Section: 800 – Clinical Trials

Subject: Adverse Events Involving JHS Study Subjects

## I. Purpose

The purpose of this policy is to implement an adverse event reporting procedure by the Principal Investigator (PI) of human subject research involving Jackson Health System (JHS) patients.

## II. Definitions

**Adverse Event (AE):** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal physical exam or laboratory findings, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

**Research-Related Subject Injury:** "Research-related subject injury" means a medical condition (1) Which is caused by and/or directly related to the research study (that is, the condition would not have existed "but for" the subject's participation in the study), and (2) which is in need of diagnosis and treatment as a matter of medical necessity and standard of care."

**Serious Adverse Event (SAE):** the OHRP Guidance defines an SAE as any adverse event that:

1. Results in death;
2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. Results in inpatient hospitalization or prolongation of existing hospitalization;
4. Results in a persistent or significant disability/incapacity;
5. Results in a congenital anomaly/birth defect; or
6. Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

## III. Procedure

A. Principal Investigator (PI) and Study Team Reporting

1. PI and study team will report adverse events and serious adverse events expected and unexpected related to study drug or device or any procedure required by the protocol as determined by PI to the JHS Clinical Trials Office through the Research Encounter Ticket (RET) sent to ClinicalTrialsOffice@jhsmiami.org as per JHS Policy No. 821 – Research Encounter Ticket, in addition to any Institutional Review Board (IRB) reporting requirements.
   a. The event must be reported as soon as PI and study team learn of the event through the RET as per JHS Policy No. 821 – Research Encounter Ticket.

2. The PI and study team shall include the:
   a. Study Identification Number or Institutional Review Board Number (IRB#)
   b. Patient name,
   c. Date of birth,
   d. Date of service,
   e. Location where the event occurred, and

f. Exact location where services at JHS were rendered.

B. JHS Clinical Trials Office and JHS Risk Management Department Procedures

1. JHS Clinical Trials Office will log the events submitted to the IRB as Reportable New Information (RNI) and contact the PI and/or study team to verify if the event occurred at JHS.

2. JHS Risk Management Department may make recommendations to the study team on the RNI's received or information provided by the Clinical Trials Office.
   a. Event may warrant reporting via JHS' safety event reporting risk management system.

3. JHS Clinical Trials Office will hold the bill, if possible and will work with PI and study team to determine items and services billable to the sponsor of the research study.

4. JHS Clinical Trials Office will investigate research bill holds generated by emergency visits or inpatient admissions and correspond with PI and study team to determine causation.

## IV. References

21 Code of Federal Regulations 312.32(a) IND safety reporting.

21 Code of Federal Regulations 314.80 Postmarketing reporting of adverse drug experiences.

45 Code of Federal Regulations part 46 Protection of Human Subjects

1998 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice. PMID: 10386329

2015 HCCA Research Compliance Conference

JHS Policy No. 105A - Managing Safety Events

JHS Policy No. 400.012 - Disclosure of Adverse Incidents and Never Events

JHS Policy No. 821 - Research Encounter Ticket

Office for Human Research Protections (OHRP) Guidance on Unanticipated Problems and Adverse Events

**Responsible Party:** Director, Clinical Research
Clinical Trials Office

**Reviewing Committee(s):** JHS Policy and Procedure Committee

**Authorization:** CEO, Jackson Health System