KESSLER FOUNDATION

Policies and Procedures Manual
IRB

SUBJECT: Suspension or Termination of IRB Approval	**POLICY # 5007**
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

To set policy on the suspension or termination of IRB approval of research according to Federal regulation 45 CFR 46.113.

POLICY

Protocol termination or suspension may be initiated by either the principal investigator (PI) or the Kessler Foundation IRB. The Kessler Foundation IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

PROCEDURE

A. Upon submission of an application to the IRB by the principal investigator (and/or sponsor) for closure of a given protocol, the IRB will review the application and provide written notice to the principal investigator that closure is approved or that further information is required.

B. In the event that a protocol is out of compliance because it has not received approval for continuation prior to the IRB expiration date, the principal investigator will be contacted by the IRB via memo and informed that all research activity must be suspended until the protocol is brought into compliance. If the principal investigator does not respond within a month, a termination notice will be sent to the principal investigator.

C. If the IRB Coordinator determines that, 1) a study has no current PI of record, 2) a study is no longer active, 3) a study is not being conducted in accordance with the IRB's requirements or 4) there has been unexpected serious harm to subjects – the IRB Coordinator will inform the IRB Chair who may immediately suspend work on the study.

The Chair will notify the IRB of his/her action and place the protocol on the next IRB agenda for consideration of further action.

The members of the study team will be informed of the Chair's decision to suspend work on the study and will be asked to submit information to the IRB explaining the circumstances of noncompliance.

D. Once a protocol is terminated, a full application must be submitted to, and approved by, the IRB before work may resume on the study.