Notification of Research Participants to the JHS Clinical Trials Office

1. Purpose/Background

To provide the JHS CTO with a consistent and effective means by which to ensure the JHS CTO maintaining accurate study/patient files and audit patient charges. The JHS CTO requires that patient's consents are faxed /hand delivered/emailed to the office to ensure an accurate/current study file is maintained on each approved clinical trial in the hospital and to facilitate compliant billing.

2. Scope

These procedures are intended to facilitate the identification of patients participating in research throughout the hospital in order to and help to ensure appropriate institutional compliance within and among departments and to make sure charges are reviewed before the patient's charges are dropped into the automated billing system..

3. Prerequisites

This policy will address patients who become enrolled in a study at any point during the course of their treatment at JHS, patients who participate in a study at JHS, scheduled patients who will be treated under an approved study protocol, emergent patients who become subjects at JHS, patients treated with Humanitarian Device Exemptions (HDEs), and patients treated under Emergency Use provisions.

4. Procedures

When the Principal Investigator reviews the informed consent with patients and obtains the signature for that approved clinical trial, the PI or study coordinator

1. Must immediately place a copy of the of the signed informed consent in the Patient's Medical Record.

2. Email, fax, or provide hard-copy of Patient Informed consent (signed by patient) to JHS Clinical Trials Office ClinicaltrialsOffice@jhsmiami.org, fax: 305-585-6144, or hand-delivery by the next business day of the patient's consenting signature date. This must be timely to ensure proper auditing of charges.

3. In addition PI must provide Monthly enrollment Logs of all research participants for each study signed by the Principal Investigator to JHS Clinical Trials Office for verification at the end of the of that month. If

there were not patients enrolled on that study send the patient enrollment log on that study reflecting 'no patients enrolled' signed by PI and send to the JHS CTO.

IN THE CASE THE CLINICAL TRIALS OFFICE DOES NOT RECEIVE ANY PATIENT CONSENTS FROM A STUDY.

If a principal investigator and staff do not send the patient's consent form by next business day or active monthly enrollment log by the end of month OR the log indicating ***No Patient Enrollment*** to the JHS Clinical Trials Office the JHS CTO will suspend study's ability to recruit/enroll patients on JHS premises. JHS CTO will notify IRB.

Marvin O'Quinn