
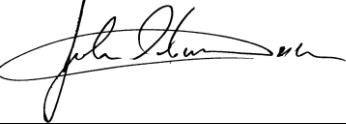


KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: IRB Confidentiality Policy and Procedures	POLICY # 5015
APPROVED:	EFFECTIVE DATE:
Richard J. Greene, M.D., Ph.D. IRB Chair 	January 1, 1998
John DeLuca, Ph.D. Senior Vice President for Research 	REVISED DATE: <u>April 10, 2014</u>

PURPOSE

In order to assure that the IRB review process is conducted in a fair and impartial manner and that the IRB operates as an independent organization, all deliberations of the IRB Committee are to be held in confidence. Further, as part of the mandate to protect human subjects, IRB members have access to confidential information within protocols including, but not limited to, intellectual property information, trade secrets of pharmaceutical and device manufacturers, and other new plans or developments which may be in process for patent purposes. All processes, documentation and correspondence, integral to the IRB review mandated by Federal Regulations (45 CFR and 21 CFR 56), NJ statutes (N.J.A.C. 8:43G-4.1 (1996), N.J.S.A., 26:2H-12.8 et seq.) and KFRC policy are to be held in strict confidence, unless otherwise noted.

DEFINITION

This policy applies to information in protocols including, but not limited to, intellectual property, trade secrets of pharmaceutical and device manufacturers, and other new plans or developments; processes, documentation and correspondence integral to IRB review.

PROCEDURES

During orientation, the IRB Administrator will present the IRB Confidentiality Procedures to the new member. The Chair and all members of the Committee will abide by these procedures throughout their term on the Committee.

The IRB Administrator and the Chair of the IRB will have the responsibility to assure and monitor compliance with the procedures set forth herein.

The IRB Administrator, the Chair of the IRB and the Senior Vice President of Research will have the responsibility to assess any possible breach of confidentiality within the IRB and act upon such a breach. These actions may include, but are not limited to expulsion from IRB membership, notification of a supervisor and Kessler Foundation administration.

To assure anonymity, and to protect IRB members and the integrity of the review process as mandated by Kessler Foundation policy and Federal regulations, IRB deliberations are carried out *in camera*. Comments should not be attributed to any IRB member when communicating IRB discussions and findings to Principal Investigators and members of the study team. Confidentiality of the IRB's deliberations is necessary to assure that outside pressures do not influence the IRB review process.

The documentation required by regulation in the form of reviewer assignments, agendas, minutes, records of inquiries and investigations are considered to be the property of Kessler Foundation and used solely in compliance with record keeping requirements.

The proceedings of the review process are disclosed to Kessler Foundation IRB Administration when required for administrative oversight and to the Food and Drug Administration (FDA) and The Office of Human Research Protections (OHRP) upon request.