



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Whom May Serve as Principal Investigator and Mentor on IRB-Approved Studies	POLICY # 5037
APPROVED: <hr/> Richard J. Greene, M.D., Ph.D. IRB Chair  <hr/> John DeLuca, Ph.D. Senior Vice President for Research 	EFFECTIVE DATE: March 29, 2006 REVISED DATE: <u>April 10, 2014</u>

PURPOSE

As part of its effort to protect research human subjects, the RIB requires that every Principal Investigator has the research training and qualifications to carryout successfully his or her IRB-approved study.

POLICY

This policy defines who may serve as principal investigator of research studies at the Kessler Foundation.

PROCEDURE

Who May Serve as Principal Investigator and/or Mentor on Research Studies at the Kessler Foundation :

- Full and part time research staff of the Kessler Foundation may serve as principal investigators and mentors with prior approval from the Senior Vice President of Research
- Trainees at Kessler Institute for Rehabilitation or Kessler Foundation (predoctoral students, medical residents, clinical fellows and postdoctoral research fellow) may serve as co-principal investigators if an approved mentor agrees to be co-principal investigator on the project. The mentor must take an active role in assuring the study is carried out using good clinical practices and conforms to the highest ethical standards for the conduct of human research. The trainee and the mentor are both responsible for the conduct of the study.

- Co-Principal Investigators who are predoctoral, medical residents, clinical fellows or postdoctoral research fellows will have their studies audited by the IRB staff after the first five subjects are enrolled to assess their compliance with good clinical practices and their protection of the rights of human subjects. Continuation for these studies beyond the initial five enrolled subjects will depend on their receiving a passing grade in the audit process. This paragraph only applies to the first research protocol on which a postdoctoral research fellow is a P.I.
- Clinical staff members of the Kessler Institute for Rehabilitation (KIR) may serve as principal investigators and mentors with the prior approval of the Chief Medical Officer of KIR (or his designee) and the Senior Vice President for Research of the Kessler Foundation R. All initial research applications of KIR staff members must obtain prior approval from the KIR Chief Medical Officer (or designee) before submission to the IRB.
- Under special circumstances, qualified researchers from other research institutions may serve as principal investigators on Kessler Foundation Research Center studies with the prior approval of the Senior Vice President for Research and laboratory director (if applicable)