# RESEARCH CLINICS

**SOP HSP-016**

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

**Service Line(s):**
Research Service

**Signatory Authority:**
Neal Peachey, Ph.D. ACOS/Research

**Effective Date:**
June 1, 2023

**Responsible Owner:**
Research Clinical Coordinator

**Recertification Date:**
June 1, 2028

## 1. PURPOSE AND AUTHORITY

a. 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.

## PROCEDURES

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 from VAIRRS/IRBNet of the research study

(2) The Research Clinic provider name and specialty (must be a medical provider)

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

(4) Non count clinic, no appointments are scheduled to research clinics.

(5) The clinic location (room number & floor)

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

c. Once the clinic has been established, training if needed can be arranged with the CPRS Clinical Access Coordinators (CACs).

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

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

## 2. ASSIGNMENT OF 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.

## 3. REFERENCES

None

## 4. REVIEW

At recertification or when there are changes to the governing documents.

## 5. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of June 1, 2028. In the event of contradiction with national policy, the national policy supersedes and controls.

## 7.SIGNATORY AUTHORITY

Neal Peachey 411157

Digitally signed by Neal Peachey 411157
Date: 2023.06.05 10:55:35 -04'00'

Neal Peachey, Ph.D.
Associate Chief of Staff/Research
**Date Approved:** June 5, 2023

***NOTE:*** *The signature remains valid until rescinded by an appropriate administrative action.*

**DISTRIBUTION:** This will be posted on the Research website:
https://www.clevelandvaresearch.org/