



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: IRB Record Keeping	POLICY # 5009
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

To ensure that appropriate IRB records are maintained as specified in 45 CFR 46.115.

POLICY

The IRB maintains its records according to the procedure specified below.

PROCEDURE

Documentation of IRB activities shall be maintained in the office of the IRB Administrator in files accessible for inspection and copying by authorized representatives of the DHHS or FDA in the following manner:

1. Records relating to research protocols, which are approved, and thereafter conducted, shall be retained during the research study, and for at least three years after completion of the research. Items to be maintained include:
 - a. Copies of all research applications reviewed, including sample consent forms, investigators' progress reports and reports of injuries to subjects
 - b. Copies of scientific evaluations, if any, that accompany the proposals.
 - c. Records of continuing review.

- d. Copies of all correspondence between the IRB and the investigators.
2. Minutes of IRB meetings and IRB membership listing, as described below, shall be retained for at least three years.
 - a. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. The minutes of the IRB meetings shall reflect the actions of the board on research projects, including date of Continuing Review.
 - b. A list of IRB members in the same detail as described in 45 CFR 46.103(b)(3).
 3. Written procedures for the IRB in the same detail as described in 45 CFR 46.103(b)(4) and 46.103(b)(5).