



Human Research Ethics Training Tips

Code of Federal Regulations

TITLE 45: PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46: PROTECTION OF HUMAN SUBJECTS

Revised January 19, 2017, and Amended January 22, 2018 and June 19, 2018

General Compliance date is January 21, 2019

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Subpart A. Basic HHS Policy for Protection of Human Research Subjects

Section: §46.115 IRB Records.

- (a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

- (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
- (2) 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.
- (3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in [§46.109\(f\)\(1\)](#).
- (4) Copies of all correspondence between the IRB and the investigators.
- (5) A list of IRB members in the same detail as described in [§46.108\(a\)\(2\)](#).
- (6) Written procedures for the IRB in the same detail as described in [§46.108\(a\)\(3\)](#) and [\(4\)](#).
- (7) Statements of significant new findings provided to subjects, as required by [§46.116\(c\)\(5\)](#).
- (8) The rationale for an expedited reviewer's determination under [§46.110\(b\)\(1\)\(i\)](#) that research appearing on the expedited review list described in [§46.110\(a\)](#) is more than minimal risk.
- (9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in [§46.103\(e\)](#).

- (b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.