Policy on Recruitment and Retention Monitoring and Reporting of Clinical Research Awards Supported by the National Institute on Drug Abuse

Purpose/Background

The mission of the National institute on Drug Abuse (NIDA) is to advance science on drug use and addiction and apply that knowledge to improve individual and public health by supporting and conducting a wide range of clinical research. Effective clinical research relies on the ability of researchers to meet recruitment and retention goals. Recruitment and retention goals should include consideration, as appropriate, for inclusion and retention of women, members of racial and ethnic minority groups, and populations across the lifespan, in accordance with National Institutes of Health (NIH) policies.

NIDA strives for effective and efficient recruitment and retention of participants in all supported active clinical research, and this policy specifies the approach for monitoring recruitment and retention of participants in NIDA-supported clinical research to facilitate the achievement of research objectives and to ensure that NIDA remains a responsible steward of public funds.

NIH-funded research involving human subjects brings with it special considerations throughout the grant life cycle. The terms outlined here are in addition to and not in lieu of other NIH policies, including standard human subjects instructions in the SF424 Application Guide and the Research Performance Progress Report (RPPR) **which require annual reporting, at a minimum, per NIH reporting requirements for study enrollment.**

Policy

The **Recruitment and Retention Monitoring and Reporting of Clinical Research Awards Supported by the National Institute on Drug Abuse policy**, as described in NOT-DA-23-033, specifies the requirement for the monitoring and reporting of recruitment and retention of participants in identified NIDA-supported contracts, grants and cooperative agreements that are active as of October 1, 2023 (FY2024) and support human subjects research (clinical research) as defined by the National Institutes of Health (NIH).

This policy applies to any active NIDA-supported clinical research which may include clinical trials, clinical research projects, and/or clinical research studies, regardless of size, to enable NIDA staff to more effectively monitor the recruitment and retention of

participants. NIDA-funded **clinical trials** will be subject to enhanced reporting of recruitment data (and retention data, at the discretion of the PO/COR) at least twice per year. Identified NIDA-funded clinical research may be deemed by the Program Official (PO) or Contracting Officer's Representative (COR) as requiring additional reporting and/or oversight. This policy ensures that investigators work with their PO/COR to establish recruitment and retention milestones of a clinical trial, clinical research project, and/or a clinical research study and establishes that progress must be reported based on the identified need by the PO/COR throughout the course of the award. This NIDA policy is aligned with the NIH Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®, Policy for the Enrollment of Participants in Clinical Trials.

In addition to the NIH reporting requirements, Principal Investigators (PIs) will be prompted by an automatically generated email from the NIDA Tracking Recruitment Assessment Query (TRAQ) system (from the address nidatraqnotifications@mail.nih.gov with subject line "NIDA TRAQ: …") to update recruitment data within the NIH Human Subjects System (NIH HSS) and, as appropriate, retention data (see Procedures and Definitions below) within the NIDA TRAQ system. PIs can use their eRA commons username and password to enter these data.

Procedures

Planned enrollment data must be established in the Inclusion Enrollment Report (IER), by the PI, for all NIDA-supported clinical trials, regardless of size. Cumulative (actual) enrollment data for all active NIDA-supported clinical trials must be entered via the NIDA TRAQ system minimally twice per year through HSS, while enrollment data for all other **identified** NIDA-supported clinical research projects and/or clinical research studies must be entered at the frequency deemed appropriate by the PO/COR. Retention data (e.g., participants that complete and those that withdraw from the clinical trial, clinical research project, and/or the clinical research study) must be entered in the NIDA TRAQ system for all identified active NIDA-supported clinical research deemed by the PO or COR as requiring additional oversight.

Recipients can access the NIH HSS through the Human Subjects link in the RPPR or the eRA Commons Status page to update inclusion enrollment reports. For more information, see: https://www.era.nih.gov/erahelp/HSS_External/about_hss_external.htm?Highlight=milestone.

When developing milestones for recruitment and retention, consideration must be given, as appropriate and in accordance with NIH policies, to recruitment and retention of women, members of racial and ethnic minority groups, and participants of all ages. In

addition, consideration must be given to the timing of milestones to ensure that recruitment and retention will take into consideration the necessary study start-up time and end with enough time remaining within the proposed project period to allow for necessary follow-up and analysis. The identified milestones, or targets, are to be cumulative in nature to eventually meet the total sample of the proposed study. The planned start and end dates for recruitment and cumulative recruitment targets are entered into the NIH HSS, and milestones should be updated at the time of the annual RPPR on the Human Subjects and Clinical Trials Information Form in HSS.

Retention data are entered into the NIDA TRAQ system, as needed. PIs can use their eRA commons username and password to enter these data.

- After the recruitment start date, and in accordance with the terms and conditions of the award, the PI submits this data through the NIH HSS.
- At any time during the project period, if modification of the total number of participants is needed based on scientific results or other unexpected events, the PI, via email from the AOR, notifies the assigned PO/COR and GMS/CMS (and other relevant regulatory bodies, as appropriate) and proposes an adjusted target number of participants. The requested changes will be evaluated, approved or disapproved by the PO/COR and GMS/CMS staff.
- If changes to the total number of participants are approved by the PO/COR and GMS/CMS, in accordance with the terms and conditions of the award, the PI submits modified recruitment targets via NIH HSS for approval by the PO/COR and continues to provide NIDA with cumulative actual recruitment updates in accordance with NIH policies or as deemed by the PO/COR if additional oversight is deemed necessary. For clinical trials, NIDA-approved (and other relevant regulatory bodies, as appropriate) modifications to trial protocols must be submitted to ClinicalTrials.gov.
- If changes to the interim (but not total) recruitment targets are needed, the PI must provide an explanation for the changes via email to the PO/COR and enter adjusted interim target numbers in the NIH HSS for PO/COR approval.
- The PO/COR will review the enrollment report, and, as necessary, will follow up with the PI to discuss recruitment challenges and efforts to improve enrollment. At the PO's/COR's discretion, a remediation plan and changes to the frequency in reporting may be implemented (e.g., every 1, 3, 6, months or any frequency that is deemed appropriate by the PO/COR).

- Once a PO/COR requests remediation, the PI will be prompted by an automatically generated email from the NIDA TRAQ system to update recruitment/enrollment data within the NIH HSS system and, as appropriate, retention data (e.g., participants that complete and those that withdraw from the clinical research project and/or the clinical research study) within the NIDA TRAQ system at the established frequency. If recruitment does not show adequate improvement, the NIDA team will determine viable options depending on the severity and duration of the recruitment shortfalls. If the deficiencies persist, the NIDA team will take further action, in accordance with NIH policy, which could include orderly phaseout, suspension, termination, or withholding of support.[1]

Responsibilities

- **Principal Investigator(s) (PI)**, determines the preliminary and updates to actual recruitment milestones for the recruitment phase of the study, ensures recruitment plans for appropriate representation of women, minorities and participants across the lifespan in accordance with the approved application and NIH policies, submitting updated data on participant recruitment and enrollment at the required frequency via the eRA Commons, in the NIH HSS (typically when submitting the annual RPPR) and ensures studies required to register at ClinicalTrials.gov are reported accordingly. Also, in the RPPR, the PI must update the Clinical Trial Milestone Plan for all studies involving clinical trials. In addition, and upon request, the PI submits interim recruitment and retention reports into the NIH HSS and NIDA TRAQ systems, respectively, and, as appropriate, provides additional information via the **Authorized Organization Representative (AOR)** to NIDA officials regarding recruitment remediation efforts, as needed.
- **NIDA Program Officials (POs) or Contracting Officer's Representatives (CORs)** review the proposed recruitment and retention milestones for appropriateness and feasibility, and request any additional information needed from the **PI/AOR** throughout the course of the award. The PO/COR, together with Grants Management (GM)/Contracts Management (CM) staff, will discuss and determine the terms and conditions of the award and inform the **PI/AOR**. In coordination with GM/CM staff, the PO/COR will monitor recruitment and retention and determine whether the recruitment goals are being met in accordance with the terms and conditions in the Notice of Award. PIs are expected to work with their POs/CORs should any modifications to approved targets or reporting frequency are needed.
- **NIDA Grants Management Specialists (GMSs) and/or Contract Management Specialists (CMSs)** ensure that NIDA actions comply with federal regulations and

NIH policy. They are responsible for the business management and other non-programmatic aspects of the award, receive official documents for inclusion in the official grant or contract files and specify the appropriate terms and conditions for the award notice.

Definitions

- Enrollment Data:

  Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began.

  - Includes the estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study. Definition will be specific to each clinical research study and/or project and should be determined between the PI(s) and PO/COR of the respective study and/or project.

    - Note: "Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.

- Retention Data:

  - Completers: Generally, individuals who completed the study, defined as those with primary study outcome assessment data available. Definition will be specific to each clinical research study and/or project and should be determined between the PI(s) and PO/COR of the respective study and/or project.

  - Dropouts: Generally, individuals who enrolled in the study who withdrew/were withdrawn prior to primary outcome assessment, with no primary outcome data available. Definition will be specific to each clinical research study and/or project and should be determined between the PI(s) and PO/COR of the respective study and/or project.

Resources

- ClinicalTrials.gov
- Inclusion of Women and Members of Racial and/or Ethnic Minority Groups in Clinical Research
- Inclusion Across the Lifespan in Human Subjects Research
- eRA commons
- NIH Human Subjects System
- NIH Grant Policy Statement
- NIH and Other PHS Agency Research Performance Progress Report (RPPR) Instruction Guide
- Federal Acquisitions Regulations

References

[1]See NIH Grants Policy Statement 8.5.2 and Federal Acquisition Regulations Part 49