Jackson HEALTH SYSTEM
Miracles made daily.

Section: 800 – Office of Research Administration

Subject: Research Encounter Ticket

I. Purpose

To ensure compliant research billing according to study protocol, Jackson Health System (JHS) study calendar and Centers of Medicare and Medicaid Services (CMS) Policy (Q1/Q0-Z00.6).

Use the Research Encounter Ticker (RET) to review and remove charges to ensure that study related charges are billed according to the study calendar.

Use the RET as a tool to notify JHS Office of Research Administration (ORA) of the participants' Adverse Events.

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.

Research Encounter Ticket (RET): Document used for all patients enrolled in a clinical trial performed at JHS, who received study related services billable to sponsor or to Centers of Medicare and Medicaid Services (CMS).

III. Procedure

A. Research Encounter Ticket Creation
   1. The RET will be created at the post-approval Institutional Review Board (IRB) and Jackson Health System (JHS) Office of Research Administration (ORA) stage.
   2. The RET is created by JHS ORA staff in collaboration with the study team in order to ensure accuracy of study procedures and proper timeline of all procedures performed at JHS.

B. Research Encounter Ticket Approval
   The Study Team will approve the final version of the RET and make sure all charges are listed before utilization.

C. Study Team Responsibility
   1. Submit the Informed Consent to the JHS ORA within 2 business days of signed consent.
   2. Submit the RET to the JHS ORA through the ClinicalTrialsOffice@jhsmiami.org within 2 business days after services have been provided to enrollee at JHS.
   3. Make sure the form has all relevant information:
      a. Medical Record Number (MRN)
      b. Date of Consent
      c. Date of Service
      d. Participant Initials
      e. Adverse Events
      f. Additional procedure/charge notification
      g. Patient status

D. Clinical Trials Office Responsibility
   1. The JHS ORA receives a copy of the research consent within 2 business days and flags the participant in the JHS medical record as research.

2. Once participant is flagged, the participant account is placed on a bill hold ("Q" hold), facilitating the review of study participant charges by the JHS ORA.
3. The JHS ORA will request the Research Encounter Ticket if study participant visit is listed on the daily report and the study team has not provided the RET.
4. Review and remove charges to ensure that study related charges are billed according to the study calendar.

E. Lack of Submission of RET
1. Results will be in non-compliance with the JHS ORA policies and procedures.
2. Will result in improper billing of charges to insurance companies rather than the study sponsor.
3. Will result in incorrect coding of standard of care items that are billable to CMS.

IV. References

JHS Policy No. 802 – Participant Enrollment & HIPAA Authorization Notification

JHS Policy No. 805 - Adverse Events Involving JHS Study Subjects

Medicare Learning Network Matters Number MM8401

Responsible Party: Director, Clinical Research
Office of Research Administration

Reviewing Committee(s): JHS Policy & Procedure Committee

Authorization: CEO, Jackson Health System