

ED Records Schedule

SCHEDULE LOCATOR NO.: 094

APPROVED DATE: 7/3/2006

TITLE: Department of Education Institutional Review Board (IRB) Files (Intramural Research)

PRINCIPAL OFFICE: Office of the Chief Financial Officer (OCFO)

NARA DISPOSITION AUTHORITY: N1-441-06-001

DESCRIPTION:

The Department of Education is one of seventeen Federal agencies that adopted the Federal Policy for the Protection of Human Subjects in 1991. The regulation requires assurances and the approval of an institutional review board (IRB) for ED-funded or ED-conducted research involving human subjects, unless the research is exempt from the Policy. This schedule is intended to cover files generated by the Department's IRB as part of its review responsibility for research subject to its jurisdiction.

This schedule addresses ED-conducted research (intramural research), which is defined as "any research activity in which an ED employee obtains information about a human subject through his/her intervention or interaction with the human subject or obtains identifiable private information about a human subject."

Extramural research (ED sponsored) is addressed in the Implementation Guidance of this schedule.

DISPOSITION INSTRUCTIONS:

a. Operating Documents

Includes the Department IRB procedures and Department IRB membership rosters.

TEMPORARY

Cut off annually when superseded or obsolete. Destroy/delete 10 years after cutoff.

b. Review Files

Includes the IRB minutes of meetings, IRB decisions/approvals projects, copies of research proposals reviewed, approved sample consent documents and related materials, progress reports submitted by investigators, and reports of injuries to subjects for intramural research.

TEMPORARY

Cut off annually after completion of research project or receipt of final report. Destroy/delete 10 years after cutoff.

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- c. Duplicate Copies Maintained for Reference Purposes and That Do Not Serve as the Record Copy

TEMPORARY

Destroy/delete when no longer needed for reference.

IMPLEMENTATION GUIDANCE:

IRB documents for extramural (ED-funded) research are maintained with the corresponding grant or contract management records. Examples of documents include a) Grants Policy and Oversight Staff (GPOS) human subjects office staff “clearance” e-mails notifying the program office that the applicant/grantee has met the requirements for assurance(s) and IRB approval(s); b) assurances of compliance; c) independent investigator agreements, and d) certifications of IRB approval.

PREVIOUS DISPOSITION AUTHORITY:

SPECIFIC LEGAL REQUIREMENTS:

34 CFR Part 97 Subpart A and Subpart D

SPECIFIC RESTRICTIONS:

LINE OF BUSINESS: Research and Statistics