Processes for review and approval of NCORP Studies Receiving Additional Support

All cancer prevention, control and care delivery clinical research studies to be conducted within NCORP must be through a Research Base. There are different approval processes required if the study is supported by Federal or by non-Federal sources.

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 externally funded research grant applications that propose to use the NCORP network for study implementation.

Research conducted using NCORP must undergo federal scientific peer review through one of the following three mechanisms:

1. NCI Scientific Steering Committee (SCC) review of a concept proposing research in NCORP that will be supported solely through NCORP funds or through non-federal funding sources.

2. Center for Scientific Review (CSR) Study Section review of grant applications proposing research in NCORP that will in part or entirely be supported by federal funding.

3. If NCI has not established a SCC with purview over a concept, the NCORP Concept Review Committee (CRC) will conduct the review using scientific expertise with NCI and NIH, as required.

A proposed study must be submitted through one of these mechanisms, with the peer review results considered binding for the proposed study. That is, a disapproved concept cannot be submitted as a federal grant to be conducted in NCORP nor can an unfunded federal grant application be submitted as a concept. If NCI Program Staff determine that a substantially similar study has been submitted as both a concept and a federal grant application, the concept will be returned without review. The study will move forward in NCORP only if federal funding is awarded.

NCI program staff will consider the following in assessing whether two proposed studies are substantially similar or different: conceptual foundation; specific aims; study population; primary endpoint; and intervention approach (if any). Investigators with questions about whether one study is substantially similar to or different from another study should consult their NCI Program Director(s).

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

The following process is used to request use of the NCORP network to implement studies supported by federal research grant applications (e.g., R series, P01s). (Note: Studies being funded by K award grants (training grants) will not be conducted in NCORP.) 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 in the NCORP network.

Prior to submission of a research grant application

Interested investigators are required to contact NCI (NCORP) Program Directors and the Research Bases to determine if the proposed research 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 Research Base contacts, so the investigator can determine the Research Base best suited to support the proposed research. When an investigator makes contact with an NCORP Research Base, the Research Base is required to notify their assigned NCORP Program Director of an investigator's intent to submit a research grant application to a federal~~ly~~ funding agency **at least four weeks prior to submission. Note**: This notification process applies to all federal grant applications, including resubmissions (e.g., R01 A1 applications).

In advance of submitting the grant application, it is expected that the study chair, NCORP Research Base and NCORP Program Director have discussed: 1) the study aim(s), 2) study population, 3) rationale for and feasibility of conducting the study within the network, 4) potential scientific overlap with existing/planned studies, 5) confirmation that the study fits within the cancer control/prevention, symptom management, care delivery or disparities NCORP research scope, 6) timeline and relevant administrative requirements/budgetary considerations and 7) is responsive to the intended FOA/RFA. It is also expected that the study chair and Research Base have communicated with NCORP sites regarding interest and participation in the study. NCI Program Staff may decline to approve use of NCORP in a federal application if the proposed study is not responsive to the FOA/RFA, is deemed infeasible or overlaps with other research being conducted in NCORP.

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. NIH applicants are encouraged to request assignment of their application to the Scientific Program Director they feel will be the most relevant. NCI Cancer Care Delivery staff 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. (For more information go to: (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-008.html)

For purposes of internal grant tracking, applications approved to move forward should include the term "NCI Community Oncology Research Program (NCORP)" within the grant abstract and/or specific aims statement.

NOTE: Studies included in federal grant applications that were submitted without following the above procedures will not be allowed to use NCORP.

Post study section review and award

Federally funded studies (e.g., R01) are not required to undergo Steering Committee concept review because they have already undergone federal scientific peer review. If the grant is funded 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.** 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 NCORP Protocol Review Committee. Once the full protocol is approved by the NCORP Protocol Review Committee and NCI Central IRB, the study chair 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.** NOTE: This notification process applies to all non-federal applications including resubmissions.

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. NCI Program Staff may decline to approve use of NCORP in a non-federal application if the proposed study is deemed infeasible or overlaps with other research being conducted in NCORP.

When an LOI is selected to be submitted as a full application, the NCORP Research Base will notify the NCORP Program Director that an application is being submitted and will provide any changes/revisions to study design. ***All of this must take place at least four weeks before submission of a full application.*** Studies included in non-federal grant applications that were submitted without following the above procedures will not be allowed to use NCORP.

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 a NCORP Steering Committee or the NCORP Concept Review Committee within **90 days of notice of award or project start date whichever is later**.
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 NCI Protocol Review Committee. *If the concept is disapproved*, the investigator will not be allowed to conduct the study in NCORP.

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.

Note: The NCI CIRB is the sole IRB of record for all sites conducting clinical trials through the NCORP and NCTN networks and is responsible for study review (initial review, amendments, continuing reviews, recruitment materials, unanticipated problems and serious or continuing noncompliance) and approval of local context considerations.