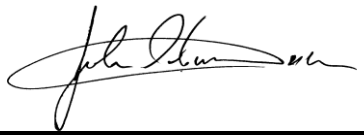
KESSLER FOUNDATION

Policies and Procedures Manual

SUBJECT: **Continuing Review of IRB-Approved Research Projects**	**POLICY #** **5005**
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:** **April 10, 2014**

PURPOSE

In order to meet the Federal requirement for continuing IRB review and approval [45 CFR 46.109(e)], each IRB-approved protocol must be reviewed at least once every 12 months.

POLICY

The Kessler Foundation's IRB conducts continuing review of each approved research project at least once a year to ensure that human subjects continue to be protected throughout the course of the project.

PROCEDURE

A. Based on the approval period granted by the IRB to a newly approved protocol, each protocol is placed on an appropriate continuing review schedule.

B. An Application for Continuation of Approval (attached) is sent to the Principal Investigator 90 days, and again at 60 and 30 days, prior to the continuing review date for each protocol. The PI is requested to submit the completed application form plus a copy of the current, stamped version of the consent form and a clean copy of the consent form. The PI should submit both hard copies and electronic copies of these documents as outlined on the Application form at least 30 days before approval expires.

C. Protocols that had been approved initially through expedited review may also have their continuing review carried out through the expedited review process.

D. For those protocols where the Full IRB carries out continuing review, the IRB members are asked to discuss the application and consent form and to vote to:

- Approve the continuation

- Approve pending clarification of items identified by the IRB
- Suspend approval pending further investigation by the IRB
- Disapprove the continuation and terminate the project