PHS Human Subjects and Clinical Trials information Form V1-0 Questions:
NOTE: placeholder narratives can be replaced during the Coeus routing and approval process.

Required Narratives:

If condition is Yes, narrative is required

Does the sponsor require additional information specific to the opportunity or have you have selected a clinical trial opportunity without including a clinical trial? → **Other Requested Information**

Does your project include one or more Delayed Onset Study? → **Delayed Onset (for each delayed study)**

For Each Study

Does the study include Human Subjects? → **Protection of Human Subjects**

Does the study include Human Subjects and is <u>NOT</u> exempt E4? → **Study Timeline**, **Inclusion of Women, Minorities, and Children**, **Inclusion Enrollment Report**, **Recruitment and Retention Plan**

Does the study include Clinical Trial? "Yes" to questions 1.4.a-1.4.d → **Data Safety Monitoring Plan**, **Dissemination Plan**, **Statistical Design and Power**, **Overall Structure of the Team**

Is the study a multi-site study that will use the same protocol to conduct non-exempt research? → **Single IRB Description**

Will the study use and FDA-regulated intervention? → **FDA-regulated Intervention**

Are additional study documents necessary for the proposal? → **Other Attachment(s)**