Jackson HEALTH SYSTEM
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Section: 800 – Clinical Trials

Subject: Participant Enrollment & HIPAA Authorization Notification

I. Purpose

This policy shall apply to all investigators and research team members engaged in clinical research study activities performed in any Jackson Health System (JHS) facility. To notify the Clinical Trials Office of Jackson Health System's patients participating in research. To ensure compliant research billing in accordance to CMS guidelines.

II. Definitions

Clinical Research Review Committee (CRRC): JHS Committee assigned to approve all research conducted at JHS.

Health Insurance Portability and Accountability Act (HIPAA) Authorization: means a patient's or patient representative's affirmative, written statement of permission that allows JHS to use or disclose the individual's protected health information (PHI) for purposes other than treatment, payment or healthcare operations.

Informed Consent Form (ICF): this form documents that consent to participate in a research study was obtained in accordance with regulations, good clinical practice (GCP) and the research protocol.

Institutional Review Board (IRB): Provides oversight of Human Subject Protections.

Principal Investigator (PI): Individual who has oversight of the research study.

Off Study: study subject no longer participating; not being followed.

III. Procedure

A. Process
   1. Notify the JHS Clinical Trials Office (CTO) of Enrolled Research Participants after obtaining IRB and JHS CRRC approval by submitting the signed Informed Consent Form (ICF) and HIPAA Authorization within two business days, after obtaining participant signature, to ClinicalTrialsOffice@jhsmiami.org.
      a. If unable to submit the ICF and HIPAA Authorization during the weekend, it must be sent the next business day.
   2. Confirmation of enrolled participants and their study status, i.e "Off Study" status, is required on a monthly basis by the study team using the patient enrollment form or chart review form; as applicable.
   3. Study Staff will be trained on this policy by the JHS CTO and will be monitored collaboratively by Internal Audit and/or Research Compliance Departments from institutions involved.

B. Special Considerations
   1. The research encounter ticket will contain all study related procedures as the final signed study calendar provided by the study team prior to start of the study.

2. If the participant has consented but sending the ICF and HIPAA authorizations are not immediately feasible, an email with participant identifiers will be required to place the bill on hold.
   a. The ICF and HIPAA authorization must be sent the next business day.
3. If there were no patients enrolled for an active study, then the PI/study team shall send a notification via email that no patients were enrolled.

C. Exceptions to the 2 business Day Rule
1. The following study types shall be exempt from the provisions of section A and B of this policy, provided there are no services billable to 3rd party payers performed in conjunction with the study activities:
   a. Registry studies.
   b. Survey and questionnaire studies.
   c. Retrospective and prospective chart review studies.
   d. Studies ONLY collecting samples for tissue banks, non-invasive exams, or
   e. Conducting tests such as:
      i. Pregnancy tests,
      ii. Blood draws,
      iii. Urinalysis, and
      iv. Other procedures where the processing services on the sample(s) are performed within a JHS research facility/laboratory and ARE NOT sent to a commercial laboratory.
      v. Recruitment from Medical Records (does not apply to recruitment with flyers or recruitment at non-JHS space.).
2. **Note**: ICF, HIPAA, enrollment/chart review forms, if applicable for above mentioned exceptions, must still be submitted to the JHS CTO.

D. Failure to Notify JHS CTO of Enrolled Research Participants
1. Failure to Notify JHS CTO of Enrolled Research Participants may cause the following:
   a. Principal Investigators and members of their study teams shall be subject to corrective measures, which may include loss of the right to conduct any clinical studies at JHS.
   b. The JHS CTO will notify the appropriate IRB of such suspensions.
   c. Delay in placing the bill on hold on patient accounts.

IV. References

National Coverage Determinations (NCD) 310.1. NCD - Routine Costs in Clinical Trials (310.1) (cms.gov).

Medicare Learning Network (MLN) Matters® Number: MM8401. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R2955CP.

Title 45 Public Welfare Part 46-Protection of Human Subjects, Subpart A- Basic HHS Policy Protection of Human Research Subjects, 46.112 Review by Institution. Code of Federal Regulations - Title 45: Public Welfare and Title 46: Protection of Human Subjects (hhs.gov).

Title 45 CFR Part 46.117. eCFR :: 45 CFR 46.117 -- Documentation of informed consent.

Title 21 CFR Food and Drugs, 50 CFR Parts 20-27. Code of Federal Regulations - Title 21 - Food and Drugs | FDA.

JHS Policy 503.9 - Use and Disclosure with Patient Authorization

University of Miami Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy. ctm-policy_revised-1-4_30_2019.pdf (miami.edu)

National Coverage Determination 310.1 https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCAId=248&NcaName=Intensive+Behavioral+Therapy+for+Cardiovascular+Disease&ExpandComments=y&NCDId=1

Medicare Learning Network (MLN) Matters® Number: MM8401. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R2955CP

Title 45 Public Welfare Part 46-Protection of Human Subjects, Subpart A- Basic HHS Policy Protection of Human Research Subjects, 46.112 Review by Institution

Title 45 CFR Part 46.117

Title 21 CFR Food and Drugs, 50 CFR Parts 20-27

JHS Policy No. 808 – Clinical Research Review Committee

University of Miami Clinical Trial Management (CTM) and Participant Enrollment and Tracking Policy. ctm-policy_revised-1-4_30_2019.pdf (miami.edu)

Responsible Party: Director, Clinical Research
Clinical Trials

Reviewing Committee(s): JHS Policy and Procedure Committee

Authorization: President and CEO, Jackson Health System