Jackson HEALTH SYSTEM
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Section: 800 – Clinical Trials

Subject: Clinical Trials Office

Table of Contents

I. Purpose

Research is a central component of being an academic health system and teaching hospital.

The JHS Clinical Trials Office must ensure that compliance requirements are adhered to for approval and conduct of all research performed at a JHS facility in accordance with, but not limited to, the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) of the U.S. Department of Health & Human Services (HHS). The JHS Clinical Trials Office and JHS Clinical Research Review Committee is responsible for the comprehensive review of proposed research activities that include JHS as a site before the research activity is initiated at Jackson.

The JHS Clinical Trials Office serves as a resource for the Principal Investigator (PI) and study team, including serving as the liaison between all JHS departments and the study team in order to ensure compliant study conduct at JHS facilities. The JHS Clinical Trials Office serves as the centralized support office for research billing compliance, and also provides training opportunities on how to comply with research processes at JHS.

The Clinical Trials Office (CTO) provides pre-award and post award services.

II. Definitions

Institutional Review Board (IRB): Under FDA regulations, it is a group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

JHS Clinical Research Review Committee (CRRC): a multidisciplinary JHS advisory committee established to assess the protections of human subjects at JHS, the financial and operational feasibility of a proposed study, and the scientific soundness of a proposed study for conduct at JHS. The CRRC is not an Institutional Review Board (IRB). Due to its nature as an advisory committee, the CRRC will not need the presence of an acting Chair.

Non-Extramurally Funded Research projects: Studies that are internally funded or lack a funding source.

Principal Investigator (PI): An individual who conducts a clinical investigation (i.e., under whose immediate direction the drug is dispensed to a subject.) If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. The principal investigator must have the appropriate and up-to-date JHS privileges to conduct research activities at JHS.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research Encounter Ticket (RET): a document produced by the JHS Clinical Trials office for each particular study that delineates all patient care procedures that will be performed at JHS.

Research Informed Consent Form (ICF): a document that memorializes that the Study Subject's consent to participate in a research study was obtained in accordance with regulations, good clinical practice (GCP), and the research protocol.

Research Protocol (Protocol): a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project. The National Institutes of Health (NIH) defines a protocol as a formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

Study Subject: refers to patients enrolled in a clinical research study. Unless an applicable Institutional Review Board (IRB) has provided a documented waiver, every study subject (or their legal guardian) must sign an Informed Consent Form (ICF) in order to participate in the research study.

III. Procedure

A. Submitting Studies to the JHS Clinical Trials Office (CTO)

1. PI's affiliated with the University of Miami (UM) and study teams submit the JHS CTO application and Study Calendar to the UM Office of Research Administration (ORA) for quality assurance review prior to submission to the JHS CTO.
2. PI's who are not affiliated with UM are encouraged to contact the JHS CTO for guidance on how to submit all required research study documents for the JHS CTOs review.

3. The JHS Office of Research CTO Application Form shall contain the following items:
   a. The study title.
   b. The name and contact information for the PI and study coordinator.
   c. The funding source, if any, for a particular study (e.g., federal, industry, PI initiated, internally funded, etc.).
   d. The location(s) for study conduct at JHS.
   e. The name of the affected JHS unit's Nurse Manager.
   f. Whether the study will involve the different JHS resources including but not limited to JHS Research Pharmacy.
   g. The number of participants expected to be enrolled at JHS.
   h. For Device Studies:

i. The study materials may be forwarded for review to JHS Procurement and may be subject to a purchasing agreement with the device manufacturer.
ii. For Investigational Device Exemption (IDE) studies, the PI must provide Centers for Medicare & Medicaid Services (CMS) confirmation of Medicare contractor approval from the sponsor to the JHS CTO. Additionally, the local Medicare contractor approval prior to the release of the CRRC's written approval (if applicable).

4. The above submission will occur in conjunction with submission to the IRB and applicable research office at the PI's institution.

5. The JHS CTO's Coverage Analyst shall review all study documentation submitted for accuracy and completeness.

6. The Coverage Analyst shall perform a comprehensive review of the study documents and shall prepare a CRRC study overview and draft study budget.
   a. The Coverage Analyst shall correspond with PI, study team, and the applicable academic institution's research office to clarify any questions and concerns that may arise during the review process prior to presentation to the CRRC.

B. JHS CRRC Presentation
1. JHS CRRC Presentation
   a. The JHS CTO Director or designee will send the studies scheduled for CRRC at least 1 - 2 weeks in advance prior to the meeting.
   b. The Coverage Analyst shall meet with the CTO Director to review all research studies scheduled to be presented to the CRRC in the event there are unresolved questions from the study teams.
   c. The JHS CTO Director shall approve the list of studies to be presented at CRRC.
      i. In the event there are major clarifications not answered by the investigator and or study team, the Director has the discretion to defer the study until the next meeting.
   d. After adequate deliberation, the CRRC, must approve, approve pending, defer, or deny each study in accordance with JHS Policy No. 808 - Clinical Research Review Committee.
      i. Only research studies approved by the CRRC may be conducted at a JHS facility.
   e. A formal communication documenting the CRRC's final decision shall be provided to the PI within three (3) business days of the CRRC's determination, granted, however, that the pertinent IRB approval and agreements necessary for the conduct of the study must already be in place.

2. Post-Approval Process
   a. PI and Study Team Responsibilities
      i. The PI must conduct an in-service training for the applicable JHS staff who will be interfacing with the study subjects or who will be conducting or administering any part of the Protocol at JHS.
         (1) The PI must schedule the in-service training with the leadership team overseeing any affected JHS staff and will provide the protocol synopsis, will document the attendance and understanding of the affected JHS staff.
      ii. The PI and study team are required to complete JHS Cerner training on entering research orders and creating a client encounter.

iii. The PI and study team shall complete training provided by the JHS CTO on how to properly fill out and submit the Research Encounter Ticket (RET) pursuant to JHS Policy No. 821 - Research Encounter Ticket.
iv. It is the PI's responsibility to notify the JHS CTO of every study subject's enrollment pursuant to JHS Policy No. 819 - Participant Enrollment & HIPAA Authorization Notification.
(1) This responsibility may be delegated by the PI to a study team member.
v. It is the PI's responsibility to submit the JHS Monthly Enrollment Form or Chart Review Form to reconcile the number of patients enrolled in each study at JHS.
(1) This responsibility may be delegated by the PI to a study team member.
vi. It is the PI's responsibility to notify the JHS CTO when a study has closed.
(1) The JHS CTO will deactivate (close) the provider account for the closed study.
vii. It is the PI's responsibility to notify the JHS CTO arch of newly assigned study coordinators and to facilitate an introduction between the JHS CTO and the new study coordinator.

3. Monitoring Requirements
a. All study documents submitted to the JHS CTO shall be copied to the CRRC's electronic file system on the JHS shared network drive.
i. Only the JHS CTO staff shall have access to the shared network drive.
ii. All pertinent correspondence (e.g., IRB correspondence, PI correspondence, and other relevant information) shall be copied to the shared network drive folder for each research study reviewed by the CRRC.
b. The JHS CTO shall maintain a master CRRC database that documents all pertinent information concerning research studies submitted for the CRRC's review and approval.
i. The database shall document the final action taken by the CRRC for each research study submission.

C. Charge Capture and Compliant Billing
1. Unless the applicable IRB has provided a documented waiver that is provided to the JHS CTO, a signed copy of the ICF and any applicable HIPAA authorization forms shall be submitted by the PI pursuant to JHS Policy No 819 - Participant Enrollment & HIPAA Authorization Notification.
a. The signed copy may be electronically transmitted to the JHS CTO via the central inbox ClinicalTrialsOffice@jhsmiami.org.
b. It is the PI's responsibility to ensure that the study staff is placing a copy of the ICF in the study subject's JHS Medical Record.

2. It is the PI's responsibility for ensuring that a RET for each study subject's study visit is submitted to the JHS CTO. This requirement assists the JHS CTO in maintaining billing compliance and facilitating reimbursement decisions.
a. The RET may be electronically transmitted to the JHS Office of Research via the central inbox ClinicalTrialsOffice@jhsmiami.org.
b. This responsibility may be delegated by the PI to a study team member.

3. The JHS CTO is responsible for reviewing the RET and ensuring that the study related items and services are properly billed to the applicable research provider account.

4. The JHS CTO is responsible for reviewing the RET and ensuring that routine care items and services have research modifiers placed on the patient's claim, as applicable.

5. The JHS CTO is responsible for billing the study sponsor or the study's financially responsible party for ongoing research related activities based on the agreed RET, contract, and budget for each study in accordance with the terms of the applicable contract or agreement.

D. Audit and Compliance
   1. Audit
      a. JHS compliance auditors will perform periodic audits on a sample of the clinical trials to monitor compliance with this policy and applicable clinical research billing requirements.
      b. Research activities performed at JHS are subject to audits by federal agencies, such as the Human and Health Services' Office for Human Research Protections, FDA, and the Office of Inspector General (OIG), among others.

   2. Compliance
      a. All JHS employees who suspect or become aware of non-compliance with this policy shall immediately report their suspicion to their supervisor and the JHS Corporate Compliance Hotline (1-800-684-6457).
         i. The notified supervisor must report any suspected or confirmed incidences of non-compliance to appropriate JHS leadership.
         JHS employees may also notify the JHS CTO Director.
      b. Non-JHS employees who suspect or become aware of non-compliance with this Policy are strongly encouraged to notify the JHS Office of Research Director or the JHS Corporate Compliance Hotline (1-800-684-6457) if they believe that the non-compliance has not been addressed.

E. Enforcement
   1. It is the JHS' intent to bill clinical research activities compliantly and accurately. Therefore, in any case when a PI violates this policy, the affected research study may be immediately suspended by JHS.

   2. A PI who violates this policy may be disciplined through any applicable personnel policies, including, but not limited to, the Medical Staff Bylaws, the applicable collective bargaining agreement, the general PHT personnel policies, etc.

IV. References

- 21 CFR 50, Protection of Human Subjects
- 21 CFR 56, Institutional Review Boards
- 21 CFR 312, Investigational New Drug Application
- 21 CFR 812, Investigational Device Exemptions
- 45 CFR 46 - Protection of Human Subjects, Subpart A- Basic HHS Policy
- 45 CFR 46.112 - Protection of Human Subjects, Review by Institution
- CMS National Coverage Determination (NCD) 310.1, Routine Costs in Clinical Trials
- JHS Policy No. 808 - Clinical Research Review Committee
- JHS Policy No. 819 - Notifying the JHS Office of Research of Research Participant Enrollment
- JHS Policy No. 821 - Research Encounter Ticket
- National Institutes of Health

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Responsible Party: Director, Clinical Research
JHS Clinical Trials Office

Reviewing Committee(s): JHS Policy and Procedure Committee

Authorization: President and CEO, Jackson Health System