

TITLE: FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

1.0 OBJECTIVE:

- 1.1 The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health System grants, cooperative agreements and contracts will be free from bias resulting from potential Investigator financial conflicts of interest.
- 1.2 This policy outlined below are intended to meet the most recent published Federal government requirements regarding Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research on August 25, 2011 (42 CFR Part 50 Subpart F and 45 CFR Part 94).

2.0 DEFINITIONS:

- 2.1 Bay Area Tumor Institute Community Clinical Oncology Program (BATI-CCOP) – BATI-CCOP was originally founded in 1979 and converted to CCOP status in 1989 with a special emphasis on the recruitment of minority, low income, pediatric, non-English-speaking, and female populations in the greater Bay Area. The BATI-CCOP then converted to BATI-NCORP (National Cancer Institute Community Oncology Research Program) on August 1, 2014. (The BATI-NCORP enables cancer patients and the general “at risk” population to participate in the National Cancer Institute (NCI) clinical, cancer control, prevention and cancer care delivery research under funding of the National Cancer Institute Community Oncology Research Program (NCORP) grant from the NCI .
- 2.2 Investigator – As defined by the BATI-NCORP, participating investigator members shall be those who have current, approved NCI Registration membership to participate in the Bay Area Tumor Institute National Cancer Institute Community Oncology Research Program. The participating investigator members are not employees of the BATI-NCORP. The FCOI regulation defines an Investigator as an individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include, for example, collaborators or consultants. For the purposes of this FCOI policy, an Investigator will be defined as an individual who has the potential to enroll clients or patients on NIH clinical trials or is employed by the BATI-NCORP and involved in the research program and activities funded by the NCI through the BATI-NCORP grant.
- 2.3 Subrecipient Institution – The BATI-NCORP has a Consortium Agreement with Children’s Hospital & Research Center Oakland (CHRCO). This hospital, for the purpose of this FCOI policy and procedure is considered a sub recipient of the BATI-NCORP grant. CHRCO has their own research staff and the BATI-NCORP

distributes funds from the NCORP grant on a quarterly basis. The funds are paid directly to the hospital. The other physician groups and remaining hospitals do not receive any direct grant funds. Their participation in the NCORP is provided indirectly by the BATI-NCORP staff performing all administrative, regulatory and data management necessary to support enrollment and management on the NIH clinical trials accessed through the BATI-NCORP.

- 2.4 Senior/key Personnel – Those individuals identified in the BATI NCORP grant as senior/key personnel will remain the same individuals identified as senior key/personnel for the purpose of this FCOI policy and procedures. These individuals are those who are in the roles of: Principal Investigator, Co-Principal Investigator, Program Administrator, President, research base responsible Principal Investigators affiliated with the BATI-NCORP.

3.0 SIGNIFICANT FINANCIAL INTERESTS

- 3.1 Any investigator, **regardless of title of position**, that is responsible for the design, conduct, or reporting of research activities funded or proposed for funding at the BATI-NCORP by the NCI must reveal all current significant financial interests within the twelve months preceding the disclosure, that may be related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

- 3.2 Significant Financial Interest (SFI) is defined as:

- 3.20 Any current financial interest of the Investigator (and those of the Investigator's spouse and dependent children) that could reasonably appear to affect the research activities proposed for funding.

- 3.20.a. With regard to any publicly traded or non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest, when aggregated, exceeds \$5000. For the purpose of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interests include any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; or intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

- 3.21 Any interest held by the investigator and his/her immediate family in a business entity (company, corporation, or other enterprise) whose financial interests might reasonably appear to be affected by such related research activities.

- 3.22 Occurrence of any reimbursed or sponsored travel that which is paid on behalf

of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available, related to their institutional responsibilities.

3.3 Specifically, significant financial interests might include, but are not limited to, any of the following:

3.30 Anything of significant monetary value, including salary or other payments for services such as consulting fees or honoraria:

3.31 Direct equity interests such as stock, stock options, or ownership interests;

3.32 Intellectual property rights owned by the investigator such as patents, copyrights, and royalties from such rights.

3.4 Significant financial interests **do not** include:

3.40 Financial interests in business enterprises or entities that, when aggregated for the investigator and his/her immediate family, meet **both** of the following tests:

a. The financial interest **does not exceed** \$5000 in value as determined through reference to public prices or other reasonable measures of fair market value, and

b. The financial interest does not represent more than a five percent ownership interest in any single entity;

3.41 Salary, royalties, or other remuneration from BATI-NCORP;

3.42 Salary, royalties, or other payments that, when aggregated for the investigator and his/her immediate family, are **not** expected to exceed \$5000 during the next 12 month period;

3.43 Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

3.44 Income from service on advisory committees or review panels for public or nonprofit entities.

3.45 Travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

3.46 Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

3.5 An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest. Disclosure can be a key factor in protecting an individual's reputation and career from potentially harmful allegations of misconduct.

4.0 RESPONSIBILITIES:

- 4.1 BATI-NCORP:
- 4.10 The BATI-NCORP will inform each Investigator of the Federal regulation and the BATI-NCORP's policy regarding Financial Conflict of Interest and the Investigator's disclosure responsibilities.
 - 4.11 The BATI-NCORP requires each PHS-supported Investigator to complete FCOI training prior to engaging in research related to any PHS-funded grant, at least every 4 years and immediately if: the BATI-NCORP revises its FCOI policy that affects the requirements of Investigators, an Investigator is new to an Institution or if an Investigator is not in compliance with the policy or management plan.
 - 4.12 The BATI-NCORP requires each Investigator to disclose a Significant Financial Interest (SFI) (and those of the Investigator's spouse and dependent children) related to the Investigator's BATI-NCORP responsibilities that meets or exceeds the regulatory definition of SFI. The SFI must be disclosed no later than at the time of application for PHS-funded research, at least annually during the period of the award and within 30 days of discovering or acquiring a new SFI.
 - 4.13 The BATI-NCORP will provide adequate guidelines consistent with the regulation for the designated BATI-NCORP official(s) to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is a financial conflict of interest (FCOI).
 - 4.14 The BATI-NCORP requires the designated official(s), prior to Institution's expenditure of funds, to review all Investigator SFI disclosures, to determine if any SFIs relate to PHS-funded research, determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of associated the NIH-funded research), and to develop and implement management plans, as needed to manage FCOIs.
 - 4.15 The process to review disclosures includes how to handle review of SFI disclosures for an Investigator new to participating in the research project or for an existing Investigator who discloses a new SFI. It includes a process for handling SFIs within 60 days that were not disclosed in a timely manner by the Investigator or not previously reviewed by the BATI-NCORP. If a subrecipient Institution agrees to follow the BATI-NCORP FCOI policy and procedures and modifies its Consortium Agreement, then the BATI-NCORP will also have a system to manage the sub recipient Investigators.
 - 4.16 The BATI-NCORP will send initial, annual and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the BATI-NCOP and its subrecipients, if applicable as required by the most recent regulation. This process will include the following timepoints: prior to the expenditure of funds, within 60 days of identification for an Investigator who is newly participating in the project, within 60 days for new, or newly identified, FCOIs for existing Investigators, at least annually (at the same time as when the BATI-NCORP is required to submit the annual progress

report) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project and following a retrospective review to update a previously submitted report, if appropriate.

- 4.17 The BATI-NCORP's FCOI reporting will include all reporting elements as required by the regulation to notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation.
- 4.18 The BATI-NCORP will notify NIH promptly if an Investigator fails to comply with the BATI-NCORP FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. This will include the BATI-NCORP's requirement to notify NIH promptly and take corrective action for noncompliance with the BATI-NCORP's policy or the management plan.
- 4.19 The BATI-NCORP will maintain all FCOI-related records. The records will be maintained for at least three years from the date the final expenditures report is submitted to the PHS (NIH) and from other dates specified in the regulations where applicable.
- 4.20 The BATI-NCORP will establish adequate enforcement mechanisms and provide for administrative actions to ensure Investigator compliance.
- 4.21 The BATI-NCORP will complete and document retrospective reviews within 120 days of the BATI-NCORP determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.
- 4.22 The BATI-NCORP will ensure that in any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator as required by the regulation, the Institution shall require the Investigator involved to: disclose the FCOI in each public presentation of the results of the research, and to request an addendum to previously published presentations.
- 4.23 The BATI-NCORP will post its FCOI policy on the BATI-NCORP's public webpage at www.bati.org.
- 4.24 The BATI-NCORP will make available information concerning identified FCOIs held by senior/key personnel accessible prior to the expenditure of funds. The information will: include the minimum elements as provided in the regulation, and will be made available within 5 calendar days of a written request, be updated at least annually. If there are any newly identified FCOI's, updates will be made within 60 days. Information will

remain available for three years from the date the information was most recently updated.

4.2 INVESTIGATOR:

4.20 The Investigator is responsible for completing FCOI training prior to engaging in research related to any PHS-funded grant, at least every 4 years and immediately if: the BATI-NCORP revises its FCOI policy that affects the requirements of Investigators, an Investigator is new to an Institution or if an Investigator is not in compliance with the policy or management plan.

4.22 The Investigator will complete a SFI Disclosure Form at least annually and immediately if the following conditions are present: if the BATI-NCORP revises its FCOI policy so that it affects the requirements of the investigators; if an investigator is new to the BATI-NCORP; or if an Investigator is not in compliance with the policy or management plan.

4.23 The Investigator must disclose a significant financial interest (SFI) (and those of the Investigator's spouse and dependent children) related to the Investigator's BATI-NCORP responsibilities that meets or exceeds the regulatory definition of SFI. The SFI must be disclosed no later than at the time of application for PHS-funded research, at least annually during the period of the award and within 30 days of discovering or acquiring a new SFI.

4.3 SUB-RECIPIENT:

4.30 Consortium agreements of the sub-recipients will be modified to accept the BATI-NCORP's FCOI policy or to reference an institutional FCOI policy that will be maintained and enforced, and that meets or exceeds the most recent regulatory requirements.

4.31 If the subrecipient chooses to accept BATI-NCORP FCOI policy and procedure as its policy, the amendment to the Consortium Agreement will include a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee BATI-NCORP to identify, manage and report identified FCOIs to the NIH.

4.31 If the subrecipient chooses to use its institutional FCOI policy, the subrecipient will provide a certification that its FCOI policy complies with the regulation. In addition, the subrecipient institution will report identified FCOI's for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the NIH as required by the regulation.

5.0 PROCEDURES:

5.1 Investigators as defined above in Section 2.2 will complete the required training of the BATI-NCORP FCOI Policy and then as outlined in Section 4.2. Required training includes the online tutorial review of the federal regulation 43 CFR Part 50 Subpart F (website link:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) to obtain certificate of completion and review of the BATI-NCORP Financial Conflict of Interest policy.

- 5.2 Investigators will complete the BATI-NCORP Significant Financial Interest (SFI) Disclosure Form as outlined in Section 3.0. The BATI-NCORP's SFI Disclosure Form is Appendix A.
- 5.3 Investigators may have their enrollment privileges suspended or revoked if the Investigator does not follow the responsibilities as outlined in Section 4.2.

6.0 DISCLOSURE REVIEW

- 6.1 The NCORP Administrator will provide timely review of completed SFI annual disclosure forms and disclosure attachments to determine whether or not a FCOI may potentially be identified. If SFI's disclosed, NCORP Administrator will discuss with NCORP President whether SFI is considered a potential FCOI related to associated PHS-funded research and if management plan is needed.

7.0 MANAGEMENT PLAN for REPORTED FCOI

- 7.1 Upon identification of potential FCOI after review of disclosed SFI's, the NCORP Administrator and NCORP President will further investigate and discuss the potential FCOI with the Investigator and draft a "management plan." These written plans will manage, reduce or eliminate the significant financial interest(s). Such plans will be designed to facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information. Final management plans are reviewed and approved by the NCORP President.
- 7.2 Key elements of the management plan will include:
 - a. The role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan;
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan;
 - e. How the management plan will be monitored to ensure Investigator compliance; and
 - f. Other information as needed.

8.0 RETROSPECTIVE REVIEW AND MITIGATION REPORT

- 8.1 If bias is found or a FCOI is not identified or managed in a timely manner, including:
 - a. Failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a Financial Conflict of Interest;
 - b. Failure by the Institution to review or manage such a Financial Conflict of

- Interest; or
 - c. Failure by the Investigator to comply with a Financial Conflict of Interest management plan;
- 8.2 Within 120 days of the Institution's determination of noncompliance, a "retrospective review" will be completed of the Investigator's NIH-funded research activities conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.
- 8.3 Key elements for documenting the retrospective review must include:
- a. project number;
 - b. project title;
 - c. Principal Investigator contact
 - d. Name of Investigator with FCOI
 - e. Name of the entity with which the Investigator has a financial conflict of interest
 - f. Reason(s) for the retrospective review;
 - g. Detailed methodology used for the retrospective review
 - h. Findings of the review; and
 - i. Conclusions of the review.
- 8.4 If bias is found, the Institution must notify NIH promptly and submit a "Mitigation Report" to the NIH. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g. disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations). Thereafter, FCOI reports will be submitted annually as prescribed in the regulation.