Things to know: Updates on Clinical Trial Policies, Rigor and Transparency at NIH

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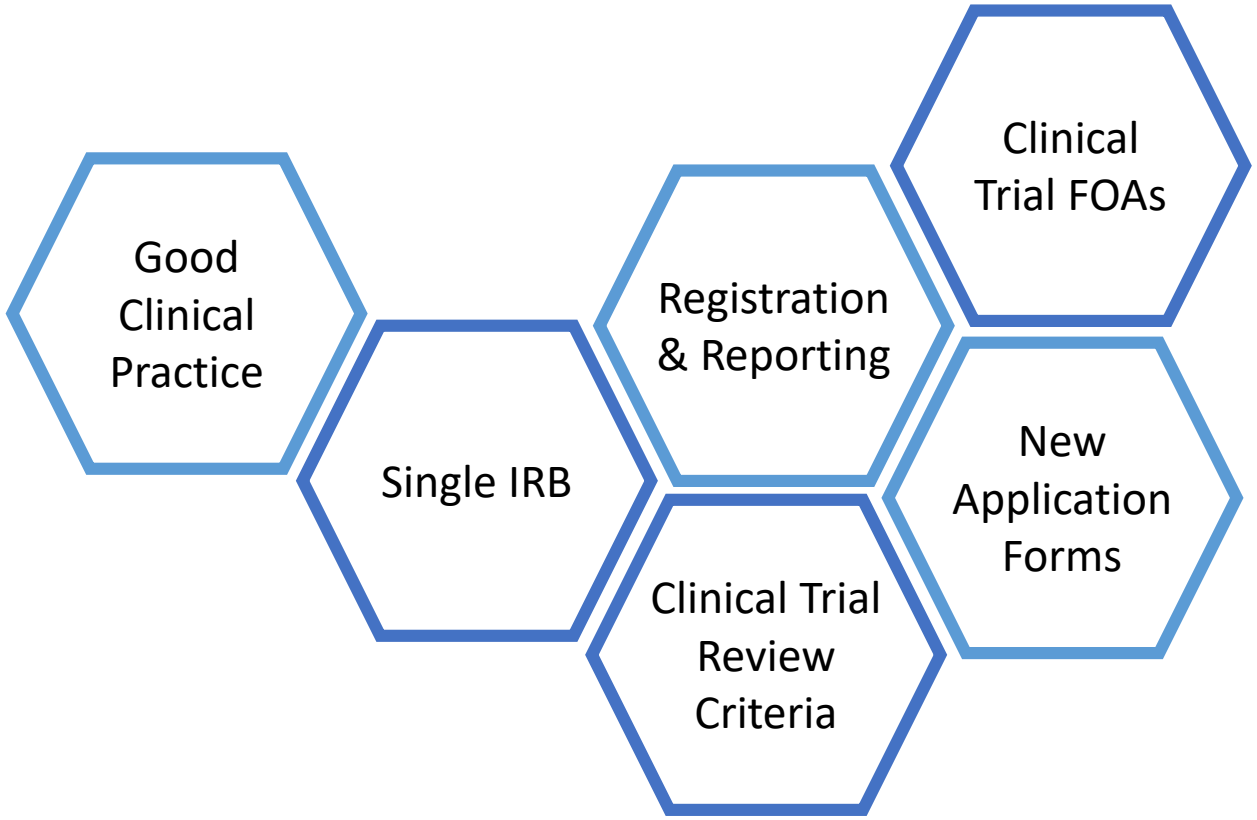
Mentored Training for Dissemination and Implementation Research in Cancer

Doing Human Subjects Research?

Changing NIH Policies May Impact You

NIH Initiatives to Enhance Clinical Trial Stewardship



Enhancing Clinical Trial Stewardship at NIH

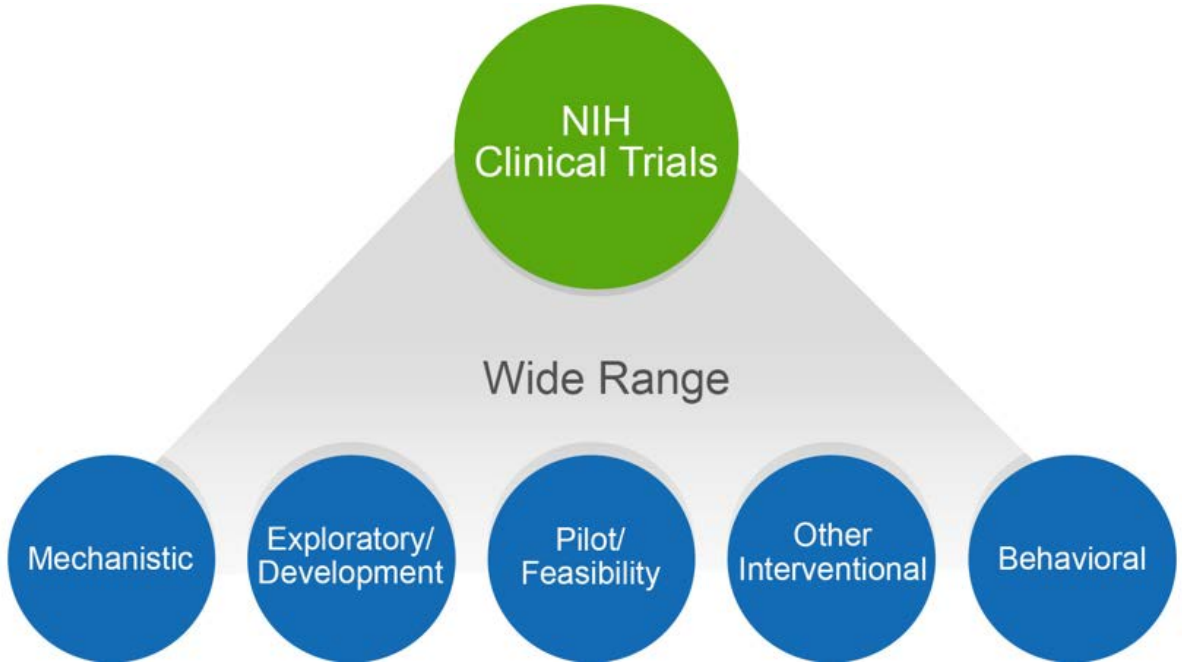
- ✓ Accountability
- ✓ Transparency
- ✓ Efficiency
- ✓ Dissemination

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

NIH Might Consider Your Human Subjects Research to be a Clinical Trial

Does your study…

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the **effect of intervention(s)** on the human subject(s)?
- ✓ Have a **health-related biomedical or behavioral outcome?**



If "yes" to ALL of these questions, your study is considered a clinical trial

Unsure how to answer the questions? We have a tool that can help! https://grants.nih.gov/ct-decision/

Identifying Whether NIH Considers Your Study to be a Clinical Trial is Crucial

It impacts whether you need to:

- ✓ Respond to a **clinical trial-specific FOA**
- ✓ Address additional **review criteria** specific for clinical trials
- ✓ **Register and report** your clinical trial in ClinicalTrials.gov

Identifying the Right Funding Opportunity Announcement (FOA) is Key

Due Dates on or after January 25, 2018	All clinical trial applications **MUST** be submitted to an FOA that allows clinical trials

How to determine if an FOA accepts clinical trials?

1. Refer to Section II. Award Information
2. Indicated in FOA title (new FOAs only)

Tip: Check your FOA at least 30 days before the due date for any updates

Clinical Trials Eligibility in FOAs

Dissemination and Implementation Research in Health (R03)	PAR-16-237	NCI	05-10-2016	05-08-2019	R03
Dissemination and Implementation Research in Health (R01 Clinical Trial Optional)	PAR-18-007	NCI	11-03-2017	05-08-2019	R01
Dissemination and Implementation Research in Health (R21 Clinical Trial Optional)	PAR-18-017	NCI	11-03-2017	05-08-2019	R21
Improving the Reach and Quality of Cancer Care in Rural Populations (R01 Clinical Trial Required)	RFA-CA-18-026	NCI	04-27-2018	09-20-2018	R01
Comprehensive Partnerships to Advance Cancer Health Equity (CPACHE) (Collaborative U54 Clinical Trial Optional)	PAR-18-767	NCI	04-30-2018	01-10-2020	U54
Investigation of the Transmission of Kaposi Sarcoma-Associated Herpesvirus (KSHV) (R21 Clinical Trial Not Allowed)	RFA-CA-18-014	NCI	05-10-2018	08-17-2018	R21

Good Clinical Practice (GCP) Training

Who: All NIH-funded investigators involved in the conduct, oversight or management of clinical trials

What: Investigators are expected to receive Good Clinical Practice training

Why: To assure the safety, integrity, and quality of clinical trials

How: Through a class or course, academic training program, or certification from a recognized clinical research professional organization

When: Effective January 2017. Training should be refreshed every 3 years

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

Clinical Trial Specific Review Criteria

FOAs will include additional criteria:

Scored Review Criteria

- ✓ Significance
- ✓ Investigator
- ✓ Innovation
- ✓ Approach
- ✓ Environment

Additional Review Criteria

- ✓ Study Timeline & Milestones

Read the FOA carefully and be sure your application addresses the review criteria appropriately

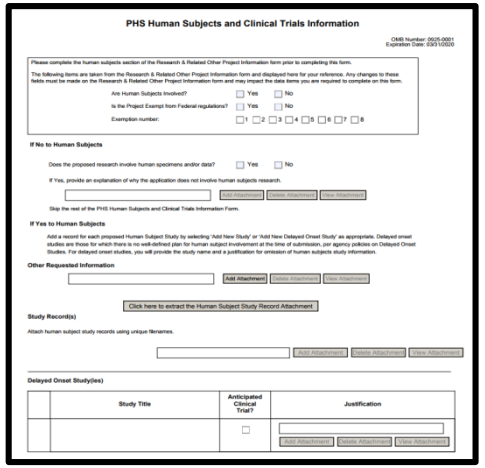
New Application Packages (FORMS-E)

Due Dates on or after January 25, 2018

FORMS-E Application Packages is **REQUIRED** (including new Human Subjects and Clinical Trials form)

PHS Human Subjects and Clinical Trials Information Form

- ✓ Consolidates information from multiple forms
- ✓ Incorporates structured data fields
- ✓ Collects information at the study-level


PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? Yes No

Is the Project Exempt from Federal regulations? Yes No

Exemption number: 1 2 3 4 5 6 7 8

If No to Human Subjects

Does the proposed research involve human specimens and/or data? Yes No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment Delete Attachment View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment Delete Attachment View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Add Attachment Delete Attachment View Attachment

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification

Add Attachment Delete Attachment View Attachment

Be sure you are using the correct application forms for your due date.

FORMS-E will be available October 2017.

See https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov

Who: All clinical trial applications requesting support for a trial that will be initiated on/after January 18, 2017

What: Register and report the results of trials in ClinicalTrials.gov

Why: Increase the availability of information about clinical trials and their results to the public in a timely manner

When: Effective for applications due on/after January 18, 2017

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

Single Institutional Review Board (sIRB) Policy for Multi-site Research

Domestic multi-site non-exempt human subjects research studies will require a single IRB of record

Key Dates

- **Grants:** Applications due on or after January 25, 2018
- **Contracts:** Solicitations published starting January 25, 2018

Exceptions

- sIRB not applicable for Career Development (K), Research Training (T), or Fellowship (F)

See https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

Reviewing Rigor and Transparency of Research: Considerations in your D&I grant

	Applies to which applications?	Where will I find it in the application?	Where do I include it in my critique?	Addition to review criteria	Affect overall impact score?
Scientific Premise	All	Research Strategy (Significance)	Significance	Is there a strong scientific premise for the project?	Yes
Scientific Rigor	All	Research Strategy (Approach)	Approach	Are there strategies to ensure a robust and unbiased approach?	Yes
Consideration of Relevant Biological Variables, Such as Sex	Projects with vertebrate animals and/or human subjects	Research Strategy (Approach)	Approach	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?	Yes

Some tips for addressing these topics

Scientific premise

- ✓ At the end of the Significance section, provide a short summary beginning: “The scientific premise of our study is…”

Rigor

- ✓ At the beginning of the Approach section, provide and overview paragraph with a statement: “Using the most rigorous methods possible…”

Sex as a biological variable

- ✓ Options: include sufficient numbers for sex differences, sex specific hypotheses, analyses/reporting by sex

- ✓ Justify only one sex


THANK
YOU