NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

NCORP Review Process for Proposed Studies Using Non-Federal Funding

Investigators seeking to use the NCI Community Oncology Research Program (NCORP) network for a study using a non-federal funding agency, such as PCORI or American Cancer Society, must complete the following NCI NCORP review prior to submission of an application to the prospective non-federal funding agency.

Investigators are strongly encouraged to engage an NCORP Research Base as early as possible to allow sufficient time for Research Base, NCORP Leadership review, and NCI Steering Committee evaluation, particularly because many non-federal funding opportunities have compressed application timelines.

Note: The following process outlines review considerations using PCORI funding/timeline as an exemplar. The following timeline and steps may need to be adapted for other non-federal funding agencies. Approval to use the NCORP network does not guarantee funding by the sponsoring organization. Likewise, receipt of non-federal funding does not replace the requirement for NCORP review and approval.

Overarching Timeline

Table 1. Timeline for NCI Review of Proposed Studies Using Non-Federal Funding

Timeline	Milestones
A minimum of 8 weeks before the Steering Committee Meeting	Research Base contacts NCI Project Scientist to schedule pre-submission call. Research Base provides NCI Project Scientist with a copy of non-federal funding agency funding opportunity, project specific aims page, project timeline, and a summary of potential overlap with ongoing and planned NCORP portfolio at least one week prior to the pre-submission call.
A minimum of 6 weeks before the Steering Committee Meeting	Pre-submission call with NCI NCORP Project Scientists, NCORP Research Base Representatives, and Principal Investigator(s).
A minimum of 4 weeks before Steering Committee Meeting	Required submission materials (Refer to Table 2) are submitted to DCP Protocol and Information Office (PIO)
Steering Committee Meeting	See NCI Scientific Steering Committee Standing Meeting Schedule for dates and time of evaluation

Note: It is recommended that the NCORP Research Base communicate with NCI NCORP Leadership as soon as consideration for an application submission to a non-federal funding agency is being considered. Additional time may be warranted to schedule pre-submission call due to conflicts or limited availability.

Pre-Submission Call

A pre-submission call with NCI NCORP Leadership and the NCORP Research Base sponsoring the study is required and should occur **at least two weeks before** the planned submission of the non-federal concept to NCI. Research Base should provide NCI NCORP leadership with a copy of the non-federal funding agency's funding opportunity, project specific aims page, project timeline, and a summary of potential overlap with ongoing and planned NCORP portfolio at least one week prior to the pre-submission call. The call will include the following:

- Review of specific aims and the study's alignment with the NCORP network;
- Discussion of operational feasibility and implementation considerations; and
- Assessment of whether the proposed study is appropriate for the NCORP network, including consideration of potential overlap with ongoing and planned portfolio.

If the proposed study is deemed to be appropriate for the NCORP network, the call will also include:

- Review of submission requirements for NCI Steering Committee evaluation (Table 2) and timelines; and
- When the proposed study will be evaluated by an NCI Steering Committee (SC).

Note: The SCs meet on a regular schedule. For Cancer Care Delivery Research studies, NCI will determine at the pre-submission call whether SC evaluation can occur at a scheduled meeting or whether an ad hoc evaluation is possible to accommodate the sponsor's application timeline.

Submission of LOI and/or Application and Supplemental Materials

The NCORP Research Base must submit the following required materials (Table 2) to the DCP Protocol and Information Office **at least four weeks before** the anticipated SC meeting to allow adequate time for planning and review of materials.

All submission materials are required to follow the non-federal funding agency submission page length requirements in addition to NCI-specific supplemental material requirements listed in Table 2. This does not include the title page, schema and references. Submission of appendix materials, other than assessment tools, is discouraged

Table 2. Required Submission Materials

Document	Description
Copy of Non-Federal Funding Agency Funding Opportunity	This document should include the following details: • Non-federal funding agency name • Funding Opportunity Title and/or Number • Funding Opportunity Description • LOI and/or Full Application Deadlines • Non-federal funding agency Program Contact with contact information (email and phone number) • Web address to the funding opportunity LOI or Application Requirements for consideration of administrative compliance
Requested Letter of Interest and/or Full Application	This document should be drafted using the requirements set by the non-federal funding agency. Submission of an LOI or full application materials is based on the specific agency request.
Feasibility within NCORP (1-2 pages maximum)	This separate document requires that the proposed project align with feasibility expectations of a standard concept-level submission. The following elements are required to be addressed: • Evidence of NCORP engagement in advance of proposal (e.g., site survey, community oncologist co-investigator, pilot data within NCORP, etc.) • Preliminary data or description of pilot work within the NCORP (and rationale for lack of data, if applicable) • Proposed site capacity, accrual projections, and operational considerations • Expected study burden on participants, community sites, and research bases (time, money, etc.) • Detailed roles and responsibilities of research bases and community sites (personnel, community oncologists, etc.) within the study activities • Alignment with NCORP infrastructure and priorities • Potential overlap with ongoing and planned portfolio
Supplemental Research Approach	Supplemental research approach is not required for full application submissions. For all other submissions, this document

(1-2 page maximum)	provides additional information describing the study design, objectives, endpoints, statistical analyses, and power analysis to support evaluation of scientific and operational feasibility.

NCI Steering Committee Evaluation

During the open session of the NCI Steering Committee (SC) meeting, the study team will:

- Provide a brief overview of the proposed study (approximately 5 minutes).
- Describe how the study will be implemented within the NCORP network.
- Respond to questions from the SC.

Whenever possible, SC questions will be provided several days before the meeting to allow investigators time to prepare. Presentation slides are optional but encouraged.

The SC will then move to a closed session to discuss and vote on the concept. The outcome will be one of the following:

- Disapproved: The study may not move forward with using the NCORP network due to scientific and/or NCORP feasibility concerns.
- Approved: Investigators may submit the NCI-approved LOI or application to the funding organization according to the sponsor's requirements and timelines.

Submission to the Non-NIH Funding Organization & Post-Award Activities

If the concept is disapproved by the SC, the investigators may not use the NCORP network for the proposed study. Disapproval does not prevent investigators from pursuing the non-federal funded study using alternate accrual infrastructure.

If the concept is approved by the SC, the investigators can submit their Letter of Interest and/or full application as evaluated by the NCI Steering Committee to the non-federal funding agency. Any LOI or application changes that impact the NCI Steering Committee approved research approach or NCORP feasibility must be reviewed by NCI NCORP Leadership prior to submission to the non-federal funding agency and in coordination with the non-federal funding agency program contact, if applicable.

NCORP Research Bases are required to notify NCI Project Scientist of non-federal funding agency's decision to accept or decline LOI or full application. It is the expectation that LOIs advancing to the full application phase will retain all NCI-approved study components. Any substantial changes in research approach or feasibility in the approved LOI to the full

application must be reviewed by NCI NCORP Leadership prior to submission to the non-federal funding agency and in coordination with the non-federal funding agency Program Contact, if applicable.

If the study is ultimately selected for funding, NCORP Research Bases are required to notify NCI Project Scientist of non-federal funding agency's funding decision. The awardee will complete the sponsor's award and contracting requirements. Following contract execution, the study protocol will be submitted to NCI for review to ensure alignment with NCORP operational requirements before activation within the NCORP network.

Throughout study implementation, NCI, the NCORP Research Base, non-federal funding agency, and the study team will work collaboratively to address operational issues and support successful study conduct. If the non-federal funding agency review requires or results in substantive revisions that could affect study feasibility or implementation within the NCORP network, investigators should promptly notify the NCORP Research Base and NCI so that any necessary reassessment and revision can occur.