Who Can Serve as Principal Investigator?

Research faculty members with a PhD, MD, OD, or equivalent doctoral degree with an appointment at Massachusetts Eye and Ear (MEE) as Investigator, Assistant, Associate, or Senior Scientist can serve as Principal Investigator (PI) on human studies protocols. These titles are typically correlated with similar ranks at Harvard Medical School (Instructor, Assistant, Associate, or full Professor). PIs assume full responsibility for the ethical and scientific conduct of the clinical research.

All others, including community physicians, Clinical Instructors, part-time appointees etc. must have approval from their respective Department Chief and the VP for Research and Academic Affairs before they can serve as PI on a human studies protocol. In some cases, a research faculty member may be asked to serve as a co-investigator. Residents, Fellows, and other trainees may not serve as PIs.

Scope of Human Studies Committee’s Responsibility:

The Human Studies Committee (HSC) is responsible for oversight of human subjects research (as defined by DHHS and FDA) conducted by employees or agents of MEE, regardless of the location of the research or funding source, that meets any of the following criteria:

• Is performed as part of an individual’s MEE institutional or employment responsibilities
• Is conducted by an MEE affiliate acting in his/her capacity as an agent of MEE
• Is performed with MEE resources, departmental funding, or MEE sponsored funds (industry, federal, foundation, etc.)
• Is performed on properties owned, controlled, or operated by MEE

Work done outside of MEE properties must be disclosed to the HSC administrative office before it is undertaken, to determine whether MEE is considered “engaged in research,” and whether HSC review, individual investigator agreement, reliance agreement, or other cooperative review arrangements may be necessary. The HSC administrative office will notify the PI and the appropriate Chair/Chief. The non-covered location may need to apply for a separate FWA if the project is federally funded. Please note that any use of the MEE name must be in accordance with applicable MEE requirements (please see memo re: Use of Infirmary’s Name referenced below). In particular, in the event that MEE is not “engaged in research” any individual’s use of the MEE name to identify his or her affiliation with MEE must be approved by the Vice President for Research & Academic Affairs, and an appropriate disclaimer may be required.

Reference:

http://www.hhs.gov/ohrp/policy/engage08.html
Use of Infirmary’s Name Policy (Board of Directors May 22, 2001)
May 25, 2001

To: Members of the Medical Staff
Massachusetts Eye and Ear Infirmary

From: F. Curtis Smith  Frederick A. Jakobiec, M.D.  Joseph B. Nadol, Jr., M.D.
President  Chief of Ophthalmology  Chief of Otalaryngology

Re: Use of the Infirmary’s Name

The purpose of this memorandum is to remind all members of the medical staff that there are certain requirements with respect to the use of the name of the Massachusetts Eye and Ear Infirmary. Those requirements were reaffirmed and updated by the Infirmary Board of Directors at its meeting on May 22, 2001, at which the following vote was adopted:

There shall be no use of, or statement of present or past affiliation with, the name, seal, or other identifying indicia ("hereinafter referred to collectively as "name") of the Massachusetts Eye and Ear Infirmary ("the Infirmary"), except as specifically permitted by the prior written consent of the President of the Infirmary or his or her designee, upon the recommendation of the respective department chief, or except as provided below.

Present or past members of the medical staff, including full-time and community-based members, fellows, and residents, members of the research staff, and employees ("Infirmary staff") may use the Infirmary name to accurately identify themselves (e.g., John Doe, M.D., member of the medical staff, Massachusetts Eye and Ear Infirmary). In using the Infirmary name to identify themselves in connection with activities conducted with non-Infirmary individuals and entities (e.g., authoring a book), Infirmary staff must assure that the Infirmary name is used in a manner that does not imply Infirmary endorsement or responsibility for the particular activity, product, or publication involved.

We are all obviously proud of the Infirmary and our affiliation with it, and the above requirements are in no way meant to unduly interfere with the expression of that sentiment. However, we are sure that you can all understand the need to monitor and protect the use of the Infirmary’s name, and to be assured that such use is appropriate.

We thank each of you in advance for your cooperation and anticipated adherence to this policy.