



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: IRB Review of Research to be Performed Off Site	POLICY # 5017
APPROVED: Richard J. Greene, M.D., Ph.D. IRB Chair  John DeLuca, Ph.D. Senior Vice President for Research 	EFFECTIVE DATE: January 1, 1998 REVISED DATE: <u>April 10, 2014</u>

PURPOSE

On occasion, Kessler Foundation investigators may wish to carryout research at other institutions. In addition, other institutions may request that the Kessler Foundation's IRB serve as their IRB of record. This policy addresses these circumstances.

POLICY

This policy assures that human subjects in Kessler Foundation IRB-approved studies will be protected even if the studies are carried out at other institutions.

PROCEDURE

Kessler Foundation Investigators may arrange to carryout research studies off site (i.e. at collaborating research institutions). The Kessler Foundation's IRB must review and approval all such studies. Kessler investigators should submit an initial application for IRB review to the IRB for any research study to be carried out off site. The determination of whether the application will be reviewed by the Full IRB Committee, will undergo expedited review, or is exempt from IRB review will be determined by the IRB, not by the investigator. Prior to final approval by the IRB, the collaborating institution must present evidence that it has submitted its own Federal Wide Assurance to the OHRP and provide the IRB with the name and contact information of its Human Protections Administrator.

Kessler Institute for Rehabilitation (KIR) has a formal agreement for research collaboration with Kessler Foundation. KIR investigators may serve as Principal Investigators on IRB-approved studies with the prior approval of the Senior Vice President of Research of Kessler Foundation and the Chief Medical Officer of KIR. KIR has submitted its own Federal Wide Assurance to OHRP. KIR's Chief Medical Officer is the responsible administrator for oversight of all IRB-approved studies at KIR.

Under special circumstances, a collaborating research institution may enter into an agreement with the Kessler Foundation whereby the Kessler IRB will serve as that institution's IRB of record. Such a collaborating institution must present evidence to the IRB that it has submitted its own Federal Wide Assurance to OHRP and provide the IRB with the name and contact information for its Human Protections Administrator.