



National Center for
Complementary and
Integrative Health

Tool Summary Sheet

Tool: Study Accrual and Retention Plan (SARP) Template

Purpose: MS Word template to be used as a starting point for preparing a SARP Template

Audience/User: Principal Investigators and Study Staff

Details: This document is the National Center for Complementary and Integrative Health (NCCIH) SARP template for clinical research.

Best Practice Recommendations:

Review this template and customize to the specific needs and requirements of the SARP. Sample text may be updated as needed.

In the template, the instructions and explanatory text are indicated by *{blue italics}*. Instructional text will also be enclosed in braces to signify this text for screen-readers used by the visually impaired.

Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.

Delete template-specific *instructional text* as well as this Tool Summary Sheet during the SARP development process.

It is easiest and cleanest to use the styles that are embedded in the document, rather than to create your own.

Ensure that all placeholder and example text is replaced with the study specific information.

Tool Revision History:

Version		
Number	Date	Summary of Revisions Made:
1.0	05Jan 2016	First approved version

<p align="center">Study Accrual and Retention Plan</p> <p align="center"><Insert protocol/project title></p>
--

Name of Sponsor:	National Center for Complementary and Integrative Health
Grant Number:	<Insert grant number>
Grant Title:	<Insert grant title>
PI Name:	<Insert PI name>

REQUIRED SIGNATURES

{Begin required text}

This Study Accrual and Retention Plan must be signed by both the Principal Investigator and the Institution's Authorizing Business Official, and then be submitted to the NCCIH. NCCIH exercises stewardship of public funds by monitoring the accrual and retention benchmarks set by the study team throughout the grant lifecycle. NCCIH works closely with study teams and their institutions to address and intervene early in clinical studies if accrual and retention challenges arise.

Signature of Principal Investigator:

X

Principal Investigator

Signature of Authorizing Business Official:

X

Authorizing Business Official

{End required text}

1. BACKGROUND

In accordance with the National Center for Complementary and Integrative Health (NCCIH) Policy on Study Accrual and Retention, all clinical research studies funded by NCCIH will be required to submit a detailed Study Accrual and Retention Plan (SARP) prior to involving human subjects. **If more than one applicable study will be conducted within the grant, a separate SARP must be submitted for each study.** The SARP must be approved by NCCIH before funds can be used for activities related to human participants including participant screening, enrollment, randomization and conduct of the study intervention.

It is understood that NCCIH will formally review human subject accrual during the study per the terms and conditions outlined in the Notice of Award. NCCIH requires updates on participant accrual and retention at least every 4 months while enrollment and data collection is ongoing. Based on the updated accrual and retention data provided by the study team, NCCIH will compare actual accrual and retention to expected accrual and retention rates found within this document.

2. DURATION OF HUMAN SUBJECTS INVOLVEMENT

{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 (month and year).}

{Begin sample text}

It is expected that participant enrollment will begin by <month and year> and that human subjects activity will be completed by <month and year>.

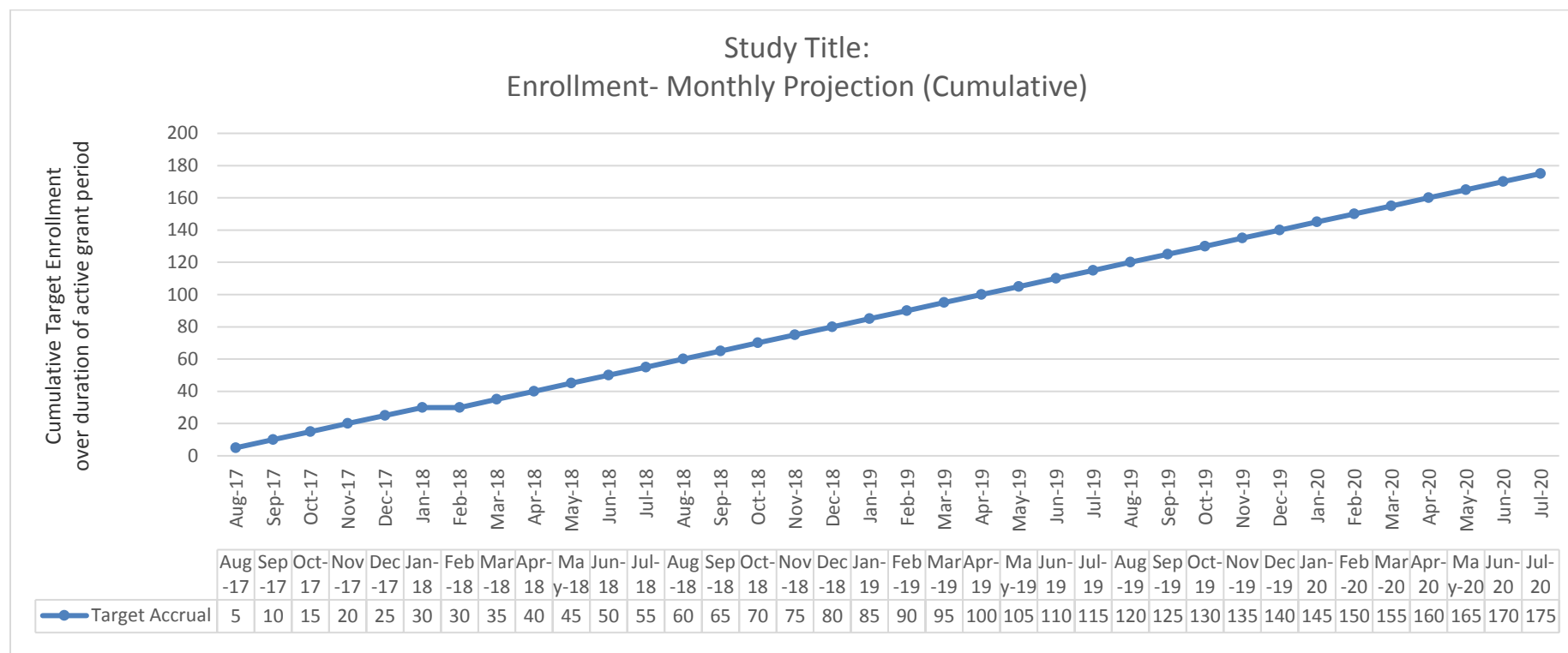
{End sample text}

3. LENGTH OF ACTIVE ENROLLMENT

{Clarify the length of active enrollment (months) and the rate of participant enrollment/randomization (if applicable) by calendar month for the duration of the active award period. Please note that accrual may not be linear. If the study plans to enroll in cohorts, this should be reflected within the accrual plan. Likewise, if the study plans to enroll only during the academic year this should be reflected in the accrual plan.}

{Begin sample text}

It is expected that enrollment/randomization will take place from <month and year> through <month and year>



{End sample text}

4. LOST TO FOLLOW-UP

{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.}

{Begin sample text}

Lost to follow-up: 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.

The anticipated lost to follow-up rate for this study will be <percentage of total enrollment>.

{End sample text}

5. RECRUITMENT 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](#) and an [accrual stage checklist](#) on the NCCIH website.}

6. CONTINGENCY PLANS

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

7. 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.}