SOP 802: Sponsor Responsibilities

1. POLICY

When an investigator holds an IND/IDE, the investigator acts as the sponsor of the study and is responsible for adhering to sponsor responsibilities in addition to investigator responsibilities.

The IRB expects the sponsor to adhere to ethical principles and monitor the conduct of the research in accordance with federal regulations and Good Clinical Practice as described by FDA when the research project is industry-sponsored and industry-funded.

Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, monitoring the investigation(s), verifying that the investigation is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and informing the FDA and all participating investigators of unanticipated problems involving risk to participants or others with respect to the drug or device.

Specific Policies

1.1 IRB Review of Research

The sponsor must require that human participant research be reviewed and approved by the IRB before any research-related procedures or interventions are initiated.

1.2 Informed Consent

The sponsor must require investigators to obtain informed consent from participants before any of the research activities involving that participant are initiated. The sponsor shall require that investigators use the informed consent document approved by the IRB.

1.3 Reporting Requirements

The sponsor must report any unanticipated problems involving risks to participants or others to the investigator for prompt reporting to the IRB, including anticipated events occurring at a higher-than-expected frequency. Additionally, if the research project involves a Data Safety Monitoring Board (DSMB), the sponsor must provide periodic DSMB reports to the investigator for reporting to the IRB during the time the study is open and for two(2)years following closure of the study or as otherwise indicated in the clinical trial agreement. Refer to SOP 407: Protocol Deviations and Unanticipated Problems, for reporting unanticipated problems involving risks to participants or others.

The sponsor must communicate with the investigator and IRB any information that may be contained in a monitoring report or may be a summary of the sponsor's assessment that could affect the rights or welfare of the research participants or their willingness to continue in the research project. Examples include, but are not limited to, major protocol deviations, failure to obtain informed consent, misuse of investigational drugs or devices, or fraud.

1.4 Modifications

The sponsor must provide any change in the research project or informed consent documents to the investigator for submission to the IRB for approval. Changes in approved research during the period for which approval has already been given may not be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to human participants. Any changes that are implemented prior to IRB approval are considered protocol deviations.

1.5 Continuing Review

The sponsor must verify that the investigator has obtained IRB continuing review approval prior to the expiration of the current approval. Additionally, if the sponsor has information that relates to research project results that could affect the risk/benefit of the research or willingness of participants to participate, the sponsor must provide that information to the investigator for submission to the IRB.

1.6 Communication with the Sponsor

If appropriate, the IRB may communicate directly with the sponsor. For example, if the IRB suspends or terminates a research project, the IRB will notify the sponsor in writing.

2. SCOPE

This SOP applies to all human participant research activities.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for tracking sponsor compliance with IRB requirements and for notifying the HRPP Director and IRB Chair of non-compliance.

3.2 The IRB Chair is responsible for facilitating compliance with IRB requirements through his/her management of IRB deliberations and for providing sponsors with clear guidelines pertaining to that compliance through IRB communications to the sponsor.

3.3 The Investigator is responsible for ensuring a written agreement containing the aforementioned requirements is executed prior to commencement of research activities as required in SOP 602C: Office of Research Administration-OUHSC.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111

21 CFR 54

45 CFR 46.109, 46.111

DHHS Final Guidance Document. Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection. May 5, 2004.

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 407: Protocol Deviations and Unanticipated Problems

SOP 602C: Office of Research Administration -OUHSC

6. ATTACHMENTS

None.

7. PROCESS OVERVIEW

7.1 The sponsor will provide investigator with the protocol, consent documents, Investigator Brochure, and any supporting documents. The investigator and/or research team will incorporate the sponsor's consent template into the IRB consent documents. The investigator submits the research project materials to the IRB in the IRB's electronic submission system.

7.2 The investigator will utilize the consent documents approved by the IRB to obtain consent from participants of the research project. Any changes to the consent documents must be approved as a modification by the IRB prior to initiating any changes.

7.3 Unanticipated problems involving risks to participants or others are reported to the IRB by the investigator. Prompt reporting is essential, as unanticipated problems may require a change to the consent documents and/or protocol.

7.4 The investigator will submit the Continuing Review documents to the IRB. The sponsor is responsible to provide any DSMB information, publication information, and any risk information to the investigator for inclusion on this submission to the IRB.

7.5 The sponsor shall report to the IRB or University any findings of serious or continuing non-compliance detected during the monitoring process that could affect the safety of participants or influence the conduct of the research. Communication to and from the sponsor is typically channeled through the investigator. However, in some situations, it may be appropriate for the IRB to communicate with the sponsor directly or for the sponsor to communicate with the IRB directly.

APPROVED BY:_____ DATE: 09/09/2016

NEXT ESTABLISHED REVIEW DATE: <u>AUGUST 2018</u>