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Standard Operating Procedure

**Ancillary Study Approval Process**

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Ancillary Study Approval Process

**Purpose**

To define the standard procedures for proposing, reviewing, and approving ancillary studies for BOOST-3 conducted within the SIREN Network.

**Definitions**

Ancillary study - A research activity undertaken to address a scientific question that requires access to data or records from the BOOST-3 study and/or involves collection of additional data, specimens, or records from patients enrolled in the BOOST-3 study.

**Closely related procedures:**

Development of grant applications for ancillary studies should follow established procedures and timelines described in the [SIREN Grant Development SOP](https://docs.google.com/document/d/1qbMVkax7Bgi8whgB0UfgUum8lLLCwl0dgOFvt4HNgcE/edit?usp=sharing) .

**Responsible Individuals**

SIREN Executive and Steering Committee members, PIs of the BOOST-3 and BOOST-3 ancillary studies, and members of the Data and Safety Monitoring Board (DSMB) for the trial.

**Principles**

BOOST-3 leadership encourages development of ancillary studies that leverage the investment and infrastructure of BOOST-3 to create additional opportunities for knowledge creation around specific aims distinct from those of BOOST-3. Ancillary studies must not threaten the integrity or successful implementation of BOOST-3 and its objectives, or result in excessive burden to participants. We encourage the lead investigators for ancillary studies to seek out other interested investigators at BOOST-3 sites.

BOOST-3 ancillary projects must pursue independent funding mechanisms, and it is the responsibility of the proposed ancillary study leadership to seek out potential sponsorship and funding opportunities.

**Procedure**

Funding opportunities for ancillary studies vary depending on the funding source (e.g. DoD, Foundation, NIH). If funding is requested from NIH, please consult with a program contact at the relevant Institute to determine both the potential level of interest and the best FOA for a particular situation.

1. Ancillary study ideas should initially be presented to the BOOST-3 PIs and statistical team for their input and to determine their interest in collaboration.
	1. A 1 – 2-page summary of the proposed ancillary study provided to the BOOST-3 PIs for review.
	2. This summary should include:
		1. Brief background of the proposed study
		2. Specific aims
		3. Number of patients
		4. Any collaborating sites
	3. A preliminary budget and potential funding source should be provided with the summary document.
2. Once approved by the BOOST-3 PIs, the ancillary study investigator(s) and the BOOST-3 PIs will then discuss the ancillary trial with the SIREN Executive Committee (EC). The EC will ask for supplemental written materials as needed.
3. After review of any supplemental materials, the SIREN EC will forward the ancillary study to the SIREN Steering Committee (SC) for their review and comment.
4. After review of submitted materials and comments, the SIREN EC will vote on proposed ancillary study. The vote can take place at a face-to-face meeting or conference call; if this is not feasible, email review and voting may be substituted. Criteria for approval of ancillary study include:
	1. The proposed study addresses a question of importance.
	2. The proposed study should not compete with any previously approved ancillary study.
	3. Conduct of the study must not adversely affect the integrity of the BOOST-3 trial and outcomes.
	4. Funding for the study is adequate and will be obtained by the PI independent of BOOST-3 study funding.
	5. Procedures for accessing necessary data and records from BOOST-3 are explicit and acceptable
	6. Additional funding required by SIREN Clinical Coordinating Center (CCC) or Data Coordinating Center (DCC) must be included in the budget of the proposal.
	7. The proposing PI has the appropriate expertise and facilities to conduct the study.
	8. Plans for publication and authorship of study results are appropriate, including review and approval of manuscripts per the SIREN publication policy.
	9. EC members will be given adequate time to review the proposal before a vote is taken.
5. All ancillary protocols will be forwarded to the BOOST-3 Data and Safety Monitoring Board for review and comment.
6. If approved by the EC and reviewed by the DSMB, the ancillary investigators and BOOST-3 trial investigators may then proceed with development of the grant application for submission for peer review. Refer to the SIREN Grant Development SOP.
7. A list of all proposed and approved ancillary studies will be maintained in WebDCU in the SIREN Database in the Project Development Progress list.