**3.5. Overall Structure of the Study Team**

The “Overall Structure of the Study Team” attachment is required for Human Subjects Research that meets the NIH definition of a Clinical Trial (Answered “yes” to all the questions in the HSS Section 1.4. "Clinical Trial Questionnaire" on the Study Record: PHS Human Subjects and Clinical Trials Information Form)

The “Overall Structure of the Study Team” attachment is optional for all other studies that do not meet the NIH definition of a Clinical Trial.

**Content:**

Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. The attachment may include information on study team composition and key roles (e.g., medical monitor, data coordinating center), the governance of the study, and a description of how study decisions and progress are communicated and reported.