**NCCIH Electronic Study Accrual and Retention Plan (SARP) Template**

Per the [NCCIH Policy: Study Accrual and Retention for Human Subject Research](https://www.nccih.nih.gov/grants/policies/nccih-policy-study-accrual-and-retention-for-human-subject-research), all clinical research studies funded by the National Center for Complementary and Integrative Health (NCCIH) are required to submit a detailed Study Accrual and Retention Plan (SARP) prior to involving human subjects. A separate SARP must be provided for each clinical research study proposed in the funded grant. Each SARP must contain all required elements including a detailed timeline and monthly target accrual goals during the period of the award. The timeline should allow sufficient time after collection of all subject data for data cleaning, analysis, and writing prior to the end of the award period. NCCIH encourages principal investigators (PIs) to consider accrual milestones in light of specific study context including slower recruitment during initial start-up. Accrual milestones can be customized by specific month and do not need to be linear.

The SARP will be submitted to NCCIH via the NCCIH Document Portal using the **Electronic SARP Template** (sample below) and log-in credentials. The corresponding PI will receive an automated email initiating completion of the Electronic SARP Template and upon successful submission. NCCIH will review the proposed benchmarks for appropriateness and compatibility with the budget and specific aims. When NCCIH has conditionally approved the SARP, it will be routed to the Authorized Business Official for countersignature with a copy to the corresponding PI. The PI will receive a final email confirming acceptance of the NCCIH-approved SARP. ***As of April 1, 2022, all new and revised SARPs must be submitted using the Electronic SARP Template.***

Please refer to the [NCCIH Policy: Study Accrual and Retention for Human Subject Research](https://www.nccih.nih.gov/grants/policies/nccih-policy-study-accrual-and-retention-for-human-subject-research) for additional information on how NCCIH might address problems with study accrual and retention during the tenure of the award. Throughout the conduct of the study, the NCCIH program director (PD) will regularly review progress to ensure that it is consistent with the accrual and retention projections outlined in the approved SARP. If study performance falls below agreed-upon benchmarks, the NCCIH PD may communicate directly with the PI to further assess the specific circumstances and context.

**Sample Electronic SARP Template**

Grant Number:

Grant Title:

Study Name:

Principal Investigator:

Anticipated Total Enrollment:

This would be your Intent To Treat (ITT) sample and total planned enrollment in the NIH Human Subjects System (HSS system). The monthly milestones below must sum to this value using the following calculation:

Anticipated Total Enrollment = Target Completers / (1-Lost To Follow-Up Rate)

Anticipated Lost To Follow-Up Rate: %

NCCIH considers lost to follow-up as a research subject who was participating in the study at a certain point in time and subsequently missed two consecutive study visits and is unresponsive to study contact, or is no longer participating in study activities.

Based on a review of existing literature and prior experience provide an anticipated lost to follow-up rate. This rate should have been accounted for in the data analysis plan/sample size calculation. Lost to follow-up rate should be reported as a percentage of total accrual.

Target Completers:

This would be your completer analysis sub-group (per protocol analysis).

SARP Start Date: Provide the anticipated date of the first participant enrollment as well as the anticipated date when the final participant will conclude clinical activity, including completion of all intervention and follow-up visits.



SARP End Date:



Anticipated Lost to Follow-Up Rate cannot be empty

Recruitment Plans

Contingency Plans

Provide a description of the planned recruitment methods including use of contact lists, databases or other pre-screening resources, advertisements, outreach, media/social media, and referral networks or groups. NCCIH provides [recruitment tips](https://nccih.nih.gov/grants/recruiting-communicating) and an [accrual stage](https://nccih.nih.gov/grants/accrual-stages) checklist on the NCCIH website.

Clarify contingency plans for participant accrual if enrollment falls significantly below accrual benchmarks.

Study Related Barriers

**If there are known participant or study-related barriers to accrual or participation (based on literature or prior experience)**, list these barriers and describe a plan to address them to optimize success. Participant barriers may include appointment scheduling, wait time, transportation, travel time and distance, child care issues, maintaining contact between study visits, language or cultural issues, and participant preferences for a specific treatment assignment. Study-related barriers may include staff workload and scheduling, scanning windows and scheduling, wait time before intervention initiation (e.g., wait list controls or cross-over designs), grouped intervention, incentive structure, or availability of intervention outside of a research setting.

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