



## **National Institutes of Health (NIH) Human Subjects Research: Changes to new Forms F**

For all NIH grant submissions, the newly released Forms F should be used for all applications with due dates on or after May 25, 2020. These new forms have several key changes within the PHS Human Subjects and Clinical Trials Information section. Here are key specific changes in the new forms related to this section:

- Main landing page of the PHS Human Subjects and Clinical Trials.  
All applications require the following question to be answered: “Does any of the proposed research in the application involve human specimens and/or data?  
If the answer is “No” you are done.  
If the answer is “Yes” you must provide supporting explanation for any use of human specimens and/or data not considered human subjects research. This allows for a scenario where an application involves both human subjects and/or humans specimens and/or data.
- Section 2.3 a - Inclusion of Individuals Across the Lifespan  
This attachment is now required for all human subject research unless your research falls under exemption 4.  
Previously, the description of the inclusion of children was discussed in the Inclusion of Women, Minorities and Children attachment. The description of inclusion of children has now been separated with the addition to not only discuss children but across the lifespan (all ages).  
The NIH expects that all ages should be included in human subject research unless there are specific scientific or ethical reasons to exclude a population. This attachment specifically requires the description of any specific age or age range group (e.g., children or older adults) that are included in the study and must specifically justify the exclusion of any specific age or age range group (e.g., children or older adults).  
Additionally, 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 relative to the purpose of the study.

- Section 2.4 - Inclusion of Women and Minorities  
Describe the planned distribution of subjects by sex/gender, race, and ethnicity. Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study. Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members. Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups.
- Section 3.2 – Single IRB Plan  
Although this remains on the forms, a single IRB plan is no longer required for NIH applications. You still must answer the question in 3.2 - Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?
- Section 4.1a – Study Design  
The “Brief Summary” field (formerly 4.1) has been removed. Now there is only the Study Design field (formerly 4.2a Narrative Study Description).
- Section 4.6 - Is this an applicable clinical trial under FDAAA?"  
This is a new section that has been added.  
Select "Yes" or "No" to indicate whether the study is an applicable clinical trial (ACT) under the Food and Drug Administration Amendments Act (FDAAA).

*Credit: NIH*

To access the guidelines regarding the new forms, go to [grants.nih.gov/grants/how-to-apply-application-guide/forms-f/sbir-sttr-forms-f.pdf](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/sbir-sttr-forms-f.pdf)

To watch a helpful NIH video regarding the NIH PHS Human Subjects and Clinical Trials Information forms, go to the [NIH YouTube Video](#).

Contact [BBCetc](#) to learn more about how we can assist you in successfully preparing and submitting your NIH applications.