

Guidance for NINR F31/F32 applicants proposing to gain clinical trial research experience (CTRE)

NINR encourages fellows supported on NIH NRSA Fellowship awards (F31 and F32) and trainees supported on NIH NRSA Institutional Training awards to receive training in clinical research, including obtaining clinical trial research experience (CTRE). All applicants should be sure to carefully read and follow the instructions in the relevant Funding Opportunity Announcement (FOA).

- For an F31 or F32 application, the research must be conducted under a mentor's guidance for CTRE, as defined in the FOA instructions:
 - *If the applicant is proposing to gain experience in a clinical trial as part of his or her research training*, the sponsor or co-sponsor (mentor) must include a statement to document leadership of the clinical trial including source of funding, ClinicalTrials.gov identifier (NCT #) and appropriate expertise to guide the applicant in any proposed clinical trials research experience. The individual receiving support for the clinical trial (i.e., the sponsor/primary mentor or a co-sponsor) is the responsible individual of record for oversight of the trial
 - In the *Research Strategy* section, *if the applicant is proposing to gain experience in a clinical trial as part of his or her research training*, describe the relationship of the proposed research project to the clinical trial.
 - The sponsor (mentor) should also describe the roles and responsibilities that both he/she and the fellow are undertaking, including contributions to the research plan, the portion of the research ideas and plan that originated with the applicant, and the relationship between the proposed research plan and funded or unfunded research projects previously devised by the sponsor.

- Trainees can propose projects in which they gain experience in the wide variety of research skills specific to clinical trials including, but not limited to: developing a clinical trial protocol; applying the principles of informed consent and requirements for human subjects research; learning about random assignment of participants to different intervention arms; analyzing trial endpoints; and/or implementing quality control standards.

- NIH expects the individual receiving support for the clinical trial (i.e., the sponsor/primary mentor or a co-sponsor) to assume responsibility and oversight of the trial and the fellow's activities regarding the trial (e.g. reporting). Oversight includes (but is not limited to): interacting with relevant Institutional Review Board (IRB) staff; reviewing all informed consent documents; reporting potential serious adverse events; and maintaining responsibility for patient safety.

- While the trainee may absolutely participate with the sponsor or mentor in some or even all of the clinical trial activities as part of their training, the trainee cannot independently lead the study.

- In the application, clearly delineate the distinct roles and responsibilities of the fellow versus the sponsor or mentor, and make sure to clearly show how the mentor will provide appropriate oversight of clinical trial related activities. This can be done in the Sponsor and Co-Sponsor attachment for the sponsor and the Research Strategy for the fellow.
- When preparing the application for CTRE, a fellowship applicant may answer all Clinical Trial Questionnaire questions in a study record as Yes. However, since the study is not considered an independent clinical trial, applicants are not allowed to provide information in Sections 4 and 5 of the study record in the PHS Human Subjects and Clinical Trials Information form. In addition, the NCT# should not be included in Section 1, item 1.5, but instead should be included in information provided by the Sponsor.
- Instead of using Sections 4 and 5 of the PHS Human Subjects and Clinical Trials information form, applicants proposing to gain mentored training experience in a clinical trial should provide details of their contribution to the study in the Research Strategy rather than in the clinical trial specific fields on the PHS Human Subjects and Clinical Trials Information form.

Additional information:

1. NIH Extramural Nexus post, “The Roles of Fellows and Trainees in NIH Supported Clinical Trials” (<https://nexus.od.nih.gov/all/2018/10/12/the-roles-of-fellows-and-trainees-in-nih-supported-clinical-trials/>)
2. NIH grants.nih.gov, Frequently Asked Questions Clinical Trial-specific FOAs (https://grants.nih.gov/grants/policy/faq_clinical_trial-specific_FOAs.htm#5693)