

Scenario C: Human Subjects Research Claiming Exemption 1, 2, 3, 4, 5, or 6

Criteria

Human Subjects Research Yes

Exemption Claimed 1, 2, 3, 4, 5, or 6

Clinical Trial Yes or No

NIH-Defined Phase III Clinical Trial No

Instructions and Required Information

Although no specific page limitation applies to this section of the application, be succinct. The exemptions appear in Part III under [Human Subjects Research Definitions and Terms](#).

Although the research may be exempt from the DHHS regulatory requirements, it is still research involving human subjects and the application must follow the instructions that are identified for each of the following topics and provide the information that is requested.

In the application narrative for paper PHS398 applications, provide the required information for each of the following topics below. For electronic SF424 (R&R) applications, provide the required information for each of the following topics below as a separate files. For applications using Forms B application packages, save each of the four files as a .pdf file and attach in the Human Subjects Sections of the PHS 398 Research Plan (for K applicants, the PHS 398 Career Development Award Supplemental Form; for F applicants, the PHS Fellowship Supplemental Form - Research Training Plan). For applications using Forms C application packages, Protection of Human Subjects, Inclusion of Women and Minorities, and Inclusion of Children remain an upload in the Research Plan Form. However, the Planned Enrollment Report is now a separate Form in the application package.

Protection of Human Subjects - Include the following statement: “This Human Subjects Research falls under Exemption(s) ...” Clearly identify which exemption(s) (1, 2, 3, 4*, 5, or 6) you are claiming and justify why the research meets the criteria for the exemption(s) that you have claimed. If the research will include a clinical trial, even if exempt, include a Data and Safety Monitoring Plan – [Section 4.1.5](#)[Section 4.1.6](#), and address the ClinicalTrials.gov requirements if applicable – .

Inclusion of Women and Minorities - [Section 4.2](#)

Planned Enrollment Report(s) - [Section 4.3](#)

Inclusion of Children - [Section 4.4](#) *NOTE: If all of the proposed research meets the criteria for Exemption 4, then the requirements for inclusion of women and minorities, planned enrollment report(s), and inclusion of children, do not need to be addressed.

Supplemental Instructions