

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0514-2024-0001

Status: APPROVED
Date Approved: 05/09/2024

General Information

Agency or Establishment	Department of Health and Human Services
Record/Scheduling Group	0514 - Records of the Office of the Assistant Secretary for Health
Records Schedule Applies To	Agency Subdivision
Major Subdivision	Office of the Assistant Secretary for Health
Minor Subdivision	Office for Human Research Protections
Schedule Subject	Investigative Case Files from the Office for Human Research Protections (OHRP)
Additional Schedule Information	<p>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.</p> <p>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.</p>
Is There a Classified Version of This Schedule?	No
Is consultation and coordination with Tribal Governments required?	No - the records covered by this schedule do not implicate Tribal interests

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Item Count

Total number of disposition items: 1

Number of Temporary disposition items: 0

Number of Permanent disposition items: 1

Number of Items with Disposition Not Approved: 0

Number of Inactive disposition items: 0

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Outline of Records Schedule Items for DAA-0514-2024-0001

Item #	Title	Disposition
0001	Investigative Case Files	Permanent

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Records Schedule Items

DAA-0514-2024-0001-0001		STATUS: Active
ITEM GENERAL INFORMATION		
Item Title	Investigative Case Files	
Item Description	<p>OHRP conducts for-cause and not-for-cause institution evaluations. Also, at OHRP's discretion, in response to OHRP's receipt of substantive written allegations or indications of non-compliance with the HHS regulations, OHRP may conduct investigations that examine alleged non-compliance with HHS regulations. Sources of such allegations or indications of non-compliance include, but are not limited to, research subjects and their family members, individuals involved in the conduct of research such as investigators and study coordinators, institutional officials, and a variety of publications. In carrying out this function OHRP conducts a Compliance Oversight Case and retains materials and other investigative documents that constitutes case files of inquiries and complaints of violations of research supported by HHS involving human subjects. These records contain all documents created by the complainant, OHRP, the institution that conducted the research and any other relevant stakeholders pertaining to that case.</p>	
Is this item media neutral?	Yes	
Is this item a Big Bucket?	No	
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS		
Does this item supersede existing disposition authorities?	No	
Is this item a deviation from the GRS?	No	
DISPOSITION INSTRUCTION		
Final Disposition	Permanent	
Cutoff Instructions	Other: Cut off at the end of the calendar year, two years after OHRP's determination that corrective action has been implemented or is unwarranted	
Are there multiple instructions for this item?	Yes	
	Instructions	
Records to which this instruction applies	Transfer Instruction	
Paper-based textual records	Transfer to the National Archives 15 year(s) after cutoff	
Electronic records	Transfer to the National Archives 15 year(s) after cutoff	

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ADDITIONAL INFORMATION	
Current Records Format	Paper-based textual records:350 cubic feet ; Digital still images:250 GB
Approximate first year of records covered by this authority	1990
End year of records covered by this authority	Still being created
Date span of the initial transfer	From: 01/01/1990 To: 12/31/1995
Frequency of transfer	1
Are any of the records covered by this item subject to a FOIA exemption?	Yes
FOIA Exemption(s)	FOIA (b)(6) Personal Information

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Signatory Information

Action	User	Date
Accept	Bethany Reiswig	01/09/2024
Approve	Colleen Shogan	05/09/2024