NIH Forms F Changes

Agency Routing Information

Applications in response to a NIH Notice of Special Interest now require the notice number (e.g., NOT-IC-FY-XXX) to be entered in this field [SF 424 R&R 4b] in order to assign and track applications and awards for the described initiative.

Letters of Support

Added clarification: Letters must not contain data/figures/tables/graphs, preliminary data, methods, background and significance details that are expected to be found in the Research Strategy section of the application. Letters of Support serve to describe terms of a collaboration or consultation and are not de facto letters of reference from persons not actively participating in the project. Applications with letters containing such excess information may be withdrawn from the review process.

PHS Assignment Request Form

Removed the "Do Not Assign to Awarding Component" and "Do Not Assign to Study Section" fields.

Added new "Rationale for assignment suggestions" (optional):

- Enter the rationale (i.e., why you think the assignment is appropriate) for your Awarding Component and Study Section suggestions.

Career Development Awards

Candidate Information and Goals for Career Development

Added additional rigor requirements for this Section: Applicants should describe in the 'Candidate Information and Goals for Career Development' upload the new or enhanced research skills and knowledge they will acquire as a result of the proposed award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches and data analysis interpretation.

Addressing Human Fetal Tissue (HFT) in the Research Strategy is required, see guidance below in the HFT Research Strategy section.

New Description of Candidate's Contribution to Program Goals for Applicants to diversity-related FOAs (e.g., diversity-related KO1 and diversity-related K22s):

All other Career Development applicants can skip the "Description of Candidate's Contribution to Program Goals" at is not required.

For diversity-related FOAs the sponsoring institution must provide a document on institutional letterhead that explains how the candidate's participation will further the goals of the career development program to promote diversity in health-related research.

Signatures: The "Description of Candidate's Contribution to Program Goals" attachment must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement.

Training Applications

Program Plan – Section C Proposed Training

Added additional rigor requirements for this Section: Describe how the program and faculty will provide training in scientific reasoning, rigorous research design, relevant experimental methods, relevant quantitative and data science approaches, and data analysis and interpretation, appropriate to the level and prior preparation of the trainees.

New "Plan for Instructions in Methods for Enhancing Reproducibility" attachment.

A "Plan for Instructions in Methods for Enhancing Reproducibility" attachment is now required for all training grant activity codes (expect D71, unless otherwise noted in the FOA). Applications lacking a Plan for Instructions in Methods for Enhancing Reproducibility will not be reviewed.

Content

The plan must describe how trainees will be instructed in principles important for enhancing research reproducibility. These principles include, at a minimum, the following:

- evaluation of the foundational research underlying a project (i.e., the rigor of the prior research);
- Rigorous experimental design and data interpretation;
- consideration of relevant biological variables such as sex;
- authentication of key biological and/or chemical resources; and
- transparency in reporting.

Include a description of how instructional strategies will be integrated into the overall training program at multiple stages of trainee development and in a variety of formats and contexts. Describe how program faculty will reiterate and augment key elements of methods for enhancing reproducibility in the context of trainees' research projects.

Progress Report (for Renewal applications only)

The Progress Report for renewal applications will be limited to five pages for the program and one page for each appointee to the grant; applications that exceed the specified page limits will be withdrawn.

The My Bibliography report of publications arising from work conducted by appointees while supported by the grant will no longer be requested Just-In-Time, but will be collected in the Interim Final Research Performance Progress Report.

Fellowship Applications

Applicant's Background and Goals for Fellowship Training – Section B. Training Goals and Objectives

Added additional rigor requirements to this section: Identify the skills, theories, conceptual approaches, etc.to be learned or enhanced during the award, including, as applicable, expertise in rigorous research, design, experimental methods, quantitative approaches, and data analysis and interpretation, as applicable.

Research Strategy

Added additional rigor requirements to this section: Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.

New Description of Candidate's Contribution to Program Goals for Applicants to diversity-related FOAs (e.g., diversity-related F31):

All other Fellowship applicants can skip the "Description of Candidate's Contribution to Program Goals" as it is not required.

For diversity-related FOAs the sponsoring institution must provide a document on institutional letterhead that explains how the candidate's participation will further the goals of the fellowship program to promote diversity in health-related research.

Signatures: The "Description of Candidate's Contribution to Program Goals" attachment must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement.

Authentication of Key Biological and/or Chemical Resources

This piece was not previously required for Fellowship applications.

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

PHS Human Subjects and Clinical Trials Information

R&R Other Project Information Form

Regardless of your answer to the question "Are Human Subjects Involved?", **you are now required to answer the question(s) about the use of human specimens and/or human data**.

Delayed Onset Study Records

If NIH's Single Institutional Review Board (sIRB) policy will apply to your study, the applicant will **now be required to provide a statement naming the sIRB of record in the Just-in-Time Submission prior to award**.

New 2.3a Inclusion of Individuals Across the Lifespan

New attachment requires you to address the Inclusion of Individuals Across the Lifespan.

For the purposes of the Inclusion of Individuals Across the Lifespan, exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section. In addition, address the following points.

- Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. See the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects for additional information about circumstances that may justify the exclusion of individuals based on age.

- Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relation to the purpose of the study.

Inclusion Enrollment Report Title Field

New title field requirement, at a maximum of 600 characters. Enter a unique title for each IER. The title should indicate specific criteria that uniquely identify each report. If the Project Title is pre-populated, you may edit it so that each IER title is unique.

Is this an applicable clinical trial under FDAAA?

New question 4.6. Is this an applicable clinical trial under FDAAA? Select "Yes" or "No" to indicate whether the study is an applicable clinical trial (ACT) under the Food and Drug Administration Amendments Act (FDAAA).

For more info: NIH Glossary's definition of an applicable trial and FAQs on the ClinicalTrials.gov & FDAAA.

Requirements for Addressing Human Fetal Tissue (HFT)

Cover Letter

Include a statement in the cover letter if the proposed studies involve human fetal tissue obtained from elective abortions (HFT), regardless of whether or not Human Subjects are involved and/or there are costs associated with the HFT.

RR Other Project Information Question 4

Question 4, a required field, is now: *Does the proposed project involve human fetal tissue from elective abortions*?

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT) check "Yes" and complete the rest of the "Human Fetal Tissue" section. Which includes:

Providing the HFT Compliance Assurance

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT) the applicant must provide a letter signed by the PD/PI, assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documenting the HFT was not obtained or acquired for valuable consideration. The PDF-formatted letter *must* be named '**HFTComplianceAssurance.pdf**'.

Providing the HFT Sample IRB Consent Form

If the proposed project involves the use of human fetal tissue obtained from elective abortions (HFT), provide a blank sample of the IRB-approved consent form. The PDF-formatted form *must* be a blank sample and named '**HFTSampleIRBConsentForm.pdf**'.

- The informed consent for use of HFT from elective abortions requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, that informed consent for donation of HFT occurred after the informed consent for abortion was obtained will not affect the method of abortion, and that no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT. The form must be signed by both the woman and the person who obtains the informed consent.

Budget Line Item

Special Instructions for Applications Proposing the Use of Human Fetal Tissue: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application, regardless of whether costs will be incurred, **it must be noted as a single line item under lines 8-10 Other Direct Costs in the R&R budget** [Do not include under Materials and Supplies]. The line item must be titled "**Human Fetal Tissue Costs**" (without quotation marks, but following exact phrase and spacing).*The line item must only be used for HFT costs and cannot include or be combined with any "Other" costs*. If no cost will be incurred (e.g. if HFT will be donated), enter "0" in the "Funds Requested" column.

Budget Justification

Details regarding HFT must be specified in the Budget Justification, including the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. This information *must be included* if costs for the HFT are assigned to the grant or if the HFT is acquired under the grant at no costs. The HFT justification *must be clearly labeled in the budget justification attachment*.

General Instructions for NIH and Other PHS Agencies-Forms Version F Series G.300-R&R Budget Form regarding HFT must be specified in the Budget Justification attachment (L), pursuant to the instructions.

Can Not Use Modular Budget

If the use of human fetal tissue obtained from elective abortions (HFT) is included in the proposed application, *regardless of whether you will incur a cost for HFT*, **you cannot use the PHS Modular Budget Form regardless of the activity code** and must use the R&R Budget Form.

Additional Instructions for Multi-project:

If the use of human fetal tissue obtained from elective abortions (HFT) is included in the proposed application, you must provide **HFT budget information in the component(s) where the research involving HFT is conducted**.

Research Strategy

If the use of human fetal tissue obtained from elective abortions (HFT) is included in the proposed application you must **include specific information in the Approach section of the Research Strategy attachment. This information must be provided regardless of whether Human Subjects research is proposed or not**.

- Use the specific heading: "Human Fetal Tissue Research Approach".
- Described the proposed characteristics, procurement, and procedures for the research use of HFT. The description should be sufficiently detailed to permit meaningful evaluation by NIH.
- Justify the use of HFT in the proposed research by indicating the following:
    - Why the research goals cannot be accomplished by using an alternative to HFT.
    - What methods were used (e.g. literature review, preliminary data) to determine that alternatives could not be used
    - Results from a literature review used to provide justifications
    - Plans for the treatment of HFT and the disposal of HFT when research is complete
    - Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissues were already obtained.

For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Human Fetal Tissue from Elective Abortions.

Applications proposing HFT that do not address these requirements will be administratively withdrawn.

AHRQ Forms F Changes

PHS Human Subjects and Clinical Trials Information

Data Safety Monitoring Plans

For AHRQ Applicants, Data and Safety Monitoring (DSM) plans are required in all non-exempt research applications when support is sought to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk.

If you seek AHRQ support to conduct non-exempt research to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk, a "Data and Safety Monitoring Plan" attachment is required.

Is this an applicable clinical trial under FDAAA?

New question 4.6. Is this an applicable clinical trial under FDAAA? Select “Yes” or “No” to indicate whether the study is an applicable clinical trial (ACT) under the Food and Drug Administration Amendments Act (FDAAA).