



Office of Research and Sponsored Programs

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NIH FDA-Regulated Intervention IP/IND/IDE Status Guidance

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The " FDA-Regulated Intervention IP/IND/IDE Status " attachment may be required if you answered "Yes" to all the questions in the "[Clinical Trial Questionnaire](#)." This document is not allowed for all other human subjects research.

This attachment is required if you answered "Yes" to the "Will the study use an FDA-regulated intervention?" question.

Attach this information as a PDF file. See NIH's Format Attachments page.

Describe the availability of study agents and support for the acquisition and administration of the study agent(s). Please indicate the IND/IDE status of the study agent, if applicable, and whether the investigators have had any interactions with the FDA. If the study agent currently has an IND/IDE number, provide that information.

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.