TITLE: Institutional Review Board Responsibilities of Investigators
RI 802 Sponsor Responsibilities

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The IRB shall expect the sponsor to adhere to established ethical and regulatory mandates, and take advantage of the sponsor's ability to communicate efficiently and effectively with investigators who are participating in the sponsored research to communicate its requirements.

GENERAL PROVISIONS:

Sponsors are responsible for:
• Selecting qualified investigators.
• Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects, unanticipated adverse device effect or risks related to the drug or device.
• Providing the investigators with the information they need to conduct an investigation properly.
• Ensuring proper monitoring of the investigation.
• Ensuring that the investigation is conducted in accordance with the general investigational plan and protocols.
• Maintaining an effective IND or IDE with respect to the investigations when applicable.

Additional specific responsibilities of sponsors are:
• Selecting only investigators who are qualified by training and experience as experts to investigate the drug or device.
• Shipping investigational new drugs or devices only to investigators who are participating in the investigation.
• Obtaining the appropriate information from the investigator.
• Selecting monitors who are qualified by training and experience to monitor the progress of the investigation.
• Monitoring the progress of all investigations involving an exception from informed consent.
• Giving each participating clinical investigator an investigator brochure.
• Keeping each participating investigator informed of new observations discovered by or reported to the sponsor on the drug or device, particularly with respect to adverse effects and safe use.
• Monitoring the progress of all clinical investigations being conducted under the sponsor’s IND or IDE.
• Upon discovering that an investigator is not complying with the general investigational plan or the regulations, will promptly either secure compliance or discontinue shipments of the investigational new drug or device to the investigator and end the investigator's participation in the investigation.
• Reviewing and evaluating the evidence relating to the safety and effectiveness of the drug or device as it is obtained from the investigator. If determining that its investigational drug or device presents an unreasonable and significant risk to subjects, the sponsor will discontinue those investigations that present the risk, notify the FDA, all institutional review boards and all investigators who have at any time participated in the investigation of the discontinuance.
• Maintaining and retaining adequate records and reports.
• Permitting the FDA to inspect records and reports relating to the clinical investigations.
• Maintaining written records of the disposition of the investigational drug or device.
• The sponsor shall require that clinical research must be reviewed by the Mercy Health IRB before any protocol mandated procedures or activities are initiated.
• The sponsor shall require investigators to obtain informed consent from participants (unless a waiver of informed consent has been approved by the Mercy Health IRB) prior to their enrollment into the research. The sponsor shall require that investigators use the informed consent document currently approved by the IRB and use the forms only during the period for which they are valid. The sponsor is expected to communicate serious breaches of the consent process to the IRB if it becomes aware of such breaches.
• Changes in approved research, during the period for which approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to human participants. If arrangements are made in advance, sponsors may submit amendments that affect the protocol directly to the IRB for review. Any changes that are implemented prior to IRB approval are considered protocol violations. The IRB may arrange for the sponsor to distribute Approval Letters with the amendment to all sites participating in the protocol.
• The sponsor should inform investigators that all unanticipated problems must be reported to the IRB. An unanticipated problem is defined as any unforeseen event or events that may affect the safety or welfare of participants, or that may affect the integrity of the research. Examples of an unanticipated problem include, but are not limited to: higher than expected adverse events, higher than expected subject drop out rate, higher than expected protocol deviation rate, or subject difficulty understanding the informed consent.
• The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for requesting renewal in anticipation of the expiration of the approval period. Investigators or their designees and/or Sponsors are required to provide a periodic report regarding their investigation prior to the end of the approval period, or upon completion of the study. If the IRB requires interim reports at a greater than annual frequency, the Investigator is required to submit such interim reports within 14 days of the date specified. An IRB Continuing Renewal Report Form will be available to the Investigator for this purpose.
• As sponsors routinely monitor investigative sites, they are in a unique position to uncover information to which the IRB may not otherwise be privy. The IRB requests that the sponsor provide the IRB with any information that may affect the rights and welfare of participants, or their willingness to continue participation. Such information may be contained within a monitoring report, or may be a summary of the sponsor's assessment. The IRB will then work with the investigator and sponsor to address findings as appropriate.

This means that the sponsor is essentially responsible for all operational aspects of the clinical trials it sponsors.

Definition:
Sponsor: An individual, company, institution or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.” (ICH)
“A person who takes responsibility for and initiates a clinical investigation. ... The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator.” (CFR)

REFERENCE:
21 CFR 312.50, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 64, 66, 68, 69, 70
21 CFR 812.3
21 CFR 812.40, 43, 46, 140, 145, 150
21 CFR 56.109, 56.111
21 CFR 54
45 CFR 46.109, 46.111

PROCEDURE:

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<th>Responsibility</th>
<th>Action</th>
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<tr>
<td>Sponsor</td>
<td>1. Abide by all federal regulations when providing sponsorship of research. 2. Abide by all Mercy Health IRB Policies and procedures. 3. Abide by all Mercy Health Institutional policies and procedures.</td>
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1. Work with sponsor as needed to assist in the development of submission materials and to secure all necessary information for ongoing IRB review and approval.

1. Serve as a resource to sponsors in answering questions regarding appropriate training, preparing IRB submissions, conducting the informed consent process and other subject protection activities.

1. Identify sponsor non-compliance as soon as possible and initiate IRB sanctions as appropriate.

1. Provide sponsor with a copy of the IRB policies as appropriate.