



# KESSLER FOUNDATION

## *Policies and Procedures Manual* *IRB*

<b>SUBJECT: Review of Amendments in IRB-Approved Research Projects</b>	<b>POLICY # 5006</b>
<b>APPROVED:</b>	<b>EFFECTIVE DATE:</b>
Richard J. Greene, M.D., Ph.D. IRB Chair 	September 1, 2005
John DeLuca, Ph.D. Senior Vice President for Research 	<b>REVISED DATE:</b> <u>April 10, 2014</u>

### PURPOSE

To abide by the Federal requirement for IRB review and approval of amendments to previously approved protocols [45 CFR 46.103(b)(4)],

### POLICY

***The Kessler Foundation's IRB must review and approve any modification to a previously approved protocol before it can be implemented.***

### PROCEDURE

1. Principal Investigators of previously IRB-approved projects are required to submit a formal Application of Amendment to the IRB for review and approval before any modification to the project is implemented.
2. Examples of protocol modifications that require IRB review and approval include, but are not limited to:
  - Amendments in the study protocol that correct errors in the protocol text or change: a) the experimental design, b) the study intervention, c) the study population, or d) the study title.
  - Amendments to the informed consent document necessitated by a protocol change, a change in the investigators, unexpected adverse events, discovery of errors or the need to clarify language in the consent form.

Changes in the team of investigators

Changes in the Investigator's Brochure

3. Amendment applications are reviewed and approved by the Full IRB unless the proposed changes are minimal and would have no direct impact on the study subjects. Such minor amendments may be reviewed through the expedited review process.
4. The IRB can take the following actions on an amendment application: approved, approved pending changes specified by the IRB, disapproved. The P.I. is notified in writing of the review decision of the IRB.
5. IRB approval of an amendment request does not change the previously set date for continuation review.

Acknowledgement: In the development of this Policy, Kessler Foundation acknowledges its reliance on the Guidelines for Advertisements for Recruiting Subjects of Partners Healthcare System, Boston, MA.