**4.5 FDA-regulated intervention**

Will the study use an FDA-regulated intervention?

Select "Yes" or "No" to indicate whether the study will use an FDA-regulated intervention (see the definition of “FDA Regulated Intervention” under the [Oversight](https://prsinfo.clinicaltrials.gov/definitions.html#oversight) section of the [ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies](https://prsinfo.clinicaltrials.gov/definitions.html) page).

If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status. This attachment is required if you answered “Yes” to the “Will the study use an FDA-regulated intervention?” question.

**Content:**

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.

Additional information such as FDA letters or correspondence with the FDA may be requested in the FOA.

Note: The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award.