Request for Records Disposition Authority

Records Schedule Number	DAA-0514-2019-0001
Schedule Status	Approved
Agency or Establishment	Office of the Assistant Secretary for Health
Record Group / Scheduling Group	Records of the Office of the Assistant Secretary for Health
Records Schedule applies to	Agency-wide
Schedule Subject	Official Files of the Office for Human Research Protections
Internal agency concurrences will be provided	Yes

Background Information

The Office for Human Research Protections (OHRP) was created in June 2000 to lead the Department of Health and Human Services' efforts to protect human subjects in biomedical and behavioral research and to provide leadership for all federal agencies that conduct or support human subjects research under the Federal Policy for the Protection of Human Subjects, also known as the Common Rule. OHRP replaced the Office for Protection from Research Risks, which was created in 1972 and was part of the National Institutes of Health. In June 2000, HHS established the National Human Research Protections Advisory Committee (NHRPAC) to provide HHS with expert advice and recommendations on human subject protections matters.

Located in HHS' Office of the Assistant Secretary for Health, OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, provides advice on ethical and regulatory issues in biomedical and behavioral research, and administers assurance of compliance and IRB registration programs. OHRP also supports the Secretary's Advisory Committee on Human Research Protections (SACHRP), which advises the HHS Secretary on issues related to protecting human subjects in research. SACHRP replaced NHRPAC on January 3, 2003 with similar responsibilities. OHRP has oversight over more than 13,000 institutions in the United States and worldwide that conduct HHS-supported non-exempt human subjects research.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
6	0	6	0

GAO Approval

Outline of Records Schedule Items for DAA-0514-2019-0001

Sequence Number	
1	Certifications for Research Involving Prisoners Disposition Authority Number: DAA-0514-2019-0001-0001
2	Federal-Wide Assurance (FWA) Disposition Authority Number: DAA-0514-2019-0001-0002
3	Institutional Review Board (IRB) Registration Documents Disposition Authority Number: DAA-0514-2019-0001-0003
4	Documents Related to Certain Research Involving Children Disposition Authority Number: DAA-0514-2019-0001-0004
5	Documents Related to Certain Research Involving Pregnant Women, Human Fetuses, and Neonates Disposition Authority Number: DAA-0514-2019-0001-0005
6	Compliance Activities Records
6.1	Incident Reports and Complaints Disposition Authority Number: DAA-0514-2019-0001-0006

Records Schedule Items

Sequence Number

1 Certifications for Research Involving Prisoners

Disposition Authority Number DAA-0514-2019-0001-0001

Documents submitted by institutions pursuant to the requirements of HHS regulations at 45 CFR 46.305(c) and 46.305(a)(1). Institutions must have this certification prior to conducting HHS-supported research on prisoners. These documents include: • Approved research protocols and consent forms, including names and contact information of researchers • Certification request letters from institutions containing the requesting institution's IRB registration #, Federal-wide Assurance #, grant #, date of IRB subpart C review, choice of subpart C category of research, name of principle investigator, name of grantor's program officer, and often a summary of the research • IRB submission and review forms • Notice of Grant Award, or sections of the grant

Final Disposition	Temporary
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at the end of the calendar year after certification has been issued.
Retention Period	Destroy 4 year(s) after cutoff

Additional Information

GAO Approval	Not Required

2 Federal-Wide Assurance (FWA)

Disposition Authority Number DAA-0514-2019-0001-0002

Institutions engaged in human subjects research (not otherwise exempt) that is conducted or supported by any agency of the U.S. Department of Health and Human Services, must have an OHRP-approved assurance of compliance with the HHS regulations (45 CFR 46.103) for the protection of human subjects. Through the FWA and the Terms of the FWA, an institution commits to HHS that it will

comply with the requirements of these regulations. The Federal-wide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. In addition, as mentioned above, other federal departments and agencies rely on OHRP-approved FWAs for some of the human subjects research they support. There is no end date when allegations of non-compliance could be made for research that is federally supported or for research in which the institution has checked the box (non-federally supported research would be covered). Therefore, if an allegation of non-compliance were made for non-federally supported research, OHRP would need access to the institution's FWA that were in place when the alleged non-compliance occurred (which could have been 30 or more years prior to the allegation of non-compliance) to determine whether OHRP would have jurisdiction over the matter.

Final Disposition	Temporary
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at the end of fiscal year after Federal-wide Assurance (FWA) was approved
Retention Period	Destroy or delete 30 years after cutoff but longer retention is authorized if required for business use.

Additional Information

GAO Approval	Not Required

3

Institutional Review Board (IRB) Registration Documents

Disposition Authority Number	DAA-0514-2019-0001-0003

The HHS regulations at 45 CFR part 46, subpart E, require all IRBs to register with HHS if they will review human subjects research conducted or supported by HHS. An organization or institution must register its IRBs with the Office for Human Research Protections (OHRP) before it reviews human subject research as required by the HHS regulations for research that is supported or conducted by HHS. Since 2009, virtually all registrations are submitted electronically and maintained by OHRP.

Final Disposition	Temporary

	Item Status	Active
	Is this item media neutral?	Yes
	Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
	Do any of the records covered by this item exist as structured electronic data?	Yes

Disposition Instruction

Cutoff Instruction	Cutoff at the end of the fiscal year after registration was submitted.
Retention Period	Destroy or delete 10 years after cutoff but longer retention is authorized if required for business use.

Additional Information

GAO Approval	Not Required

4 Documents Related to Certain Research Involving Children

Disposition Authority Number	DAA-0514-2019-0001-0004

The HHS regulations at 45 CFR part 46.407 requires that research involving children not otherwise approved (by an institutional review board) which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children undergo a so-called “46.407” process. The Office for Human Research Protections (OHRP) on behalf of OASH/HHS, in response to an institution’s/IRB’s request and submission of documents related to the proposed research, conducts the 46.407 process. The 46.407 process involves consultation with a panel of experts in pertinent disciplines and providing the public an opportunity to review and comment on the proposed research. The ASH, in response to recommendations from OHRP, determines whether or not the proposed research can be conducted.

Final Disposition	Temporary
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes

Disposition Instruction

Cutoff Instruction	Cutoff at the end of the fiscal year after registration was submitted
Retention Period	Destroy or delete 10 years after cutoff but longer retention is authorized if required for business use.

Additional Information

GAO Approval	Not Required

5 Documents Related to Certain Research Involving Pregnant Women, Human Fetuses, and Neonates

Disposition Authority Number	DAA-0514-2019-0001-0005

The HHS regulations at 45 CFR part 46.207 requires that research involving pregnant women, human fetuses, or neonates not otherwise approvable (by an institutional review board) which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, human fetuses, or neonates undergo a so-called “46.207” process. The Office for Human Research Protections (OHRP) on behalf of OASH/HHS, in response to an institution’s/IRB’s request and submission of documents related to the proposed research, conducts the 46.207 process. The 46.207 process involves consultation with a panel of experts in pertinent disciplines and providing the public an opportunity to review and comment on the proposed research. The ASH, in response to recommendations from OHRP, determines whether or not the proposed research can be conducted.

Final Disposition	Temporary
Item Status	Active
Is this item media neutral?	Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes

Disposition Instruction

Cutoff Instruction	Cut off at the end of the calendar year after OHRP’s review
Retention Period	Destroy 10 years after cutoff but longer retention is authorized if required for business use.

Additional Information

GAO Approval Not Required

6 Compliance Activities Records
The OHRP Division of Compliance Oversight (DCO) maintains tracking of certain compliance activity information including complaints, incident reports from institutions (IRPTs), meeting notes and contact with the public.

6.1 Incident Reports and Complaints

Disposition Authority Number DAA-0514-2019-0001-0006

Reports of incidents and/or events that institutions are required by HHS regulations at 45 CFR part 46 to report to OHRP: (1) unanticipated problems involving risks to subjects or others; (2) serious or continuing noncompliance; and (3) suspension or termination of IRB approval. OHRP record(s) includes OHRP correspondence; internal OHRP e-mails; and correspondence and documents submitted by institutions). These records contain all documents created by the complainant, OHRP, the institution that conducted the research and any other relevant stakeholders pertaining to that report.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? Yes

Do any of the records covered by this item exist as structured electronic data? Yes

Disposition Instruction

Cutoff Instruction Cut off at the end of the calendar year after OHRP's determination that corrective action has been implemented or is unwarranted

Retention Period Destroy 30 years after cutoff but longer retention is authorized if required for business use.

Additional Information

GAO Approval Not Required

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 in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
05/30/2019	Certify	Karen Ballesteros	Management Analyst	Department of Health and Human Services - Office of Secretary
01/09/2020	Return for Revision	Jessica Blessman	Appraisal Archivist	National Archives and Records Administration - ACRA
03/18/2020	Submit For Certification	Karen Ballesteros	Management Analyst	Department of Health and Human Services - Office of Secretary
03/18/2020	Certify	Karen Ballesteros	Management Analyst	Department of Health and Human Services - Office of Secretary
01/04/2021	Return for Revision	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3
01/06/2021	Submit For Certification	Karen Ballesteros	Management Analyst	Department of Health and Human Services - Office of Secretary
01/06/2021	Certify	Karen Ballesteros	Management Analyst	Department of Health and Human Services - Office of Secretary
10/25/2021	Submit for Concurrence	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3
11/18/2021	Return to Submitter	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
11/18/2021	Submit for Concurrence	Richard Green	Archivist Specialist	National Archives and Records Administration

				- ACR3, Appraisal Team 3
12/01/2021	Return to Submitter	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
12/01/2021	Submit for Concurrence	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3
12/01/2021	Concur	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
12/01/2021	Concur	Laurence Brewer	Chief Records Officer	National Records and Archives Administration - National Records and Archives Administration
12/02/2021	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist