



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Investigations of Unauthorized or Noncompliant Research on Human Subjects	POLICY # 5008
APPROVED: <hr/> Richard J. Greene, M.D., Ph.D. IRB Chair  <hr/> John DeLuca, Ph.D. Senior Vice President for Research 	EFFECTIVE DATE: September 1, 2005 REVISED DATE: <u>April 10, 2014</u>

PURPOSE

This policy describes the procedures for investigating allegations of unauthorized or noncompliant research as required by 45 CFR 46.103b (5).

POLICY

This policy requires the prompt reporting to the IRB and/or officials of Kessler Foundation of any unauthorized research or serious or continuing noncompliance with IRB policies, requirements or determinations on the part of any Kessler Foundation personnel*.

PROCEDURE

Once an allegation is made that a Kessler Foundation employee may have engaged in unauthorized research or may have been noncompliant with IRB policies, the IRB will take the following actions*:

A member of the IRB will be designated to meet separately with the person who submitted the allegation (the complainant) and with the Principal Investigator (PI) of the protocol and any other members of the research team involved in the allegation, to discuss the allegation. The IRB member will prepare a brief written report to the IRB Chair who will determine if work should be suspended on the protocol while further investigation is undertaken. If work is suspended, the sponsor and the Office of Human Research Protection (HHS) are to be informed of the investigation.

The President of Kessler Foundation and the Senior VP for Research will be notified of the allegation and the results of the preliminary discussions with the complainant and the PI. The IRB Chair, in consultation with the President and Senior VP for Research, will

determine whether a formal investigation of the allegations is warranted, and whether an audit of the protocol in question should be carried out by IRB staff.

Formal Investigation: If a formal investigation is required, the following will take place: The IRB will inform the President and Senior VP for Research in writing a formal investigation of the matter will take place.

The PI and other involved members of the research team will be informed that a preliminary inquiry indicated unauthorized or noncompliant research had taken place and that a formal investigation will proceed.

The IRB will appoint an IRB member or an outside party who is an expert in the research area in question to review all aspects of the project to determine 1) if the researchers carried out research that was not approved by the IRB, 2) if any subjects were exposed to excess risk as a result of noncompliance or unauthorized research activities, 3) if there was evidence the investigators failed to obtain informed consent from any subjects and 4) if confidentiality of protected health information was violated.

The IRB-appointed investigator will prepare a written report of his/her findings to the full IRB.

The IRB will give the researcher(s) an opportunity to meet with the Committee to discuss the findings of the formal investigation.

After review of the investigator's written report and consideration of the meeting with involved researchers, the IRB will take final action that may include, but not be limited to, the following:

- Approval of continuation of the research without change.
- Conditional approval of continuation of the research pending major or minor changes in the protocol or the consent form.
- Termination of the protocol.
- Disqualification of the investigator from future human research at Kessler Foundation.
- Determination that the data collected in this study may not be used for publication.
- Require that subjects in this study be contacted and given additional information or re-consented if the study is continued.
- Require that editors and publishers be informed of the findings of the investigation if manuscripts resulting from the research have been submitted or published.
- Recommend to Kessler Foundation administration that further administrative action be taken.

The final report of the investigation, including the actions taken by the IRB, will be submitted to the President and Senior VP for Research, and a copy will be sent to the researchers whose actions were investigated.

If the protocol is terminated or other disciplinary action is taken by the IRB, a report of these actions will be submitted to OHRP and the research sponsor.

*This policy and these procedures will be followed if the researcher is a Kessler Institute for Rehabilitation employee, with the IRB Chair consulting with KIR clinical leadership.