



NIH FORMS-F
Human Subjects and Clinical Trials Information
Worksheet
SUMMARY OF CHANGES FROM FORMS-E

*Below is a summary of the changes related **only to the Human Subjects and Clinical Trials Information** section of the National Institutes of Health (NIH) SF424 (R&R) Application Packages – Version F, commonly referred to as “FORMS-F,” from Version E (“FORMS-E”).*

*FORMS-F must be used for all NIH submissions with **due dates on or after May 25, 2020**. See [NIH - How to Apply - Application Guide](#) for information related to NIH forms and applications.*

Summary of Changes – FORMS-F:

General

1. Updated OMB Expiration Date to 2/28/2023.

PHS Human Subjects and Clinical Trials Information

2. The question, “Does any of the proposed research in the application involve human specimens and/or data?” is **required**.

Study Record: PHS Human Subjects and Clinical Trials Information

3. Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments – “Inclusion of Individuals Across the Lifespan” (attachment 2.3.a) and “Inclusion of Women and Minorities” (attachment 2.4).
4. Renamed “Enrollment of First Subject” field to “Enrollment of First Participant” (field 2.8).
5. Added field number (2.9) for “Inclusion Enrollment Report(s).”
6. Removed “Brief Summary” field (formerly 4.1); renumbered subsequent fields.
7. Added “Is this an applicable clinical trial under FDAAA?” (field 4.6).

Inclusion Enrollment Report

8. Added “Inclusion Enrollment Report Title” field (field 1).