



Section: 800 – Office of Research Administration

Subject: Office of Research Administration

Table of Contents

I. Purpose 1

II. Definitions..... 1

III. Procedure.....2

 A. Submitting Studies to the JHS Office of Research Administration2

 B. JHS ORA engagement with facility administrators.....3

 C. Charge Capture and Compliant Billing4

 D. Audit and Compliance5

 E. Enforcement.....5

IV. References5

I. Purpose

The purpose of the JHS Office of Research Administration (ORA) is to ensure that submission requirements are adhered to for approval and conduct of all research performed at a JHS facility in accordance with the Code of Federal Regulations §46.112 Review by Institution, as it does not have an Institutional Review Board. Additionally, if applicable meet standards of 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 ORA also serves as, the liaison between all JHS departments and researchers in order to ensure compliant study conduct, provide training opportunities on policies and procedures at JHS. Lastly, the JHS ORA serves as the centralized support office for research billing compliance.

II. Definitions

Externally Funded Projects: Studies that are funded by federal, state, industry and or foundation.

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 Expert Collaborators: JHS employees who may be involved in the decision making process of the research study. Those whose operations may be impacted by the research conduct. i.e., Research Pharmacy, Nursing, Procurement, Pathology, etc.

JHS Facility Administrators: Personnel that hold an administrative role at JHS and can make an informed decision on a proposed research study. i.e., CMO, CFO, and/or CEO.

Non- 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



Section: 800 – Office of Research Administration

Subject: Office of Research Administration

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 Office of Research Administration 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 Office of Research Administration
 1. University of Miami (UM) affiliation:
 - a. For Extramurally Funded Industry Research Projects, PI's and study teams submit the JHS ORA application and Study Calendar to the UM Office of Research Administration (ORA) for quality assurance review prior to submission to the JHS ORA.
 - b. For Non-Industry Extramurally Funded and Non-Funded Research Projects: PI's and study teams submit the JHS ORA application to the UM IRB and add JHS as a site and Ancillary Reviewer. If a study calendar applies, study teams submit to the general ORA inbox: JHS-CTO-Submissions@jhs-miami.org
 2. Non-UM affiliation: PI's are encouraged to contact the JHS ORA general inbox for guidance on how to submit all required research study documents for the JHS ORAOs review.
 3. The JHS Office of Research ORA 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) where the study will be conducted 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:



Section: 800 – Office of Research Administration

Subject: Office of Research Administration

- 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 ORA.
 - (1) Additionally, the local Medicare contractor approval prior to the release of the ORA'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 ORA's Financial Analyst shall review all study documentation submitted for accuracy and completeness.
 6. The Financial Analyst shall perform a comprehensive review of the study documents and shall prepare a study budget projection.
 - a. The Financial 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 facility administrators or designees.
- B. JHS ORA engagement with facility administrators
 1. JHS ORA prepares study packet
 - a. The JHS ORA Director or designee will send the studies scheduled for ORA review via JHS SharePoint to JHS expert collaborators based on study needs.
 - b. The Financial Analyst and Research Program Coordinator shall meet with the ORA Director to review all research studies scheduled for review, in the event there are unresolved questions from the study teams.
 - c. The JHS ORA Director shall approve the list of studies to be submitted for facility administrator or designee approval.
 - i. In the event there are major clarifications not answered by the investigator and or study team, the Director has the discretion to place the study on hold.
 - d. After review by the ORA, JHS expert collaborators and facility administrators/ designee, the study can be approved or disapproved.
 - e. A formal communication documenting the facility administrator's or designee's final decision shall be provided to the PI within three (3) business days of the determination, granted, however, that all JHS clarifications have been resolved, the pertinent IRB approval and agreements necessary for the conduct of the study are 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 shall complete training provided by the JHS ORA on how to properly fill out and submit the Research Encounter Ticket (RET) pursuant to JHS Policy No. 821 - Research Encounter Ticket.
 - iii. It is the PI's responsibility to notify the JHS ORA 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.



Section: 800 – Office of Research Administration

Subject: Office of Research Administration

- iv. It is the PI's responsibility to submit the JHS Monthly Enrollment Form or Chart Review Form (if applicable) 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.
 - v. It is the PI's responsibility to notify the JHS ORA when a study has closed.
 - (1) The JHS ORA will deactivate (close) the provider account for the closed study.
 - vi. It is the PI's responsibility to notify the JHS ORA of newly assigned study coordinators and to facilitate an introduction between the JHS ORA and the new study coordinator.
3. Monitoring Requirements
- a. All study documents submitted to the JHS ORA shall be copied to the ORA's electronic file system on the JHS shared network drive.
 - i. Only the JHS ORA 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 ORA.
 - b. The JHS ORA shall maintain a master research database that documents all pertinent information concerning research studies submitted for the ORA's review and approval.
 - i. The database shall document the final action taken by the ORA and by the facility administrators or designee 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 ORA, a signed copy of the ICF and any applicable Health Information Portability and Accountability Act (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 ORA via the central inbox ClinicalTrialsOffice@jhsmiami.org.
 - i. It is the PI's responsibility to ensure that the study staff is sending the ICF to the ORA as per JHS Policy 819 - Participant Enrollment & HIPAA Authorization Notification.
 - b. Once the ICF is received by the JHS ORA, the ORA will upload the ICF in participant's Electronic 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 ORA as per JHS Policy 821 - Research Encounter Ticket.
 - a. This requirement assists the JHS ORA in maintaining billing compliance and facilitating reimbursement decisions.
 - b. The RET may be electronically transmitted to the JHS ORA via the central inbox ClinicalTrialsOffice@jhsmiami.org.
 - c. This responsibility may be delegated by the PI to a study team member.
 3. The JHS ORA 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 ORA is responsible for reviewing the RET and ensuring that routine care items and services have modifiers placed on the patient's claim, as applicable.
 5. The JHS ORA 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.



Section: 800 – Office of Research Administration

Subject: Office of Research Administration

D. Audit and Compliance

1. Audit

- a. JHS compliance auditors will perform periodic audits on a sample of the Office of Research Administration 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 ORA 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 intent of JHS 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:
 - a. The Medical Staff Bylaws,
 - b. The applicable collective bargaining agreement,
 - c. The general Public Health Trust (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. 802 - Participant Enrollment & HIPAA Authorization Notification
- JHS Policy No. 803 - Research Encounter Ticket
- [National Institutes of Health](#)

Responsible Party: Director, Clinical Research
JHS Office of Research Administration

Reviewing Committee(s): JHS Policy and Procedure Committee

Authorization: CEO, Jackson Health System