



RURAL Ancillary Study Procedures and Process: EXTERNAL

Version 7: April 2nd, 2020

Procedures

Reviewers of the AS Initial Concept Proposal and Full Proposal

- The three multi-PIs and the Chairs of the AS Subcommittee will review the Initial Concept Proposal. They will provide feedback to the proposer and determine if the proposal is:
 - Approved
 - Disapproved
- A simple majority is required for the Initial Concept Proposal to be accepted, requiring the AS investigator to submit a Full Proposal
- The AS Subcommittee will review the Full Proposal form. They will provide feedback to the proposer and determine if the proposal is:
 - Approved
 - Approved with revisions
 - Disapproved

External Reviewers

- If an AS requires DNA or laboratory samples, the DNA/Laboratory Committee will review the DNA/Laboratory sections of the Full Proposal before it is sent to the AS Subcommittee for their review.
- External reviewers may be added to the review process to ensure balance.

Revisions to Ancillary Study Proposals

- The AS Subcommittee may have no revisions, recommended revisions, or required revisions to the Initial Concept Proposal or Full Proposal.
- It is highly likely that there will be revisions to the Initial Concept Proposal or Full Proposal, which will require additional processing time

Determining Outcomes for Similar AS Proposals

- If the AS Subcommittee receives two or more AS Initial Concept or Full Proposals that have significant overlap in their aims and/or research design, the AS Subcommittee could recommend one of the following options:
 - Invite the different AS investigators to collaborate and submit a new joint proposal that combines the different proposals into one proposal. This will require communication between the different AS investigators, the AS Chairs, and the SCC Administrator.
 - Suggest that the different AS investigators revise their proposals so there are significant differences between them. This will require communication between the different AS investigators, the AS Chairs, and the SCC Administrator.
 - The SCC Administrator sends the proposals to the Steering Committee for their review. The Steering Committee could:
 - Approve only one proposal
 - Approve more than one proposal. Investigators with approved AS proposals could submit them to peer review, where only the one deemed most meritorious would become an AS.

Budget

- If the AS proposal is submitted as a grant application to the NIH and requires a budget of greater than \$500,000 in direct costs in any funding year, investigators must be aware of the budget approval



process from the NIH for such grant applications (see [Section 2.3.7.2 of the NIH Grants Policy Statement](#)). Please allow at least 6 weeks for the NIH to review the budget.

Participant Burden

- Proposals that involve RURAL participants in the Mobile Examination Unit (MEU), will be reviewed provisionally by the Ancillary Study Subcommittee at this juncture. However, it is unlikely that they can be approved with finality at this early stage in the RURAL study as the RURAL exam is still being finalized, rendering it challenging to develop a framework for what constitutes acceptable participant burden in the MEU. The Ancillary Study Subcommittee will review such applications because we understand it takes time to obtain grant funding for ancillary studies, by which time there may be greater clarity around what is acceptable participant burden in RURAL.

Feasibility Review

- It is critical for ancillary study applicants to understand that even if grant funding were to be successfully obtained, there will be a feasibility review at the time of funding by the Ancillary Studies subcommittee to determine whether or not to subject RURAL participants to the projected burden as written in the grant application.
- If an AS receives final approval, the approval remains effective for **24 months** beginning from the date of notification of approval to the submitting PI. This allows time for submission and resubmission of an application for funding. If an AS receives funding the AS investigator must notify the Study Coordinating Center (rural@bu.edu) immediately, who will notify the AS Subcommittee members.
- If an AS proposal is not selected for funding within the 24-month approval timeline, the initial AS proposal approval is no longer active or valid. After this time the RURAL study will work with the investigator to renegotiate terms of the ancillary study, which may include a resubmission of a full ancillary study proposal or slight change in the original proposal

Process

1. AS Investigator Contacts Relevant RURAL Cores

- AS investigators must contact the RURAL liaisons from each relevant core prior to submitting an AS proposal to discuss the proposal and obtain Impact Statements from relevant cores, such as BRAC or Genomics Core.
- If the AS investigator does not know who to contact, please email the Study Coordinating Center (SCC) (rural@bu.edu) who can assist in connecting the AS investigator to the relevant RURAL core(s).

2. Submission and Review of AS Initial Concept Proposal

- Investigators will complete the RURAL AS Initial Concept Proposal form and send it to the Study Coordinating Center (SCC) at BU (rural@bu.edu).
- The AS Chairs and three multi-PIs will review the proposal and inform the SCC Administrator of their group decision. They will determine if the proposal is:
 - Approved
 - Approved with revisions
 - Disapproved



- The SCC Administrator will then inform the AS applicant of the review decision, reviewers' feedback, and next steps. If the Initial Concept Proposal was approved, the SCC Administrator will ask them to complete the AS Full Proposal.

3. Submission and Review of AS Full Proposal

- The AS Investigator should submit the AS Full Proposal within **20 working days** of the Initial Concept Proposal being approved by the AS Chairs and three multi-PIs.
- If an AS requires DNA or laboratory samples, the DNA/Laboratory Committee will review the DNA/Laboratory sections of the Full Proposal before being forwarded to the AS Subcommittee for their review.
- The AS Subcommittee discusses the AS proposal and votes on the recommended action:
 - Approved
 - Approved with revisions
 - Disapproved
- The SCC Administrator will send the AS Subcommittee's recommendation to the Steering Committee, who will make the final decision. The AS investigator may address the comments and feedback from the AS Subcommittee and/or the DNA/Lab Committee before it is sent to the Steering Committee. In some cases, the AS Subcommittee and/or DNA/Lab Committee will require AS investigators to make changes before the Full Proposal is sent to the Steering Committee.

4. Steering Committee Review

- The Steering Committee will review the materials for each Full AS proposal and consider the recommended action from the AS Subcommittee. The Steering Committee will determine if the proposal is:
 - Approved
 - Approved with revisions
 - Disapproved

5. Actions after the Steering Committee Meeting

- The SCC Administrator will inform the AS investigator of the Steering Committee's final decision and next steps. If the AS is approved by the Steering Committee, the SCC Administrator will inform the AS investigator that they can only proceed **after** receiving approval from the OSMB. The SCC Administrator will also request a final version of the AS proposal with any incorporated edits.
- If the Steering Committee approves the AS proposal, the AS investigator must contact the SCC Administrator/ Jason Miller (rural@bu.edu) to discuss the budget and fees for the AS.

6. OSMB Provides Approval

- The SCC Administrator will send the final version of the AS proposal and the Steering Committee's final decision to the NHLBI Project Officer and the OSMB Executive Secretary.
- The OSMB and NHLBI will review the AS proposal
- The NHLBI notify the SCC of the OSMB's decision
- With OSMB approval, the SCC Administrator prepares a final letter on behalf of the Steering Committee stating that all approvals are in place and the AS investigator may apply for funding and develop contractual agreements with external funders or the necessary RURAL Study cores.

7. Actions after OSMB Approval

- Applicant must inform the Ancillary Studies Subcommittee within 10 working days of receiving Notice of Award (NOA) if they receive funding for the proposed AS.
- AS investigators are required to complete a Data and Materials Distribution Agreement (DMDA) in order to receive study biosamples and/or data



8. Overall Anticipated Review Time

- The AS Initial Concept Proposals will typically be reviewed and returned to AS investigators within **7-15 working days of receipt**.
- The AS Full Proposals will typically be reviewed and returned to AS investigators within **12 weeks of receipt**, which includes review and approval by the Steering Committee and OSMB.
- Review times are an estimate and may vary. Please allow for extra processing time during public holidays.
- **Please submit the AS Initial Concept Form at least 12 weeks before [NIH grant submission deadlines](#).**
 - If an AS proposal requires new participant contact, tests novel technologies or other methods, or requests DNA/Laboratory specimens, please allow for extra processing time for the DNA/Laboratory Committee or additional external reviewers to review the proposal. AS investigators must assess the complexity of their proposal to ensure they submit their proposal with sufficient time for it to be reviewed.
 - An expedited process for submission may be allowed on a case-by-case deadline based on grants with smaller timelines.