NIH Clinical Trials
https://osr.northwestern.edu/policies/nihct

Preparing an Application for the January 25, 2018 Deadline?
Please note that a number of NIH-mandated changes related to NIH clinical trial requirements affect applications with receipt dates on or after January 25, 2018, including:

- Clinical Trial-Specific Funding Opportunities
- Clinical Trial-Specific Review Criteria
- New Human Subjects and Clinical Trial Information Form [FORMS-E]
- Clinical Trials Protocol Template
- Single IRB Policy for Multi-Site Research

This page highlights key points and selected resources related to NIH's 2017-2018 clinical research initiatives - both new changes for 2018 and those that went into effect in 2017. For complete information on these initiatives, visit the Clinical Trial Requirements for Grants and Contracts page on the National Institutes of Health website.

NIH Clinical Trial Definition
NIH has revised its definition of “clinical trial.” The revision is designed to make the distinction between clinical trials and clinical research studies clearer and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials.

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. (NOT-OD-15-015: Notice of Revised NIH Definition of “Clinical Trial”)

The differences between a clinical trial and a clinical study can be determined using the following four questions (answering “Yes” to all means a study is a clinical trial):

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Need help?
Use these resources provided by NIH to help determine if your research study meets the definition of a clinical trial

- Clinical Trial Definition FAQ's (A series of questions about the definition itself as well as specific cases)
- Clinical Trial Definition Case Studies (Simplified case studies that apply the four questions to determine whether NIH would consider the research study to be a clinical trial)
NIH Clinical Trial Policies Changes

Clinical Trial-Specific Funding Opportunities
Effective January 25, 2018, all grant applications with plans to conduct clinical trials must be submitted in response to an FOA which specifically states that clinical trials are allowed. All current parent announcements will no longer allow clinical trials. There will be some new parent announcements that will allow clinical trials, and the specifics will depend upon the discipline. Some of the institutes will be joining certain parent announcements specifically for clinical trials, but that's something to be determined by each individual IC.

- Policy on Funding Opportunity Announcements (FOA) for Clinical Trials (NOT-OD-16-147)
- NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 Funding Opportunity Announcements (NOT-OD-18-010)

Clinical Trial-Specific Review Criteria
New review criteria will be used to evaluate applications proposing clinical trials or proposing clinical trial research experience (i.e. individual career development (K) awards, fellowship (F) awards and training (T) awards). New questions related to the following areas will be used to review clinical trials: significance, investigator(s), innovation, approach, environment, and study timeline.

- The NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials (NOT-OD-17-118)

New Human Subjects and Clinical Trial Information Form
A new Human Subjects and Clinical Trial Information form will be included in the new FORMS-E Application Packages and will be required for all applications with due dates on or after January 25, 2018. This new form consolidates all Human Subjects and Clinical Trial related information into one place and expands the information required for studies that meet the NIH definition of a clinical trial. NIH has created a Preview of FORMS-E Grant Application Form Changes as well as a short (9-minute) Video Walk-through of PHS Human Subjects and Clinical Trials Information.

- New NIH "FORMS-E" Grant Application Instructions Available for Due Dates On or After January 25, 2018 (NOT-OD-17-119)

Clinical Trials Protocol Template
If your application includes phase 2 or 3 clinical trials that require Investigational New Drug application (IND) or Investigational Device Exemption (IDE) applications, a NIH-FDA template with instructional and sample text can help you write your protocols. Use of this template is optional. Exemption (IDE) applications, a NIH-FDA template with instructional and sample text can help you in writing your protocols.

- NIH and FDA Release Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials (NOT-OD-17-064)

Single IRB Policy for Multi-Site Research
For applications with due dates on or after January 25, 2018, and contract solicitations published on or after January 25, 2018, NIH expects that all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects.


Good Clinical Practice Training
Effective January 1, 2017 NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP).

- Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials (NOT-OD-16-148)

Clinicaltrials.gov Registration and Reporting
A new regulation and NIH policy expanded Clinicaltrials.gov registration and reporting to ALL NIH-funded clinical trials. All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov for competing applications and contract proposals submitted on or after 01/18/2017.

- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149)