

**POLICY ON HOUSE STAFF AS PRIMARY INVESTIGATOR
GRADUATE MEDICAL EDUCATION**

I. Purpose

To establish a policy for all graduate medical education (GME) training programs within MedStar Health related to the role of house officers as primary investigator on a research study or protocol.

II. Scope

This policy applies to all House Staff who participate in GME training programs within the MedStar Health system. The policy applies to all research involving human subjects conducted at MedStar Health facilities. It also applies to research involving human subjects conducted outside of MedStar Health facilities in which MedStar Health is engaged in research. This policy applies regardless of the Institutional Review Board (IRB) reviewing the study.

III. Definitions

House Staff or House Staff officer – refers to all interns, residents and fellows enrolled in a MedStar Health graduate medical education training program.

Graduate Medical Education Training Program – refers to a residency or fellowship educational program.

Research Study or Protocol – any research study or protocol, regardless of IRB status, taking place within MedStar Health entities, or by trainees currently enrolled in a MedStar Health training program.

IV. Responsibilities/Requirements

A. The Primary Investigator (PI) is responsible for all aspects of the study – including design, IRB submission, following protocol, and delegating work. The ultimate responsibility of the PI is to oversee the body of work, and he or she is responsible if any patient or regulatory concerns arise.

B. Individuals who serve as a Principal Investigator of research involving human subjects must be qualified by education, training and experience to assume responsibility of the conduct of the research. Considering the longitudinal responsibilities for research studies, trainees may not serve in the role as primary investigator on MedStar Health research studies. This designation must be reserved for faculty mentors/supervisors.

V. Right to Change or Retire Policy

Modifications or retirement of this policy may be made at the direction of the Institutional Official for research at MedStar Health or the Vice President, Academic Affairs, as necessary, to remain in compliance with MedStar Health policies.

VI. Responsibilities

It is the responsibility of all trainees participating in research within MedStar to be familiar with this policy. It is the responsibility of the MedStar GME program to inform trainees of this policy.

VII. Exceptions

Exceptions to this policy may be granted on a case by case basis jointly by the Institutional Official for research at MedStar Health and the Vice President of Academic Affairs or their designees.

Policy Approved by: System GMEC

Policy Maintained by: MedStar Academic Affairs/MedStar Health Research Institute