
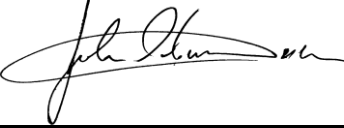


KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Certification of Study Team Members	POLICY # 5025
APPROVED: <hr/> Richard J. Greene, M.D., Ph.D. IRB Chair  <hr/> John DeLuca, Ph.D. Senior Vice President for Research 	EFFECTIVE DATE: February 13, 2004 REVISED DATE: <u>April 10, 2014</u>

PURPOSE

Kessler Foundation has an obligation to safeguard the rights and welfare of volunteers in research studies, and to assure the highest standards are being followed to maintain the integrity of our research programs.

POLICY

In order to receive IRB approval for initial protocols and protocol continuations, all members of the study team, including principal investigators, co-principal investigators, sub-investigators, research assistants, study coordinators and consultants, must demonstrate completion of courses in human subjects protection (effective August 2001) and the Health Insurance Portability and Accountability Act (effective April 2003).

Kessler Foundation will accept IRB applications for review, however, approval will be withheld until the IRB receives certification of course completion for all required training for all members of the study team. Investigators and study team members are reminded that the certification requirements will be strictly enforced. Effective immediately (February 13, 2004), initial applications for IRB protocol review will not be approved until certifications have been completed for all study team members; applications for continuing review will not be approved until certifications have been completed for all study team members. All proposed human subjects research must be reviewed and approved by the Kessler Foundation Institutional Review Board (IRB) as established under the Federal Wide Assurance certification with the Office for Human Research Protections (OHRP) – see Kessler Foundation policy #5001 “Human Subjects Research: Protection of Human Subjects. Subject enrollment and other

study procedures may not commence until IRB approval has been provided. Studies will be suspended after a final notice (requesting study team certifications) has been provided; studies which have been suspended are required to submit a new application (initial application form) for review.

Exceptions may be applied in limited situations, i.e. participation of study team member is limited and there will be NO contact with subjects and NO access to subject data/information. Exemptions will be considered on a case-by-case basis and should be forwarded to the IRB Administrator for review.

Kessler Foundation's IRB will honor Certificates of Completion of training offered by Rutgers and the NIH. The IRB will honor certificates from other institutions, provided the curriculum satisfies NIH requirements and includes federal regulations, regulatory guidance, and state law that define the rules and regulations which govern human subjects protections. Training programs offered by Rutgers and NIH can be accessed by the following links:

<http://rbhs.rutgers.edu/hsp/education/index.html> and <http://www.cc.nih.gov/training/training/jppcr.html>