



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Review of Grant Proposals by IRB	POLICY # 5027
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

To comply with Federal Regulation 45 CFR 46.103(f) requiring that all applications or proposals for funding of research involving human subjects be reviewed and approved by an Institutional Review Board.

POLICY

A review of the applications for grant or contract funding for all proposed or ongoing human subjects research projects is conducted according to the procedure outlined below.

PROCEDURE

The IRB shall approve research based on its determination that the following requirements are satisfied.

- I. The IRB application is an accurate representation of all of human subjects research proposed in any application submitted to public or private funding agencies.
- II. Submission of Grant Proposals
 - a. Prior to implementing any research protocol involving human subjects, an application must be submitted to the Kessler Foundation IRB for its review and approval. If a member of the study team has submitted an application for funding of the study to a public or a private agency, a complete copy of that application (minus information on

investigators' salaries) must accompany the IRB application. The receipt of the application for funding will be recorded in the IRB database.

- b. When an application or funding support is submitted to a funding agency AFTER the initial IRB review and approval of a study, a copy of the funding application should be sent to the IRB at the time it is submitted to the funding agency. Two members of the IRB will review the funding application or consistency with the IRB-approved protocol.
- c. For studies implemented prior to the effective date of this Policy, any funded or pending applications for funding should be submitted to the IRB as part of the package submitted for the next Continuation Review.

III. Review Process

The current review process for IRB applications will be amended to accommodate a review of applications for study funding. As part of the RIB review, applications for funding will be reviewed by IRB members designated by the IRB Chair. As required by 45 CFR 46.103(f), the reviewers will determine whether the application or funding is consistent with the IRB application.