



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: IRB Membership	POLICY # 5001
APPROVED: <hr/> Richard J. Greene, M.D., Ph.D. IRB Chair  <hr/> John DeLuca, Ph.D. Senior Vice President for Research 	EFFECTIVE DATE: January 1, 1998 REVISED DATE: <u>April 10, 2014</u>

PURPOSE

The Kessler Foundation has adopted as policy the terms of Federal regulations 45 CFR 46.107(a) through (d) for the selection of members to serve on the IRB.

POLICY

The Kessler Foundation has an IRB that complies with Federal policy.

PROCEDURE

- A. The IRB shall be made up of at least five voting members.
- B. Members shall be selected with the following attributes:
 - Scientific experience and purpose
 - Non-scientific perspectives
 - Diversity of race, gender and culture
 - Affiliation with the Kessler Foundation
 - No affiliation with the Kessler Foundation
 - Sensitivity to community attitudes
 - Sensitivity to vulnerable populations
 - Ability to promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects

- C. Members will be appointed for indefinite terms by the Senior Vice President for Research who, in consultation with the IRB Chair, will periodically review the composition of the IRB and add and subtract members to maintain balance. Members are expected to attend at least 60% of the scheduled IRB meetings.
- D. The IRB Chair will be appointed for an indefinite term by the Senior Vice President for Research. The Chair will serve at the pleasure of the Senior Vice President for Research.
- E. A new IRB member will be provided with a copy of the IRB Policy and Procedure Manual and will attend an IRB meeting as an observer before he or she becomes an official IRB member.
- F. Up to two alternate IRB members may be appointed by the Senior Vice President for Research. Alternates can substitute for regular members when needed to achieve quorum.
- G. When research is reviewed involving any category of vulnerable subjects (e.g. pregnant women, prisoners, children, individuals with mental disabilities, economically or educationally disadvantaged), the IRB shall include in its reviewing body one or more persons who have a primary concern for the welfare of these subjects.
- H. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB.
- I. The IRB, may at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote on matters before the IRB.