This template is based on the NIH instructions here https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.5

This attachment is required only if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." (i.e. your study is an NIH-defined clinical trial) and if you answered "Yes" to "Will the study use an FDA-regulated intervention?" (see the definition of "FDA Regulated Intervention" under the Oversight section of the ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies page). This attachment's typical length is approximately 3,000 characters.

When document is complete, delete this box and save as PI Last Name_4.5 FDA-regulated Intervention_ DDMOYEAR (example-01JAN2022)

NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype, 11 pt or larger, margins .05 or larger https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

4.5 FDA-REGULATED INTERVENTION

Provide a summary describing the availability of study agents and support for the acquisition and administration of the study agent(s).

Please indicate, if applicable, the IND/IDE status of the study agent, including whether a clinical investigation is exempt from the IND/IDE requirement. Also indicate whether the investigators have had any interactions with the FDA (e.g., indicate if the FDA has stated that research may proceed). If the study agent currently has an IND/IDE number, provide that information.

Do not include the IND/IDE application, manufacturer's product specifications, study protocol, or protocol amendments in this attachment.