

evaluate a petition to designate a class of employees for the Metals and Controls Corporation in Attleboro, Massachusetts, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

*Facility:* Metals and Controls Corporation.

*Location:* Attleboro, Massachusetts.  
*Job Titles and/or Job Duties:* All Atomic Weapons Employer employees who were exposed to thorium.

*Period of Employment:* January 1, 1952 through December 31, 1967.

**FOR FURTHER INFORMATION CONTACT:**

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to [OCAS@CDC.GOV](mailto:OCAS@CDC.GOV).

**Christine M. Branche,**

*Acting Director, National Institute for Occupational Safety and Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Research Integrity; Privacy Act of 1974; Report of an Altered System of Records**

**AGENCY:** Office of Research Integrity (ORI), Office of Public Health and Science (OPHS), Office of the Secretary (OS), Department of Health and Human Services (HHS).

**ACTION:** Notice of revision to the Privacy Act system of records.

**SUMMARY:** HHS proposes to revise the Privacy Act exempt system of records 09-37-0021, entitled "Public Health Service Records Related to Inquiries and Investigations of Scientific Misconduct, HHS/OASH/ORI." This system became effective on August 29, 1994 (59 FR 36717, July 19, 1994). Changes were made in response to comments received, and the revised systems notice was published on January 6, 1995 (60 FR 2140). The proposed revisions include changing the routine uses and changing the title of the system to "HHS Records Related to Research Misconduct Proceedings, HHS/OS/ORI." The revisions are necessary to reflect the

changes made by the Public Health Service Policies on Research Misconduct ("PHS Policies on Research Misconduct"), 42 CFR Part 93 ("Part 93"), and to update the system to reflect current practices and procedures under that regulation.

**DATES:** This notice will be effective without further notice on September 30, 2009 unless modified by a subsequent notice making changes in response to public comments. Although the Privacy Act requires only that changes in the routine uses be published for comment, HHS invites comments on all parts of the systems notice. You may submit comments by electronic mail to [AskORI@hhs.gov](mailto:AskORI@hhs.gov). Comments must be received on or before September 30, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852. (240) 453-8800. *E-mail:* [AskORI@hhs.gov](mailto:AskORI@hhs.gov).

**SUPPLEMENTARY INFORMATION:** After making changes in response to public comments, ORI published its current systems notice entitled "Public Health Service Records Related to Inquiries and Investigations of Scientific Misconduct, HHS/OASH/ORI" on January 6, 1995 (60 FR 2140). Since that time, the organizational location of ORI has changed from the former Office of the Assistant Secretary for Health to OPHS, and a new HHS regulation concerning research misconduct was promulgated and codified at 42 CFR Part 93. That regulation substantially changed the previous regulation on scientific misconduct (42 CFR Part 50, Subpart A), including changing the term "misconduct in science" to "research misconduct."

This revision updates the ORI system notice to be consistent with the definitions and procedures promulgated by the PHS Policies on Research Misconduct. The description of the categories of individuals covered by the records system and categories of records in the system have been amended to reflect the changes made by Part 93, specifically, the applicability of that part in terms of the individuals, types of research, and types of PHS support that are covered. Pertinent provisions of Part 93 are referenced to explain the records system coverage. The category of individuals covered by the system remains the same: individuals who are the subject of allegations of research misconduct. Similarly, the categories of records in the system remain essentially the same: records related to all stages of the research misconduct proceeding.

The location of the system is now limited to the premises of ORI and the Federal Records Centers (for inactive records). PHS officials outside of ORI who are involved in extramural and intramural research misconduct proceedings have access to this system of records as necessary to carry out their duties.

We have amended the statement of purposes to state more generally that ORI will use the system of records to exercise its oversight authority relating to research misconduct proceedings, and to document these activities.

The order of the routine uses has been changed, and the terminology used has been updated to reflect the terms used in Part 93. The listing of routine uses begins with disclosures that may be made in the course of a research misconduct proceeding in roughly the order that they might occur, and ends with disclosures that may be necessary for more general administrative purposes.

Routine use 1 is an expanded version of routine uses 2 and 5 in the current system notice. It now provides for disclosure to a person able to "obtain" information, as well as provide information or assistance, in a research misconduct proceeding or related proceeding, ORI oversight of an institutional research misconduct proceeding or ORI oversight of the implementation of HHS administrative actions. The reference to ORI oversight functions has also been added. We have also added a condition for each disclosure under this routine use. Prior to disclosure, ORI will determine whether limited disclosures or confidentiality agreements are needed to protect the privacy of respondent(s), complainant(s), witnesses, research subjects or others who may be identified in the records to be disclosed.

Routine use 2 is new. It is based on 42 CFR 93.401 that, in part, authorizes ORI to notify and consult with other Federal, State, or local offices, if ORI has reason to believe that a research misconduct proceeding may involve that office. The second routine use in the current system notice, relating to disclosures to qualified experts, has been deleted because that disclosure is now covered by the more general disclosure in the new routine uses 1 and 9.

Except for editorial changes, routine use 3 is the same as use 8 in the current system notice and routine use 4 is the same as use 3 in the current notice.

Routine use 5 is new. It permits additional disclosures after a final HHS/ORI finding of research misconduct that are aimed at conserving public funds,

protecting Federal records, and otherwise protecting the interests of the Federal Government.

Routine use 6 is an amended version of use 10 in the current notice. We have moved "after \* \* \* a final HHS/ORI finding of research misconduct" to the front, deleted the reference to remedial actions, and minimally expanded the list of those to whom disclosures may be made.

Routine use 7 is an amended version of use 6 in the current notice. We have moved the reference to an HHS/ORI finding of research misconduct to the front, added "final" to it, deleted the reference to the imposition of remedial actions, and added "other similar entity." Use 7 in the current notice, disclosures to IRBs, research sponsoring institutions, research subjects, and the public has been deleted, because these types of disclosures would now normally be made by the institutions and, in any case, these types of disclosures would be covered by the more general disclosure covered by new routine uses 2 and 3.

Routine use 8 is an amended version of routine use 11 in the current notice. We have added a reference to suspension actions and a reference to the General Services Administration's (GSA's) Excluded Parties List System.

Routine use 9 is essentially the same as routine use 9 in the current notice. It permits disclosures to volunteers and contractors engaged by ORI in support of its research misconduct oversight functions, if they need access to the records to perform their assigned tasks for the agency; provided, however, that in each case ORI determines whether limited disclosures or confidentiality agreements are needed to protect the privacy of respondent(s), complainant(s), witnesses, research subjects or others who may be identified in the records to be disclosed. Routine use 10 is authorized by 42 CFR 93.410(a) to permit disclosure in cases that do not result in an ORI finding of research misconduct and that ORI decides to close.

Routine uses 11 and 12 are derived from use 1 in the current notice. That previous use addressed both disclosures to the Department of Justice (DOJ) and to courts or other tribunals. Routine use 11 addresses disclosures to the DOJ and routine use 12 addresses disclosure to courts or other tribunals. In addition, the language has been clarified.

The description of record source categories has been revised to describe more accurately the many sources from which the records are received or obtained. Other changes to improve accuracy, update information, terms,

and citations, and clarify language have been made throughout the systems notice.

This record system remains exempt from certain requirements of the Privacy Act in accordance with the Department's determination published in the system notice. (59 FR 36717, July 19, 1994).

Dated: August 14, 2009.

**Donald Wright,**

*Principal Deputy Assistant Secretary for Health.*

**09-37-0021**

**SYSTEM NAME:**

HHS Records Related to Research Misconduct Proceedings, HHS/OS/ORI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION(S):**

Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, and Federal Records Centers for inactive, permanent records.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

The individuals covered by this system are referred to as "respondents." Part 93 defines the term "respondent" to mean "the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding." 42 CFR 93.225.

Part 93 and this system notice apply to an allegation of research misconduct involving: (1) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information; (2) PHS supported biomedical or behavioral extramural or intramural research; (3) PHS supported biomedical or behavioral extramural or intramural research training programs; (4) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training; and (5) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

The term "research misconduct" is defined to mean "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." "Fabrication" is defined to mean "making up data or results and recording or reporting them." "Falsification" is "manipulating

research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record." "Plagiarism" is "the appropriation of another person's ideas, processes, results, or words without giving appropriate credit." Research misconduct does not include honest error or differences of opinion. 42 CFR 93.103.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system contains records related to research misconduct proceedings. The term "research misconduct proceeding" is defined to mean "any actions related to alleged research misconduct taken under this part, [Part 93] including but not limited to allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals." 42 CFR 93.223.

The records include all information that must be submitted to ORI by institutions under Part 93 in connection with a research misconduct proceeding, and all information that ORI receives or generates in overseeing or conducting research misconduct proceedings. This information includes, but is not necessarily limited to information about respondents (this may include social security numbers), complainants, and witnesses; the nature of the allegations; the PHS funding involved, including grant numbers; the institutions and officials responsible for conducting the actions that are part of the research misconduct proceeding; the documentation used in the inquiry and investigation, including relevant research data and materials, applications, proposals and documentation related to review and award actions, reports, abstracts, manuscripts and publications by the respondent(s) and other relevant reports, abstracts, manuscripts and publications, correspondence; memoranda of telephone calls, summaries of interviews and transcripts or recordings of interviews; statistical, scientific, and forensic analyses; interim and final institutional reports, and records of institutional appeal proceedings, if any.

The system also includes records relating to: (1) ORI oversight of institutional assessments, inquiries and investigations, ORI findings of research misconduct, and ORI proposals for HHS administrative actions or for settlement of the case; (2) final HHS findings of research misconduct, final HHS decisions regarding administrative actions, and documentation of the implementation of those actions; and (3)

ORI coordination with other Federal, State, and local offices/agencies, including the Department of Justice.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

The authorities for maintaining the system are: Sections 301 and 493 of the Public Health Service Act, 42 U.S.C. 241, and 289b; 5 U.S.C. 552a, 5 U.S.C. 301 and 44 U.S.C. 3101; 42 CFR Part 93; 2 CFR Part 376; 48 CFR Subpart 309.4.

**PURPOSE(S):**

The purposes of this system are to:

(1) Enable HHS, ORI, and the Federal Government to protect the health and safety of the public, to promote the integrity of PHS supported research, and to conserve public funds;

(2) Enable ORI to implement its authority relating to research misconduct proceedings as set forth in 42 U.S.C. 289b and 42 CFR Part 93, and to document HHS and ORI activities in implementing that authority;

(3) Ensure that research misconduct proceedings, including institutional implementation of HHS administrative actions, are carried out in accordance with 42 CFR Part 93 and other applicable Federal statutes and regulations;

(4) Enable ORI to inform PHS agency officials who have a need for the records in the performance of their duties, of the status and results of research misconduct proceedings; and

(5) Enable ORI to notify, consult with, and provide assistance to other Federal, State, or local governmental agencies to permit them to take action to protect the health and safety of the public, to promote the integrity of PHS supported research, to conserve public funds, or to pursue potential violations of civil and criminal statutes.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING THE PURPOSES OF SUCH USES AND CATEGORIES OF USERS:**

The HHS Privacy Act regulation lists, at 45 CFR 5b.9(b), disclosures of records that may be made without the consent of the individual who is the subject of the records. Among the permitted disclosures are disclosures to those officers and employees of the Department who have a need for the record in the performance of their duties and routine uses that are listed in the notice of the system of records. A "routine use" is defined in 45 CFR 5.1(j) to mean "the disclosure of a record outside the Department, without the consent of the subject individual, for a purpose which is compatible with the purpose for which the record was collected." The routine uses for this system of records are listed below.

1. Disclosure may be made to any person able to obtain information or provide information or assistance in a research misconduct proceeding or related proceeding, ORI oversight of an institutional research misconduct proceeding, or ORI oversight of the implementation of HHS administrative actions. Recipients of disclosures under this routine use may include experts asked to perform statistical, forensic or other analyses, the relevant PHS supported institution(s), institutions with which the respondent(s) was previously or is currently affiliated, Federal, State and local agencies, the respondent(s), the complainant(s), witnesses, and organizations or individuals acting on behalf of those agencies, institutions and individuals; provided, however, that in each case ORI determines whether limited disclosures or confidentiality agreements are needed to protect the privacy of respondent(s), complainant(s), witnesses, research subjects or others who may be identified in the records to be disclosed.

2. Disclosure may be made to other Federal, State, or local agencies and offices, if ORI has reason to believe that a research misconduct proceeding may involve that agency or office.

3. When a record on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local or Tribal, or other public authority responsible for enforcing, investigating or prosecuting such violation, if the information disclosed is relevant to the responsibilities of the agency or public authority.

4. Disclosure may be made to responsible officials of PHS-supported institutions or organizations, when in connection with a research misconduct proceeding concerning an individual previously or currently employed by, or affiliated with the institution or organization, or when ORI or HHS makes a finding or takes an action potentially affecting the institution or organization or its PHS support for research, research training, or related activities.

5. After there is a final HHS/ORI finding of research misconduct, disclosure may be made to a Federal, State, local or Tribal agency in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, or the issuance of a license or other benefit by the agency, to the extent that the record

is relevant to the agency's decision on the matter.

6. After there is a final HHS/ORI finding of research misconduct, disclosure may be made to professional journals, other publications, news media, other individuals and entities, and the public concerning research misconduct findings and the need to correct or retract research results or reports that have been affected by research misconduct. No information will be released that would reveal a confidential source.

7. After there is a final HHS/ORI finding of research misconduct, disclosure may be made to a State licensing board, certifying body, or other similar entity conducting a review of the respondent, to aid the entity in meeting its responsibility to protect the health of the population in its jurisdiction or the integrity of the profession.

8. After there is an HHS decision to suspend, or a final HHS decision to debar the respondent from Federal procurement and nonprocurement programs, disclosure may be made to GSA for the purpose of adding the respondent to GSA's Excluded Parties List System.

9. Disclosure may be made to volunteers and contractors engaged to perform a service in support of an ORI research misconduct oversight function, if such persons need access to the records to perform their assigned task; provided, however, in each case ORI determines whether limited disclosures or confidentiality agreements are needed to protect the privacy of respondent(s), complainant(s), witnesses, research subjects or others who may be identified in the records to be disclosed; and ORI determines that the disclosure is for a purpose compatible with the purpose for which the agency collected the records.

10. When ORI closes a case without a settlement or finding of research misconduct, disclosure may be made to the respondent, relevant institution, and complainant(s); provided, however, that in each case ORI determines whether limited disclosures or confidentiality agreements are needed to protect the privacy of respondent(s), complainant(s), witnesses, research subjects or others who may be identified in the records to be disclosed.

11. Disclosure may be made to DOJ when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the DOJ has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation and,

prior to disclosure, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the DOJ is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

12. Disclosure may be made to a court or other tribunal, when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the DOJ has agreed to represent the employee; or (c) the United States Government is a party to the proceeding or has an interest in such proceeding and, prior to disclosure, the agency determines that the records are both relevant and necessary to the proceeding and the use of such records is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders, electronic and magnetic media and other types of data storage devices.

**RETRIEVABILITY:**

Records are retrieved by manual or computer search of the case-tracking system using the name of the respondent(s) (i.e., the individual or individuals who are the subject of an allegation of research misconduct or of a research misconduct proceeding).

**SAFEGUARDS:**

1. *Authorized users:* Records are available to the system manager, to the Director, ORI, and to other appropriate ORI staff when they have a need for the records in the performance of their duties. Records are also available to the head of intramural research for the PHS agency involved, and to other appropriate HHS officials, including attorneys in the Office of the General Counsel, the Agency Research Integrity Liaison Officer (ARILOs), the Agency Intramural Research Integrity Officer (AIRIOs), the Agency Extramural Research Integrity Officer (AERIOs), and the Research Integrity Officers (RIOs) located in the Institutes and Centers of the National Institutes of Health (NIH) that are involved in the research misconduct proceeding, when there is a need to know in the performance of their duties. All authorized users are informed that the records are confidential and are not to be further disclosed.

2. *Procedural safeguards:* Access is strictly controlled by the system manager and the Director, ORI, in compliance with the Privacy Act and this system notice. Access to the records is limited to ensure confidentiality. All questions and inquiries from any party should be addressed to the system manager.

3. *Physical safeguards:* ORI records are kept in locked file cabinets in a room that is locked during non-working hours. Access to this room is restricted to specific personnel. The ORI office suite is protected by access and intrusion alarms at the front and emergency entrances. Access to computer files is strictly limited through passwords and user-invisible encryption. Special measures commensurate with the sensitivity of the record are taken to prevent unauthorized copying or disclosure of the records.

**RETENTION AND DISPOSAL:**

The files are retained and disposed of in accordance with the General Records Schedule (accessions) and a disposition schedule approved by the National Archives and Records Administration (cases).

**SYSTEM MANAGER AND ADDRESS:**

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852.

**NOTIFICATION PROCEDURES:**

This system is exempt from access; however, consideration will be given to requests addressed to the system manager. The requester must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act, subject to a five thousand dollar fine. The request should include: (a) Full name, (b) address, and (c) year of records in question.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should reasonably specify the record contents being sought. Although the system is exempt, respondents may, upon request, receive records from this system and an accounting of disclosure of their records, if the system manager determines the disclosure would not compromise the activities of ORI or the confidentiality of information.

**CONTESTING RECORD PROCEDURES:**

Exempt. However, consideration may be given to requests addressed to the system manager. Requests for corrections should reasonably identify the record and specify the information to be contested, the corrective action sought and the reasons for the corrections with supporting justification. The right to contest records is limited to information that is incomplete, irrelevant, incorrect, or obsolete.

**RECORD SOURCE CATEGORIES:**

Information in this system is received or obtained from many sources, including: (1) Directly from the respondent or complainant or his/her representative; (2) derived from materials supplied by the respondent or complainant or his/her representative; (3) from information supplied by the institutions, witnesses, scientific publications and other nongovernmental sources; (4) from observation and analysis made by ORI staff and scientific experts; (5) departmental and other Federal, State, and local government records; (6) from hearings and other administrative proceedings; and (7) from any other relevant source.

**SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

This system is exempt pursuant to 5 U.S.C. 552a(k)(2) and (k)(5) of the Privacy Act from access, notification, correction, and amendment provisions of the Act (5 U.S.C. 552a(c)(3), (d)(1)-(4), (e)(4)(G)-(H), and (f)).

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.