

## **Proposed Approach to Ancillary Studies Recruitment Management in WHI**

**Background:** Multiple ancillary studies (AS) are recruiting WHI participants to studies requiring direct participant involvement. Considerable overlap exists in the target populations as most studies wish to recruit from the Long Life Study (LLS), the Medical Records Cohort (MRC), and/or women from racial/ethnic minority groups. WHI seeks to give each ancillary study as much opportunity for recruitment success as possible while avoiding participant confusion and burden with too many requests over a short timeframe.

This document outlines a proposed approach to managing timely participant recruitment of simultaneously active Ancillary Studies. The intent of this approach is to minimize delays and to create a fair and defined timeline for each ancillary study to approach participants who are sampled for multiple studies.

This approach will be applied prospectively to new studies as they develop detailed recruitment plans with the CCC. For existing studies, the CCC will work with each ancillary study to apply the proposed timelines to existing recruitment plans. The expectation is that each AS PI will work collaboratively with the CCC and other AS PIs to help assure the success of all affected studies.

**Proposed Approach:** When funded, each ancillary study will develop a detailed recruitment plan, including eligibility, proposed start and end, and recruitment protocol and cadence.

- a. Once a study is active at the CCC, recruitment documents are IRB-approved, and recruitment is planned to launch within 3 months, the CCC will begin to reserve participants according to their recruitment plan.
  - b. Reservations may be made no more than 3 months before each mailing wave. Ancillary studies are asked to minimize this wait time as much as possible.
  - c. If multiple studies plan to start recruitment of the same population at the same time, they will be asked to split the sample and rotate reservations as was done for OPACH2 and MsLILAC.
1. Each ancillary study will have up to 6 months from the receipt of each mailing wave list to complete recruitment of those participants.
  - a. Participants should be released from reservation as soon as possible. This includes those who have
    - i) declined/refused consent,
    - ii) been determined to be ineligible for the recruiting study,
    - iii) been determined to be unreachable.
    - iv) completed the expected activities of the recruiting study
    - v) withdraw after consent but before completion of the AS protocol
  - b. Once the 6-month period has expired for each wave, the reservation will be automatically released, and that ancillary study will refrain from further recruitment attempts for participants in that wave. These participants will become eligible for approach by the next study. If they are not eligible for other studies, they may be considered for additional recruitment attempts by the existing study.

2. Each ancillary study is asked to provide a monthly participant-level status update to the CCC. Status update codes will be provided by the CCC and may be customized to align with the AS recruitment protocol.

Additional considerations:

In general, the planned pace of recruitment should allow for all study recruitment to be completed within ASC-approved timelines as provided in the AS application. Exceptions will require ASC approval.

The time windows specified here are an initial attempt to define what is reasonable. Adjustments will be made with experience.

Ancillary studies who seek to re-design their study or expand recruitment must seek ASC approval for the changes in study design and revised recruitment plan. Refer to AS policy.

Where significant conflicts between study recruitment populations and timelines exist, WHI will ask the PIs of each ancillary study to work together to resolve them, with CCC assistance as needed. If an agreement cannot be reached, the ASC will be asked to help resolve the matter.