LOUIS STOKES CLEVELAND VA MEDICAL CENTER
Medical Research Service
Standard Operating Policy and Procedure (SOP)

Effective Date: June 1, 2017

SOP Title: Research Clinics

SOP Number: HSP-016

SOP Version: .03

1. **PURPOSE:** To establish a mechanism for capturing workload and distinguishing patient's visits for research purposes from standard of care. To avoid billing for tests and procedures performed for research purposes. To comply with documentation requirements for patient's research visits in the VHA health record.

2. **POLICY:** A Research Clinic will be established for each Research Study.

3. **DEFINITIONS:** A Research Clinic is a non-billable computer location in VISTA to capture workload performed for research purposes.

4. **RESPONSIBILITIES:**

a. The Principal Investigator (PI) or designee is responsible for initiating a "Research Clinic" for studies:

(1) Involving subjects who are admitted as in-patients treated as outpatients, or when research procedures or interventions are used in the medical care of the research subject.

(2) That require the use of any clinical resources, such as radiology, cardiology (e.g., EKG, stress test, etc.), clinical laboratory, and pharmacy.

(3) Involving a research intervention that may lead to physical or psychological adverse events.

5. **PROCEDURE**:

a. To initiate set up of the Research Clinic, the PI or designee will contact the Research Service Program Assistant and provide the information noted below:

(1) The name and IRB number of the research study

(2) The Research Clinic provider name and specialty

(3) The point of contact and telephone number for questions

(4) Details regarding appointments, days and times the clinic will be open and length of appointment.

(5) The clinic location.

c. The Program Assistant will submit the request into the Patient Care Administration Service (PCAS) Clinic Management SharePoint site for approval, and notify the PI and/or designee when the clinic has been established.

d. Once the clinic has been established, the Program Assistant will assist in arranging CPRS training for the PI and/or designee, if needed.

e. Study staff will use the Research Clinic to document study activities and contact the Clinical Coordinator when additional assistance is needed.

f. Once the Study is complete, the PI will notify the Research Service Program Assistant to initiate inactivation of the clinic.

6. **REFERENCE**: None

7. **RESCISSION:** May 31, 2020

8. **FOLLOW UP RESPONSIBILITY:** Research Clinical Coordinator