

September 16, 2016

Notice Number: [NOT-OD-16-147](#)

Effective Date Target: September 27, 2017

Policy on Funding Opportunity Announcements (FOA) for Clinical Trials

- NIH will require that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials.

September 16, 2016

Notice Number: [NOT-OD-16-148](#)

Effective Date: January 1, 2017

Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

- GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training.

September 16, 2016

Notice Number: [NOT-OD-16-149](#)

Effective Date: January 18, 2017

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

- The National Institutes of Health (NIH) is issuing this policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov.

September 21, 2016

Federal Register Wednesday, FR Volume 81, No. 183, 64982

Effective Date: January 18, 2017

Clinical Trials Registration and Results Information Submission

- Clarifies and expands the requirements for submission of clinical trials registration and results information to ClinicalTrials.gov. Does not impose requirements on the design or conduct of clinical trials. It specifies how data that were collected and analyzed are submitted to ClinicalTrials.gov.
- Definition: all interventional clinical trials with one or more arms and with one or more pre-specified outcome measure to be controlled clinical trials.
- Must be registered by Sponsor or designee no later than 21 calendar days after enrollment of first study participant. Update at least annually.

February 17, 2017

NIH Notice: [NOT-OD-17-043](#)

New Effective Date: January 25, 2018

Update on Clinical Trial Funding Opportunity Announcement Policy

- 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.

April 27, 2017

NIH Notice: [NOT-OD-17-062](#)

Effective Date: January 25, 2018

New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018

- New PHS Human Subject and Clinical trials Information form - use January 25, 2018 and beyond – new human subject and clinical trial form at time of proposal.

September 20, 2017

Notice Number: [NOT-OD-17-114](#)

Effective date: January 25, 2018

Updates to Active Funding Opportunity Announcements to Prepare for Policy Changes Impacting Due Dates On or After January 25, 2018

- This notice informs the community that we will make a series of updates to existing funding opportunity announcements (FOAs) between September 20 and October 6, 2017 to prepare for grant application form and policy changes impacting applications for due dates on or after January 25, 2018. We will also take advantage of this effort to clean-up FOA text associated with other previous policy changes. This notice does NOT introduce any new policies. We are simply updating FOA text to align with existing policy.

September 21, 2017

Notice Number: [NOT-OD-17-118](#)

Effective Date: January 25, 2018

New Review Criteria for Research Project Applications Involving Clinical Trials

- A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

October 6, 2017

Notice Number: [NOT-OD-17-121](#) Replaced by [Notice Number: NOT-OD-18-109](#)

Effective Date: January 25, 2018

New Review Criteria for Career Development Award Applications Involving Clinical Trials

- This notice informs the community of additional review criteria that NIH will apply to individual career development (K) award applications submitted to due dates on or after January 25, 2018. The reviewers will consider that the clinical trial may include study design, methods, and intervention that are not by themselves innovative, but address important questions or unmet

needs. Reviewers should also consider the scope of the clinical trial relative to the available resources, including the possibility that research support provided through K awards may be sufficient to support only small feasibility studies.

October 6, 2017

Notice Number: [NOT-OD-17-122](#)

Effective Date: January 25, 2018

New Review Criteria for Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Applications Involving Research Experiences in Clinical Trials

- This notice informs the community of additional review criteria that NIH will apply to Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowships if the applicant fellow is proposing to gain research experience in an ongoing clinical trial led by a sponsor or co-sponsor, submitted to due dates on or after January 25, 2018. Reviewers will consider the nature of the research experience proposed by the applicant fellow and the scope of proposal relative to the available resources, including the sponsor's and/or co-sponsor's research support.

October 6, 2017

Notice Number: [NOT-OD-17-123](#)

Effective Date: January 25, 2018

New Review Criteria for Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants Involving Research Experiences in Clinical Trials

- This notice informs the community of additional review criteria that NIH will apply to Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants if one or more appointed trainees will propose to gain research experience in an ongoing clinical trial led by a mentor or co-mentor, submitted to due dates on or after January 25, 2018. Reviewers will consider the nature of the research experience proposed by the trainee(s) and the scope of proposal relative to the available resources, including the mentor's and/or co-mentor's research support.

October 24, 2017

Notice Number: [NOT-OD-18-009](#)

Reminder: FORMS-E Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2018

- This notice reminds the biomedical and health services research communities that applicants must use FORMS-E application packages for due dates on or after January 25, 2018 and must use FORMS-D application packages for due dates on or before January 24, 2018 (see NOT-OD-17-062 for details).

October 25, 2017

Notice Number: [NOT-OD-18-010](#)

Effective Date: January 25, 2018

NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 Funding Opportunity Announcements

- The purpose of this Notice is to announce NIH's plan to publish NIH Research Project Grant (Parent R01 Clinical Trial Required) and NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required) Funding Opportunity Announcements (FOAs) in November 2017 to be used for applications targeting due dates on or after January 25, 2018. Some NIH Institutes and Centers will join these parent FOAs and others will jointly or alone publish IC-specific Clinical Trial FOAs using the same definition of trials described below but will also include additional IC requirements.

November 3, 2017

Notice Number: [NOT-AR-18-008](#)

Effective Date: Immediate

Revision: NIAMS Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements

- The purpose of this Notice is to inform potential applicants that, effective immediately, NIAMS will accept only mechanistic studies that meet NIH's definition of a clinical trial in response to PA-18-345 NIH Research Project Grant (Parent R01 Clinical Trial Required) and PA-18-344 NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required) and its reissues. A mechanistic study is defined as one designed to understand a behavioral or biological process, the pathophysiology of a disease, or the mechanism of action of an intervention.

November 3, 2017

Notice Number: [NOT-AT-18-001](#)

Effective Date: January 25, 2018

NCCIH Policy for Submission of Parent R01 Applications Proposing Clinical Trials

- The purpose of this Notice is to define the types of clinical trials/studies that may be submitted to NCCIH in response to the NIH Research Project Grant (Parent R01 Clinical Trial Required) Funding Opportunity Announcement (FOA) and subsequent reissues of this FOA. For applications submitted on or after January 25, 2018, NCCIH will only accept applications to this FOA that propose human mechanistic trials/studies; no applications will be accepted that include any specific aims that propose to assess efficacy or effectiveness of any intervention. NIH defines a mechanistic study (which can be a type of clinical trial) as "A mechanistic study is designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention."

November 3, 2017

Notice Number: [NOT-HL-17-546](#)

Effective Date: next submission date

NHLBI Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for the NIH Parent R01 Clinical Trial Required Announcement

- The purpose of this Notice is to inform potential applicants that NHLBI will only accept mechanistic studies that meet NIH's definition of a clinical trial in response to PA-18-345 NIH Research Project Grant (Parent R01 Clinical Trial Required) and its reissues. A mechanistic study is designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention.

November 3, 2017

Notice Number: [NOT-MH-18-004](#)

Effective Date: next submission date

NIMH Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements

- The purpose of this Notice is to inform potential applicants that NIMH will accept mechanistic studies only (as described below), that meet NIH's definition of a clinical trial, in response to PA-18-345, NIH Research Project Grant (Parent R01 Clinical Trial Required) and its reissues or PA-18-344, NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required) and its reissues. A mechanistic study is designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention.

November 30, 2017

Notice Number: [NOT-OD-18-106](#)

Reminder: Policy on Funding Opportunity Announcements (FOA) for Clinical Trials Takes Effect

January 25, 2018

- This notice reminds the community that, effective for due dates on or after January 25, 2018, NIH will require all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed and designated for clinical trials.

December 1, 2017

Notice Number: [NOT-OD-18-109](#)

Revision: The NIH Announces Additional Review Criteria for Career Development Award Applications Involving Clinical Trials

- This notice revises and replaces the previous notice (NOT-OD-17-121) to inform the community of additional scored review criteria that NIH will apply to individual career development (K) award applications submitted for due dates on or after January 25, 2018.