



**Entrepreneurial  
Training & Consulting**

## **NIH ALERT:**

**FORMS-F will be REQUIRED for due dates beginning May 25, 2020**

NIH Grant applicants must use new FORMS-F for all applications with due dates on or after May 25, 2020, including SBIR and STTR applications. NIH's application system, ASSIST, has been updated to support the new FORMS-F and is ready to process those applications.

Changes to xTRACT training tables to accommodate FORMS-F will take place in a release scheduled for Friday, April 24. Any Research Training Datasets finalized in the xTRACT system on or after April 24, 2020 will automatically create the FORMS-F version of the Training Data Tables.

### **Changes Implemented in ASSIST**

The most substantial changes in FORMS-F are found in the PHS Human Subjects and Clinical Trials Information and associated study record forms. The other forms listed below will also see changes.

#### **· PHS 398 Cover Page Supplement form**

A new Human Fetal Tissue Section was added to the form. Applicants must answer the question: *Does the proposed project involve human fetal tissue obtained from elective abortions?*

If yes, applicants will be required to provide two attachments:

- The HFT Compliance Assurance, and
- The HFT Sample IRB Consent Form.

#### **· Career Development and the Fellowship Supplemental forms**

A new field and place for an attachment was added to provide the *Description of Candidate's Contribution to Program Goals*. The requirement for the inclusion of this attachment will be specified in the Funding Opportunity Announcement.

If applicable, fellowship candidates will be required to include the Authentication of Key Biological and/or Chemical Resources attachment.

- Research Training Forms**

The requirement to include a Plan for Instruction in Methods for Enhancing Reproducibility attachment has now been expanded to all training grant applications. (For more information, please see [NOT-OD-20-033](#)).

- PHS Human Subjects and Clinical Trials Information and associated study record forms**

The form now requires all applicants to answer the question: *Does any of the proposed research in the application involve human specimens and/or data?*

The supporting explanation attachment field is now always available. Previously, the question and attachment were only available when Human Subjects was No, which didn't allow for scenarios where an application involved both human subjects and human specimens or data.

Changes have been made to the associated study record form.

- Since study records are only created when Human Subjects are involved, study record question 1.4.a: *Does the study involve human participants?* is set to **Yes** by default.
- In study record Section 2: *Study Population Characteristics*:
  - The inclusion of children is now covered in a new “Inclusion of Individuals Across the Lifespan” attachment.
  - The “Women, Minorities, and Children” attachment was relabeled the “Inclusion of Women and Minorities.”
  - The “Enrollment of First Subject” field has been renamed to “Enrollment of First Participant.” This is consistent with the language used in the Clinical Trial Questionnaire in Section 1.
  - A field number has been added to the Inclusion Enrollment Reports field for usability and instruction clarity.

- Inclusion Enrollment Report**

A title field has been added.

In Section 4: *Protocol Synopsis*

- The “Brief Summary” attachment field has been removed.
- The “Narrative Study Description” attachment has been renamed to “Detailed Description.”

These two changes have been done to reduce overlap in requested information and align with [ClinicalTrials.gov](#).

A new question has been added: *Is this an applicable clinical trial under the Food and Drug Administration Amendments Act - FDAAA?*

- **The PHS Assignment Request Form**

The form has been reworked to improve usability. Among the changes are:

- Clarified instructional text.
- Improved field labels.
- New “Rationale for assignment suggestions” text box.

- **SBIR/STTR Information form**

The Application Type field has been expanded to include Phase IIC. This new application type was requested by non-HHS agencies.

### **Changes Coming to xTRACT on April 24**

It is important to note that any **Research Training Datasets (RTD) finalized in the xTRACT system on or after April 24, 2020 will automatically create the FORMS-F versions of the Training Data Tables.**

Here is a summary of the changes to Training Data Tables:

- Table 1 – Applicants proposing research training in settings where there are no students in predoctoral research training (such as some clinical departments or divisions) may now skip Part I.
- Table 2 – Applicants may now report on faculty in non-academic settings.
- Table 4 – Ability to manually report Project Leads. Instructions clarified for the reporting of (a) types of grants that should be included/excluded and (b) costs associated with multi-PI, multi-year-funded, and multi-component awards.
- Table 5 – Abstracts should no longer be reported.
- Table 6 – Applicants will now be asked to report on percent of entrants and appointees from underrepresented groups, and instructions have been clarified to indicate that applicants are only expected to report on underrepresented groups for which they collect data.
- Table 8 – Option to report leave of absence, when applicable. When reporting initial and current position, users will be asked to report Workforce sector and Principal Activity.

For more information, see the NIH Guide Notice [Reminder: FORMS-F Grant Application Forms & Instructions Must be Used for Due Dates On or After May 25, 2020- New Grant Application Instructions Now Available.](#)

Additional Resources:

- [How to Apply - Application Guide](#)
- [Grants Administration Take 10: NIH FORMS-F Application Forms Update video](#)
- [High-level Summary of Form Changes in FORMS-F Application Packages](#)
- [Annotated Form Set for NIH Grant Applications](#)
- [Do I Have the Right Form Version for My Application?](#)
- [Application Forms, Form Updates, and Choosing the Correct Forms FAQs](#)
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