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ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY INSTITUTIONAL MEMBERSHIP INFORMATION APPLICATION INSTRUCTIONS

Alliance for Clinical Trials in Oncology

The purpose of the Alliance for Clinical Trials in Oncology (Alliance) is to reduce the impact of cancer on people by uniting a broad community of scientists and clinicians from many disciplines, committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer.

The mission of the Alliance is to reduce the impact of cancer by:

- conducting high quality multidisciplinary cancer control, prevention, and treatment trials that engage a comprehensive research network;
- furthering our understanding of the biological basis of the cancer process and its treatment, from discovery, to validation, to clinical practice; and
- providing a scientific and operational infrastructure for innovative clinical and translational research in the academic and community settings.

Alliance Institutional Membership

Members of the Alliance will be institutions meeting all requirements for membership, which include accrual, data quality and timeliness, adherence to Alliance policies and procedures, and participation in Alliance scientific activities.

Institutional membership of the Alliance shall be structured in different levels representing the magnitude of accrual to Alliance trials provided by the member institution. A Main member institution may have affiliate members or may be a stand-alone institution. Affiliate members are institutions that by themselves do not meet the requirements for membership, but are granted membership by virtue of a formal association with a Main member. The Main member network is expected to credit the Alliance for at least 15 patient registrations annually to cooperative group clinical trials. An affiliate member is expected to credit the Alliance for at least 5 patient registrations annually to cooperative group clinical trials.

Each member institution shall have a Principal Investigator (PI), who is primarily responsible for any and all activities related to Alliance at the institution/network. Each Main member institution shall also have a Co-Principal Investigator, who shall assume responsibility in place of the Principal Investigator if for any reason the Principal Investigator is unable to perform duties required for Alliance institutional membership. All Principal Investigators are required to follow

the Alliance Policies and Procedures, including maintenance of current roster data and other membership information.

All institutions must comply with the following regulations and guidelines:

- The *institution must have a Federalwide Assurance (FWA)* from the Office of Human Research Protections (OHRP). Documentation of the FWA must be submitted with the application and must specify the applicant. Sample assurance document forms may be obtained from the OHRP web site: <http://www.hhs.gov/ohrp/assurances/index.html>
- *Audits will be conducted at each institution* and the institution is responsible for collecting all the medical records if the patient was treated at other locations.
- *Each institution will be responsible for ordering and tracking investigational drugs* according to the policies outlined in the National Cancer Institute Investigator's Handbook. The Investigator's Handbook is on the web at the following address: http://ctep.cancer.gov/investigatorResources/investigators_handbook.htm

Membership Application

Institutions must submit the following as part of the membership application:

- Cover Letter from the Principal Investigator of the Main Member that briefly summarizes the following.
 - If applicable, the relationship between the main member and its affiliates
 - If applicable, integration of legacy (ACOSOG, CALGB, NCCTG) programs
 - Patient population
 - Prior clinical research experience
 - Institutional resources for clinical trials
 - Areas of scientific interest, e.g., disease, modality, specific scientific discipline
- A completed Membership Application
- Federalwide Assurance Application/Documentation
- NIH Bio-Sketch/CV for the PI
- List of Investigators and Specialties/Disciplines (e.g., medical oncology, radiation oncology, surgical oncology, etc.)
- List of affiliate sites, if applicable

If the main member is a current member of more than one legacy group (ACOSOG, CALGB and NCCTG), the PI should address the integration of the legacy programs into a combined Alliance membership.

Before completing the application, please confirm with an institutional official that you are using the accurate legal name of your institution. The membership packet contains all forms that must be completed for your membership except for the OHRP assurance document, if applicable. All required documentation must be complete prior to submission of your application. The Alliance Membership Committee will not review incomplete applications. All applications must be submitted with a cover letter from the main member principal investigator. The appropriate institutional official must also sign applications for main membership.

The Alliance must be able to accurately document accruals by the registering treatment performance site/institution. A performance site is defined by the NCI as an institution meeting one or more of the following criteria:

- Direct receipt of agent from CTEP;
- Holds an FWA or listed as a component of an FWA;
- Contract with a Cooperative Group or other CTEP-supported network;
- Enrollment of patients;
- Direct receipt of federal funds; and/or
- Responsible for submission of data to the study sponsor or their designee

A **separate affiliate application** is required for each additional performance site. In order to track accruals and audit institutions appropriately, it is crucial for institutions to register patients at the appropriate performance site. CCOP institutions are not required to submit separate applications for CCOP components. However, CCOPs are strongly advised to carefully consider the ability of their components to actively participate in Alliance clinical trials, before placing the components on the roster.

Locations such as physician practices and satellite clinics that are used solely for the convenience of patients do not need to be added to the Cooperative Group, grantee or contractor rosters for reporting or auditing. These locations may be used to administer research related treatment as allowed by protocol, research related exams and tests, or for follow up and consulting purposes. They must meet one of the following criteria to waive roster requirements.

- Physician practices covered under an existing NIA or IIA, and are by extension covered under an institutional FWA and an IRB.
- Satellite location legally owned by a rostered institution and covered by the organization's FWA and IRB.

Membership Application Review

The Alliance Membership Committee meets twice a month to review applications. The Board of Directors considers the Membership Committee recommendations and makes the final decision regarding approval of Alliance members. The Board is scheduled to meet face-to-face twice annually. However, if there are membership applications ready for approval, a special session by conference call may be scheduled, in order to ensure that membership applications are reviewed within 3 months of submission.

Roster Information

Following approval of the Membership Application, institutions must submit the following roster information for new participants. Members of the Alliance legacy groups will be asked to verify the current roster information in the legacy group roster database and the Cancer Trials Support Unit (CTSU) Regulatory Support System (RSS).

- Roster information for participants, as follows.
 - Roster Update Form including NCI ID (investigators) or CTEP ID (non-investigators)
 - Certification on Protection of Human Subjects Training
 - NIH Biosketch or Curriculum Vitae (investigators only)
 - FDA 1572 (investigators only)
 - Financial Disclosure Form (investigators only)
- As appropriate, the following institutional information may be provided.
 - Certificate of FACT Credentials

- Laboratory Certification and Lab Normal Values
- Transplant Facilities Information
- Radiation Therapy Facilities Information
- Imaging Facilities Information

Service Agreement and Per-case Payment

Main member institutions must submit a signed *Services Agreement and W9 Form*. The Services Agreement outlines responsibilities of membership in the Alliance, and also permits Alliance to pass through per-case payments from federal funds for which your institution is eligible. Per-case payments, in general, are available to defray costs related to enrollments to Alliance treatment studies, selected ancillary studies, selected cancer control and prevention studies, etc. At this time, institutions holding Community Clinical Oncology Program grants at the time of the registration are not eligible for most federal per-case payment programs. Also, non-federal per-case payments may be available.

The federal grants supporting the Alliance for Clinical Trials in Oncology will provide capitation or per case payments according to the payment levels determined by the NCI. Per-case payment information will be posted to the member section of the Alliance website for members to view. Payments for the various programs will be made to main member institutions at a minimum of twice annually. It will be the responsibility of the main member to disperse these payments to their affiliate institutions within three months of receiving the payment.

The Principal Investigator is confirming acknowledgement of this financial obligation by signing and submitting a membership application.

If you have any questions regarding the application materials or process, please contact the Alliance Membership Coordinator, Marcia Kelly at 773-834-7676 or marciak@uchicago.edu.