

REQUEST FOR RECORDS DISPOSITION AUTHORITY

(See instructions below)

LEAVE BLANK (NARA use only)

JOB NUMBER

721-441-06-1

DATE RECEIVED

3/16/2006

NOTIFICATION TO AGENCY

In accordance with the provisions of 44 U.S.C. 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10

DATE

3/16/06

ARCHIVIST OF THE UNITED STATES

Allen W. ...

TO NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR)
WASHINGTON, DC 20408

1 FROM (Agency or establishment)

U.S. Department of Education

2 MAJOR DIVISION

Office of the Chief Financial Officer (OCFO)

3 MINOR DIVISION

Grants Management Improvement Team, Grants Policy and Oversight Staff

4 NAME OF PERSON WITH WHOM TO CONFER

Helene Deramond

5. TELEPHONE

202-245-6154

6 AGENCY CERTIFICATION

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached 2 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

is not required;

is attached, or

has been requested.

DATE

3/10/06

SIGNATURE OF AGENCY REPRESENTATIVE

Barbara M. ...

TITLE

Department Records Officer

7
ITEM
NO

8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION

9 GRS OR
SUPERSEDED
JOB CITATION

10 ACTION
TAKEN (NARA
USE ONLY)

See attached schedule for 094 - Protection of Human Subjects in Research Institutional Review Board Files.

Helene Deramond

Helene Deramond, Team Leader
Human Subjects Protection

February 28, 2006
Date

cc Agency NWMW NWMW



ED Records Schedule



SCHEDULE LOCATOR NO.: 094

DRAFT DATE: 11/14/05

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

PRINCIPAL OFFICE: Office of the Chief Financial Officer

NARA DISPOSITION AUTHORITY:

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 when superseded or obsolete. Destroy 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 file after completion of research project or receipt of final report. Destroy 10 years after cutoff.

c. Electronic version of records created by electronic mail or word processing systems

TEMPORARY

Delete when recordkeeping copy is generated or when no longer needed for reference or updating, whichever is sooner.

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.

FORMAT: Paper, electronic

PREVIOUS NARA DISPOSITION AUTHORITY:

SPECIFIC LEGAL REQUIREMENTS:

34 CFR Part 97 Subpart A and Subpart D

SPECIFIC RESTRICTIONS:

BUSINESS LINE: Research and Statistics