



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Cooperative Research	POLICY # 5014
APPROVED: <hr/> Richard J. Greene, M.D., Ph.D. IRB Chair  <hr/> John DeLuca, Ph.D. Senior Vice President for Research 	EFFECTIVE DATE: January 1, 1998 REVISED DATE: <u>April 10, 2014</u>

PURPOSE

To set forth guidelines and procedures (in conformance with 45 CFR 46.114) to be followed by Kessler Foundation research investigators when engaging in cooperative research projects with other institutions.

DEFINITION

Cooperative research projects are those projects covered by 45 CFR 46 which involve more than one institution.

PROCEDURE

- I. Kessler Foundation may engage in cooperative research projects provided that each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 45 CFR 46.
- II. Kessler Foundation cooperative research agreements require the approval of the IRB Chair, the Vice President for Research, and the President.
- III. The cooperating institutions may enter into a joint IRB review arrangement, rely upon the review of another qualified IRB or make similar arrangements for avoiding duplication of effort. However, in instances when subject(s) in a study undergo research procedures on-site at Kessler Foundation facilities, prior approval must be granted by the Kessler Foundation IRB.

Similarly, if any subjects are to undergo research procedures at a site not covered by any other IRB (for example, the subject's home) and the person conducting the research procedures is a Kessler Foundation employee, the Kessler Foundation IRB must give approval to the study.

- IV. Responsibilities and rights of the investigators at each facility must be clearly delineated prior to the initiation of the study. These include: tasks and duties; timelines of completion; publication and authorship plans; ownership and storage of data (including both original data and copies); and ownership of intellectual property.
- V. When Kessler Foundation is the secondary institution, it is (generally) required that a Kessler Foundation employee be appointed as investigator or co-investigator on the project. When this is not feasible, a Kessler Foundation contact person must be designated.
- VI. Kessler Foundation must have the right to the return of data and to the equitable use of and access to the entire data set, except where otherwise agreed by the Senior VP for Research.