MARQUETTE UNIVERSITY

Office of Research and Sponsored Programs
1324 W. Wisconsin Ave.
Holthusen Hall, 341
414-288-7200
www.marquette.edu/orsp

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

December 2017

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.

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

Content:
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.

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.