FORMS-E Human Subjects Information

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#1.4

- The answers to the questions in the Clinical Trial Questionnaire will determine which sections of the Study Record are Required.

1.4 Clinical Trial Questionnaire

The Clinical Trial Questionnaire is required.

Note for mechanistic studies: Many mechanistic studies (i.e., those designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention) meet the NIH definition of a clinical trial.

Answer "Yes" or "No" to the following questions to determine whether this study involves a clinical trial. Answer the following questions based only on the study you are describing in this study record.

1.4.a. Does the study involve human participants? Yes/No

1.4.b. Are the participants prospectively assigned to an intervention? Yes/No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? Yes/No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes/No

If you answered "Yes" to all the questions in the Clinical Trial Questionnaire, this study meets the definition of a clinical trial.

Refer to the table below for information about what sections of this form are required, based on your answers to Question 1.4 "Clinical Trial Questionnaire."

Form Section	If you answered "yes" to all the questions in the Clinical Trial Questionnaire	**If you answered "no" to any of the questions in the Clinical Trial Questionnaire**
Section 2 - Study Population Characteristics	Required	Required
Section 3 - Protection and Monitoring Plans	Required	Required
Section 4 - Protocol Synopsis	Required	Do not complete
Section 5 - Other Clinical Trial-related Attachments	Required if specified in the FOA	Do not complete

Section 2 - Study Population Characteristics

Who must complete "Section 2 - Study Population Characteristics:"

All of "Section 2 - Study Population Characteristics" is required for all human subjects studies unless either or both of the following apply to you:

- If you selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question, then "Section 2 - Study Population Characteristics" is not required.
- If you selected "**No**" to the "1.4.a. Does the study involve human participants?" question, then certain questions in "Section 2 - Study Population Characteristics" are not required, as noted in the individual field instructions below.

Section 3 - Protection And Monitoring Plans

Who must complete "Section 3 - Protection and Monitoring Plans:"

All of "Section 3 - Protection and Monitoring Plans" is required for all studies involving human subjects, unless otherwise noted.

Section 4 - Protocol Synopsis

Who must complete "Section 4 - Protocol Synopsis:"

If you answered "Yes" to all the questions in the "Clinical Trial Questionnaire:" All the questions in the "Protocol Synopsis" section are required.

If you answered "No" to any question in the "Clinical Trial Questionnaire:" Do not provide information in this section. Inputting information in this section will result in errors and will prevent your application from being accepted.

Section 5 - Other Clinical Trial-Related Attachments

Who must complete "Section 5 - Other Clinical Trial-related Attachments:"

If you answered "Yes" to all the questions in the "Clinical Trial Questionnaire:" Include an attachment only if your FOA specifies that an attachment(s) is required or permitted; otherwise, do not include any Other Clinical Trial-related attachments.

If you answered "No" to any question in the "Clinical Trial Questionnaire:" Do not provide information in this section. Inputting information in this section will result in errors and will prevent your application from being accepted.