

Ancillary Study Process within the HCHS/SOL Management Structure

1. Submission of Ancillary Studies (AS)

Investigators submit their AS proposal (concept or full), using the appropriate AS Form on the study web site, via the HCHS/SOL web portal Ancillary Studies Proposal Submission page.

2. Distribution to the Ancillary Study Committee

The CC AS Coordinator verifies that the proposal is complete and emails the proposal to the AS Committee immediately.

3. Review by the Ancillary Study Committee

The AS Committee Chair assigns reviewers (2-3) to provide a primary review of the proposal, although every eligible person on the Committee should read the proposal and make appropriate comments. If a member of the AS Committee is listed as an investigator on the proposal the AS member may not review the proposal nor comment on it unless asked nor vote on it during the review process. If a perceived conflict of interest is involved, a member of the AS Committee may be asked to recuse her- or him-self from the review. External reviewers may also be added to the review to insure balance. The primary reviewers will provide a written critique using the review criteria listed on the website as 5.5 under ancillary studies policy. Each primary reviewer will indicate whether the proposal should be 1) approved, 2) deferred for revision, or 3) disapproved. Reviewers from the laboratories, reading centers, field centers or coordinating center will review with particular attention to aspects that relate to their sites.

The AS reviewers email their critiques to all members of the AS committee as well as to the Coordinating Center Coordinator.

4. Ancillary Study Committee Meeting

The AS Meetings are held by conference call or in person if appropriate. The AS Committee Chair establishes the agenda and each proposal is discussed by the primary reviewers and by the full AS Committee. These meetings are scheduled as needed to provide a timely review of proposals, but within 4 weeks of submission to the CC. The AS Committee will arrive at a decision on the recommended action for each proposal with the final decision to be made by the Steering Committee. The recommended action will be based on a vote of members with majority rule.

If an AS Committee member is in conflict, the member will recuse him/herself as described above. If the AS Chair is in conflict, the chair will appoint a deputy Chair to conduct the review

For a concept proposal, the recommendation is whether or not the proposer should submit a full proposal. For a full proposal, the recommendation is whether or not the proposer may submit an application for funding.

The AS Committee will be responsible for all questions and discussions with AS proposing investigators related to decisions to defer. In such cases, the AS Chair will email a draft of the reasons for deferral and all supporting materials to the AS Committee for its review and approval before distributing the documents to the proposer. The proposer may then modify the

proposal for re-review by the AS Committee. The AS Chair will inform the Steering Committee of the actions of deferral during the next available Steering Committee Meeting.

In the event that the ASC receives two or more AS Concept or Full Proposals that demonstrate significant overlap in their aims and/or research design, the ASC could:

- a. Recommend to the proposing investigators to submit either a new, joint AS Full Proposal or individual revised Concept or Full proposals that complement but do not overlap with each others' aims and/or research designs. Either option will require communication and cooperation among the AS proposing investigators involved.
- b. Forward both or all proposals to the Steering Committee for review. In that case, the Steering Committee could either
 - i. Approve up to only one proposal.
 - ii. Approve more than one proposal. All investigators with approved AS proposals could then submit their proposals to peer review, with the understanding that only the one deemed most meritorious would be allowed to become an active AS.

5. Actions after the Ancillary Study Committee Meeting

The AS Chair will not directly convey recommendations to **approve or disapprove** AS Concept or Full proposals to the proposing investigator since the decision depends upon Steering Committee action. Consequently, the AS Chair will prepare the AS committee recommendation and supporting materials and send them (with copy to the CC AS Coordinator) to the Steering Committee for its review and approval at its next meeting.

6. Steering Committee Review

The Steering Committee will review the materials for each full and concept AS proposal, will consider the recommended action from the AS Committee, and will vote at its regularly scheduled meeting on whether the proposal should be approved or not. If there is a justifiable need for a time sensitive review the Steering Committee review could be done by email, but any Steering Committee member could request a review via conference call. The Steering Committee's decision to approve, defer or disapprove the proposal will be communicated to the proposing investigator by the Steering Committee Chair. If the Steering Committee so wishes it may request clarification from the AS committee before reaching a decision to approve, defer or disapprove.

7. Actions after the Steering Committee Meeting

A letter to the proposer conveying the Steering Committee decision to approve or disapprove will be prepared by the AS Coordinator, signed by the Steering Committee Chair, and sent along with supporting materials to the proposer. If the decision is to approve, this letter will also

- a. Request from the AS proposer a final and clean version of the AS proposal that incorporates all changes agreed to during the review process, to be sent to the AS Coordinator

- b. Explain to the AS proposer that submission of the AS proposal for peer review or commencement of the proposed project as an active ancillary study can only proceed after receiving approval from the OSMB and NHLBI

When this final and clean version of the AS proposal is received, the AS Coordinator will forward it with a copy of the Steering Committee Chair's approval letter to the Project Officer and the OSMB Executive Secretary for OSMB and NHLBI review. When the OSMB and NHLBI reviews are complete, the NHLBI will notify the AS proposing investigator and the AS Coordinator of the NHLBI's final decision. If approved, the proposing investigator may apply for funding or, if funds are available, proceed with the project as an active ancillary study.