

RURAL Ancillary Study Process (EXTERNAL)

Version 4: February 4 2020

Step 1: Ancillary Study Investigator Submits Initial Concept Proposal

AS Investigator contacts liaison in appropriate RURAL core(s) to discuss proposal and obtain impact statements. If AS investigator does not know who to contact, email rural@bu.edu

AS Investigator submits Initial Concept Proposal to rural@bu.edu

The AS Chairs and three multi-PIs review the AS Initial Concept Proposal, provide comments, and make a decision

Disapproved Approved

The SCC Administrator informs the AS investigator of the review decision, reviewers' feedback, and next steps

Step 2: Ancillary Study Investigator Submits Full Proposal and Ancillary Study Subcommittee Meets to Review Proposal

If AS Initial Concept Proposal is accepted, AS Investigator submits Full Proposal to rural@bu.edu

The AS Subcommittee discusses the AS proposal and votes on the recommended action

Disapproved Approved with revisions Approved

The SCC Administrator informs the AS investigator of the review decision, reviewers' feedback, and next steps

If approved, the SCC Administrator sends the AS Subcommittee's recommendations to the Steering Committee

Step 3: Steering Committee Reviews Proposal

The Steering Committee members review the materials for each proposal and vote on the recommended action

Disapproved Approved with revisions Approved

The SCC Administrator informs the AS investigator of the Steering Committee's final decision and next steps

If the AS is approved, 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 incorporated revisions

The AS investigator contacts the SCC Administrator (rural@bu.edu) to discuss the AS fees and budget

Step 4: OSMB Provides Approval

The OSMB and NHLBI will review the AS proposal

With OSMB approval, the SCC Administrator will prepare a final letter on behalf of the Steering Committee stating that all approvals are in place and the AS investigator may apply for funding