

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

September 14, 2017

Impacted FOAs

All active Fellowship 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 Fellowship 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 independent clinical trials Note: Applicants may propose to gain experience in a clinical trial led by a sponsor/co-sponsor as part of their research training. Need help determining whether you are doing a clinical trial?
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- In preparation for FORMS-E application forms ([NOT-OD-17-062](#) and [NOT-HS-17-015](#)), 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.

Sample text prior to change:

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.

Sample text after change:

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](#) and [NOT-HS-17-015](#)), 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 (and when applicable, clinical trials research experience) 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.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions:

- For FOAs that do not allow independent clinical trials, do not complete Section 4 – Protocol Synopsis information or Section 5 – Other Clinical Trial-related Attachments.

Delayed Onset Study

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