

**St. John Providence Health System
St. John Hospital and Medical Center**

IRB RESEARCH MONITORING POLICY

1. POLICY

Quality assurance auditing will be performed randomly on research studies approved by the SJHMC and PHMC Institutional Review Boards (IRB) and/or studies referred for audit by the respective IRB or others involved as a study participant, or in the conduct or oversight of research studies. The IRB may make the determination that a study requires internal auditing.

1.1 Purpose and Objectives:

- To define the policy regarding the monitoring of research studies under the oversight of the St. John Providence Health (SJHMC and PHMC), Institutional Review Boards (IRB).
- To define and promote Investigator, institution, and IRB compliance with federal rules, regulations, and guidance plus St. John Providence Health (SJHMC and PHMC) Policy and Standard Operating Procedures (SOPs) in the conduct of research, through the creation of an ongoing, comprehensive self-monitoring program.
- To assure research study participants' rights, safety and welfare are protected.
- To ensure research study data integrity and control of bias.
- To foster a culture of responsible research conduct and review.

2. PROCEDURE

The IRB Nurse Monitor will schedule an appointment with the study site coordinator(s) with a minimum of 10 business days notice. Investigators and research coordinator(s) will be informed in writing of the date(s), time(s), and protocol(s) selected for the audit and will be provided with a description of the audit process and audit criteria.

The IRB's oversight of research includes the review of ongoing research through a comprehensive research-monitoring program. The IRB may initiate an inspection of a study at any time. The essential site documents (see *Investigator's Responsibility*) will be audited as well as the documentation for the research study maintained by the IRB Office.

2.1 The audit plan may consider the following issues:

- Review of regulatory documents for completeness, accuracy and compliance with protocol and regulatory requirements.
- Informed Consent Form (ICF) has been properly approved by the IRB and if more than one version of the ICF exists, the most recently approved ICF is in use.
- Correct version of the ICF was administered to study participant.
- Verification that the ICF was signed and dated by the study participant or legally authorized representative and by the Investigator/designee prior to any study related procedures.
- Documentation that potential study participant has had ample time and sufficient information to make a true informed decision and was provided with a signed copy of his/her ICF.
- Documentation of the consenting process in the study participant's medical and/or research record.

- Documentation in source documents that study participant meets all eligibility criteria.
- Documentation that study procedures follow study plan in protocol.
- Verification that investigational materials are stored in a secure and proper environment, and accountability records are adequate.
- Review of case report forms and/or databases for completeness and clarity in comparison to source documents.
- Documentation that all serious adverse events and major protocol deviations/ violations have been reported to the IRB.
- Documentation that all changes in research activity have been approved by the IRB prior to implementation.
- Documentation that any unanticipated problems involving risks to study participants or others have been promptly reported to the IRB, appropriate institutional official(s), study sponsor(s), and any department or agency supporting or regulating the research.
- Assurance that study is being conducted in compliance with applicable federal regulations and IRB requirements

An exit interview will be scheduled with the Investigator and research coordinator to review the findings from the audit. A written audit report, itemizing and describing all the findings, will be sent to the Investigator and/or research coordinator at the study site within 14 business days of the audit completion. The report will indicate any areas of concern and a corrective action plan request.

2.2 The audit observations will be categorized as follows:

Critical: Significant departure from standard operating procedures, protocols, or governing regulations and guidelines which **negatively affect** data integrity and/or patient safety.

Major: Departure from standard operating procedures, protocols, or governing regulations and guidelines, which if uncorrected, **could negatively affect** data integrity and/or patient safety.

Minor: Departure from standard operating procedures, protocols, or governing regulations and guidelines, which if uncorrected, **would not negatively affect** data integrity and/or patient safety.

A response from the Investigator with an appropriate action plan will be required within 30 days of the Investigator notification of audit results. A copy of the audit report and the Investigator's response and action plan will be forwarded to the IRB for review.

2.3 The IRB Response to the audit report and the Investigator response will be classified as follows:

- 1) Acceptable
- 2) Acceptable – Needs follow-up
- 3) Unacceptable (Any indication that study participant safety is at risk)

The IRB will decide on the action to be taken.

2.4 Failure to Respond to Audit Report

If there is no response from the Investigator within the requested 30 business days, a reminder will be sent. Sustained lack of response up to 60 business days will be brought to the attention of the IRB. If no response, the IRB may suspend the research study in accordance with the noncompliance policy.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.