

SF424 (Grants.gov) Application Changes

FORMS-F application packages are to be used for due dates **on or after May 25, 2020**.

FORMS-E application packages are for due dates **on or before May 24, 2020**.

Links to notices and updated instructions:

- [Notice Number: NOT-OD-20-026](#)
- [FORMS-F checklist](#)
- [SF424 Application Guide Instructions Version F](#) - Updated Application Guides for Form F:
- [Annotated Forms F](#)
- [High Level Form Change Summary Forms F](#)

Key Changes

Cover Letter

- Instructions updated to indicate that it must not be used to communicate assignment preferences
- If using Human Fetal Tissue obtained from elective abortions (HFT), include a statement

PHS Assignment Request Form

- Language updated to clarify that this form is for suggestions.
- Removed the “Do Not Assign to Awarding Component” and “Do Not Assign to Study Section” fields and instructions.
- Added new “Rationale for assignment suggestions” field.

R&R Budget

Applications including HFT:

- R&R Budget must be used for applications including HFT. Modular budgets cannot be used, regardless of activity code
- Must include “Human Fetal Costs” line item in budget section (F. Other Direct Costs, lines 8-10) whether or not you incur costs to obtain HFT. If no costs are incurred, enter 0 under funds requested. This line item cannot be combined with any other costs.
- The Budget Justification is to include the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. The HFT Justification must be clearly labeled.

Additional updates:

- Section F. Other direct costs –note removed regarding requesting an exception to sIRB policy
- Lines “8-10 Other” may be used to request direct costs related to the use of single Institutional Review Board (sIRB) for multi-site human subjects research.

PHS 398 Research Plan Form

- For applications proposing HFT, must include specific information in the Approach section of the Research Strategy attachment. Detailed instructions can be found in the SF424 Application Guide.

PHS Cover Page Supplement form

- New Human Fetal Tissue Section
- New field: "Does the proposed project involve human fetal tissue obtained from elective abortions?" field.
 - For multi-projects, if human fetal tissue will be used in any component, you must answer Yes in the Overall Component.
 - Attachment for HFT Compliance Assurance – **Required if YES**
 - Attachment for HFT Sample IRB Consent Form– Required if YES

PHS Human Subjects and Clinical Trials Information

Use of Human Specimens and/or Data

- Reworked landing page to require an answer and supporting explanation (if applicable) for the question "Does any of the proposed research in the application involve human specimens and/or data?" for all applications.

Study Record: PHS Human Subjects and Clinical Trials Information

Clinical Trial Questionnaire

- Does the study involve human participants? – defaults to YES when the answer to "Are Human Subjects Involved" question on the R&R Other Project Information form is YES.
- Added NEW "Inclusion of Individuals Across the Lifespan" attachment. Updated instructions for the "Inclusion of Women and Minorities" attachment to reflect separate "Inclusion of Individuals Across the Lifespan" attachment.
- **NIH: Single IRB plan no longer required**. A statement naming the sIRB of record will be provided at Just-In Time. AHRQ: Single IRB plan required.
- Is this an applicable clinical trial under FDAAA?" – New field and checkbox
- "Provide the ClinicalTrials.gov Identifier": -Optional. Enter NCT # for the study if available. Newly proposed studies do not need to be in ClinicalTrials.gov at time of application.
- "Section 2 – Study Population Characteristics" instructions now reflect updated exceptions for required questions.
- "Data and Safety Monitoring Plan" attachment – required for CT study; optional for HS study
- Added new "Inclusion Enrollment Report Title" field.
- Removed the "Brief Summary" field.
- Changed the "Narrative Study" field to "Detailed Description."

R&R Senior/Key Person Profile

- Career Development and Fellowship applications
 - eRA Commons profile associated with the credential agency username must be include an ORCID ID.

PHS Fellowship Supplemental Form

- New attachment "Description of Candidate's Contribution to Program Goals" to the Institutional Environment and Commitment to Training Section
- This attachment is only for applicants to diversity-related FOAs. All other fellowship applications should skip this section.
- Not required as part of the Admin Shell; however, needs to be attached prior to finalization.