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.