Policy Name: Participant Categories	**Policy Number:** 3.1
Section: Participants – 3	**Date Revised:** December 16, 2024

3 Participants

Individual members of the Alliance fall into three categories: institutional, staff (Alliance operations, statistics and data management), and special member.

3.1 Participant Categories

Institutional members belong to an Alliance member institution and are involved with Alliance studies. This category includes the following**:**

- Principal investigators
- Investigators in all modalities and disciplines
- Pharmacists
- Clinical research professionals and oncology nurses
- Coordinators (e.g., pharmacy, radiation oncology, imaging, surgery, pathology)
- Cytogeneticists
- Administrative staff
- Laboratory researchers
- Fellows in oncology-related disciplines

Alliance staff may be located at an Alliance institution, but are responsible for group functions, including network group management, protocol development, regulatory affairs, statistical support and management of group data. This category includes Alliance operations and program staff as follows:

- Statistics and Data Management Center
- Operations Center
- Central Protocol Operations Program
- Cancer Control Program
- Procedure Based Therapy Program
- Translational Research Program
- Biorepositories

Special members are not located at an Alliance institution but interact with other Alliance participants in group activities. This category includes the following:

- Laboratory personnel handling Alliance samples at a non-Alliance institution
- Imaging/RT personnel evaluating data from Alliance studies
- Active participants relocated to non-Alliance member institutions (e.g., a study chair who has moved to a non-Alliance institution but is continuing to serve as chair)
- Patient advocates

- Investigators who participate in Alliance committees or studies but are not located at Alliance institutions
- Consultants who provide advice to Alliance leadership/committees within their area of expertise but do not actively participate in the research of the research programs of the group
- Data and Safety Monitoring Board (DSMB) members
- Representatives from federal agencies (FDA, NIH, etc)

3.2 Membership and participant registration

3.2.1 Applying for membership and registration

The institutional membership application is available on the Alliance public website (http://www.allianceforclinicaltrialsinoncology.org).

The lead Clinical Research Professional (CRP) or Secondary Lead CRP is responsible for adding and withdrawing all institutional members via CTSU Roster Update Management System (RUMS) or NCORP-SYS.

NCI policy requires all persons participating in any NCI sponsored clinical trial to register and renew their registration annually. Registration is accomplished via the NCI Registration and Credential Repository (RCR). RCR utilizes five person registration types:

- **Investigator (IVR)** — MD, DO, or international equivalent
- **Non-Physician Investigator (NPIVR)** — advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD)
- **Associate Plus (AP)** — clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications (e.g., RUMS, OPEN, RAVE, TRIAD)
- **Associate (A)** — other clinical site staff involved in the conduct of NCI-sponsored trials
- **Associate Basic (AB)** — individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems

All Investigators (IVRs), Non-Physician Investigators (NPIVRs), and Associate Plus (APs) are required to obtain Human Subjects Protocol and Good Clinical Practice (GCP) Training to be in compliance with the NIH. The training provider, course title, completion date, and expiration date, if applicable, and the provider's training certificate must be uploaded in the NCI Required Training subsection of the NCI Biosketch.

All persons applying for Alliance membership must obtain an NCI/CTEP-I.D me account, access the RCR system, and complete an annual NCI person registration.

Additional details are available on the CTEP website https://ctep.cancer.gov/investigatorResources/default.htm. Alliance leaders and committee chairs may request special membership for an individual. The request is sent to the Operations Center.

3.2.2 Alliance person database

The CTSU maintains a database of all Alliance individual members in the Regulatory Support System (RSS).

The institutional principal investigator and the lead CRP are responsible for ensuring that the roster of institutional members is accurate and up-to-date, utilizing the CTSU Roster Update Management System (RUMS) and providing timely notification to Alliance of changes to PIs and lead CRPs.

Alliance staff claim individual members as "persons" in the Alliance roster and ensures the accuracy of the Alliance person roster.

The Alliance may release portions of the roster to persons who are not Alliance members upon approval by the Alliance group chair or designee. Individuals who wish to request the roster should send a request and justification to the chief operating officer.

Policy Name: Traveling on Official Alliance Business	**Policy Number:** 3.3
Section: Participants – 3	**Date Revised:** December 16, 2024

3.3 Traveling on official Alliance business

Alliance members whose travel expenses are paid by an Alliance grant must follow federal guidelines regarding reimbursement of travel expenses. Each institutional grants and contracts office that reimburses travel has its own policy regarding how federal travel funds are to be reimbursed. Please refer to the specific grants and contracts office of the institution that is funding travel expenses for instructions on how to file expense reports.

For information on travel support available from the Alliance, see the Alliance Travel Policy (refer to the Alliance website under Meetings). In addition to support for travel to group and committee meetings, the Alliance also provides travel support for the institutional audit program.

3.4 Individual scientific misconduct

The integrity of Alliance data is dependent upon the work of many individuals at all levels of the group. No event is more damaging to the reputation of the clinical research that Alliance and the other network groups perform than the discovery of submission of false or fraudulent data. Inclusion of such data in our analyses may invalidate the scientific conclusions reached. These invalid conclusions may result in the setting of inappropriate medical practice standards consigning large groups of patients to inferior therapy. Moreover, the violation of the trust between the patient and the healthcare team by such an event will erode the relationships required for conduct of clinical trials and harm the public's perception of all medical investigations. As such, evidence of any systematic or intentional attempt to submit false data of any sort to the Alliance will be dealt with in the most rapid and vigorous manner possible. In addition to withdrawing Alliance membership from those affected, and suspending accrual from the institution(s), the Alliance will assist appropriate governmental bodies in the prosecution of the individuals involved.

The Alliance publicizes its policies concerning scientific misconduct in a variety of forums, including the group meeting sessions, the group newsletter, and other means. Specific training sessions in ethics for investigators, clinical research professionals, statisticians, and other personnel are offered.

This training includes instructions on means whereby Alliance members can bring possible instances of scientific misconduct to the attention of those required to investigate it, how to deal with improper data that may have been recorded, and how to correct, if necessary, the scientific record based upon data that are inaccurate.

3.4.1 Receipt of allegations of scientific misconduct

Individuals who have been asked to falsify data or who believe they have knowledge that others are falsifying data must inform the Chief Operating Officer (COO) at the Alliance as soon as possible via whatever means (phone, letter, fax, e-mail, personal contact) is practical. The COO completes a detailed accounting of the notification. If this notification occurs by phone, the COO asks the party making the call if a witness to the call is desired. The policies of Alliance and NCI require a thorough investigation of any allegation of scientific misconduct while at the same time taking whatever actions are reasonable and proper to preserve the confidentiality of the informant and, until misconduct is proven, to protect the reputation of those accused. Although anonymous calls for the purpose of notification are discouraged since they may lead to less effective resolution of the matter, they are, nevertheless, accepted. This notification does not supersede or replace any notification also required by the institution from which the report originates. Alliance participants should contact the grants and contracts offices of their institutions to ascertain the correct procedures for reporting such matters at their institution.

3.4.2 Processing of allegation within Alliance

Upon receipt of an allegation of scientific misconduct, the COO immediately brings the matter to the attention of the group chair or, in the absence of the group chair, the group vice chair.

When notification is complete, the group chair, group vice chair, or CO O immediately contacts the Cancer Therapy Evaluation Program (CTEP) Clinical Trials Monitoring Branch to report the incident. Subsequent to this notification, other actions may be required. These may include the immediate suspension of accrual to protocols in the involved institution and further investigation (see below).

3.4.3 Investigation of the allegation

In concert with NCI or other agencies, Alliance develops and implements a plan to investigate the allegation. This investigation usually consists of a thorough audit (see section 2.8).

The terms to be used by various committees and officers in connection with the investigation of possible episodes of scientific misconduct have been deliberately chosen to remove any restriction or impediment to whatever action Alliance committees, Executive Committee and Board of Directors may eventually choose to take in a given case. The Alliance may take action against a participant or institution independently whether or not the individual is found guilty in civil or criminal proceedings by others.

The terms used in the audit section of these policies to define institutional performance are used to describe adherence to protocol as well as the quality of data and other submitted materials. In this section we distinguish between erroneous data that result from unintentional mistakes and omissions, and data that are systematically erroneous or untrue.

It is acknowledged that in any process as complex as clinical research occasional errors of many sorts may occur. These may include typographical mistakes, miscalculations of numeric data, omissions of tests, doses, or procedures, delays of treatments, etc. These events when encountered are characterized by the terms used in the audit section and may generate actions concerning the institution as specified elsewhere in these policies.

Falsification of information is to be distinguished from inaccuracies arising from sources noted in the preceding paragraph. Examples include an ineligible patient falsely made eligible, a non-responding patient said to have responded, an abnormal laboratory result made normal, omitted doses of treatment said to have been given, etc. When wrong information is provided systematically, intent to deceive may be inferred. Occasional divergences of opinion among investigators are to be expected in any clinical trial, and data

arising from such divergences are to be distinguished from those that are systematic attempts to deceive. When necessary, the Alliance Audit Committee, Institutional Performance Evaluation Committee, Membership Committee, Executive Committee, and Board of Directors render judgment as to whether a given problem represents scientific misconduct and take appropriate actions as defined elsewhere in these policies.

Notwithstanding procedures for revoking membership, halting institutional accrual, or taking other action as defined in these policies or in the Alliance Constitution and Bylaws, the Alliance group chair takes immediate action as defined here when allegations or proof of scientific misconduct occurs within Alliance.

3.4.4 Actions to be taken if allegation of scientific misconduct is proved

If false data have been submitted to the Alliance Statistics and Data Management Center, the data are segregated and reviewed. The SDMC staff is responsible for determining what data changes may be required (see also section 2.8).

3.4.5 Publication and retractions

If the data have been used in any analyses in preparation of an abstract, the abstract will be revised, if possible, based on a new analysis without the suspect data, or a disclaimer will be offered during the presentation of the revised data. If such data have been used for preparation of a manuscript, the paper will be withdrawn until a new analysis can be conducted. If the manuscript with the false data has been published, the journal will be asked to publish a retraction and re-analysis at the earliest possible time.

It is understood that correction of published information derived from flawed data is of great importance to the public and the scientific community. The Alliance will issue such corrections to relevant journals within 30 days of the time that false data are discovered, or with CTEP consent, whenever a re-analysis can be completed. In addition Alliance has agreed to make its computer data and documentation available to CTEP for analysis when necessary in a national health emergency.

3.4.6 Actions against individuals

An allegation of scientific misconduct may result in immediate action on the part of the group chair to suspend patient registrations by a participant or a member institution. Subsequently, possible actions relevant to institutions occur through usual committee processes described elsewhere in these policies.

Allegations of scientific misconduct by individuals are brought by Alliance staff, the Audit Committee, or others to the Alliance Executive Committee for investigation. Those accused may be asked to appear before the Committee. In such matters, because of the possibility of injury to patients or the public health, time is of the essence. The Executive Committee sets the schedule for the appearance and testimony of the accused. On the basis of the investigation, the Committee may either take no action or may make recommendations to the Alliance Board of Directors. Recommendations to the Board may include severing the membership of the accused, removing the accused from study chairmanship or authorship, censure, or any other action the Executive Committee feels is appropriate.

The accused is provided with the written recommendation of the Executive Committee to the Board. At the meeting of the Board, or in writing prior to the meeting, the accused may offer a rebuttal of the Executive Committee recommendations, but may not offer evidence not previously considered by the Executive Committee. The Board acts on the recommendation of the Executive Committee, accepting it, rejecting it, or changing it, as the Board deems appropriate.

3.4.7 Confidentiality

The action of the Board is final and is a matter of record. It is documented in the minutes of the Board and communicated to the relevant Alliance institution. The deliberations of the Board, the Executive Committee, evidence and audits collected by the committees of the group, and the statements of the accused are held confidential by the Alliance. However, any and all evidence of misconduct is shared with the NCI and/or other appropriate governmental bodies.

Policy Name: Conflict of Interest	**Policy Number:** 3.5
Section: Participants – 3	**Date Revised:** December 16, 2024

3.5 Conflict of Interest

3.5.1 Introduction

A financial conflict of interest (FCOI) in research means a significant financial interest that could directly and significantly affect the design, conduct, analysis, or reporting of research. The Alliance for Clinical Trials in Oncology has implemented procedures designed to "promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest.[i]"

3.5.1.1 Policy

This **POLICY** intends to provide well-defined and transparent requirements for disclosures of conflict of interest, the administrative processes for reviewing the disclosures, and procedures for identifying potential, perceived, and actual conflicts of interest. This POLICY will identify when a management plan will be implemented, when an Investigator may be precluded or limited from participation in Alliance activities, and for maintaining such records.

3.5.1.2 Scope

The Alliance Study chairs/Co-chairs, Committee chairs/Vice chairs, Board of Directors, Executive Committee, Group leaders, Data and Safety Monitoring Board, Main Member Principal Investigators, Institutional Investigators, members of the Statistics and Data Center, and Alliance operations staff members, including Executive Officers, must comply with this POLICY.

3.5.1.3 Disclosure

3.5.1.3.1 Disclosure Requirements

Financial arrangements >$5000 per year must be disclosed and submitted as outlined in this POLICY. Disclosures are for the 12 months preceding the date of the disclosure. An Alliance Conflict of Interest form must be completed before participation in research activities and attending group meetings. and at least annually and more depending on the role within the Alliance. For example, Study leaders are required to submit Conflict of Interest disclosure forms before study activation and annually until the study results are published; Authors are required to submit Conflict of Interest disclosure forms before manuscripts will be approved by the Alliance publication committee; and before abstracts can be presented. Conflict of Interest disclosure forms are required before study concept

submission. Updated Conflict of Interest disclosure forms are required to be submitted within 30 days of material changes in financial arrangements.

3.5.1.4 Management of De Minimus and Maximum Thresholds

The Alliance manages financial interests that fall between Public Health Service Policy (PHS) the de minimus threshold and the Food and Drug Administration maximum threshold.[ii]

3.5.1.5 Training

On an annual basis, the Alliance will provide Conflict of Interest training to Investigators and staff by distributing this POLICY. Additionally, this POLICY is available on the Alliance website (https://allianceforclinicaltrialsinoncology.org/P&Ps/Chap3) and will be available during the annual Alliance Group Meetings. The Alliance reserves the right to require additional training, as necessary. Financial Conflict of Interest training and review of the Alliance Conflict of Interest (COI) POLICY is requisite for participation in research activities.

3.5.1.6 Alliance Member Responsibilities

Members should recognize financial arrangements that may be perceived as potential or actual Conflicts of Interest. These include personal investments or other business relationships, including those of the members' Immediate Family and the connection between the Alliance Group structure and the members' involvement. It is expected that material conflicts of interest will be resolved before an individual assumes leadership roles within the Alliance.

3.5.1.7 Roles within the Alliance

Table 3-1. provides general guidance on the management of potential, perceived, or actual Conflicts of Interest based on the roles within the Alliance and the linkage between the Conflict of Interest and the drugs, devices, technology, and/or therapies currently under or will be under investigation by the Alliance.

All Financial arrangements of the Investigator/Individual and those of their Immediate Family Member with shared income of >$5000 per year must be disclosed.

Table 3-1. Alliance Roles and General Management of Financial Conflicts of Interest

ROLE	**GENERAL MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST (FCOI)** *The Alliance reserves the right to modify the Management of FCOI at any time as it deems necessary*
Group Chair (GC)/ Vice Chair (VC), Program Directors (PD) and Executive Committee Members (EC)	FCOI with financial relationship>$25,000 (such as compensation) per year in a privately held business, and/or equity interest in a publicly traded company sponsor >$50,000 per year, or ≥5% ownership interest (including common stock) in either a privately held or publicly traded business, that has a product currently under investigation, in consideration of investigation or in direct competition with products under investigation with the Alliance must: • Disclose their conflict; and • Recusal from discussions and voting if a topic presents a conflict or an appearance of a conflict
Study Chair/ Study Co-Chair	FCOI with financial relationships>$5000 to ≤$25,000 (such as compensation), and/or equity interest in a publicly traded entity ≤$50,000 per year that has a product/s currently under investigation in a trial in which they serve as a study chair or study co-chair requires the implementation of a Management Plan consisting of the following: • Public disclosure of their conflict at meetings/presentations and for publications when engaged in Alliance activities • A copy of the Investigator's Institutional Management Plan for review by the COI Committee • Depending on the impact of the FCOI, they may be required to recuse themselves from discussions involving the entity in which they have a conflict • The assignment of a non-conflicted study co-chair is required, and the study co-chair or their designees are required to take a significant role in reviewing data and preparing study results for publication or presentation FCOI that have **one** or **more** of the following: the Investigator will be prohibited from serving as a Study Chair or co-chair on the study(while the study is under development, newly activated, or ongoing and accruing subjects) and this will remain in effect for one year following the completion of the study.[iii] • Personal payment >$25,000 per year from an entity in which they have a product/s under investigation in a study in which they have a material role; • Any financial arrangement in which the value of compensation could be influenced by the outcome of

	the study. • Equity interest in a publicly traded entity in which they have a product under investigation in the trial of >$50,000 per year, or ≥5% ownership interest in a public or privately held entity (including common stock) or direct employment with an industry partner. The Management Plan for the Study Chair or Study Co-Chair with a FCOI at the **maximum threshold** will be implemented and include the following: • The Committee chair will appoint a new study chair who is non-conflicted to assume responsibility for study oversight. The new study chair and the study statistician will assume primary responsibility for data management, analysis, and presentation and publication of study results • Public disclosure of their conflict at meetings/presentations and for publications when engaged in Alliance activities • A copy of the Investigator's Institutional Management Plan for review by the COI Committee • Recusal from discussions involving the entity in which they have a conflict.
Disease Discipline and Modality Committee Chairs/ co-Chairs and Vice Chairs	FCOI of >$5000 to ≤$25,000 (such as compensation) and/or an equity interest in a publicly traded by entity ≤$50,000 per year, in which they have a product under investigation in the trial requires the implementation of a Management Plan consisting of the following: • Public disclosure of their conflicts at meetings/presentations and for publications when engaged in Alliance activities • A copy of the Investigator's Institutional Management Plan for review by the COI Committee • Depending on the impact of the FCOI, they may be required to recuse themselves from discussions involving the entity in which they have a conflict FCOIs with **one** or **more** of the following, the Investigator *will be prohibited* from serving as the *Committee Chair (or the Committee co-Chair or Vice Chair)* sponsoring a study (while the study is under development, newly activated, or is ongoing and accruing subjects) and this will remain in effect for one year following the completion of the study. • Personal payment of >$25,000 per year from an entity

	that has a product/s under investigation in the trial in which they have a material role. • Any financial arrangement in which the value of compensation could be influenced by the outcome of the study • Equity interest in a publicly traded entity in which they have a product under investigation in the trial of >$50,000 per year or ≥5% ownership interest in a public or privately held entity (including common stock) or direct employment with an industry partner. The Management plan that will be implemented for a FCOI at the maximum threshold for the Committee Chair (co-Chair or Vice Chair) includes the following: • The Vice-chair or designee will assume responsibility for study oversight • Public disclosure of their conflict at meetings/presentations and for publications when engaged in Alliance activities. • A copy of the Investigator's Institutional Management Plan for review by the COI Committee • Recusal from discussions involving the entity in which they have a conflict
Data Safety Monitoring Board (DSMB)	**At each DSMB meeting:** FCOIs >$5000 to ≤$25,000 (such as compensation) and/or equity interest in a publicly traded entity ≤$50,000 per year that has a product/s in a trial under review: Each member will verbally disclose any conflicts pertinent to studies under review. FCOI >$25,000 (such as compensation) and/or >$50,000 per year or >5% ownership interest including stock options or other forms of equity interest from a public or private entity that has a product/s in a trial under review. Each member will verbally disclose their conflict/s and recuse themself from discussions from the pertinent studies under review
Executive Officers (EO) and Statistics and Data Management (SDMC) Trial Statisticians	FCOIs with **one** or **more** of the following, the individual will no longer be involved with any aspect of the study in which there is a conflict (while the study is under development, newly activated, or ongoing and accruing subjects). This will remain in effect for one year following the completion of the study. • Personal payment of >$25,000 per year from an entity that has a product/s under investigation in the trial in which they have a material role;

	• Any financial arrangement in which the study's outcome could influence the value of compensation • Equity interest in a publicly traded entity with a product/s under investigation in the trial of >$50,000 per year, or ≥5% ownership interest (including common stock), or direct employment with an industry partner Requires: • Public disclosure of conflicts at meetings/presentations and for publications when engaged in Alliance activities. • A copy of the Investigator's Institutional Management Plan for review by the COI Committee
Alliance Operations and SDMC Members	FCOI with financial relationships >$25,000 (such as compensation) per year in a privately held business and/or equity interest in a publicly traded company sponsor >$50,000 per year, or ≥5% ownership interest (including common stock) in either a privately held or publicly traded business that has a product currently under investigation, in consideration of investigation or in direct competition with products under investigation with the Alliance; a Management Plan will be implemented that may include the following: • The individual will no longer be involved with any aspect of the study in which there is a conflict (while the study is under development, newly activated, or ongoing and accruing subjects). • The individual will recuse themselves from any discussions about the trial or trials. • Public disclosure of the conflict/s at meetings/presentations and for publications when engaged in Alliance activities This will remain in effect for one year after the conflict no longer exists.
Main Member Institutional Principal Investigator (Board of Directors), Investigators participating in Alliance studies	The COI committee may request an Institutional management plan from investigators with multiple disclosures of >$5000 or exceeding the threshold from one or more entities.
Institutional Investigator	Financial conflict disclosures of institutional investigators are subject to institutional conflict of interest policies. The Alliance may request a management plan from investigators exceeding thresholds, including documented institutional management plans in compliance with institutional requirements. The Alliance may disapprove of the study participation of institutional investigators exceeding maximum thresholds upon review of the institutional plan to mitigate bias.

3.5.2 Decisions on matters of conflict of interest

It is not possible for this POLICY to provide guidelines for every situation that could give rise to a potential, perceived, or actual conflict of interest. For this reason, the Conflict-of-Interest Committee is broadly charged with using the guidance of the definitions and the roles offered in the tables to arrive at a recommendation that is consistent with regulations and takes all reasonable steps to ensure any potential bias is minimized or eliminated. In this activity, the Conflict-of-Interest Committee members understand the committee has considerable latitude and flexibility with respect to rendering its decisions.

Table 3-2. Definitions

Term:	Definition
Conflict of Interest (COI)	A professional, proprietary, and/or financial arrangement on the part of an individual, their spouse, domestic partner, dependent children, and other dependent family members with whom the individual directly shares income, which may directly and significantly affect the design, conduct, analysis, or reporting of research. A COI can be potential, perceived, or actual.
De Minimus Threshold [1]	The Public Health Service (PHS) defines a significant financial interest >$5000 related to the investigator, their spouse, and dependent children that must be disclosed: • For publicly traded entities: the value of any remuneration received from an entity in the twelve months preceding the disclosure is >$5000 per year, and any payment for services not otherwise identified as salary (e.g., consulting fee, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value. • For a non-publicly traded entity: significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated is >$5000, or when the investigator holds any equity interest (e.g., stock, stock options, or other ownership interest); or • Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. • Reimbursed or sponsored travel related to their institutional responsibilities; however, disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institute of higher education. The term does not include the following:

[1] Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

	• Salary, royalties, or other remuneration from the applicant institution; • Any ownership interests in the institution if the institution is an applicant under the SBIR Program (42 CFR 50 (F): Promoting Objectivity in Research)
Disclosure requirements	For purposes of this POLICY, a disclosure includes compensation received >$5000 in the 12 months preceding the date of the disclosure.
Financial Arrangement	Anything of monetary value, whether or not the value is readily ascertainable remuneration or in which any person has an ownership or equity interest.
Financial Conflict of Interest (FCOI)	A financial conflict of interest (FCOI) in research may exist whenever an Investigator or immediate family member with shared income has a direct or indirect interest or financial relationship, with an Entity that may conflict, be perceived as conflicting or be inconsistent with the Investigators duties, responsibilities or ability to exercise judgment in any Group Research.
Immediate Family Member	Includes a spouse, domestic partner, dependent children, and other dependent family members with whom the individual directly shares income
Institution	Any domestic or foreign, public, or private entity or organization (excluding a Federal agency) that is applying for or that receives PHS research funding.
Investigator	Any person who is responsible for the design, conduct, analysis, or reporting of research. The investigator must disclose potential conflicts of interest and/or related financial arrangements of any individual with whom the investigator directly shares income (e.g., spouse, children, or domestic partner).
Management of Financial Conflicts of Interest (FCOI)	Taking action to address (FCOI) can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias, *See* Management Plan
Management Plan	A documented plan of action is implemented to ensure, to the extent possible, unbiased data collection and to mitigate potential, perceived, or actual conflicts of interest by protecting the integrity of the research surrounding the design, conduct, analysis, or reporting of research conducted by the Alliance.
Material Changes	For purposes of disclosing financial arrangements >$5000, material changes include decreases or

	increases to previously reported amounts or new arrangements not previously reported.
Maximum Threshold	Significant Financial Interests (SFI) is when an investigator cannot be involved in the development and management of a clinical trial. The FDA defines significant financial interest related to the investigator, spouse, and dependent children to include the following: • Payments from the sponsor in >$25,000 per year *during* the research and *for one year after*, not including compensation for research costs. • Any financial arrangement in which the value of compensation could be influenced by the outcome of the study. • Equity interest in a publicly traded corporation >$50,000 a year during the time of research and one year after. Any ownership interest, stock options, or other financial interest in a non-publicly traded company whose value cannot be readily determined through reference to public prices. [iv]
Ongoing Affiliation	Relationship with an entity having a role in the development or sale of a product or technology, including entity/organization holding *patents, trademarks,* or *licenses* for the development or sale of research products.
Public Health Services (PHS)	Public Health Service ("PHS") of the US Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institute of Health ("NIH").
Professional Interest	Involvement (current or prior) in the development of a product, technology, or service with an entity being studied by the Alliance, or in consideration for Alliance-related activities or where the product, technology, or service competes with a product, technology, or service under consideration by the Alliance. Financial relationships with the entity having a role in the development or sale of a product or technology, including organizations holding *patents, trademarks,* or *licenses* for the development or sale of research products, including service as an *Officer, Director, Trustee, Partner, Employee* or on a *Scientific Advisory Board* or in a similar capacity for such an organization. An entity the investigator is negotiating for or has an arrangement on prospective employment or affiliation or compensation >$5000 annually for services such as *honoraria, consultative services, paid authorship* either by the entity or a third party (medical services companies or

	continuing medical education companies) Receipt of *unrestricted educational grants* of ≥$100,000 over a three-year period for research funding not designated for a particular study or contracted product through their employee institution, i.e., the funds are not managed by the institution but are managed by the investigator. All non-government or non-academic travel reimbursement from a for-profit entity (*See* reimbursed or sponsored travel)
Proprietary Interest	The investigator has a financial interest in the research product being evaluated because the investigator or an Immediate family member has: a). a material interest in the product or technology that may result in financial gain, e.g., the investigator is receiving compensation that could be affected by study outcome, such as compensation that is explicitly greater for a favorable result or the investigator is receiving annual royalties or other compensation at a value exceeding $5000 per year following the commercial sale of the product or technology. Such royalties may be in the form of personal compensation to the investigator or may be used to support the investigator's research. b). an equity interest (including common stock) exceeding $5000 per year, or ≥5% ownership interests (including stock options) in a start-up company, the stock of which is not publicly traded, or options exceeding $5000 per year in a commercial enterprise that will benefit from the sale of the product or technology.
Research	Any Alliance study under development or ongoing that involves the analysis of a drug, treatment, medical device, technique, or technology and any correlative, biological investigation/s related to such protocols, investigations, or analyses, including any type of publication, presentation, or other public disclosure of results.
Reimbursed or Sponsored Travel	Non-government or non-academic travel reimbursement from a for-profit entity for the Investigator and/or Immediate Family Member. For the purposes of this POLICY. the following must be disclosed: the purpose of the trip, sponsor/entity, destination/duration, and any additional information as requested.
Research Product	A drug, treatment, medical device, technique, or technology that will be or is currently under

	investigation by the Alliance.
Significant Financial Interest (SFI)	A Financial Conflict of Interest (FCOI) in research is present when a Significant Financial Interest (SFI) affects or could appear to affect, the professional judgment of a researcher when designing, conducting, or reporting research. For purposes of this POLICY, any remuneration when aggregated >$5000 is considered an SFI.
Sponsor funding the study	For purposes of financial disclosure, "sponsor of the covered clinical study" means the party providing all or some kind of support (funding, drugs, devices, assays, etc.) for a particular study when it was conducted.
Unrestricted research/ educational grant	Receipt of $100,000 or more over a three-year period for research or an educational grant that is not designated for a particular study or educational program. The funds are “unrestricted” and are managed by the investigator. *See* Professional Interest

3.5.3 Review of Disclosure Statements

The Conflict-of-Interest Committee meets no less than twice per year and reviews the disclosure statements. The Committee provides recommendations concerning conflicts of interest to the Alliance Executive Committee.

3.5.4 Actions on conflict of interest

The Executive Committee provides recommendations to the group chair on actions to be taken involving conflicts of interest.

3.5.5 Penalties for failure to observe the conflict-of-interest policy

Lack of compliance with this POLICY is referred to the Alliance Executive Committee. The Executive Committee will conduct and complete a retrospective review within 120 days of identified noncompliance and document its findings. The Executive Committee will recommend appropriate corrective action, which will be presented to the Alliance Board of Directors. The Board of Directors will review the recommendation and will either accept or modify the corrective action. Failure to submit conflict of interest forms or to comply with a Management Plan by individuals subject to this POLICY may result in suspension or termination of Alliance membership privileges, including serving as a study or committee chair.

3.5.6 Public disclosure

Financial conflicts of interest must be disclosed in *any* public presentation of research results. Financial conflicts of interest must be disclosed during Alliance committee meetings, including study development discussions. In addition, the Alliance will make information about financial conflicts of interest publicly available within five business days of a written request to AllianceConflictOfInterest@alliancenctn.org. Questions about this POLICY may be sent to the same address.

3.5.7 Record Retention

Records of all financial disclosures and any actions the Alliance took concerning the disclosures, including the recommendations by the Conflict-of-Interest Committee reported to the Executive Committee, will be maintained for at least three years after the grant has ended.

3.5.8 Reporting Financial Conflicts of Interest (FCOI)

The Alliance reports Financial Conflicts of Interest (FCOI) that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

The Alliance submits Conflict of Interest disclosures to the Cancer Therapy Evaluation Program (CTEP), as a part of the Central Institutional Review Board (CIRB) Submission. A management plan is provided as appropriate.

The Alliance provides a Financial Conflict of Interest report to the awardee Institution receiving Alliance grants according to the requirements of the Institution.

3.5.9 Alliance Conflict of Interest Committee

The Alliance Conflict of Interest Committee is a volunteer committee appointed by the Group Chair. The Conflict-of-Interest Committee is comprised of Alliance investigators and staff. The committee reviews the financial conflict of interest disclosure forms related to research supported by the Alliance and Alliance for Clinical Trials in Oncology Foundation, reviews the information on the disclosure forms, and provides recommendations to the Executive Committee on Management of Conflicts of Interests identified. The Executive Committee considers these recommendations and may request additional information prior to rendering a decision.

End of Chapter Notes

Examples of Financial Conflicts of Interest

- The investigator or sponsoring committee chair or vice chair has played a substantial role in the prior development of the product or technology being studied by the Alliance.

- An Investigator submits a study proposal using two agents; one is under an IND, and the other is commercially available. The investigator is in the speaker's bureau for the company with the agent under an IND and a consultant for the agent that is commercially available. A third party reimburses the investigator.

- An Investigator's spouse is employed by an organization that has a product frequently used in Alliance research. The spouse has employee stock options with a value of >$150,000. The Investigator is a co-chair of a study that will use an agent from his/her spouse employer. A favorable outcome would add another indication of use for the agent.

Additional Information on Conflict-of-Interest Management Plans

1. Independent review of study by Cooperative Group or Network Group beyond Disease Committee	An independent review of studies by network group leadership beyond the sponsoring committee will be undertaken.
2. Independent Review by NCI	CTEP will be informed of the Management Plan for a Study Chair/ Study (3 below)
3. Independent review by the Data Safety Monitoring Board	Independent review by a Data and Safety Monitoring Board (DSMB) will continue for all phase III trials. For the studies that have a study chair with a conflict, the Management Plan will be shared with the DSMB before the review of the study. A representative from CTEP will participate in DSMB meetings and have access to this information at that time.
4. Trial Management of data Independent of the Study chair	For non-DSMB monitored studies, no aggregate outcome data is shared with the study chair until it is deemed ready for sharing by the trial statistician. The study statistician, the study co-chair or his or her designee, and the professional staff of the Alliance Statistics and Data Management Center will undertake the management of data independently of the study chair.
5.Any Additional measures proposed by the Group	• Public disclosure of conflict of interest at meetings/ presentations and publications • Recusal from deliberations • Sharing Institutional Management Plan • Divestiture of the conflicting interest

General Elements that pertain to assuring unbiased data collection and review in Group Trials for Study Leaders with Conflicts >$5K-$25K (*Taken from the Conflict-of-Interest Policy for NCI/DCTD-Supported Cooperative Group or National Clinical Trials Network Randomized Phase 2 or Phase 3 Clinical Trials,* August 2012)

Other Considerations for the Conflict-of-Interest Committee

- Committee chairs with financial interests in products actively under investigation or proposed in committee-sponsored studies may be required to publicly disclose potential conflicts and/or recuse themselves from relevant discussions.
- Alliance leaders may have individual financial interests related to industry partnerships or other affiliations that do not exceed the threshold of $25,000. However, multiple disclosures of >$5000 are subject to review by the Alliance COI Committee. The Committee may recommend a management plan that includes oversight by co-leaders.
- If all of the key individuals of a study show a significant conflict of interest such that they are ineligible for authorship, the COI committee will be asked to provide a recommendation. Under these circumstances, it is possible the COI Committee will prepare a report for adjudication by the Executive Committee.

Authorship (*See* Publications Policy No 10.0)

- An individual with a conflict of interest may lose authorship rights on a publication. In general, an individual with a significant conflict of interest such that they are ineligible for a study chair or co-chair role cannot serve as either the first, corresponding, or senior (last) author of an Alliance publication.
- When a conflict exists with the Committee chair or Vice-chair, the committee leader may not serve as either first, corresponding, or senior author.
- However, an investigator may be precluded from authorship due to the magnitude and nature of an FCOI. Under this circumstance, the Investigator would likely have had prior notification of this determination.

[i] 42 CFR 50.603 (F), Promoting Objectivity in Research.
[ii] 42 CFR 50(F); 21 CFR § 54.2 (f), *Conflict-of-Interest Policy* for NCI/DCTD-Supported Cooperative Group or National Clinical Trials Network Randomized Phase 2 or Phase 3 Clinical Trials, August 2012)
[iii] 21 CFR § 54.2 (f) states the FCOI exists during the time the clinical investigator is carrying out the study and for *one year* following the *completion* of the study
[iv] *Id,* Financial Disclosure by Clinical Investigators