I. **Purpose**

To ensure compliant research billing according to CMS Clinical Research Policy 310 and facilitate the identification of patients participating in research throughout the hospital in order to assist and ensure appropriate institutional compliance.

Once a research study is approved by the appropriate Institutional Review Board (IRB) and Jackson Health System (JHS) Clinical Research Review Committee (CRRC), the Principal Investigator (PI) and/or designated study personnel shall submit the patient's signed research informed consent form (ICF) to the office within 24 hours. This will ensure appropriate bill hold is placed, patient charges are reviewed, and appropriate billing modifiers are added to the patient’s claim.

This policy applies to all patients enrolled in a research study conducted at JHS.

This policy also applies to patients receiving a Humanitarian Use Device (HUD), and to patients treated with Emergency Use or Compassionate Use Drugs.

II. **Definitions**

Informed Consent: 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.

III. **Procedure**

A. Notifying the JHS Office of Research of Enrolled Research Participants

1. When the PI and/or designated study personnel reviews the informed consent with patients and obtains the signature for that approved research study, the PI or designated study member:

   a. Shall give the person signing the ICF a copy for their personal records.

   b. Shall immediately place a copy of the signed ICF in the Patient’s Medical Record.

   c. Shall e-mail, fax, or provide a hard-copy of the patient’s ICF (signed by patient or their legal guardian) to JHS Office of Research ClinicaltrialsOffice@jhmiami.org, fax: 305-355-2417, or hand-deliver a copy within 24 hours of the patient’s or legal guardian’s consenting signature date.

   d. In addition, PI must provide Monthly Enrollment Logs of all research participants enrolled at JHS for each study signed by the PI to JHS Office of Research for reconciliation at the end of the month. If there were no patients enrolled for a particular active study then the PI shall send the patient enrollment log reflecting “no patients enrolled” along with the PI’s signature.
B. Failure to Notify JHS Office of Research of Enrolled Research Participants
   1. If a PI and/or study team member does not send a copy of the patient’s ICF to the JHS Office of Research within 24 hours of consenting a patient, the JHS Office of Research may suspend study’s ability to recruit or enroll patients on JHS premises.

   2. The JHS Office of Research will notify the appropriate IRB of any such suspensions.

   3. Untimely Submission of Informed Consent Forms can result in:
      a. Improper billing of charges to insurance companies rather than study sponsor
      b. Double billing of study related charges to both insurance companies and study sponsor
      c. Incorrect coding of standard of care items that are billable to third party payers

IV. References

- NCD 310.1
- 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 #TBD UM-JHS Dual Consent Form
- JHS Policy 808 – Clinical Research Review Committee
- MLN Matters® Number: MM8401

**Responsible Party:**
Director
JHS Office of Research

**Reviewing Committee(s):**
Not Applicable

**Authorization:**
Department Head

Revised: 05/30/2017
Supersedes: 12/07/2009