Process to Utilize the NCORP Network for Externally Funded Research Grants

Federally Funded Studies (e.g., NIH, AHRQ, DOD)

Federally funded studies are not required to undergo Steering Committee concept review because they have already undergone peer review. Such studies may come to the attention of NCORP Research Bases and NCI Program Directors without full consideration of feasibility, budget planning, and overlap with open or planned studies. Making necessary adjustments can create delays in study implementation that are inconsistent with the goals of clinical trial stewardship established by the NIH. (http://jamanetwork.com/journals/jama/fullarticle/2553888?guestAccessKey=554e0981-9434-45f2-b122-d0e673cd1182).

Thus, in order to promote the efficient and equitable use of resources in the initiation, implementation, and completion of research studies, the following guidelines outline the process for submitting research grant applications (e.g. R series, P01s) that propose to use the NCORP network for study implementation. These guidelines describe the required process for coordinating communication between NCORP Research Bases and their respective NCI NCORP Program Directors, as well as the review and approval requirements for conducting research through the NCORP network.

Because NIH Institutes and NCI Divisions differ in their approach to handling applications and funded grants, there are some variations in process as follows:

- **Cancer Control (including Symptom Science) Prevention & Screening**: The Program Directors in the NCI Division of Cancer Prevention (DCP), Community Oncology and Prevention Trials Research Group, are responsible for the scientific oversight for cancer control/symptom science applications and funded grants using the NCORP network. Some grants outside of NCI are monitored in conjunction with Scientific Program Directors in other NIH Institutes. At the time of submission, applicant(s) may request assignment of their grant application to the NCI and to a specific NCI NCORP Program Director. (For more information go to: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-008.html). By doing so, the application can be more easily/directly/quickly brought to the attention of the interested/involved NCI Program Director after it has been received, logged-in, and assigned to the NCI.

- **Cancer care delivery research**: The primary Scientific Program Director for all cancer care delivery research applications and funded grants will be the person with the most relevant scientific expertise within any NCI Division, NIH Institute, or other federal agency. Staff in the NCI Division of Cancer Control and Population Sciences Healthcare Delivery Research Program will serve as a resource and monitor progress on these grants. Applicants, Research Bases and NCI staff should work together well in advance of submission to establish the appropriate relationships. NIH applicants are encouraged to request
assignment of their application to the appropriate Scientific Program Director.
(For more information go to: [https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-008.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-008.html)

**Prior to submission of a research grant application**

Interested investigators are required to contact NCI (NCORP) Program Directors or the Research Bases to determine if the concept is within the research scope of the program. Investigators contacting the NCORP Program Directors in either the Division of Cancer Prevention or the Division of Cancer Control and Population Sciences will be directed to the Research Base that is best suited for the concept and provide contact information. When the initial contact is with an NCORP Research Base, the Research Base notifies their assigned NCORP Program Director of an investigator's intent to submit a research grant application to a federally funding agency at least four weeks prior to submission.

Regardless of the first point of contact, the NCORP Research Base should provide the NCORP Program Director a brief abstract describing the study aim(s), study population, and a statement of rationale for use of the NCORP network. The NCORP Program Director will provide feedback regarding: 1) the feasibility of conducting the study within the network, 2) potential scientific overlap with existing studies, and 3) confirmation that the study fits within the cancer control/prevention, symptom management, care delivery or disparities NCORP research scope. In advance of submitting the grant application, it is expected that the PI and Research Base have communicated with NCORP sites regarding interest and participation in the study.

**Post study section review and award**

The study will be submitted as a protocol to NCI DCP Protocol Information Office (PIO) via a Research Base within 90 days of receipt of the Notice of Award or start of Project Period (as indicated on the Notice of Award); whichever is later. This 90-day requirement will apply to studies that are funded after April 1, 2017. Therefore, as soon as the Summary Statement is released (usually within 6-8 weeks after completion of the review) the investigator should contact the Scientific Program Director assigned to the grant as well as the NCORP Program Director for the Research Base that will be submitting the protocol to discuss next steps. Communication with the NCORP Program Director and Scientific Program Director is critical during this time, particularly if the grant is supported by a Federal Agency, NIH Institute or Center other than NCI. Inability to meet the 90-day submission time frame may result in forfeiture of access to the NCORP Network.

The full protocol will undergo review by the NCI Protocol Review Committee. Once the full protocol is approved by the NCORP Protocol Review Committee and NCI Central IRB, the PI and Research Base may proceed with conducting the federally funded study within NCORP
Non-Federally Funded NCORP Studies, Applications and Letters of Intent (LOI) - (e.g. PCORI, American Cancer Society, Leukemia and Lymphoma Society)

The following process is used to request use of the NCORP Network to implement studies supported by non-Federal funders. The process supports coordination of communication, review, and approval requirements between NCI and the non-Federal funder. The NCI has established communications with some non-Federal funding organizations to accommodate their respective review processes.

Application planning and/or Letter of Intent (LOI)

Interested investigators are required to contact NCI (NCORP) Program Directors or the Research Bases to determine if the concept is within the research scope of the program. Investigators contacting the NCI Program Directors will be directed to the Research Base that is best suited for the LOI or concept and provide additional information. When the initial contact is with an NCORP Research Base, the Research Base notifies their assigned NCORP Program Director of an investigator's intent to submit a research grant application or LOI to a non-federally funding agency or organization at least four weeks prior to submission.

The NCORP Research Base or investigator should provide the NCORP Program Director a brief abstract describing the study aim(s), study population and a statement of rationale for use of the NCORP network. The NCORP Program Director will provide feedback regarding: 1) the feasibility of conducting the study within the network, 2) potential scientific overlap with existing studies, and 3) confirmation that the study fits within the cancer control/prevention, symptom management, care delivery or disparities NCORP research scope.

When an LOI is selected to be submitted as a full application. The NCORP Program Director will be notified that an application is being submitted and updated on any changes/revisions to study design. All of this must take place at least four weeks before submission of a full application.

Post award

If the application is approved for funding by the non-Federal sponsor, there are two additional steps required to conduct the research within the NCORP infrastructure.

1. The NCORP Research Base shall submit a concept to the NCI DCP Protocol Information Office (PIO) for scientific review by an NCORP Steering Committee or the NCORP Concept Review Committee.
2. If the concept is approved, the NCORP Research Base will then submit a full protocol to the NCI DCP Protocol Information Office (PIO) for review by the NCORP Protocol Review Committee within 90 days.

Once the full protocol is approved by the NCORP Protocol Review Committee and NCI Central IRB, the Research Base may proceed with conducting the non-federally funded study within NCORP.