1. BACKGROUND MISSION STATEMENT:

This Intellectual Property Policy ("Policy") is intended to set forth concisely the basic objectives and principles of the Translational Genomics Research Institute ("TGen") with respect to the ownership, commercialization, and sharing of income relating to intellectual property developed in the course of TGen research. As a private not-for-profit research institute, supported by public and private funds, and having a strong economic development goal, TGen is dedicated to new discovery in the scientific fields of genomics and bioinformatics and its translation into practical use for the public good, including the development of useful and commercially viable medical products, methods, and procedures. TGen will seek the maximum protection of selected intellectual property developed by its scientists and staff, and will be creative in its selection of mechanisms for commercialization. These are expected to include not only traditional licensing and assignment but also new company formation and other business models. TGen is committed to allowing participation in the financial rewards of successful commercialization of TGen intellectual property by legal inventors, authors or creators of Intellectual Property and also, in TGen’s discretion, to other individuals who have contributed materially to the creation or successful commercialization of TGen intellectual property.

2. APPLICABILITY:

This Policy applies to all employees of TGen, including primary scientific staff, technical staff, students under work-for-hire arrangements, and postdoctoral fellows (known collectively as Institute Personnel), and to all collaborating faculty and visiting scientists. As a condition of his or her employment or other association with TGen, each such person will be expected to (a) acknowledge and abide by the terms of this Policy, and (b) enter into an Intellectual Property Agreement further defining his or her and TGen’s respective rights and obligations with respect to Intellectual Property developed in the course of the employment or other association. In the event of any conflict between this Policy and any Intellectual Property Agreement, the latter will govern.

This Policy does not apply to independent contractors to TGen. The respective intellectual property rights of TGen and each such independent contractor shall be as defined by applicable law, and the terms and conditions of the independent contractor’s agreement with TGen.

1 The application of this policy to TGen personnel holding faculty appointments at Arizona Universities may be adjusted by a final Academic Affiliation Agreement now being developed.

2 Capitalized terms are defined in Appendix 1.
3. DEFINITION OF INTELLECTUAL PROPERTY:

TGen’s intent is to define Intellectual Property broadly for purposes of this Policy and all Intellectual Property Agreements entered into under this Policy. The term “Intellectual Property” is defined for purposes of this Policy by each particular Intellectual Property Agreement, and includes without limitation inventions, discoveries, works of authorship, and other subjects of patent, copyright, or trade secret law. Under the terms of its Intellectual Property Agreements, TGen will waive in advance certain rights with respect to some forms of Intellectual Property (such as published academic or scholarly works), subject to certain restrictions.

4. OWNERSHIP OF INTELLECTUAL PROPERTY:

TGen shall be the exclusive owner of all Intellectual Property developed by a covered individual (a) in the course of his or her employment or other association with TGen or (b) using TGen information, facilities, or other resources, except to the extent otherwise provided in a TGen agreement with the Arizona Board of Regents. In some cases TGen, in its discretion, may elect to waive or assign its ownership rights in certain Intellectual Property in favor of an inventor or creator of Intellectual Property, or another person or entity. Any such waiver or assignment shall be based upon a determination by the Vice President for Research Administration, in consultation with the Scientific Director of TGen.

In the absence of the Vice President for Research Administration the Chief Operating Officer or his/her designee shall perform the duties of the Vice President for Research Administration described herein.

5. DISCLOSURE, ASSIGNMENT, AND COMMERCIALIZATION

Under this Policy, and as further provided in individual Intellectual Property Agreements, Institute Personnel and other covered individuals are contractually obligated to disclose promptly to TGen any Intellectual Property covered by section 4, to assign to TGen any rights that they may have in such Intellectual Property, and to cooperate with TGen in following the procedures necessary to perfect TGen’s patent or other rights in such Intellectual Property. TGen has sole discretion to determine whether to attempt commercialization of Intellectual Property and the specific pathway to commercialization, e.g. license or assignment to a commercial company vs. equity in a spinoff/startup, etc. In making such determinations, however, TGen will consult to the extent practicable with the inventors or creators of such Intellectual Property. Any actual or potential financial interest or benefit that any employee of TGen may acquire in connection with any such commercialization shall be subject to disclosure and other applicable terms of TGen’s Conflict of Interest Policy.

TGen can, with the agreement of the VP for Research Administration and any required sponsor agreement, waive its ownership rights which then become the property of the Inventor/Developer. The VP for Research Administration shall consult with the Scientific Director in making these decisions. Appeals by inventors shall be made to the Scientific Director, whose decision is final.
6. CONFLICT OF INTEREST DISCLOSURE

Inventors and developers of Intellectual Property and other researchers are required to comply fully with TGen’s separate Conflict of Interest Policy.

7. ROYALTY (AND OTHER INCOME) DISTRIBUTION:

In general, TGen’s Intellectual Property Agreements with Institute Personnel will provide for an allocation of royalties and other income in connection with the commercialization of Intellectual Property based on a formula established and reviewed annually by the Vice President for Research in consultation with the Scientific Director. The current allocation formula is set forth below. This formula may be changed prospectively at any time by TGen in its discretion as applied to all Intellectual Property disclosed thereafter. The “Recipient(s)” referred to in this formula, as further defined in the Intellectual Property Agreements, are in general the inventor(s) or creator(s) of the Intellectual Property.

Up to $250,000 in any given calendar year, Recipient(s) shall receive 50% of Net Intellectual Property Income, (i.e., Intellectual Property income net of Costs Related to Development and Protection of Intellectual Property including allocations of TGen overhead related to technology transfer), with the balance to TGen for possible allocation in part to non-inventor/contributors on a case by case basis as determined in the discretion of the Scientific Director upon the recommendation of the Vice President for Research Administration. The balance of income shall accrue to TGen for general support of research.

Of any increment over $250,000 in any given calendar year, but less than $2,000,000 in any given calendar year, Recipient(s) shall receive 35% of Net Intellectual Property Income, with the balance to TGen for possible allocation in part to non-inventor/contributors on a case by case basis as determined in the discretion of the Scientific Director upon the recommendation of the Vice President for Research Administration. The balance of income shall accrue to TGen for general support of research.

Of any increment over $2,000,000 in any given calendar year, Recipient(s) shall receive 25% of Net Intellectual Property Income with the balance to TGen for possible allocation in part to non-inventor/contributors on a case by case basis as determined in the sole discretion of the Scientific Director upon the recommendation of the Vice President for Research Administration. The balance of income shall accrue to TGen for general support of research.

If there is more than one eligible Recipient, shares generally shall be divided equally among all eligible Recipients, unless all eligible Recipients agree in writing to a different distribution or a different distribution is established pursuant to the terms and procedures of Intellectual Property Agreements.

8. EQUITY DISTRIBUTION:
TGen may create subsidiaries or affiliated entities for the purpose of commercializing Intellectual Property, and TGen or such entities may accept and hold equity (e.g., stock, options, warrants) or other ownership interests in entities received as consideration for licensing or assigning (to a subsidiary, an affiliate or unrelated parties) Intellectual Property or otherwise supporting new technology ventures. In such cases, eligible Recipient(s) will be permitted to receive, on terms to be determined on a case by case basis, a share of such equity or ownership interest that is expected by TGen in its reasonable discretion to be usually or generally consistent with the royalty distribution formulas contained in section 7. However, it is acknowledged that such determinations are uncertain and subject to many factors not known or controlled by TGen, and that in addition, fair distribution of equity interests may depend on additional factors beyond the formula, including other roles or relationships TGen may have. Recipients shall not accept actual or beneficial equity or ownership interests in such entities to which TGen licenses or assigns Intellectual Property, under any terms or arrangements outside of this Policy.

9. DISAGREEMENTS WITH RESPECT TO APPLICATION OF THE POLICY

As provided by the terms of the Intellectual Property Agreements, Institute Personnel may appeal to the Scientific Director with respect to any disagreement or dispute concerning the application of this Policy, and the Scientific Director’s decision shall be TGen’s final and binding decision.

10. WAIVERS

Waiver of any provisions of this Policy will be granted only in extraordinary and compelling circumstances as determined in the discretion of the Scientific Director. Any waiver request must be in writing addressed to the Vice President for Research Administration, and must identify specific respects in which a waiver (or notification) is sought, and a full explanation of the reasons for the requested waiver.

11. DEFERENCE TO SUPERSEDED LAWS, REGULATIONS, AND TERMS

This Policy is not intended to prevent TGen from participating in research agreements or other arrangements with governmental or private sponsors that are subject to laws, regulations or terms requiring a different disposition of rights than provided in this Policy. Any specific instance or application of the provisions of this Policy that would be inconsistent with such laws, regulations or terms will be considered to be superseded thereby, and TGen in its discretion will devise a lawful and fair alternative.

12. INTELLECTUAL PROPERTY MANAGEMENT AGENCIES

TGen may make appropriate arrangements not otherwise inconsistent with the provisions of this Policy with intellectual property management agencies or firms for the purpose of obtaining services and advice with respect to the patentability or other legal status of Intellectual Property,
the obtaining of patents thereon or other rights therein, and the management and licensing of any such Intellectual Property.
APPENDIX 1: DEFINITIONS

**Contractors**: Those individuals who are working for a separate organization under a contract to TGen that provides for advice and other support.

**Costs Related to Development and Protection of Intellectual Property**: The sum of (a) external charges, either as allocated by TGen in its reasonable discretion from aggregate charges, taken in the aggregate or specific to an invention, for support of identification and protection of Intellectual Property (including patent prosecution) and subsequent defense of such Intellectual Property including litigation and payment of damages and settlements, and (b) Institute overhead attributable to Technology Transfer efforts.

**Developer**: Institute Personnel who are not Inventors but are determined by TGen in its sole discretion to have made significant enough contributions to development of Intellectual Property to merit some compensation under this Policy.

**Institute Personnel**: Includes Primary Research Staff, Technical Staff, Contractors, Visiting Scientists, Students under work for hire and Postdoctoral Fellows.

**Intellectual Property**: Intellectual Property includes, but is not limited to, Inventions made as Institute Personnel (whether or not patentable), copyrights (excluding academic or Scholarly Works), and Tangible Research Property including, but not limited to, biologic materials, engineering drawings, computer software and computer code, integrated circuit chips, computer databases, chemical compounds, genomic code, genomic data and analysis and prototype devices (including circuit diagrams and equipment). Also included are trademarks, service marks, domain names, trade secrets, trade dress rights, formulas, designs, techniques, processes, procedures, systems, or formulations and any other Intellectual Property rights existing under federal, State or local law. Intellectual Property may or may not be patentable or copyrightable, and it can be created by one or more persons, each of whom, to be a Developer, must have conceived of an essential element of the Intellectual Property or have contributed substantially to its conceptual development.

**Inventions**: An Invention is any new and useful process, machine, composition of matter, life form, article of manufacture, or new or useful improvement thereto.

**Inventor**: Inventor shall mean any Institute Personnel who is an Inventor, under applicable United States law, of a new and useful process, machine or composition of matter, or any new and useful improvement thereof, whether patentable or not. Inventorship shall be determined by the Director of Technology Transfer, in consultation with the Vice President for Research, and subject to ultimate decision of the Scientific Director.

**Medical Products**: Products and services for human and other animal health that generally require approval by the federal Food and Drug Administration prior to commercial marketing.

Postdoctoral Fellows: Individuals who at the time of their appointments to the Institute have received an advanced degree, e.g., Ph.D., D.Sc., M.D., etc but do not hold appointments to the Primary Research Staff.

Recipient: A person entitled to certain Intellectual Property revenue distribution under this Policy.

Scholarly Works: Publications and other means of dissemination of research and scholarly studies that do not constitute Intellectual Property.

Students: Individuals who at the time of their appointments to the Institute are matriculating to an undergraduate, graduate or other school or university in a degree-granting program.

Technical Staff: Those individuals who are not Research Scientists but who are employed by the Institute as research support personnel and who are employed for at least 75% of normal FTE effort.

Tangible Research Property: Tangible Research Property includes, but is not limited to, biologic materials, engineering drawings, computer software and computer code, integrated circuit chips, computer databases, chemical compounds, genetically-engineered biological organisms, genomic code, genomic data and analysis and prototype devices (including circuit diagrams and equipment). Also included are video/audio tapes, CD-ROM, DVD-ROM, Internet based media, and other multimedia materials that are used for the purpose of research and/or education or the dissemination of knowledge.

Visiting Scientists: Research personnel who are considered Research Scientists for the purposes of this policy, but do not hold continuous appointments to the Institute, but shall be required to sign a Visitor’s Intellectual Property Agreement.
I hereby certify that I have read and understand the TGen Intellectual Property Policy. I agree to abide by the terms and conditions set forth in the policy, including the assignment of rights to TGen.

Print Name: ____________________________________________

Signature: ______________________________________________

Date: ________________________