

High-level Summary of Form Changes: FORMS-E

Agencies periodically update application forms in order to remain current with the most recent form sets available through Grants.gov and approved by the Office of Management and Budget and to align data collection with current policy.

NIH and some other agencies serviced by eRA use the 'Competition ID' field of Grants.gov application packages for quick and easy identification of the form versions used in an application package.

NIH will require the use of application packages with a Competition ID of **'FORMS-E'** for **due dates on or after January 25, 2018**. Applications prepared using "FORMS-D" application packages for due dates after January 24, 2018 will not be reviewed.

Changes to Agency-specific PHS Forms Included in 'FORMS-E' Application Packages

The majority of form changes introduced in FORMS-E packages relate to the consolidation of human subjects and inclusion enrollment report information previously collected across multiple forms into a new PHS Human Subjects and Clinical Trials Information form. The new form also expands clinical trial data collection to ensure the appropriate level of information for review and to improve oversight.

PHS 398 Career Development Award Supplemental Form

- Updated OMB Expiration Date to 03/31/2020
- Removed Human Subjects Section, including the following attachments:
 - Protection of Human Subjects
 - Data Safety Monitoring Plan
 - Inclusion of Women and Minorities
 - Inclusion of Children
- Renumbered form fields
- Made minor text edits

PHS 398 Cover Page Supplement

- Updated OMB Expiration Date to 03/31/2020
- Removed Human Subjects Section, including:
 - "Clinical Trial" question
 - "Agency Defined Phase III Clinical Trial" question
- Renumbered form fields
- Made minor text edits

PHS 398 Modular Budget

- Updated OMB Expiration Date to 03/31/2020

PHS 398 Research Plan

- Updated OMB Expiration Date to 03/31/2020
- Removed Human Subjects Section, including the following attachments:
 - Protection of Human Subjects
 - Data Safety Monitoring Plan

- o Inclusion of Women and Minorities
 - o Inclusion of Children
- Renumbered form fields
- Made minor text edits

PHS 398 Research Training Program Plan

- Updated OMB Expiration Date to 03/31/2020
- Removed the following attachments from the Other Training Program Section:
 - o Human Subjects
 - o Data Safety Monitoring Plan
- Renumbered form fields
- Made minor text edits

PHS 398 Training Budget

- Updated OMB Expiration Date to 03/31/2020

PHS 398 Training Subaward Budget Attachment(s) Form

- Updated OMB Expiration Date to 03/31/2020

PHS Additional Indirect Costs

- Updated OMB Expiration Date to 03/31/2020

PHS Assignment Request Form

- Updated OMB Expiration Date to 03/31/2020
- Made significant text edits

PHS Fellowship Supplemental Form

- Updated OMB Expiration Date to 03/31/2020
- Removed Human Subjects sub-section from Other Research Training Plan Section, including:
 - o “Human Subjects Involvement Indefinite” question
 - o “Clinical Trial” question
 - o “Agency Defined Phase III Clinical Trial” question
 - o Protection of Human Subjects attachment
 - o Data Safety Monitoring Plan attachment
 - o Inclusion of Women and Minorities attachment
 - o Inclusion of Children attachment
- Removed Vertebrate Animals Use Indefinite question from the Vertebrate Animals sub-section of the Other Research Training Plan Section
- Renumbered form fields
- Made minor text edits

PHS Human Subjects and Clinical Trials Information Form

- Introduced new form for consolidated human subjects, inclusion enrollment report and clinical trial information

PHS Inclusion Enrollment Report

- Discontinued use (data collection moved to new PHS Human Subjects and Clinical Trials Information Form)

Changes to Federal-wide R&R Forms Included in 'FORMS-E' Application Packages

FORMS-E application packages incorporate the latest versions of the federal-wide forms managed by Grants.gov (OMB Number: 4040-0001, Expiration Date: 10/31/2019).

R&R Budget and associated R&R Subaward Attachment Form

- Added new "Total Costs and Fee" calculation to budget periods and cumulative budget

R&R Other Project Information

- Added two human subject exemption codes (7 and 8) in preparation for implementation of Common Rule

SBIR/STTR Information

- Added "Agency to which you are applying" question with options for DOE, HHS, USDA and Other
- Added "SBC Control ID" field for the 9-digit code obtained from the Small Business Administration
- Added "Direct Phase II", "Phase IIA", "Phase IIB" and "Commercialization Readiness Program" as Application Type options
- Added "Phase I Letter of Intent Number" field
- Added "Agency Topic/Subtopic" field
- Added two additional questions regarding eligibility
 - o "1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms?"
 - o "1d. Is your small business a Faculty or Student-Owned entity?"
- Added "DUNS Number of non-profit research partner for STTR" field
- Minor text changes