

Policy Name: Participant Categories	Policy Number: 3.1
Section: Participants – 3	Date Revised: January 1, 2018

3 Participants

Individual members of the Alliance fall into three categories: institutional, staff (Alliance operations, statistics and data), 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 Center
- Office of the Group Chair
- Central Protocol Operations Program
- Cancer Control Program
- American College of Surgeons Clinical Research 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)

Policy Name: Participant Categories	Policy Number: 3.1
Section: Participants – 3	Date Revised: January 1, 2018

- 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)

Policy Name: Membership and Participant Registration	Policy Number: 3.2
Section: Participants – 3	Date Revised: January 1, 2018

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-IAM 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 Office of the Group Chair.

Policy Name: Membership and Participant Registration	Policy Number: 3.2
Section: Participants – 3	Date Revised: January 1, 2018

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 in 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 administrative officer.

Policy Name: Traveling on Official Alliance Business	Policy Number: 3.3
Section: Participants – 3	Date Revised: January 1, 2018

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 the ‘Meetings’ heading). In addition to support for travel to group and committee meetings, the Alliance also provides travel support for the institutional audit program.

Policy Name: Individual Scientific Misconduct	Policy Number: 3.4
Section: Participants – 3	Date Revised: January 1, 2018

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 administrative officer (CAO) at the Alliance as soon as possible via whatever means (phone, letter, fax, e-mail, personal contact) is practical. The CAO completes a detailed accounting of the notification. If this notification occurs by phone, the CAO 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

Policy Name: Individual Scientific Misconduct	Policy Number: 3.4
Section: Participants – 3	Date Revised: January 1, 2018

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 CAO 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 CAO 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.

Policy Name: Individual Scientific Misconduct	Policy Number: 3.4
Section: Participants – 3	Date Revised: January 1, 2018

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 Center, the data are segregated and reviewed. The SDC 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.

Policy Name: Individual Scientific Misconduct	Policy Number: 3.4
Section: Participants – 3	Date Revised: January 1, 2018

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: January 1, 2018

3.5 Conflict of interest

3.5.1 Disclosure

3.5.1.1 Introduction

A financial conflict of interest (FCOI) in research means significant financial interest that could directly and significantly affect the design, conduct, analysis or reporting of research. For Alliance for Clinical Trials in Oncology, each person proposed to hold a leadership or staff role that impacts the design, conduct, analysis or reporting of research results must comply with financial disclosure requirements.

The Alliance study chairs/co-chairs, committee chairs, group leaders, Data and Safety Monitoring Board, institutional investigators and Alliance operations staff members are required to disclose financial arrangements >\$5,000 per year, as defined in this policy.

FCOI training, review of the Alliance Conflict of Interest (COI) Policy and submission of the Alliance COI form must be completed prior to research participation and at least annually. Updated COI forms are required to be submitted within 30 days of a change in financial arrangements. Study specific COI forms must be submitted until study results are published. Alliance training on the COI Policy and other educational materials will be provided during the annual Alliance Group Meeting.

3.5.1.2 Study chairs/co-chairs

Prior to concept submission, proposed study chairs/co-chairs complete the Alliance Conflict of Interest Disclosure Form (see [Alliance website](#)).

The Conflict of Interest Disclosure Form is updated annually or more until the study is published. The Conflict of Interest (COI) Committee, appointed by the group chair, reviews the information on the disclosure form and makes a recommendation to the Alliance Executive Committee concerning possible conflict of interest. The Executive Committee considers this recommendation and, if necessary, additional information, and decides whether a conflict of interest exists that would prevent the individual from serving as a study chair/co-chair. The recommendation of the

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

Executive Committee is sent to the group chair for action. Disclosure is required for all financial arrangements >\$5,000/year.

3.5.1.3 Committee chairs/group leaders/institutional investigators/Alliance staff

The Alliance disease, discipline and modality committee chairs and vice chairs complete the Alliance Conflict of Interest Form annually. Institutional principal investigators of Alliance main members, members of the Executive Committee, and staff (defined as all employees) of the Alliance Statistics and Data Center, Alliance Operations/Program Offices also complete the disclosure statement.

This statement is updated annually or more frequently when it is deemed necessary by the individual involved. The COI Committee reviews all disclosure statements. The COI Committee makes recommendations to the Executive Committee concerning possible conflicts of interest. The Executive Committee considers the recommendation(s) and, if necessary, additional information, and decides whether action is needed to manage or prevent a potential conflict of interest. The recommendation of the Executive Committee is sent to the group chair for action. Disclosure is required for all financial arrangements >\$5,000/year.

In addition to main member principal investigators, institutional investigators participating in an Alliance study may be required, on a study-specific basis, to disclose financial arrangements as defined in this policy.

3.5.1.4 Data and Safety Monitoring Board

The Data and Safety Monitoring Board (DSMB) members submit the Alliance Conflict of Interest Disclosure Form. At the time of each DSMB meeting each member verbally discloses any conflicts pertinent to studies under review and/or recuses themselves from participation in the deliberations of the DSMB. Disclosure is required for financial arrangements >\$5,000/year.

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

3.5.2 Decisions on matters of conflict of interest

The ramifications of the procedures described in this policy preclude preparing guidelines for every possible situation that could give rise to conflict of interest or the perception thereof. For this reason, the COI Committee is broadly charged with using the guidance of the definitions offered below in arriving at a recommendation that is in the best interest of the public, the patients, and the advancement of science. In this activity, the COI Committee members understand that the committee has considerable latitude and flexibility with respect to rendering its decisions. In arriving at a recommendation as to the presence of actual or perceived conflict of interest the COI Committee uses the following definitions as guidance.

3.5.3 Definitions of potential conflict of interest

- **Research Product.** A research product includes a drug, technique, or technology or medical device.
- **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).
- **Conflict of Interest.** A professional, proprietary and/or financial arrangement on the part of the individual, or any individual with whom the individual directly shares income, that may directly and significantly affect the design, conduct, analysis, or reporting of research.

3.5.3.1 Professional 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. A professional interest may exist not only where the entity's products or services are the subject of Alliance-related activity or otherwise under consideration by the Alliance, but also where the entity's products or services are in competition with those under consideration.

Financial relationships that exist between an individual and a commercial entity in circumstances such as those described below for which compensation is provided in amounts that exceed those listed. A financial arrangement may also exist if the investigator has had a substantial ongoing affiliation with an organization

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

having a role in the development or sale of a product or technology including organizations holding patents to or licenses for the development or sale of research products including instances in which the investigator serves as an officer, director, trustee, general partner, employee, or on a scientific advisory board or in a similar capacity for such an organization. Such organizations also include those with which the investigator is negotiating for or has an arrangement concerning prospective employment or affiliation, or those from which the investigator receives or expects to receive compensation exceeding \$5,000 annually for honoraria, consultative services, paid authorship or from their fiscal intermediaries such as medical services or continuing medical education companies. All non-government or non-academic travel reimbursement from a for-profit entity must be disclosed including the purpose, sponsor/organizer, destination, duration and additional information as needed. Conflict of interest may also exist if an individual receives \$100,000 or more over a three-year period for research funding that is not designated for a particular study or contracted product through their employing institution (i.e., “unrestricted educational grants”). The significance of the conflict will depend, to some degree, on whether reimbursement for professional activities involves compensation limited to that normally required to support the scientific process, or is substantially larger, leading to actual or potential personal financial gain to the investigators or any individuals with whom they directly share income.

An investigator with financial relationships >\$25,000/year in a privately held business, equity interest in a publicly traded company sponsor that exceeds \$50,000/year, or $\geq 5\%$ ownership interest (including common stock) in either a privately held or publicly traded business, will generally be prohibited from assuming chairmanship of a study. An investigator with financial relationships >\$25,000/year or equity interest in a publicly traded company sponsor that exceeds \$50,000/year, or $\geq 5\%$ ownership interest (including common stock) in either a privately held or publicly traded business, who also serves on the Executive Committee must recuse themselves from participation in the deliberations of the Executive Committee where a conflict or appearance of conflict of interest may exist.

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

3.5.3.2 Proprietary interest

The investigator has financial interest in the research product being evaluated because the investigator or any individuals with whom they directly share income has 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 \$5,000/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 in support of the investigator's research.

The investigator has financial interest in the research product being evaluated because the investigator or any individuals with whom they directly share income has an equity interest (including common stock) exceeding \$5,000/year, or $\geq 5\%$ ownership interests (including stock options) in a start-up company, the stock of which is not publicly traded, or options exceeding \$5,000/year in a commercial enterprise that will benefit from the sale of the product or technology.

3.5.3.3 Miscellaneous and multiple financial interests

There may be other instances in which an investigator or any individuals with whom they directly share income has an affiliation or relationship such that objective impartiality could be questioned. In such instances, the investigator should disclose the nature and extent of such affiliation or relationship on the disclosure form.

Alliance leaders may have individual financial interests related to industry partnerships or other affiliations that do not exceed the threshold of \$25,000. Multiple disclosures of $> \$5,000$ are subject to review by the Alliance COI Committee. The Committee may request a management plan including oversight by co-leaders.

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.

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

Committee chairs with financial interests exceeding thresholds defined in this policy may be subject to management plans and restrictions, per section 3.5.4 below.

3.5.4 Management plan for conflicts of interest

Prior to concept submission, study activation, as financial arrangement change and at least annually, all members of the study leadership team are required to complete a Conflict of Interest Form as described above. When the Alliance staff identifies potential conflicts of interest, these issues are referred to the Conflict of Interest Committee for review. If the COI Committee determines that a conflict of interest exists, then the management plan for study leaders with financial arrangements between \$5,000/year and \$25,000/year or equity interest in a publicly traded company sponsor ≤\$50,000/year, outlined below will be enacted to ensure accurate and unbiased data collection and reporting for studies undertaken by the Alliance.

- The study chair and the study statistician jointly oversee all trials. No aggregate outcome data are shared with the study chair until it is released from the DSMB oversight for DSMB monitored studies or deemed ready for sharing based on the trial statistician for non-DSMB monitored studies. For all phase III trials, the study chair does not have access to the raw data except for what is provided in the eligibility and case evaluation summary. When a potential conflict of interest exists for the study chair, the study co-chair or their designees will be required to take a significant role in reviewing data and preparing study results for publication or presentation. These steps will be taken in addition to the existing policy of distributing drafts of all manuscripts to the relevant disease committee members and the Alliance principal investigators for review prior to external submission.
- Independent review by NCI: CTEP will be informed of the COI Committee determination that the potential for a conflict of interest exists on the part of the Study Chair.
- Independent review by a Data and Safety Monitoring Board will continue to be provided for all phase 3 trials. In cases where a potential conflict of interest exists for the study chair, copies of relevant COI findings will be forwarded to the DSMB during their review of the relevant study. A representative from CTEP participates in DSMB meetings and will have access to this information at that time.

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

- The study statistician, the study co-chair, or his or her designee, and the professional staff of the Alliance Statistical Center will undertake management of data independent of the study chair.
- Financial conflict disclosures of institutional investigators are subject to institutional conflict of interest policies. The Alliance may request a mitigation plan from investigators exceeding thresholds, including documented institutional management plans in compliance with institutional requirements. Independent review of studies by network group leadership beyond the sponsoring committee will be undertaken.

In the event of conflicts exceeding the \$25,000 annual threshold or equity interest in a publicly traded company sponsor of \$50,000 annual threshold, or $\geq 5\%$ ownership interest (including common stock), or direct employment with an industry partner, the following policies will be enacted.

- The individual in question may not serve as study chair or co-chair or serve in an oversight capacity as chair of the committee sponsoring the trial if such a conflict is deemed to exist while the study is actively accruing patients and until the primary study analysis has been completed. In this circumstance, the group chair will appoint a new study chair without such a conflict, or when a conflict exists for the committee chair, then the committee vice-chair or their designee will 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.
- The individual with a conflict of interest may retain rights of authorship on publications derived from the study in accordance with the requirements for disclosure of conflicts of interest established by the relevant publishing authorities. Any individuals with a significant conflict of interest such that they are ineligible for a study chair or co-chair role cannot serve as either first, corresponding, or senior (last) author of an Alliance publication. When a conflict exists for the committee chair or vice-chair the committee leader may not serve as either first, corresponding or senior author. If all of the key individuals of a study show a significant conflict of interest such that they are ineligible, then the disclosures are sent to COI committee for review.

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

- The Alliance may disapprove study participation of institutional investigators exceeding maximum thresholds, upon review of the institutional plan to mitigate bias.

3.5.5 Review of disclosure statements

The Conflict of Interest Committee meets no less frequently than once per year and reviews disclosure statements and makes recommendations concerning possible conflicts of interest to the Alliance Executive Committee.

3.5.6 Actions on conflict of interest

The Executive Committee recommends to the group chair actions to be taken with respect to significant conflict of interest.

3.5.7 Penalties for failure to observe conflict of interest policies

Lack of compliance with these policies 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 findings. The Executive Committee recommends whatever action it deems appropriate to the Alliance Board of Directors. The Board of Directors receives this recommendation and takes whatever action it deems appropriate, accepting the recommendation or applying a greater or lesser penalty than that recommended. Failure to submit conflict of interest forms or to comply with COI management plans by individuals subject to the COI policy may result in suspension or termination of Alliance membership privileges including study or committee chairpersonship. Public disclosure

3.5.8 Public disclosure

Financial conflicts of interest must be disclosed in each 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 FCOI information publicly available within five days of a written request.

3.5.9 Record keeping

The Alliance Staff maintains records of all financial disclosures and all actions taken by the Alliance with respect to each conflicting interest for a minimum of three years after the grant period within which the forms were collected has ended. Summary recommendations of the Conflict of Interest

Policy Name: Conflict of Interest	Policy Number: 3.5
Section: Participants – 3	Date Revised: January 1, 2018

Committee are reported to the Executive Committee and become part of the minutes of that committee.

3.5.10 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 COI disclosures to the Cancer Therapy Evaluation Program (CTEP), as a part of the CIRB Submission. A management plan is provided as appropriate.

The Alliance provides an FCOI report to the awardee Institution receiving Alliance grants (e.g., Brigham and Women’s Hospital) according to the requirements of the Institution.

3.5.11 Alliance Conflict of Interest Committee

The Alliance Conflict of Interest Committee is a volunteer committee comprised of Alliance investigators. The committee reviews financial conflict of interest disclosures related to trials supported by the Alliance and Alliance for Clinical Trials in Oncology Foundation.