Training Funding Opportunity Announcement Edits for NOT-OD-17-114

September 14, 2017

Impacted FOAs

All active Training FOAs with due dates on or after January 25, 2018 will be updated with the following exceptions:

- Parent announcements will NOT be updated since they will be reissued (with new FOA numbers) for due dates on or after January 25.

Specific changes to Training announcements include:

- In preparation for clinical trial-specific FOA policy (NOT-OD-17-043), we will add clinical trial allowability indicator in table in FOA *Part 2, Section II. Award Information.*

  Sample:

Clinical Trial?	Clinical Trials Not Allowed for due dates on or after January 25, 2018: Only accepting applications that do not propose independent clinical trials Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor. Need help determining whether you are doing a clinical trial?

- In preparation for FORMS-E application forms (NOT-OD-17-062) for D43 and K12 FOAs only, we will add text for the PHS Human Subjects and Clinical Trials Information form and instructions in *Part 2, Section IV. Application and Submission Information* and indicate the form is only available in FORMS-E application packages for due dates on or after January 25, 2018.

  Sample text insert:

> **PHS Human Subjects and Clinical Trials Information**
> Form only available in FORMS-E application packages for use with due dates on or after January 25, 2018.
>
> When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:
>
> If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include a **Delayed Onset Study** record. DO NOT complete a full study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form.
>
> **Delayed Onset Study**

If you check the "Anticipated Clinical Trial" box within your Delayed Onset Study, then the Justification attachment must acknowledge that additional clinical trial information will be provided to the awarding component before any appointed Trainee begins independent clinical trial research.

- Remove any occurrences of the following note since the referenced changes are incorporated into the announcement text as part of this update

  Important Update: See NOT-OD-16-006 and NOT-OD-16-011 for updated review language for applications for due dates on or after January 25, 2016.

- To align announcements with recent vertebrate animals changes (NOT-OD-16-006), we will replace the Vertebrate Animals section of the Additional Review Criteria in *Part 2, Section V. Application Review Information* as follows (when appropriate – does not apply to all training activity codes or FOAs):

  Old text:

  The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: (1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; (2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of veterinary care; (4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and (5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

  New text:

  The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.