HRP-1897 | July 1, 2023

**WORKSHEET: Sponsor-Investigator Policy Compliance**

The purpose of this worksheet is to provide support for HRPP Quality Assurance staff conducting ancillary reviews involving internally held INDs, IDEs and/or NSR IDEs. This review is done as part of additional efforts to remain compliant with the UMN Policy titled: “University Sponsor and Sponsor-Investigator IND/IDE and FDA Pre-Submission Requirements”.

**Applicability of Sponsor-Investigator Regulations**

1. **Does the activity involve both of the following?** (Check all that apply. If “No” to either, this worksheet does not apply, and ancillary review can be submitted.) (NOTE: If review does not apply, indicate as such in the comments section of the ancillary review and provide the reason.)

The research involves at least one of the following per the Drug/Device Guidance Regulatory Ancillary Review:

IND

IDE

NSR IDE (Final confirmation made by IRB)

The research involves an Internal Regulatory Sponsor:

The IND or IDE is sponsored by an employee of the University of Minnesota and eligible to serve as PI on human research .

The NSR IDE research is investigator-initiated.

**ETHOS Submission, Completeness and Accuracy**

1. **Is the Drug/Device section of the ETHOS SmartForm filled out correctly?** (Check if **“Yes”**.All must be checked prior to IRB approval, unless otherwise noted.)

All information matches the Central File documentation and the Drug/Device Guidance Regulatory Ancillary Review:

Holder Name

IND/IDE Number

FDA Determination (Note: this is especially important with NSR IDEs.)

Product Name

Internal/External is entered correctly (i.e. ensure that if the person listed as “holder” is internal, they listed it as “internally sponsored”)

**1899 Form Submission, Completeness and Accuracy**

1. **Is the 1899 Form filled out correctly?** (Check if **“Yes”**. All must be checked, unless otherwise noted.) (NOTE: The 1899 Form must be submitted, complete and accurate prior to IRB approval.)

The product information **matches** the ETHOS smart form, the Central File and the Drug/Device Guidance Regulatory Ancillary Review

Product Manufacturing (Select all that apply. Workbook information only; no action needed)

The product is manufactured or altered at UMN

The product is stored, manufactured or altered at MCT

Other

Monitoring (Both must be checked)

Confirm CTSI is tagged for ancillary review

Monitoring information in 1899 matches information in the protocol

Who will be responsible for monitoring this research? (One must be checked prior to IRB approval. Monitoring is required for all investigator-initiated IND/IDE/NSR IDE research.)

CTSI

Other Monitoring Service confirmed by CTSI.

**Central File Submission, Completeness**

1. **Is the Central File submission complete?** (Check **“Yes”.** Both must be checked prior to IRB approval, unless the product was determined to be an NSR IDE.)

FDA documentation for this IND or IDE has been submitted to the Central File.

Application

FDA approval/acknowledgement

N/A-NSR IDE

**Additional Review Considerations**

1. The Sponsor (and PI) have completed and are up to date on all required training (Workbook information only; no action needed):

GCP CITI

HIPAA (NOTE: Course title changes annually)

RCR (NOTE: If this is not in ETHOS, check training by visiting this link: <https://reports.research.umn.edu/Auth/Main/>, and clicking on “Research Education by Internet ID”)

1. Conflict of Interest is indicated (Check all that apply. Workbook information only; no action needed)

Individual Conflict of Interest - note role on study

PI/Sponsor

Co-Investigator

Other study team member

Institutional Conflict of Interest

Conflict Management Plan is included

1. Review notes (if any): Click or tap here to enter text.