

Operating Policy	
<b>TITLE:</b> Housestaff as Research Subjects	
<b>ISSUING DEPARTMENT:</b> Graduate Medical Education Office, Creighton University School of Medicine-Phoenix	<b>ORIGINALLY ISSUED:</b> 04/14/25
<b>DOCUMENT CATEGORY:</b> Institutional	<b>LAST REVIEWED:</b>

## PURPOSE

Provide clear, fair, and consistent guidance for the inclusion of Creighton University School of Medicine–Phoenix (CUSOM-PHX) house staff physicians as research subjects, with careful consideration of the potential impact on their ability to engage in a meaningful and appropriate training experience.

## SCOPE

The policy applies to all research protocols that seek the recruitment and participation of CUSOM-PHX HSPs in research projects as subjects.

## DEFINITIONS

**Designated institutional official (DIO):** The individual in a Sponsoring Institution who has the authority and responsibility for all of that institution’s ACGME-accredited programs.

**Graduate Medical Education (GME):** The period of training following medical school that prepares physicians for independent practice in a specific specialty or subspecialty.

**House Staff Physician (HSP):** Any resident or fellow in a CUSOM-PHX GME program.

## PROCEDURE

- A. Research protocol and accompanying documents are forwarded to the DIO/GME Office.
- B. The DIO or designee conducts a focused review of the research protocol, concentrating on its potential impact on the HSP’s ability to receive a meaningful and appropriate training experience if participating as a research subject. This review does NOT assess the scientific merit or methodological quality of the research.
- C. DIO or designee reviews indicating:
  1. DIO *approval*
  2. DIO approval *withheld*, pending revisions/clarification
  3. DIO *rejection*
- D. If approved by DIO/GME office, the protocol proceeds with the appropriate Creighton University research approval procedures.

## GUIDANCE

The US Supreme Court has determined that house staff physicians (HSPs) are considered employees (“staff”) for federal tax purposes. While they are formally employed by Creighton University and compensated for their work, they are simultaneously engaged in ongoing medical education and training. HSPs develop their clinical skills under the supervision of faculty and attending physicians, distinguishing them from other employee groups. These distinctions may influence considerations regarding their participation as research subjects.

To ensure that HSP participation in research does not compromise their rights or educational experience, oversight by the Graduate Medical Education (GME) office is essential.

Key domains assessed during focused review of the protocol:

- Freedom of participation: Participation, non-participation, or withdrawal from a study should not interfere with teacher-learner relationship.

- **Avoidance of over-solicitation:** Consider the number of ongoing studies; potential impact on other requirements (e.g. mandatory ACGME annual survey completion/"survey fatigue")
- **Management of time dedicated to participation in research:** Consider potential impact on training requirements
- **Emotional safety:** Consider need for debriefing and confidential counseling
- **Educational safety:** Data collected during a study should not influence clinical assessment of the resident, especially when the investigator has a dual role as researcher and evaluator.

### **ADMINISTRATION AND INTERPRETATIONS**

The Graduate Medical Education Office – Creighton University School of Medicine-Phoenix is responsible for the administration of this policy and may interpret its provisions as needed.

### **AMENDMENTS OR TERMINATION OF POLICY**

This policy supersedes all program level policies regarding this area/topic. In the event of any discrepancies between program policies and this GME policy, this GME institutional policy shall govern. The University reserves the right to modify, amend or terminate this policy at any time.

**ACGME ACCREDITATION STANDARD REFERENCE:** 3.2.f.2.