Commons Working Group – Discussion Aides

September 6, 2018

Current plan for Fellowship (F) and Training (T) FOAs:

- In title, include the phrase "No independent clinical trials"

Funding Opportunity Title	**Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32 – No Independent Clinical Trials)**

- In FOA Part 2, Section 2

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New Resubmission The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose independent clinical trials. Note: Applicants may propose to gain experience in a clinical trial led by a sponsor/co-sponsor as part of their research training. Need help determining whether you are doing a clinical trial?

Question for discussion:

Given that Fellowship and Training FOAs will always be set to "Clinical Trial Not Allowed" (Fellows and appointed Trainees cannot propose independent clinical trials but can gain experience under a sponsor/mentor), is it better to include the "No independent Clinical Trials" text in the title or stay silent?

Communications & Training Resources: Public OER Website

https://grants.nih.gov/policy/clinical-trials.htm

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NEWS & EVENTS | ABOUT OER

Home » Policy & Compliance » Clinical Trial Requirements for Grants and Contracts

Policy & Compliance

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight

Select Policy Topics

- Animal Welfare
- Application Submission Policies
- Clinical Trial Requirements
  - Clinical Trial Definition
  - Why the Changes
  - Good Clinical Practice
  - Specific Funding Opportunities
  - New Form
  - Single IRB Policy
  - Protocol Template
  - Registration and Reporting
- NIH Funding Strategies
- Human Subjects Research
- Intellectual Property Policy
- Lobbying Guidance for Grantee Activities
- Early Stage and Early Established Investigator Policies

Clinical Trial Requirements for Grants and Contracts

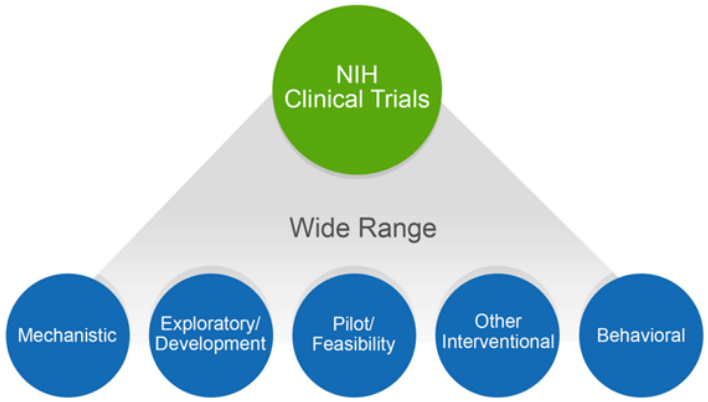
NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Learn more

Your human subjects study may meet the NIH definition of a clinical trial.

FIND OUT HERE



On This Page:

- Why Changes to Clinical Trial Policies?
- Good Clinical Practice Training
- Clinical Trial-specific Funding Opportunities
- New Human Subject and Clinical Trial Information Form
- Single IRB Policy for Multi-site Research
- Clinical Trials Protocol Template
- Clinicaltrials.gov Registration and Reporting

Related Resources

- FAQs
- Training Resources
- Research Involving Human Subjects
- ClinRegs: international clinical trials regulations
- Clinicaltrials.gov
- For NIH Staff

Reducing Risk of Late Submissions

All

- Take advantage of available resources (e.g.., https://grants.nih.gov/policy/clinical-trials.htm; annotated form sets)
- Lots of changes. Need to leave extra time to work through errors/warnings.
    - Many new validations associated with the PHS Human Subject and Clinical Trials Information form. Our submission validation service currently won't run until all the form fields marked with an asterisk (i.e., fields required by the schema are completed). Plan accordingly.

ASSIST

- Take advantage of the ASSIST Copy feature to move data from one FOA or package to another (e.g., FORMS-D package to FORMS-E; Clinical Trial Not Allowed FOA to Clinical Trial Required FOA)
- The PHS Human Subject and Clinical Trials Information form has multiple levels (main form, study records, inclusion enrollment reports), you'll be prompted to save often

System-to-System

- System-to-system solution providers should take advantage of available web services (e.g., submission image service – SIL, submission validation service – SVS)
    - Our clinical trial implementation is evolving. Our system issue policy only covers federal systems. If you rely on our services and we have a bug that prevents your submission, you're covered. If you implement our rules yourselves and code a bug that prevents submission you are not covered.
    - Code "overrides" for the validations you choose to implement
- Downloadable forms will not be a back-up option for FORMS-E
    - Be prepared to use either ASSIST or Workspace for FORMS-E application packages

Workspace

- Use the "Preview Grantor Validation" tab to check your application data against NIH business rules and correct any errors identified prior to submission
    - NIH business rules are NOT checked using the standard "Check for Errors" and "Check Application" buttons
- If errors are identified by eRA after submission, you will need to "Reopen" your application in order to make any needed changes
- Use the "Grantor Image" tab to view an image of your application in the NIH format used for funding consideration
    - The NIH format is NOT displayed using the standard "Preview Application Forms" button
- "The "Agency Received" status DOES NOT indicate that NIH has received a viable application for funding consideration. It simply means we picked up the application from Grants.gov and processed it at which time we may have found show-stopper errors. When you see the "Agency Received" status

checked in the progress bar, you are still responsible for logging into eRA Commons and tracking your application. If you don't see an assembled application image in eRA Commons (even if you were able to preview the application in Workspace), then we do not have it.

- As a federal system, our policies for Dealing with System Issues extend to Workspace. With Workspace, Grants.gov runs most of their checks prior to completing the submission. If errors are found, you do not get to the point where a Grants.gov tracking number is assigned. NIH no longer has visibility to the fact you attempted to submit or any associated errors encountered. This simply means, you need to take a more active role in carefully documenting the details of your good faith submission attempt (e.g., screen shots with date/time stamps, exact messages received, Grants.gov ticket numbers, etc.) and provide that information to the eRA Service Desk when reporting your issue.