

Translational Genomics Research Institute Organization Policy	Doc. ID.: COI-001-POL	Effective Date: 05/12/2004
	Version No.: 6.0	Revision Date: 09/26/2018
Doc. Title	<i>Financial Conflict of Interest</i>	

I. Introduction

The Translational Genomics Research Institute (“TGen”) is a non-profit corporation organized under the laws of the State of Arizona. As a tax-exempt, non-profit organization, no part of the net earnings of TGen may inure to the benefit of private individuals. This policy further covers TGen’s subsidiaries, including the TGen Foundation and Ashion Analytics, LLC, such that any reference to TGen should include such subsidiaries and their personnel.

It is the policy of TGen that all TGen Personnel shall comply fully with this Policy, which requires (1) advance disclosure of Financial Interests of TGen Personnel or members of their Immediate Family and Associated Entities, and (2) the management, reduction, or elimination of all real and apparent Conflicts of Interest (“COI”) in accordance with the procedures set forth in this Policy.

II. Purpose

Integrity of TGen Research and Activities. TGen’s ability to conduct innovative Research and other activities depends upon the integrity of each person involved and the confidence of the community it serves. All Research and Transactions in which TGen is involved should be carried out in accordance with the highest ethical and professional standards. To the fullest extent possible, all individuals charged with carrying out TGen’s mission should at all times remain free from the influence of conflicting financial or other interests. In all professional activities, an individual's first allegiance is to TGen. External activities should not compromise an individual's ability to perform TGen job responsibilities.

A Conflict of Interest arises when there is a divergence between an individual’s private interests and his/her professional obligations to TGen, such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by consideration of personal gain, financial or otherwise. TGen Research facilities and TGen Personnel are to be used solely for the benefit of TGen's research and educational purposes. Use of TGen facilities and resources for personal gain is prohibited.

The purpose of this Policy is (i) to promote objectivity in Research by establishing standards to ensure that the design, conduct, or reporting of Research, including Research under Public Health Service grants or cooperative agreements, will be biased by any conflicting financial interest of an Investigator and (ii) to safeguard the integrity and reputation of TGen and its personnel by identifying Transactions that may involve a Conflict of Interest or the appearance of a Conflict of Interest and to provide a framework for the approval of such Transactions. It is not the purpose of this Policy to discourage or prohibit participation by TGen Personnel in community and outside activities but to provide for the early identification and resolution of potential Conflicts of Interest. It is TGen’s policy to deal with such conflicts in a manner that is as open and appropriate as possible.

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III. Applicability

This policy applies to all TGen Personnel, as defined in this policy, including personnel at TGen's subsidiaries.

IV. Key Definitions

- A. Associated Entity. An Associated Entity is any Business over which any TGen Personnel or his/her immediate family, exercises a controlling interest.
- B. Business. A Business is any corporation, partnership, limited liability company, sole proprietorship, firm, franchise, unincorporated association, organization, holding company, joint-stock company, business or real estate trust, or any other legal entity organized for profit or charitable purposes, excluding TGen and its subsidiaries.
- C. Conducting Research. Conducting Research means, with respect to a Research protocol, designing Research, directing research or serving as an Investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions relating to eligibility to participate in Research, analyzing or reporting research data, or submitting manuscripts concerning the Research for publication. This term does not apply to TGen Personnel who primarily provide technical support and/or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis or, in the case of clinical research, to the trial participants), unless they are in a position to influence the Research results or have privileged information as to the outcome.
- D. Conflict of Interest. A conflict of interest exists when any TGen Personnel or his/her Immediate Family, or any Associated Entity, possesses a Financial Interest in an activity that involves his/her responsibilities to TGen (including Research, patient care and administration), that could directly and significantly affect the design, conduct, or reporting of Research.
- E. Conflict of Interest Committee (or Committee). The standing TGen Committee that performs the functions described in Article IV of this Policy.
- F. Conflict of Interest Official. The TGen Official who performs the functions described in Article III of this Policy or his/her designee.
- G. Equity Interest. Equity Interest includes stock, stock options, debt instruments, warrants or other vehicles of similar nature, or entitlement to the same.
- H. Equity Principles. The Equity Principles approved by the TGen Board of Directors and located in the TGen Handbook

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I. **Financial Interest.** Financial Interest includes the following interests held by TGen Personnel or their Immediate Family or an Associated Entity:

- Honoraria, gifts or other emoluments, “in kind” compensation or remuneration (including salary, payment for services and other payments) from a Financially Interested Company for any purpose not directly related to the reasonable cost of conducting the Research (as specified in the Research agreement) or engaging in the activity, that when aggregated for the TGen Personnel and his/her Immediate Family or Associated Entity in the prior fiscal year exceeded, or in the next fiscal year are expected to exceed, \$5,000.
- Equity Interests of any amount in a private or non-publicly-traded Financially Interested Company.
- Equity Interests in a publicly-traded Financially Interested Company (excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the individual or his/her Immediate Family does not exercise control) that when aggregated for the covered individual and his/her Immediate Family exceeds \$5,000 in value (when valued in reference to current public prices) and/or represents more than a 1% ownership interest in any single entity.
- Proprietary interests or intellectual property rights (e.g., patents and/or copyrights).
- Royalty income or the right to receive future royalties under a patent license or copyright agreement or any other type of agreement, where the Research or activity is directly related to the licensed technology or work.
- Any non-royalty payments (or entitlements to payments) in connection with any Research or activity that are not directly related to the reasonable costs of the Research (as specified in the Research agreement between the sponsor and TGen) or activity. This includes any bonus or milestone payments to Investigators in excess of reasonable costs incurred, whether such payments are received from a Financially Interested Company or from TGen.
- Service as an officer, director, or in any other fiduciary role for a Financially Interested Company, whether or not remuneration is received for such service.
- Significant non-cash items such as travel expenses or business gifts (e.g., non-business related upgrade to first class trip).

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- Reimbursed travel or sponsored travel related to responsibilities at TGen. This does not include travel sponsored by a government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Services as a consultant or otherwise in any role that is within TGen's or their affiliates' fields.

Exceptions. Financial Interest does not include the following:

- Salary, bonuses, royalties, or other remuneration from TGen.
- Reasonable and customary income and expenses from seminars, lectures, or teaching engagements paid for by public or nonprofit entities.
- Reasonable and customary income from service on advisory committees or review panels for public or nonprofit entities.
- An Equity Interest in a publicly traded company that, when aggregated for the TGen Personnel and his/her Immediate Family, meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a 1% ownership interest in any single entity.
- Equity Interests held only in diversified mutual funds or similar vehicles over whose holdings the TGen Personnel and their Immediate Family have no individual investment control.
- Payments made to TGen, or via TGen to the individual, that are directly related to the actual costs incurred in the conduct of Research, including fair compensation for time spent in Research activities, as specified in the Research agreement between TGen and the sponsor (or in Research-related meetings with Research sponsors or regulators).
- Income from seminars, lectures or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1011(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Travel that is reimbursed or sponsored by federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, medical center, or a research institute that is affiliated with an Institution of higher education.

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- J. Financially Interested Company. A commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the Research or activity in question. With regards to Research this term includes companies that compete with the sponsor of the Research or the manufacturer of an investigational product, if the person actually knows that the financial interests of such a company would reasonably appear to be affected by the Research. This term also includes any entity acting as the agent of a Financially Interested Company (e.g., a contract research organization).
- K. Financially Interested Individual. A person who holds a Financial Interest that could reasonably appear to be affected by the person's activities in the scope of his/her employment.
- L. Immediate Family. A person's spouse, domestic partner, parent, dependent children, sibling and any other individual whose association is similar to any of these relationships, including any person living in the same household as the TGen Personnel.
- M. Investigator. The principal investigator and any other person who is responsible for the design, conduct, or reporting of Research.
- N. Management Plan. A plan under which Research can be conducted or an activity undertaken despite a Conflict of Interest because adequate safeguards are established, which may include notifications to certain employees or departments. It shall include facts that describe whether a Financially Interested Individual should be permitted to engage in the conduct in question and any procedures that are to be implemented in order to minimize the conflict.
- O. PHS Awarding Component(s). PHS Awarding Component(s) means the organizational units(s) of the PHS that funds the Research that is subject to 42 CFR Part 50, Subpart F.
- P. PHS-Funded Personnel: TGen Personnel who serves as a project director/ principal investigator of a PHS-funded research project, and any other TGen Personnel identified as a project director/ principal investigator of PHS-funded research by TGen in the grant application, progress report, or any other report submitted to the PHS by TGen.
- Q. Research. The systematic investigation designed to develop or contribute to generalizable knowledge broadly to public health, including behavioral and social- sciences research. The term encompasses basic and applied research (e.g., a service, product, published article, book or book chapter) and product development.

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- R. Research Monitoring Board. A board, similar in nature, composition, and responsibilities to a Data Safety Monitoring Board (DSMB) that independently monitors Research to ensure its safety and integrity in a situation where a particular Conflict of Interest warrants such monitoring.
- S. Senior/Key Personnel. Personnel identified by TGen who play significant roles in the grant application, progress reporting or other reporting submitted to a PHS Awarding Component.
- T. Small Business Innovation Research. Small Business Innovation Research means the extramural research program for small businesses that is established by the PHS Awarding Components and certain other federal agencies under the Small Business Innovation Development Act, as amended. It also includes the Small Business Technology Transfer Program.
- U. TGen Personnel. For the purposes of this Policy, TGen Personnel refers to TGen employees who are faculty members; all TGen employees in a Director level and above position, all employees who serve as members of a research review committee (e.g., Institutional Biosafety Committee); all faculty, staff and post-doctoral fellows who are responsible for the design, conduct or reporting of research; and any TGen employees whom TGen determines the nature of the individual's job responsibilities present a Conflict of Interest risk.
- V. TGen Subsidiary. TGen subsidiaries include the TGen Foundation, Ashion Analytics, LLC, TGen Accelerators, LLC, and any other entity in which TGen directly or indirectly, owns or controls a 50% or greater interest.
- W. Transaction. A Transaction is any agreement or relationship involving the sale or purchase of goods, services, or rights of any kind, the providing or receipt of a loan or grant, or the establishment of any type of pecuniary relationship.

V. The TGen Conflict of Interest Official

- A. Appointment. The TGen President/Scientific Director or his/her designee will appoint the TGen Conflict of Interest Official (the "Official"), who shall have the authority to implement and oversee compliance with, TGen's conflict of interest policies, procedures and requirements.
- B. Function. The Official shall be responsible for developing procedures for, and overseeing the implementation of, the process and mechanism for disclosure of real or apparent Conflicts of Interest, and for reviewing and evaluating all disclosures, making preliminary determinations on whether an actual or apparent Conflict of Interest exists, and making recommendations for the management, elimination, or reduction of any identified Conflicts of Interest. The Official shall further be responsible for overseeing compliance by all

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TGen Personnel with the Policy, including reviewing all breaches of the disclosure process. The Official may delegate certain responsibilities to staff (“Designee”).

- C. Absence. In the absence of the Official, a designee of the Chief Operating Officer will perform the functions of the Official as needed until the Official is again available. All reference to the Official in this policy refers to the Official’s designee.

- D. Responsibilities. Without limiting the foregoing, the Official is responsible for:
 1. Reviewing all disclosures and otherwise investigating any actual, perceived, or potential Conflicts of Interest that come to his/her attention;
 2. Evaluating each disclosure to determine if an actual Conflict of Interest exists and, if it warrants Committee review;
 3. Developing a Management Plan for the elimination, management, or reduction, as necessary and appropriate, of any identified Conflicts of Interest;
 4. Preparing a summary report and, if warranted, presenting for review to the Committee detailing his/her finding: the bases for his/her determinations, including the nature of the Conflict of Interest and amount of any Financial Interest; and his/her recommendations with respect to the Management Plan;
 5. Communicating the terms of any Management Plan to the affected Financially Interested Individual;
 6. Overseeing the implementation of any Management Plan;
 7. Overseeing compliance with TGen’s conflict of interest policies, procedures, training and requirements;
 8. Reporting the results of the review to the affected TGen Personnel, the appropriate TGen regulatory affairs personnel, and other TGen officials and department heads and responsible personnel as appropriate to direct compliance with any Management Plan, and, after consultation with the President/Scientific Director, to the Board of Directors or a designated committee thereof, to the extent appropriate.

VI. TGen Conflict Of Interest Committee

- A. Function. The Committee shall meet as deemed necessary to review Conflict of Interest determinations and if warranted, determine Management Plan recommendations.

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B. Members. The Committee shall be appointed by the Chief Operating Officer.

VII. TGen Procedures For Conflict Of Interest Disclosure And Management

A. Disclosure.

1. Certification. It is the policy of TGen that all TGen Personnel submit a Potential Conflicts of Interest Disclosure Form that discloses, for themselves and their Immediate Family and any Associated Entities, any Financial Interest that may give rise to a Conflict of Interest.

This Policy requires disclosure of any Financial Interest that reasonably may be a Conflict of Interest, even if the disclosing person believes that it is not an actual Conflict of Interest. Disclosure of a Financial Interest shall be made unless the Financial Interest falls clearly within an exception to the definition of Financial Interest in this Policy.

The Official may request, and the disclosing person shall cooperate and be required to provide, additional information in order to clarify certain Conflict of Interest situations. If an individual has any questions concerning the disclosure requirements, the Policy, or any requested additional information, s/he should discuss these questions with the Official. Disclosures will be considered confidential and the information disclosed therein will be made available only to those individuals on a need to know basis, as directed under a Management Plan, or who are duly charged with the responsibility for review and oversight of the implementation of this Policy.

2. Form FDA 3454 / 3455. Investigators conducting Research involving FDA-regulated test articles also must submit, both to the sponsor of the Research and the Official, the applicable FDA form: (i) Form FDA 3454, for certification of no financial interests, or (ii) Form FDA 3455, for disclosure of financial interests.
3. Timing of Disclosures. **TGen Personnel must submit the Potential Conflict of Interest Disclosure Form in advance of engagement in reportable activities. TGen Personnel may not engage in any reportable activity without approval in advance by the Committee.**

TGen Personnel shall make the required disclosures:

- a) Annually by the deadline designated by the Official.

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- b) **Prior** to the submission of an application or proposal for external federal funding of a Research project;¹
 - c) **Prior** to initiating the development, technology transfer and/or licensing process for the results of Research supported or conducted at TGen or using TGen money, facilities, resources, or TGen Personnel;
 - d) **Prior** to entering into an employment arrangement or services agreement with or becoming a Board Member for any organization or entity other than TGen or a TGen Subsidiary or TGen affiliate;
 - e) **Prior** to becoming involved in the formation of a new company, organization, or other entity, either as a founder, holder of an Equity Interest or as a Board Member;
 - f) **Prior** to engaging in a Transaction involving TGen or one of its subsidiaries;
 - g) **Prior** to entering into a Transaction with a Financial Interested Company;
 - h) Promptly upon a change in financial or other circumstances that under this Policy may (i) give rise to an actual, perceived or potential Conflict of Interest, or (b) eliminate a previously disclosed Conflict of Interest;
 - i) **Prior** to engaging an activity requiring review and approval under the Equity Principles; and
 - j) Within 30 days of the acquisition or discovery of a Financial Interest.
4. Equity Principles. The Equity Principles are incorporated herein by reference. TGen personnel shall adhere to the Equity Principles and the Equity Principles, including without limitation the approval processes set forth in paragraphs 7 and 10 for Executive Management (or disqualified person as determined appropriate) shall govern as appropriate.

¹ Grant application(s) for federal funding will not be approved until a disclosure form for the Investigator and all support personnel involved in the project have been submitted. Personnel added to an existing Research project must complete and submit a disclosure form before they can be added to

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B. Review of Conflicts of Interest Disclosed

1. Bases For Findings and Determinations. As soon as possible, and as required, within 60 days of the disclosure of the Conflict of Interest, the Committee will consider on a case-by-case each potential Conflict of Interest identified by the Official and render a reasonable decision as to whether a Conflict of Interest exists, how it should be managed or eliminated in order for TGen Personnel to participate in Research or engage in the activity in question, or whether circumstances exist such that TGen Personnel should be permitted to participate in the activity or conduct the Research subject to conditions and/or restrictions that ensure effective management of the conflict and credible oversight of the Research or activity. If it is determined that a Conflict of Interest exists, the Committee's decision may fall within three categories:
 - (1) It will determine that a Conflict of Interest subject to this Policy is "de minimis" or is subject to a specific exemption in the Policy; or
 - (2) It will determine that a Conflict of Interest subject to this Policy does exist, but that it can be effectively managed under a Management Plan; or
 - (3) It will determine that a Conflict of Interest exists and is of such a nature that it either cannot be managed under a Management Plan or that no circumstances exist that are sufficiently compelling to warrant proceedings with the activity under Section 2.

2. Compelling Circumstances. If in conducting his/her preliminary review of a disclosure, the Official identifies a Conflict of Interest that might prohibit the disclosing person from conducting the Research or engaging in the activity in question, the Financially Interested Individual will be afforded the opportunity to provide information regarding circumstances s/he believes exist that would justify permitting him/her to conduct the Research or engage in the activity in question despite the existence of the Conflict of Interest. The Financially Interested Individual also may suggest procedures, protocols, or other measures designed to manage, reduce or eliminate the Conflict of Interest.

Whether the circumstances are deemed compelling will depend in each case upon the nature and magnitude of the interest, the degree to which the interest is related to the research or activity, the extent to which the interest may be directly and substantially affected by the research or activity, whether the individual holding an interest is uniquely qualified by virtue of expertise and experience to perform the research or engage in the activity in question, and the extent to which the interest is amenable

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to effective oversight and management. In the Research context, the circumstances to be considered include the nature of the science, the degree of risk to any human subjects involved that is inherent in the Research protocol, and whether the Research could not be conducted as safely or effectively without the Financially Interested Individual.

When the Financial Interest is directly related to the Research or activity and may be substantially affected by it (e.g., an equity interest in a start-up company that manufactures the investigational product being studied), the risk is greatest and the standard must be high; however, even a direct and potentially lucrative Financial Interest may be justified in some circumstances. An example of such a "circumstance" includes Research that would not likely be conducted by another Investigator anywhere due to the Investigator's unique experience and expertise. There may be other circumstances as well.

C. Management Plans. After reviewing the relevant facts and documenting the compelling circumstances, the Committee may recommend that a Financially Interested Individual be permitted to conduct the research or engage in the activity subject to conditions and/or restrictions that ensure effective management of the conflict and credible oversight of the Research or activity. Examples of conditions or restrictions that might be imposed include:

1. Disclosure to state and federal officials, as required by statute or regulations.
2. Monitoring of the Research or other activity either internally by a Research Monitoring Board or by independent reviewers, including regular audits of the informed consent and enrollment process and/or the use of a patient representative or ombudsman at the time of recruitment and provision of informed consent when the Research involves human subjects.
3. Modification of the Research plan or other activity, including a requirement that informed consent be obtained by a clinician with no financial ties to the Research, if appropriate, or selection of another clinician to serve as the principal investigator.
4. Disqualification from participation in all or a portion of the Research or other activity.

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5. Disqualification from participation in any and all negotiations concerning research agreements, license arrangements, service agreements, equipment purchases, or other arrangements involving the Conflict of Interest.
 6. Escrowing the Financial Interest until the investigational product, device or technology has been approved and on the market for a specified period of time.
 7. Divestiture of the Financial Interest.
 8. Severance of the relationship that creates the Conflict of Interest.
- D. Implementation and Monitoring of the Management Plan. If TGen Personnel are permitted to participate in the activity under a Management Plan, the Official will inform the individual in writing of the terms and conditions of the Management Plan that has been imposed. The Official may request that the individual acknowledge in writing his/her willingness to comply with the terms and conditions of the Management Plan. The individual in question may request modifications to the Management Plan by submitting a written proposal to the Official, who shall review the proposal and forward it along with his/her recommendation concerning its adoption to the Committee for review and a final determination. The Official, or designee, shall be responsible for enforcing the terms and conditions of the Management Plan. If the Conflict of Interest involves a clinical trial, the appropriate IRB will be notified of the Management Plan. In each instance, the individual or body responsible for enforcing the Management Plan must certify in writing that the Plan has been imposed. Copies of the COI Disclosures, Management Plans, and, if required by the Official, have the Financially Interested Individual's agreement to comply, as well as the enforcing individual's or body's certification shall be kept on file with the Official as specified in Section VII.
- E. Appeals Process. Any determination made by the Committee pursuant to this Policy may be appealed to the President/Scientific Director or his/her designee. If an affected individual does not accept the Management Plan, the individual will be informed that s/he can request a personal hearing before the President/Scientific Director. The President/Scientific Director or his/her designee will review the disclosure, the proposed Management Plan, and any other information deemed relevant by the affected individual. The President/Scientific Director or his/her designee will determine if the proposed Management Plan should be revised and communicate the final proposed Management Plan to the Committee. The decision of the President/Scientific Director or his/her designee shall be final. The Committee will notify the affected individual of the changes made to the Management Plan, if any.

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- F. PHS Certification. The appropriate TGen Official shall certify on each PHS funded proposal that:
1. There is a written and enforced administrative process to identify, manage, reduce or eliminate conflicting interests;
 2. Prior to the expenditure of any funds, a report will be made to PHS as set forth in Section H(1) below;
 3. Upon request, TGen will make information available to the Department of Health and Human Services regarding all conflicting interests and how those interests have been managed, reduced or eliminated.
- G. Reporting. Once the Completed Disclosures and all Management Plans (collectively the "Records") have been finalized, the Records shall be made available to the President/Scientific Director, Chief Operating Officer, TGen Legal Department, and the TGen Research Administrator as well as other appropriate TGen officials and administrators, including without limitation, Finance and Grants Administration.
1. Research supported by PHS Awards (including NIH and NCI Awards). This section applies to Research that has PHS funding, including grants or cooperative agreements. This section does not apply to Small Business Innovation Research Program Phase I applications.
 - a) If TGen identifies a Conflict of Interest and eliminates it prior to the expenditure of the PHS-awarded funds, TGen shall not submit a Conflict of Interest report to the PHS Awarding Component. If a COI is not eliminated prior to the expenditure of any PHS funds, the TGen Research Administrator will report to the PHS Awarding Component, after consultation with TGen Legal Counsel, the existence of any COI. The COI report shall contain the following information:
 - i) PHS- funded research project number;
 - ii) TGen Personnel with Conflict of Interest,
 - iii) Name of entity with which the Investigator has a Conflict of Interest,
 - iv) Nature and approximate value of Financial interest,
 - v) Description of how the Financial Interest relates to the PHS-funded research and TGen's basis for determining that there is a Conflict of Interest, and

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vi) Description of the key elements of TGen’s management plan to enable the PHS Awarding Component to understand the nature and extent of the Conflict of Interest and to assess the appropriateness of TGen’s engagement plan.

TGen must also ensure the implementation of the Committee’s management plan.

b) For any Conflict of Interest in PHS-funded research that TGen identifies during an ongoing PHS-funded research project, the TGen Research Administrator shall provide the PHS Awarding Component within sixty days of identifying the COI (and after consultation with TGen Legal Counsel), a COI report regarding the Conflict of Interest. TGen’s Committee must review the Financial Interest and make a determination with regard to the elimination, management or reduction of the COI.

TGen must also ensure the implementation of the Committee’s management plan.

c) For any Conflict of Interest previously reported by TGen with regard to an ongoing PHS- funded research project, the TGen Research Administrator shall provide to the PHS Awarding Component an annual COI report that addresses the status of the Conflict of Interest and any changes to the management plan for the duration of the PHS-funded research project. The annual COI report shall specify whether the Conflict of Interest is still being managed or explain why it no longer exists. TGen shall provide these annual reports for the duration of the project period (including extensions with or without funds).

d) Within five days of a request from the public for information about a Conflict of Interest where TGen Personnel are Senior/Key Personnel and still hold the Financial Interest, the TGen Research Administrator (after consultation with TGen Legal Counsel) will make available the information specified by 42 CFR § 50.605(a)(4).

2. NSF Awards. The TGen Research Administrator shall keep the NSF Office of General Counsel appropriately informed if TGen finds that it is unable to satisfactorily manage a Conflict of Interest under an NSF funded project.

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3. Technology Licensing Agreements. Prior to executing a technology licensing agreement, the Officer responsible for licensing shall notify the Official of the proposed terms of the agreement. The Official will review the terms of the agreement in light of the affected individual's disclosure and determine whether the agreement would create a Financial Interest in ongoing or proposed Research, be it humans subjects research or otherwise. If the Official determines that the agreement would create a Financial Interest, s/he will inform the Officer responsible for licensing of the existence of the potential Conflict of Interest and forward the potential conflict to the Committee for review as set forth above.

- H. Compliance Update. The Official shall review and, if needed, update the status of each Management Plan periodically, and shall report on the status and any changes to the Committee, the affected individuals, the IRB, others participating in the Research, and the TGen President/Scientific Director or Chief Operating Officer, as appropriate.

- I. Enforcement, Sanctions, and Non-Compliance. Failure to comply with this Policy may result in disciplinary action ranging from a letter of reprimand to dismissal and termination of employment or affiliation with TGen. If an individual has reasonable cause to believe that any TGen Personnel has (a) failed to comply with the process, whether by virtue of his/her refusal to respond or by his/her responding with incomplete, or knowingly inaccurate, information; (b) failed to appropriately disclose or otherwise comply with the policy; and/or (d) failed to comply with a prescribed Management Plan, s/he shall inform the Official. The Official shall inform such TGen Personnel of the basis for such a belief and afford the individual the opportunity to explain the alleged violation. If, after hearing the individual's response and making such further investigation as may be warranted in the circumstances, the Official determines that the individual has in fact violated the Policy, s/he shall refer the matter to TGen General Counsel, who shall handle the establishment of oversight protocols for cases involving non-compliance and breach, and the designing of appropriate subsequent disciplinary actions, including immediate removal of the individual from his/her duties if such is warranted.
 1. PHS Funded Research.

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- a) If TGen determines that a PHS- funded project of clinical research evaluating the safety or effectiveness of a drug, medical device or treatment, was designed, conducted or reported by an Investigator or support personnel with a conflicting interest that was not disclosed or managed, TGen shall require the Investigator or support personnel to disclose the conflicting interest in each public presentation of the results of the Research.
- b) For PHS- funded research or as required by the Official or Committee, if TGen determines that
 - i) TGen Personnel did not timely disclose a Financial Interest; or
 - ii) TGen failed to review TGen Personnel's timely disclosure; or
 - iii) TGen Personnel failed to comply with a Management Plan, then TGen shall within 120 days of the determination of non- compliance complete a retrospective review.
- c) Retrospective review may include;
 - i) PHS- funded research project number and title,
 - ii) TGen Personnel involved,
 - iii) Entity in which TGen Personnel has the Conflict of Interest,
 - iv) Reason for retrospective review,
 - v) Detailed methodology for review,
 - vi) Findings of the review, and
 - vii) Conclusions.
- d) If TGen finds any bias in the design, conduct or reporting of the PHS- funded research arising from a newly identified financial Conflict of Interest then it must notify the PHS Awarding Component and promptly submit a mitigation report.
 The mitigation report must include;
 - i) key elements of the retrospective review,
 - ii) a description of the impact of the bias on the research project; and

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iii) TGen's plan of action to eliminate/ mitigate the bias.

- J. Reporting. In the case of a Conflict of Interest involving the President/Scientific Director, the Official and any TGen COI committee members shall report to the Chairman of the TGen Board of Directors for that purpose.
- K. Sub-grantees/ Contractors/ Collaborators. This Policy also applies to sub-grantees, contractors, or collaborators ("Sub-recipient") of TGen involved in any Research funded by the Public Health Service ("PHS"), National Science Foundation ("NSF"), or National Institutes of Health ("NIH") being conducted by TGen Personnel or at TGen unless such Sub-recipient provides written assurance to the Official that it is subject to a Conflict of Interest Policy that complies with 42 Code of Federal Regulations, Part 50, Subpart F (Promoting Objectivity in Research) and TGen has a written agreement in place with the Sub-recipient that requires the Sub-recipient to comply with its own Conflict of Interest policy and that specifies the time period for the Sub-recipient to report all identified Conflicts of Interest to TGen (which time must be sufficient to allow TGen to comply with its reporting obligations in this policy).

VIII. Training

- A. All TGen Personnel must complete the Conflict of Interest training prior to engaging in research related to any PHS-funded grant or contract, at least every four years, at the direction of the Official, and immediately upon the following events:
 - 1. TGen revises its Conflict of Interest policies or procedures in any manner that affects the requirements of TGen Personnel;
 - 2. A new employee is deemed to be a TGen Personnel; or
 - 3. TGen finds that a TGen Personnel is not in compliance with the Department of Health and Human Services regulations, TGen's Conflict of Interest policy, or a Management Plan required by the Committee.
- B. TGen will document the content of all training provided, and document the employee that attended the training.

IX. Records Management

- A. Maintenance. Completed Disclosures and Management Plans (collectively "Records") with respect to each conflicting interest shall be maintained as follows:

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1. PHS funded Research. Three (3) years after the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. §74.53(b) when appropriate;
2. NSF Funded Research. Three (3) years beyond the termination or completion of the project, or until the resolution of any NSF action involving those records, whichever is longer;
3. All other Research or activities. Three (3) years beyond the completion of the activity or Research at issue or commercialization of the Research products that were the subject of the disclosure, or the retention period required by the contract with a commercial sponsor of a clinical trial, whichever is longer.
4. Litigation or Audit. If any litigation, claim, financial management review, or audit is started before the expiration of the aforementioned period, the Records shall be retained until all litigation claims or audit findings involving the Records have been resolved and final action taken.

B. Confidentiality. TGen recognizes that some information concerning an individual's Financial Interests and/or Conflicts of Interest may be sensitive and confidential and will strive, therefore, to be respectful of the privacy of individuals while still implementing this Policy effectively. TGen will not disclose such confidential information except as consistent with law and/or this Policy and in the best interest of TGen. For PHS- funded research and as determined by the Official or the Committee, TGen may make available certain information available within 5 days of a written request that meets TGen's requirements and policies.

C. Public Accessible Website Information. TGen will post its COI Policy on a publicly accessible website.

X. Requirements Regarding Conflicts Of Interest

A. In addition to, and not in lieu of, the requirements of this policy, TGen Personnel shall abide by all legal and disclosure requirements, including the following to the extent that they are applicable:

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1. Disclosures. TGen Personnel must comply with requirements concerning public disclosure of the Financial Interest and other relevant information, including, where applicable and necessary, full disclosure to any reviewing IRBs², study sponsors or research funders, the IRBs of other institutions in the case of multi- center trials, research subjects, and in any manuscripts or substantive public communication of the results of the Research, whether oral or written.
2. Public Health Service (PHS) Regulations. Institutions receiving research support from PHS Agencies (such as the National Institutes of Health, the Centers for Disease Control and Prevention, and the Indian Health Service) must comply with PHS regulations at Title 42, Part 50, Subpart F of the Code of Federal Regulations (CFR) (42 CFR Part 50, Subpart F). Institutions receiving support from NSF must meet identical requirements.
3. Food and Drug Administration (FDA) Regulations. FDA regulations at 21 CFR Part 54 require investigators conducting research regulated by the FDA to submit disclosure of any Financial Interests (or lack thereof) to the sponsor of the research (or, in the case where the institution or a particular investigator holds the investigational new drug number (IND) or investigational device exemption (IDE), directly to FDA).
4. Federal Regulations for the Protection of Human Research Subjects. The Federal Policy for the Protection of Human Subjects in Research, commonly called the Common Rule and codified at 45 CFR 46.107(e), prohibits IRB members who have a conflicting interest from participating in the IRB's initial or continuing review of research, except to provide answers to questions from the IRB. FDA IRB regulations at 21 CFR 56.107(e) include the same prohibition.

XI. Conflicting Agreements

TGen Personnel may not enter into any agreement (i) with a third party with which they may have an actual or potential Conflict of Interest without prior review and approval by TGen, and ii) that is consistent with TGen's policies and procedures or the TGen Intellectual Property Agreement.

² The IRB is ultimately responsible for protecting the rights and welfare of human subjects and, if it determines, shall independently review the Financial Interest and either refuse to approve the Research or recommend its own requirement to manage, reduce or eliminate the Conflict of Interest.

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XII. Relevant Policies, SOPS, Work Instruction & Templates

- A. Forms FDA 3454 and 3455

XIII. References

- A. 21 CFR Part 54 Food And Drugs Administration Financial Disclosure By Clinical Investigators
- B. 21 CFR 56.107(e) and 45 CFR 46.107(e) Food And Drugs Administration Institutional Review Boards and OHRP IRB Membership
- C. 42 CFR Part 50, Subpart F Promoting Objectivity in Research

XIV. Attachments

N/A

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Revision History

Version Number	Date of Revision	Responsible Person	Comments/Description of Changes
2.0	08/30/05	NA	Reviewed and updated
3.0	10/10/07	NA	Reviewed and updated
4.0	08/23/12	S. McRae	Reviewed and updated
5.0	12/16/13	S. Buchholtz	Reviewed and updated
6.0	09/26/18	S. Buchholtz	Reviewed, updated, and reformatted.