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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 Structure

Members of the Alliance are 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.

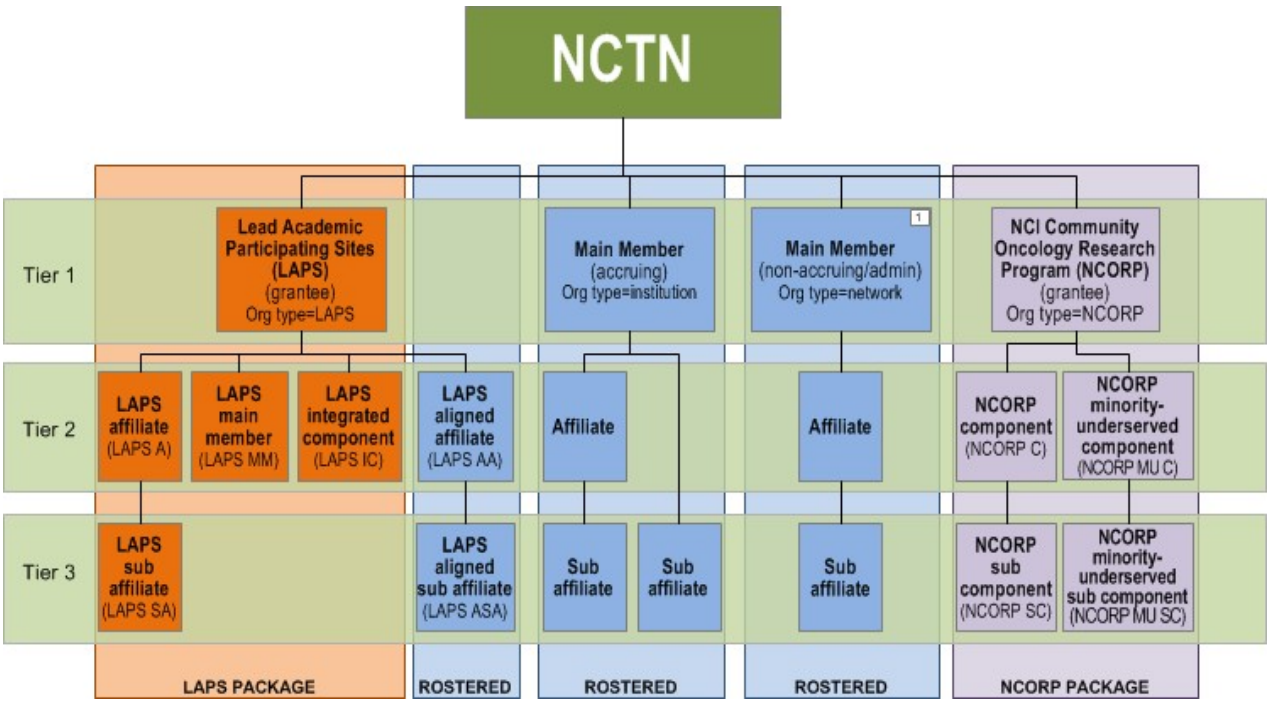
The Alliance adheres to the institution membership structure as mandated by the NCI (refer to diagram 1 on the next page). As indicated in the diagram, there are four types of member networks that are structured based on their funding mechanism. The member networks can have up to 3 levels (tiers) of member types:

- Tier 1 members of Lead Academic Performance Site (LAPS) and NCI Community Oncology Research Program (NCORP) represent the administrative offices of the member network. Tier 1 of the Main member networks (non-LAPS, non-NCORP) can either be an administrative office of a health system (if approved by CTSU) or an accruing institution.

- Tier 2 members include affiliates of Main members, NCORP components, and LAPS Main Member, LAPS affiliates, LAPS Integrated components as identified in the LAPS grant. LAPS can also have aligned affiliates. Aligned affiliates are institutions/performance sites that are affiliated with the LAPS network but are not included in the LAPS grant. The Chair's grant provides the per case payments for aligned affiliates.

- Tier 3 members are sub-component/sub-affiliates. A sub-component or sub-affiliate is an institution or practice site that shares the same FWA, IRB, governance structure, employees of either a Tier I or Tier II member. An example of a sub-affiliate is a physician practice that has a primary clinical site and has additional office locations where the same physicians treat patients. The primary clinic site is the parent and the additional locations are sub-affiliates.

Diagram 1



A Main member institution may have affiliate and/or sub-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.

Membership Accrual Requirements

LAPS and NCORP networks and Main member network (non-LAP, non-NCORP) are expected to earn at least **15** accrual credits annually based on a 3-year average. An affiliate member is expected to earn at least **5** accrual credits annually based on a 3-year average. Sub-affiliates are not held to an accrual requirement but the enrollments are counted toward the parent (Main member or affiliate) site. Accrual credits are earned by crediting the Alliance when enrolling a patient on a cooperative group clinical trial. All stand-alone studies receive 1 accrual credit and 0.25 accrual credits are provided for Alliance sub-studies. Select screening studies and pre-registrations receive a partial credit and select treatment studies receive 2 accrual credits.

Member Responsibilities

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 LAPS, NCORP and Main

Member network shall have a PI and a Co-Principal Investigator (Co-PI), who shall assume responsibility in place of the PI if for any reason the PI is unable to perform duties required for Alliance institutional membership. All PIs 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

- Each institution will be audited 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.html

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 and/or sub-affiliates
  - 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 and/or sub-affiliate sites, if applicable

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 Tier I membership.

The Alliance must be able to accurately document accruals by the treatment performance site/institution. *Any site that is engaged in research must be on the roster. In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private*

information about the subjects of the research; or (3) the informed consent of human subjects for the research.

A **separate affiliate or sub-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. NCORP institutions are required to submit an abbreviated application for NCORP components/sub-components. LAPS and Main members (non-LAPS, non-NCORP) must submit an application for all Tier II performance sites (aligned affiliates/affiliates, etc) and an abbreviated application for Tier III performance sites (sub-aligned affiliates/affiliates, etc).

Membership Application Review

The Alliance Membership Committee meets monthly to review applications. The Board of Directors considers the Membership Committee recommendations and makes the final decision regarding approval of Alliance Tier I applications. The Membership Committee has authority to approve affiliates and sub-affiliates.

Roster Information

Following approval of the Membership Application and activation of the site, the designated Lead Clinical Research Professional (Lead CRP) must add persons to the site roster via the CTSU Roster Update Management System (RUMS) or the NCORP administrator must add the persons via NCORPSys. All participants are required to complete Human Subject Protection training. The Alliance Membership Manager maintains all Lead roles (PI, Co-PI, Lead CRP and Secondary Lead CRP).

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 NCORP 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 Manager, Jacquelynn Carroll at Membership@AllianceNCTN.org.