PHS HUMAN SUBJECTS & CLINICAL TRIALS INFORMATION (HSCTI)

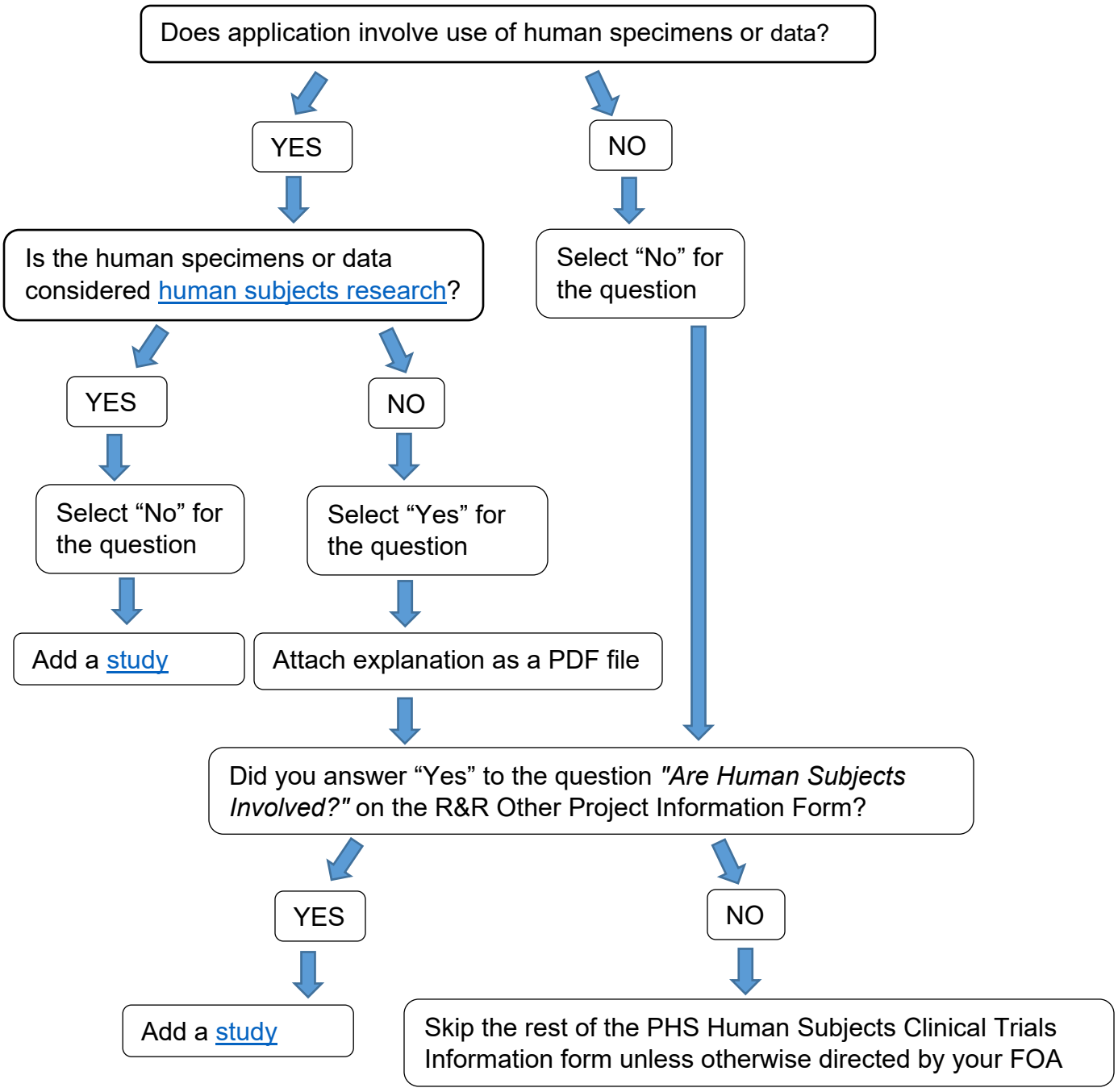
Revised June 16, 2022

OVERVIEW

This resource document will assist in differentiating when HSCTI sections need to be included in a proposal. Resource Material: NIH Decision Tool Questionnaire

Use of Human Specimens and/or Data

"Does any of the proposed research in the application involve human specimens and/or data?"



*For more details, see SF424 RR Instructions: Section G.500. Use of Human Specimens and/or Data.

If you answered "Yes" to the question "Are Human Subjects Involved?" on the G.220 - R&R Other Project Information Form, **add a Study Record** for each proposed study involving human subjects by selecting "Add New Study" or "Add New Delayed Onset Study," as appropriate.

Study Record

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	If you selected only Exemption 4 and no other exemptions on the "1.3 Exemption Number" question
Section 2 - Study Population Characteristics	Required	Required Optional: 2.7 Study Timeline	Do not complete
Section 3 - Protection and Monitoring Plans	Required Optional: 3.5 Overall Structure of Study Team	Required Optional: 3.3 DSMB & 3.5 Overall Structure of Study Team	Required Optional: 3.5 Overall Structure of Study Team
Section 4 - Protocol Synopsis	Required	Do not complete	Required if answered "yes" to all questions in CT Questionnaire Do not complete if answered "no" to any of the questions in the CT Questionnaire
Section 5 - Other Clinical Trial-related Attachments	Required if specified in the FOA	Do not complete	Required if answered "yes" to all questions in CT Questionnaire Do not complete if answered "no" to any of the questions in the CT Questionnaire

*For more details, see SF424 RR Instructions: Section G.500. Study Records.