Webinar: NCCIH Policy on Study Accrual and Retention for Human Subject Research

May 18, 2017; 2:00-3:00 p.m. ET
NCCIH Policy on Study Accrual and Retention Plans (SARP)

During the Webinar, please send questions to: NCCIHwebinarQ@mail.nih.gov

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Webinar Speakers

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Presentation Overview

1. Overview of current and upcoming NIH Policy Reforms
2. SARP Background and Applicability
3. Required Elements of the SARP
4. SARP Performance Levels
5. NCCIH Action Based on SARP Performance Levels
6. Question and Answer Session
7. Important Links
NIH Policy Reforms - Building Better Clinical Trials Through Stewardship and Transparency
Background

- All human research studies funded by NCCIH on or after January 1, 2017, must submit a detailed Study Accrual and Retention Plan (SARP) prior to involving human subjects.
- The SARP must be approved by NCCIH before funds can be used for activities related to human participants including screening, enrollment, randomization and study conduct.
- The SARP further clarifies the existing NCCIH oversight process for clinical research (as detailed in the clinical terms of award).
Applicability

- For each clinical study covered by this policy, the study investigator in consultation with the NCCIH program director shall agree to benchmarks for monitoring accrual and retention as outlined in the approved SARP.
- A SARP Template is available to assist investigators in developing a comprehensive plan.
- If a grant application proposes more than one clinical research study, a separate SARP must be proposed for each clinical research study.
SARP Required Information

- Anticipated date of the first participant enrollment (month/year)
- Anticipated date when the final participant will conclude clinical activity including all intervention and follow-up visits (month/year)
- Rate of active enrollment by calendar month for the duration of the active award (# participants/ calendar month)
- Based on review of existing literature and prior experience, Anticipated lost to follow-up rate (percentage of total enrollment)
- Countersignature of Authorizing Business Official for finalized SARP
Performance Based on SARP Milestones

- Accrual and retention performance is compared with the approved SARP milestones.
- NCCIH requires updates on participant accrual and retention at least every 4 months while active enrollment and data collection is ongoing.
- Four performance levels have been established. Current performance level will cue NCCIH follow-up actions.
- In addition to the NCCIH actions described in each of the performance levels, NCCIH may take action according to all preceding performance levels.

For example, all Level 1 actions are applicable to Level 2.
On-Track Performance (studies meeting any of the following criteria):

- If study accrual is < 100% and ≥80% of the benchmark for a given time point; or
- If study initiation is delayed by no more than one accrual reporting period (approximately 4 months); or
- If the actual lost to follow-up rate is less than or equal to the expected lost to follow up rate.

**NCCIH Action:** NCCIH staff may increase monitoring frequency or inquire about the success of recruitment strategies consistent with the approved SARP. If study initiation has been delayed, NCCIH staff will query the reasons for the delayed start.
Level 1 Performance

Level 1 Performance (studies meeting any of the following criteria):

- If study accrual is < 80 percent and ≥60 percent of the benchmark for a given time point
- If study initiation is delayed by more than one accrual reporting periods (approximately 5-8 months)
- If the actual lost to follow-up rate exceeds the expected lost to follow-up rate by up to 5 percent.

For example, the expected lost to follow-up rate is 10 percent while the actual lost to follow-up rate is 15 percent.
NCCIH Actions for Level 1 Performance

NCCIH staff may:

- Increase monitoring frequency.
- Request a formal report evaluating barriers to meeting benchmarks and/or a screening evaluation.
- Ask the study team to discuss and document the relative success of current recruitment strategies.
- Encourage the study team to engage their NCCIH-approved IMC/DSMB and institutional resources in developing strategies for augmenting accrual & retention.
Level 2 Performance (studies meeting any of the following criteria):

- If study accrual is < 60 percent of the benchmark for a given time point
- If study initiation is delayed by more than three accrual reporting periods (approximately 12–18 months)
- If the actual lost to follow-up rate is between > 5 percent and < 9 percent more than the expected lost to follow-up rate.

For example, the expected lost to follow-up rate is 10 percent while the actual lost to follow-up rate is between 16 percent and 19 percent.
NCCIH Action for Level 2 Performance

NCCIH staff may:

- Engage the study team in bi-monthly or weekly phone conversations to assess ongoing progress.
- Request that the PI and study coordinator meet on a routine basis.
- Perform a site visit.
- Request that the study expand study eligibility criteria or add additional site(s).
- Propose revisions to the study design or primary aims.
- Request that the original SARP be revised.
- Request Interim Progress Reports until SARP benchmarks are reached.
- Request a formal corrective action plan and consider budgetary controls.
NCCIH Level 3 Performance

Level 3 Performance (studies meeting any of the following criteria):

- If study accrual remains < 60 percent of the benchmark for two or more consecutive reporting periods
- If study initiation is delayed by more than 18 months
- If the actual lost to follow-up rate exceeds the expected lost to follow-up rate by 10 percent or more.

For example, the expected lost to follow-up rate is 10 percent while the actual lost to follow-up rate is 20 percent or more.
NCCIH Action for Level 3 Performance

NCCIH staff will:

- Request a formal Corrective Action Plan with revised accrual/retention targets and timelines (Revised SARP).
- Implement budgetary controls including restricting funds already awarded, withholding funds not yet awarded, extending the period of active award and/or requesting a revised budget.
- If a study has not yet commenced, request that the proposed study be suspended.
- When ongoing efforts to stimulate accrual lack viability, request an orderly shut-down of the clinical study and no further data collection will be permitted.
SARP Takeaways

✓ The SARP clarifies accrual and retention benchmarks before the clinical study is initiated.
✓ The NCCIH Program Director will work closely with the study team to remedy departures from the approved SARP to facilitate early and frequent intervention with the intent to improve overall study success.
✓ The approved SARP is the rubric for evaluating performance toward reaching the study’s stated aims.
✓ **NCCIH is here to help!!!** The SARP provides a starting point for ongoing dialogue between NCCIH and the study team regarding opportunities to stimulate, refine and maximize the funded study.
Important Links

NCCIH SARP Policy https://nccih.nih.gov/grants/policies/SARP
NCCIH SARP Template https://nccih.nih.gov/grants/policies/SARP-template
NCCIH Research Blog Post https://nccih.nih.gov/research/blog/new-policy-on-clinical-study
AccrualNet: Advice and training on patient recruitment https://accrualnet.cancer.gov/
Questions?

Please email your questions to:
NCCIHwebinarQ@mail.nih.gov