Multi-project Funding Opportunity Announcement Edits for NOT-OD-17-114

September 14, 2017

Impacted FOAs

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

- FOAs that will allow applications proposing clinical trials will NOT be updated since they will be reissued (with new FOA numbers) for due dates on or after January 25.

Multi-project activity codes include: G12, M01, P01, P20, P2C, P30, P40, P41, P42, P50, P51, P60, PL1, PM1, S06, U10, U19, U2C, U41, U42, U45, U54, U56, U60, UC7, Ul1, UM1, UM2

Specific changes to multi-project 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.*

Clinical Trial?	Clinical Trials Not Allowed for due dates on or after January 25, 2018: Only accepting applications that do not propose clinical trials Need help determining whether you are doing a clinical trial?

- In preparation for FORMS-E application forms (NOT-OD-17-062), we will add text to PHS Inclusion Enrollment Report form instructions in *Part 2, Section IV. Application and Submission Information* to indicate the form is only available in FORMS-D application packages for due dates on or before January 24, 2018.

  Old text:

  > **PHS Inclusion Enrollment Report**
  > When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

  New text:

  > **PHS Inclusion Enrollment Report**
  > Form only available in FORMS-D application packages for use with due dates on or before January 24, 2018.
  >
  > When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

- In preparation for FORMS-E application forms (NOT-OD-17-062), 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 for Overall Component:

PHS Human Subjects and Clinical Trials Information (Overall)

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, there must be at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or a Delayed Onset Study record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

Study Record: PHS Human Subjects and Clinical Trials Information
All instructions in the SF424 (R&R) Application Guide must be followed.
Delayed Onset Stud

All instructions in the SF424 (R&R) Application Guide must be followed.

Sample text insert for Other Components:

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 at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record.

Other Requested Information: All instructions in the SF424 (R&R) Application Guide must be followed.

Study Record: PHS Human Subjects and Clinical Trials Information: All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study: All instructions in the SF424 (R&R) Application Guide must be followed.

- 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:

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.