. Late charges will be applied to any overdue

payments as required by the U.S. Department of Treasury in the Treasury Fiscal Requirements Manual, Section 8025.40. The payment of such late charges shall not prevent PHS from exercising any other rights it may have as a consequence of the lateness of any payment.

6.2 THE INSTITUTION shall submit to PHS annual statements of itemized Expenses, and may deduct its Recoverable Costs from any royalties due PHS under Paragraph 6.1 of this Agreement, except where PHS has identified discrepancies in billing by THE INSTITUTION, in which case deduction of the contested item from royalties shall be delayed pending resolution thereof under Paragraph 9.2 of this Agreement.

6.3 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the subject INVENTIONS any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

7. RECORDS AND REPORTS

7.1 THE INSTITUTION shall keep complete, true and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the INVENTIONS and shall permit PHS or PHS's designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.

7.2 Upon request by PHS, THE INSTITUTION shall submit to PHS an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the INVENTIONS for the preceding calendar year.

8. PATENT INFRINGEMENT

8.1 In the event PHS or THE INSTITUTION, including its licensees and sublicensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of such infringement. THE INSTITUTION and its licensees and sublicensees, in consultation with PHS, shall use their commercially reasonable efforts to eliminate such infringement without litigation; provided, however, that such requirement shall not apply in instances where counsel to PHS, THE INSTITUTION or its licensees or sublicensees advise that it may be advantageous to commence litigation without prior notification to or communication with a suspected infringer. If the efforts of the parties are not successful

in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by THE INSTITUTION, or if the proviso in the preceding sentence applies, THE INSTITUTION or its licensees or sublicensees shall have the right, after consulting with PHS, to commence suit on their own account, but PHS may join in any such suit. If THE INSTITUTION or its licensees or sublicensees determine not to commence such litigation, then PHS may bring its own suit against the suspected infringer.

8.2 THE INSTITUTION may permit its licensees and sublicensees to bring suit on their own account. PHS shall retain the right to join any licensee's suit.

8.3 Neither THE INSTITUTION nor its licensees or sublicensees shall take action to compel PHS either to initiate or to join in any suit for patent infringement. Should the government be made a party to any such suit by motion or any other action of a licensee, sublicensee or THE INSTITUTION, the licensee, sublicensee or THE INSTITUTION shall reimburse the government for any costs, expenses or fees which the government incurs as a result of such motion or other action, including any and all costs incurred by PHS in opposing any such joinder action.

8.4 Legal action to eliminate infringement and/or recover damages pursuant to Paragraphs 8.1 and 8.2 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for their expenses in connection with such legal action and the remainder of such damages shall be considered "Net Revenues".

8.5 Each party agrees to cooperate with the other in litigation proceedings. Nothing in this Agreement shall limit PHS's conduct in such proceedings.

9. GOVERNING LAWS, SETTLING DISPUTES

9.1 This Agreement shall be construed in accordance with Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

9.2 Any controversy or any disputed claim by either party against the other arising under or related to this Agreement shall be submitted jointly to THE INSTITUTION President and to the Director of the National Institutes of Health (NIH) or designee for resolution. THE INSTITUTION and PHS will be free after written decisions are issued by those officials to pursue any and all administrative and/or judicial remedies which may be available.

10. TERM & TERMINATION

10.1 This Agreement is effective when signed by all parties and shall extend to the expiration of the last to expire of the patents included within the INVENTIONS unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.

10.2 THE INSTITUTION may terminate this Agreement upon at least sixty (60) days written notice to PHS, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.

10.3 If THE INSTITUTION terminates this Agreement, PHS, at its sole discretion, may elect to require transfer of THE INSTITUTION's rights in the INVENTIONS or the control of any or all patent prosecutions being performed by THE INSTITUTION or its agents related to the INVENTIONS or the assignment of any and all licenses issued by THE INSTITUTION for said INVENTIONS. PHS shall make its election and shall advise THE INSTITUTION in writing within thirty (30) days after receipt of notice of termination, and THE INSTITUTION shall thereupon assign to PHS its rights in the INVENTIONS, control of any or all patent prosecutions, and licenses. THE INSTITUTION shall do all things necessary to transfer file wrappers and other files related to such rights and licenses to PHS or its designee. This paragraph shall not be construed to have any effect on the rights in the INVENTIONS of Myriad or any party that has not or was not required to assign its rights to either PHS or THE INSTITUTION or any assignee of said party's rights in the INVENTIONS.

10.4 In the event PHS elects to request the transfers or assignments provided for in Paragraph 10.3, and upon perfection of said transfers or assignments, THE INSTITUTION shall have no further rights or obligations under this Agreement, except that PHS shall distribute royalties due to THE INSTITUTION's inventors in accordance with PHS royalty-sharing policy.

10.5

, PHS may terminate this Agreement for any reason upon sixty (60) days written notice to THE INSTITUTION. During the term of any option agreement or license agreement to any third party for exclusive license rights pertaining to the INVENTIONS between THE INSTITUTION and an optionee or licensee, PHS may terminate this agreement if:

- i) **THE INSTITUTION** or its licensee has not taken and is not reasonably expected to take effective steps to achieve practical application of the **INVENTIONS**; or
 - ii) termination is necessary to alleviate health or safety needs which are not reasonably satisfied by **THE INSTITUTION** or its licensee; or
 - iii) termination is necessary to meet requirements for public use specified by Federal law or regulations and such requirements are not reasonably satisfied by **THE INSTITUTION** or its licensees; or
 - iv) termination is necessary because the requirement of 35 USC 204 has not been satisfied or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204, and
- (A) **THE INSTITUTION** or affected third party has been notified of this determination and has been given at least sixty (60) days to provide a response to this determination, and
 - (B) **THE INSTITUTION's** or affected third party's response to the determination of (i-iv) above is determined to be unsatisfactory in the reasonable judgment of the Office of Technology Transfer.

10.6

PHS may terminate this Agreement in whole or in part if:

- a) **THE INSTITUTION's** fails to make any payment or periodic reports required by this Agreement;
- b) **THE INSTITUTION** has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the Agreement or in any report required by the Agreement; or
- c) **THE INSTITUTION** has committed a substantial breach of a covenant or duty contained in this Agreement.

Prior to invoking the right to terminate this Agreement pursuant to this paragraph 10.6, **PHS** shall give written notice to **THE INSTITUTION** providing **THE INSTITUTION** specific notice of, and a sixty (60) day opportunity to respond to, **PHS's** concerns as to the previous items a) to c). If **THE INSTITUTION** fails to alleviate **PHS's** concerns as to the previous items a) to c) or fails to initiate reasonable corrective action within such

sixty (60) day period, PHS may terminate this Agreement. If the Agreement is terminated under this paragraph 10.6, PHS agrees to provide affected licensees an opportunity to license the INVENTIONS subject to the restrictions of 37 CFR 404, under such terms as may have been agreed to by THE INSTITUTION.

10.7 Following termination by PHS, PHS shall have no further rights or obligations under this Agreement, except that THE INSTITUTION shall be obligated to administer subsequent gross proceeds from licensing the INVENTIONS according to THE INSTITUTION policy, and to distribute royalties to PHS for PHS Inventor(s) as though they were Inventor(s) of THE INSTITUTION under that policy with respect to royalty amounts and payment schedules. Termination of this Agreement by PHS shall not affect the rights and obligations of either PHS or THE INSTITUTION under the funding agreements identified in paragraph 1.1 above.

11. GENERAL

11.1 THE INSTITUTION agrees that, for use and sale of the INVENTIONS in the United States, any products embodying the INVENTIONS, or produced through use of the INVENTIONS will be manufactured substantially in the United States.

11.2 Any notice required or permitted to be given to the parties hereto shall be deemed to have been properly given if delivered, in writing, in person or mailed by first-class or certified mail to the addresses for notices appearing on the Signature Page of this Agreement, or such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement. PHS and THE INSTITUTION shall each send copies of any notices they provide to each other to each of THE INSTITUTION'S licensees, and THE INSTITUTION and its licensees shall provide PHS with copies of any notices they provide each other pursuant to such license agreements.

11.3 This Agreement or anything related thereto shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this Agreement shall not be immunized from the operation of State or Federal law by reason of the source of the grant.

11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.

11.5 This Agreement is binding upon and shall inure to the benefit of the parties hereto, their successors or assigns, but this Agreement may not be assigned by either party without the prior written consent of the other party.

11.6 This Agreement confers no license or rights by implication, estoppel or otherwise under any patent applications or patents of PHS other than INVENTIONS regardless of whether such patents are dominant or subordinate to INVENTIONS.

11.7 Any modification to this agreement must be in writing and agreed to by both parties.

11.8 It is understood and agreed by THE INSTITUTION and PHS that this Agreement, together with the Settlement Agreement of even date among PHS, THE INSTITUTION, and Myriad (to which this Agreement is subject), constitute the entire agreement, both written and oral, between the parties with respect to the subject matter hereof, and that all prior agreements respecting the subject matter hereof (other than the funding agreements identified in paragraph 1.1 above), either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.

11.9 This Agreement may be executed on one or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

SIGNATURES BEGIN ON NEXT PAGE

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

FOR PHS:



Maria C. Freire, Ph.D.
Director, Office of Technology Transfer
National Institutes of Health

2-10-95
Date

Mailing Address for Notices: Office of Technology Transfer
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, Maryland 20852-3804

FOR THE INSTITUTION (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of THE INSTITUTION made or referred to in this Agreement are truthful and accurate.)



Signature

2-10-95
Date

Richard K. Koehn

Printed Name

Vice President for Research

Title University of Utah

Mailing Address for Notices:

c/o Tom Major, Director

Technology Transfer Office

421 Wakara Way, Suite 170

Salt Lake City, UT 84108
