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DOE HANDBOOK

Access Handbook – Conducting Health Studies at Department of Energy Sites

U.S. Department of Energy
Washington, D.C. 20585

AREA OCHS

This Department of Energy (DOE) Handbook provides guidelines for the successful conduct of health studies at DOE sites. The Handbook does not establish requirements and any requirements that must be met are explicitly stated to be requirements in a DOE requirements document.

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FREQUENTLY USED ABBREVIATIONS

AEC	Atomic Energy Commission
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Prevention
CEDR	Comprehensive Epidemiologic Data Resource (DOE's de-identified database)
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CIRC	Cyber Incident Response Capability
DSHEFS	NIOSH Division of Surveillance, Hazard Evaluations, and Field Studies
DOE	Department of Energy
EEOICPA	Energy Employees Occupational Illness Compensation Program Act
ECI	Export Controlled Information
EPA	Environmental Protection Agency
ERDA	Energy Research and Development Administration
ES&H	Environment, Safety and Health
FIPS	Federal Information Processing Standards
FOIA	Freedom of Information Act
FWP	Former Worker Medical Screening Program
FRD	Formerly Restricted Data
OERP	NIOSH Occupational Energy Research Program
HS-10	Office of Health and Safety
HHS	Department of Health and Human Services
HSS	DOE Office of Health, Safety and Security
IRB	Institutional Review Board
MED	Manhattan Engineer District
NCEH	National Center for Environmental Health
NIOSH	National Institute for Occupational Safety and Health
NNSA	National Nuclear Security Administration (a semi-autonomous part of DOE)
NPL	National Priorities List
NSI	National Security Information
NNPI	Naval Nuclear Propulsion Information
OUO	Official Use Only
OHRP	Office for Human Research Protection
OMB	Office of Management and Budget
PHA	Public Health Assessment
PII	Personally Identifiable Information
RSB	NCEH Radiation Studies Branch
RD	Restricted Data
UCNI	Unclassified Controlled Nuclear Information
WFO	Work for Others

FOREWORD

The purpose of this handbook is to outline procedures that facilitate access to information needed for outside researchers conducting public health activities at Department of Energy (DOE) sites. The handbook is intended for use by these researchers conducting studies, and by personnel at DOE sites who are responsible for making the requested information available. The use of the term “public health researcher” throughout this document refers to the entire spectrum of health and environmental professionals. This includes Government officials who study the past, present, and future impacts that DOE sites and their associated activities may have upon workers, the community, and its inhabitants. Public health researchers may be employed by a variety of organizations, including local, State, or Federal Government agencies, academic institutions, non-profit organizations, and contractors.

"Public health activities" comprise both practice and research involving health outcomes in potentially affected community and worker populations. Public health activities at DOE sites include, but are not limited to, medical screening of former workers, community studies, environmental dose reconstruction, worker surveys, cluster investigations, feasibility studies, and epidemiologic investigations that are funded by DOE through grants, cooperative agreements, and interagency agreements.

Questions may be directed to the Office of Domestic and International Health Studies (HS-13) at 301-903-4343 (Fax 301-903-1413).

ACKNOWLEDGEMENT

The Access Handbook is the product of many individuals over nearly a decade. The moving force and champion behind the new Access Handbook was Marsha Lawn, who diligently served as the program director for Worker and Public Health Activities. We are indebted for her steadfastness and vision that workers and communities would be the beneficiaries of studies and investigations. Research at DOE is necessarily complex with the need to balance researcher needs with competing national security issues. Her goal was to bring clarity on navigating through this complex environment for all those who engage in research across DOE facilities so that the vision can be realized.

1. PURPOSE

The purpose of this handbook is to outline procedures that facilitate access to information needed for outside researchers conducting public health activities at Department of Energy (DOE) sites. The handbook is intended for use by these researchers conducting studies, and by personnel at DOE sites who are responsible for making the requested information available.

2. INTRODUCTION

DOE supports a diverse program of public health activities designed to increase understanding of the health effects of radiation, chemicals, and other hazards to workers and to the public that are related to current and past operations of its facilities. The major components of these public health activities are:

- Epidemiologic studies of occupational exposures among DOE workers, health studies of communities located near DOE facilities and other public health activities.

- A medical screening program to evaluate the health of former workers at DOE sites.

Notes to the Reader: The use of the term “public health researcher” throughout this document refers to the entire spectrum of health and environmental professionals. This includes Government officials who study the past, present, and future impacts that DOE sites and their associated activities may have upon workers, the community, and its inhabitants. Public health researchers may be employed by a variety of organizations, including local, State, or Federal Government agencies, academic institutions, non-profit organizations, and contractors.

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This handbook is not a guidance document for any access issues concerning the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). Please refer to

DOE's Office of Health, Safety and Security's (HSS) Security Plan for EEOICPA, dated January 23, 2009, http://www.hss.energy.gov/healthsafety/FWSP/Advocacy/HSS_Security_Plan_EEOICPA.pdf .

This handbook is also not a guidance document relevant to either: 1) the medical screening/surveillance of current workers by the DOE site occupational medicine clinics; or 2) activities of DOE site medical providers to evaluate the outcomes of medical surveillance that do not generally constitute research.

Reference is made throughout this handbook to various requirements documents, which include two general categories: 1) Federal regulations (see, http://www.gpoaccess.gov/cfr/); and 2) DOE directives/orders, which are DOE-specific requirements and generally apply to DOE Headquarters, site offices, and site contractor personnel (https://www.directives.doe.gov/). DOE's human subjects research protection directive (DOE Order 443.1B) includes requirements that must be complied with for all human subjects research funded by DOE, conducted by DOE or DOE site personnel, or using data from DOE sites. Outside researchers must also comply with such requirements if they are to use DOE employee data.

3. RECORDKEEPING AT DOE AND ITS PREDECESSOR AGENCIES

DOE is committed to allowing access to DOE sites and making records fully available for approved public health activities, while taking into account legal restrictions on the disclosure of an individual's personal information and/or security clearance classification.

A number of factors relating to DOE recordkeeping practices and culture affect access to records at DOE sites. A general knowledge of these practices will facilitate records access by public health researchers working at DOE sites.

- DOE and its predecessor agencies—the Manhattan Engineering District, the Atomic Energy Commission, and the Energy Research and Development Administration—have primarily used private contractors to carry out the work at field sites on behalf of DOE. The site contractors have traditionally operated with a great deal of independence within the scope of their contract and continue to do so today.

- As a consequence of this independence, recordkeeping practices and procedures for accessing records often differ significantly from site to site. However, all sites and site

contractors must adhere to basic Department-wide requirements for records access (DOE Order 243.1 and 36 Code of Federal Regulations (CFR) 1222.32, [http://www.archives.gov/about/regulations/part-1222.html#1222.32]).

- Not all records at DOE sites are Federal records. Some records may belong to contractors and, therefore, are not subject to laws governing the management of and access to Federal records. Contractor-owned records are governed by the specific terms of its DOE contract. Most DOE contracts contain clauses that provide the right to access contractor records that are needed for health studies and/or public health activities.

- As a result of differing management practices among contractors, as well as the timely development of nuclear weapons production during the Cold War, the recordkeeping process was not applied as it is today. This may have resulted in the loss of Government custody for some records. These factors, combined with general problems in recordkeeping that exist across the Federal Government, mean that records sought by public health researchers may be difficult and time-consuming to retrieve. In some cases, the records may no longer exist. Experience suggests that data collection generally takes more time than the public health researchers' estimated timeline.

- The Department and its predecessor agencies operated in a culture of secrecy for many years due to the nature of nuclear weapons development. Access to some sites and records, even today, may be limited for reasons of national security. Public health researchers should be aware that some of the records needed for their studies might have restricted access based on a need-to-know.

- In the past, many DOE records were classified at the time they were created ("born classified"), and some have not yet been reviewed for declassification. DOE is committed to ensuring that declassification requests for health studies are met in a timely manner. However, declassification is a time-consuming and labor-intensive process and project schedules should include lead-time for document declassification.

- Public health researchers should be mindful that while the Department is committed to openness, the measures necessary to provide access may be slow relative to the timeframe of a study. The Department is confident that any difficulties associated with access can be resolved through the use of the guidelines set forth in this handbook.

- It is advised that all DOE public health activities be coordinated through the HSS. HSS will help to ensure that the appropriate Departmental elements are engaged and that researchers know who to contact to carry out their projects.

4. WHAT IS MEANT BY ACCESS?

A. Table 1 - What is meant by "Access"?

What is Meant by "Access"?	
"Access" to records and information gives public health researchers the ability to do any or all of the following at a DOE site:	
1.	Review record systems.
2.	Review classified material (for public health researchers with appropriate security clearance).
3.	Take sample copies of records.
4.	Make copies necessary for research and other public health activities.
5.	Obtain copies of electronic records and the documentation necessary to understand them.
6.	Provide to the site point of contact an additional copy of any records that are copied or scanned.
7.	Acquire rosters of former workers.
8.	Observe work and processes in progress.
9.	Talk privately with workers.
10.	Collect exposure data.
11.	Hold meetings with all interested parties.

5. STEPS IN CONDUCTING A STUDY OR PUBLIC HEALTH ACTIVITY

This section explains the major steps in the process of planning and performing a public health activity.

A. When Does a Public Health Activity Begin?

A research study begins when an investigator (1) requests records from site officials; (2) requests permission to perform walk-through surveys; or (3) seeks permission to interview employees about health issues or working conditions. The public health activity under the FWP begins with a cooperative agreement award from DOE Headquarters. The public health activity under Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) 104.1 begins when a site is proposed for inclusion on the Environmental Protection Agency's (EPA) National Priorities List (NPL) or when the Agency receives a petition to perform a Public Health Assessment (PHA) or other public health activity.

All public health activities are coordinated through DOE's Office of Health and Safety (HS-10) and if National Nuclear Security Administration (NNSA) sites are involved, NNSA-SH-20. Public health activities are conducted in accordance with the protocol outlined in this handbook. Issues that are not covered in this handbook should be raised to the appropriate contacts in HS-10 and NNSA-SH-20, as well as to the appropriate contacts in the relevant DOE Headquarters program secretarial offices (PSOs), for resolution.

i. Notification of DOE by the Agency or Organization Sponsoring the Public Health Researcher

When DOE sites have been selected for a study, the funding entity or sponsor supporting the study provides written notification to HS-10. If research is to be conducted at an NNSA site or using data from an NNSA site, NNSA-SH-20 also provides written notification prior to the initiation of the study

The notification includes a list of people needing access to DOE/NNSA facilities.

Notice of the initiation of new public health activities are shared in a timely manner with the sponsoring Agency and with relevant DOE/NNSA Headquarters and site offices. Each Agency acts in accordance with a specific communication plan as appropriate for the Agency and public health activity.

A copy of the study plan or protocol, Institutional Review Board (IRB) documentation, and any special local agreements aree provided by the public health researcher to HS-10, the site Human Subjects Protection (HSP) Program Manager/IRB Administrator, the DOE/NNSA HSP Program Manager(s), and the DOE Site Office that manages the selected site.

ii. Notification of the Site and the Workers

For each new public health activity at a particular site, HS-10 prepares a notice that outlines the basic intent of the activity and list site representatives who may be contacted for additional information. This notice is sent to the DOE Site Office (and for NNSA Sites, NNSA and the NNSA Site Office, for review) for distribution to all current workers at the site.

For public health activities that do not involve worker records, HS-10 prepares a short notice that outlines the basic intent of the public health activity. The notice includes a communications plan. The communications plan includes (1) the name and telephone number of the person responsible for communicating the activity; (2) the expected frequency of communications; and (3) the place where notices of upcoming meetings are posted or advertised. The notice requests that the site communications point of contact work directly with the sponsoring Agency point of contact. HS-10 works with the applicable site(s) (and for NNSA sites, NNSA and the NNSA site office) and the funding entity or sponsoring Agency conducting the public health activity to develop the site-specific communication plan.

iii. Preliminary Site Visit

HS-10 schedules and coordinates a preliminary site visit, working closely with the DOE Site Office HSS point of contact. Participants in the meeting should include representatives from DOE (and if it is an NNSA site, also NNSA), site contractors, the site Human Subjects Protection Program Manager/IRB Administrator and IRB Chair, organized labor, and public health researchers involved in the project. Once a date has

been established for the visit, the site office initiates advance badging procedures for visitors and public health researchers.

The preliminary visit ensures that all parties are provided information about the purpose of the public health activity and understand the process that will take place. It also establishes the lines of communication and cooperation essential to a successful investigation. During the preliminary visit, the parties:

- Discuss the work plan for data collection and identify information needs of public health researchers.
- Determine appropriate technical contacts at the DOE Site Office and among DOE contractors.
- Gather preliminary information relevant to the public health activity.
- Discuss procedures.
- Determine whether IRB approval is required, and if so, whether the DOE site IRB or the Central DOE IRB is responsible for reviewing the protocol. Release of DOE human subjects data is contingent upon DOE/IRB review approvals.
- Identify potential issues needing resolution.

As a result of the initial site meeting, the DOE/NNSA Site or Area Office designates a DOE/NNSA site point of contact and the public health researcher designates a lead point of contact. When contractors, cooperative agreement holders, or grantees are conducting research or other studies, a point of contact is designated by the sponsoring Agency.

iv. Site Work Plan

After the preliminary site visit, the public health researcher works with the DOE/NNSA and site points of contact to continue the dialogue regarding process or other information needed to perform the public health activity. Continuing discussion between participants may include the following topics:

- Estimated timetable for completion of major tasks.
- Identification of resources needed from the site.
- Agreements from the site regarding the availability, time commitment, and roles of DOE and contractor personnel.
- Progress in receiving previously requested data and information.
- Identification of additional information needs.

- Requirements for document declassification, security clearances, IRB review, and special training.

v. Site Access Requirements

Each DOE/NNSA site is unique, and, therefore, access procedures may vary from site to site, depending on the contract with DOE/NNSA and the work conducted at that site. Authorization or a DOE security clearance is generally required for entry to the various areas of many DOE sites. It may be necessary for public health researchers to attend special training sessions before site access is granted.

Arrangements are made with the site point of contact to bring equipment onsite. Approval of such requests may be governed by Federal regulations or by the requirements of the specific site. The public health researcher provides the site point of contact an additional copy of any records that are copied or scanned.

vi. Resolving Conflicts

If public health researchers encounter problems that cannot be resolved by negotiation with DOE site officials, they should immediately notify HS-10 (and in the case of an NNSA site, also NNSA-SH-20) and the Agency sponsoring the public health activity in writing. The notification should include a detailed description of the problem, the efforts made to resolve it, and proposed solutions, if any.

Similarly, DOE/NNSA site officials should immediately notify HS-10 (and for NNSA Sites, also NNSA-SH-20), the public health researcher, and the sponsoring entity of any problems that cannot be resolved at that level, particularly instances where requested support, records, or information cannot be provided. This notification should include the nature of the request, the reason it cannot be met, and any proposed alternatives.

HS-10 (and for NNSA Sites, NNSA-SH-20), with the support of the sponsoring entity, other DOE/NNSA safety and health (ES&H) site officials, and representatives from the DOE Office of General Counsel mediate these disputes. As necessary, officials from other DOE line and staff organizations may be involved.

Public health researchers may be requested by their sponsoring agencies to provide regular assessments of how the public health activity is proceeding at the site relative to the issues covered in this handbook. This information is shared with HS-10, NNSA sites, and NNSA-SH-20.

Similarly, DOE/NNSA site officials, both Federal and contractors, are polled regularly by HS-10 to evaluate how the process is working. HS-10 shares this information with senior officials within HSS, NNSA, the public health researcher, and the sponsoring entity.

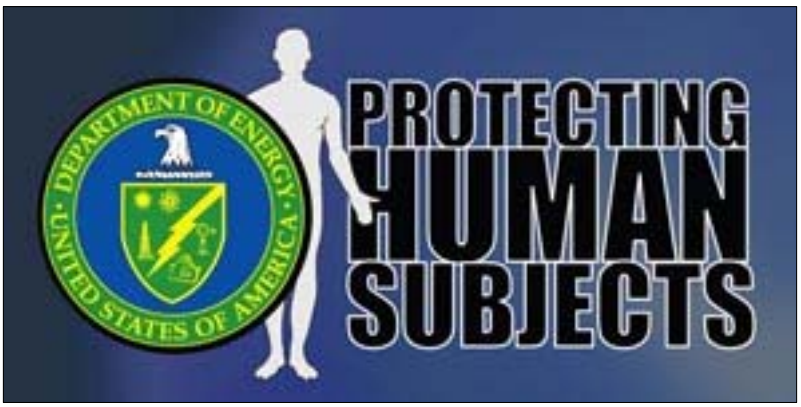
B. Study or Other Public Health Activities Checklist – This is a checklist that serves as a quick reminder of tasks. For more details, please refer to Section 5 through 7.

i. Table 2 - Study or Other Public Health Activities Checklist

Study or Other Public Health Activities Checklist	
Listed Activities	Check if Applicable
Obtain initial and continuing annual approval of applicable IRB(s), and report annually to the DOE Human Subjects Research Database (See Section 6).	
Apply for security clearances.	
Draft initial site visit and communication plan.	
Identify key individuals (management, worker, and union groups).	
Arrange for key individuals to participate.	
Arrange special site meetings between key individuals.	
Identify need for worker time away from job.	
Notify Records Management officials of special records requirements.	
Approve worker time away from job.	
Determine availability of requested records.	
Arrange for sample of requested records to be made available.	
Ensure compliance with all PII requirements and security regulations and ensure all training has been completed.	
Provide pre-visit site questionnaires.	
Approve site questionnaire effort and complete site survey.	
Identify equipment to be brought onsite.	
Obtain property passes for equipment to be brought onsite.	
Identify classified information issues.	
Refer classified information issues to Site Office.	

Study or Other Public Health Activities Checklist	
Listed Activities	Check if Applicable
Prepare declassification plan.	
Arrange required facility-specific training.	
Identify space and equipment needs.	
Arrange for space and equipment needs.	
Complete initial site visit plan.	
Conduct initial site visit.	
Complete and sign facility-required agreements.	
Agree on site work plan.	
Complete security training.	
Complete and distribute site work plan.	
Prepare communication plan to report results to workers.	
Report results.	
Submit study data for inclusion into the Comprehensive Epidemiologic Data Resource.	

6. PROTECTING HUMAN RESEARCH SUBJECTS



A. DOE Human Subjects Protection Requirements

All human subjects research conducted at DOE facilities, supported by DOE funds, performed by DOE or DOE contractor employees, or involving former or current DOE or contractor employees as participants or their data, must comply with Federal regulations and the DOE requirements to protect human subjects. The Federal Policy for the Protection of Human Subjects is 45 CFR Part 46, Protection of Human Subjects. For DOE, it is codified in Title 10 CFR 745 and DOE Order 443.1B. DOE Order DOE O 481.C, Work for Others, also governs protection of human subjects in research that is conducted by DOE or in DOE facilities but is funded by sources other than DOE. (*Note*: Some public health activities, such as ATSDR's public health assessments that evaluate whether communities may have potential exposures to hazardous substances from DOE operations are not considered research and are not subject to IRB approval.)

Human subjects' research includes a broader range of research than many public health researchers and program managers may realize. In addition to traditional biomedical and clinical studies, human subjects research may include studies that:

- Use humans to test devices, products, or materials with the express purpose of investigating human-machine interfaces or evaluating environmental alterations when humans are the subjects being tested;
- Use personally identifiable bodily materials, such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research;
- Collect and use personally identifiable information, such as genetic information or work history, medical and exposure records, even if the information was collected previously for a purpose other than the current research;
- Collect personally identifiable data, surveys, or questionnaires through direct intervention or interaction with individuals; and
- Search for generalizable knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous or adverse health outcomes).

(See also the DOE website for its Human Subjects Protection Program, http://humansubjects.energy.gov/).

Note: Medical screening/surveillance of current workers by the DOE site occupational medicine clinics is neither considered human subjects research nor is it covered by the guidance in this Access Handbook.

B. DOE IRB Review Procedures

There are three general areas of human subjects research covered by this Access Handbook that may invoke DOE IRB review. These areas are: 1) The DOE Former Worker Medical Screening Program; 2) Research that is funded by DOE and conducted or

managed by the Department of Health and Human Services (HHS), (National Institute for Occupational Safety and Health (NIOSH), National Center for Environmental Health (NCEH), or Agency for Toxic Substances and Disease Registry (ATSDR)); and 3) DOE's Program of Independent Studies. The DOE review requirements vary slightly depending on the type of research to be conducted.

It is important that all researchers be aware of the need to annually, and upon completion of the project, report to the DOE Human Subjects Research Database (see: http://www.orau.gov/hsrdreport/). General guidance on review requirements in these three areas is provided below.

i. DOE's Former Worker Medical Screening Program

The DOE Former Worker Medical Screening Program, otherwise known as the Former Worker Program (FWP) (http://www.hss.energy.gov/HealthSafety/FWSP/formerworkermed/) provides medical screening for all former DOE Federal, contractor, and subcontractor workers from all DOE sites across the complex to identify adverse health conditions that may have resulted from working at DOE facilities. The Central DOE IRB (CDOEIRB) is responsible for initial and continuing review of all projects conducted as part of the FWP. Once the project has been approved for initiation by HS-10, (and for NNSA sites, also NNSA-SH-20), the researcher should submit an application and the protocol to the CDOEIRB Administrator for review by the CDOEIRB.

ii. Research that is Funded by DOE and Conducted or Managed by HHS (NIOSH, NCEH, and ATSDR)

The HHS IRB or the HHS grantee's IRB serves as the IRB of record for studies that are conducted as part of a long-standing partnership between HHS and DOE that promotes health studies of workers exposed to ionizing radiation and other agents in the course of their employment at DOE. The applicable DOE IRB is also concurrently responsible for initial and continuing review, and the HHS IRB or the HHS grantee IRB considers comments from the DOE IRB in its deliberations. When an HHS/HHS grantee research protocol is ready for DOE IRB review, the researcher should e-mail the list of the affected DOE sites to the HS-10 Program Manager and the DOE Human Subjects Protection Program Manager (and for work to be conducted at NNSA site(s), also the NNSA Human Subjects Protection Program Manager). The researcher should complete a DOE IRB application and forward the materials to the applicable DOE IRB for review. The DOE IRB reviews that application, with the goal of notifying the researcher and the HHS/HHS grantee IRB of its recommendation within 6 weeks. Additionally, the DOE IRB provides copies of its written recommendation to the HS-10 Program Manager and the DOE Human Subjects Protection Program Manager (and for work to be conducted at NNSA site(s), also the NNSA Human Subjects Protection Program Manager). The same process is followed for annual continuing reviews by the DOE IRB. In the event of a disagreement between the DOE IRB and the HHS or the HHS grantee's IRB, the HHS/HHS grantee's IRB makes the final determination regarding approval of the human subjects research. In such a case, the Centers for

Disease Control and Prevention (CDC) Human Subjects Office and DOE and NNSA Human Subjects Protection Program Managers should be notified before the research is initiated.

iii. DOE's Program of Independent Studies

HS-10 is committed to ensuring that studies of DOE worker exposure and health outcomes, as well as other public health activities, may be conducted by independent public health researchers. These researchers may receive funding from sources other than HS-10 (e.g., DOE Office of Science, foundations, universities, state health departments, and other Federal agencies) and are provided access to DOE data (per HS-10's (and for NNSA sites, also NNSA-SH-20's) review and approval of the proposed research). It is expected that the research protocol has already received IRB approval by the researcher's institution and that that institution has a Federal-wide Assurance. The researcher should provide copies of the protocol and the IRB approval to the HS-10 Program Manager and the DOE Human Subjects Protection Program Manager and for NNSA sites, also the NNSA Human Subjects Protection Program Manager. The HS-10 Program Manager and the DOE and/or NNSA Human Subjects Protection Program Manager(s), in conjunction with the Chair of the applicable DOE IRB, determine whether initial and continuing review by the DOE IRB is warranted. If determined to be necessary, the researcher would need to complete an application and forwards the materials to the DOE IRB for review.

For all three categories of research described above, the responsible DOE IRB holds project-specific IRB records for the period of 3 years after project completion in accordance with 10 CFR Part 745. However, if the IRB determines that a longer retention is appropriate because of their greater significance, they should be retained accordingly.

C. DOE Protection of Personally Identifiable Information (PII)

All public health researchers must also comply with DOE's requirements for protecting PII of research subjects, as articulated in DOE Order 206.1 (https://www.directives.doe.gov/directives/current-directives/206.1-BOrder/view?searchterm=206.1), DOE Privacy Program, and DOE Order 471.1B, Administrative Change 1, Identification and Protection of Unclassified Controlled Nuclear Information, and DOE Order 471.3, Administrative Change 1, Identifying and Protecting Official Use Only Information. See DOE Checklist in Section 7 under Security Regulations.

7. SECURITY REGULATIONS

The Privacy Act of 1974 governs access to DOE-owned records that contain personally identifiable information (PII). DOE has established Privacy Act Systems of Records that allow access to, and review of, all necessary Privacy Act records by authorized public health

researchers. Records owned by DOE contractors that contain PII will be made available to authorized users under the access authority of the ownership-of-records clause of the governing contract. When public health researchers obtain a security clearance (described in Section D), they sign an agreement to comply with the procedures specified for classified or controlled information, including PII.

DOE Privacy Act Systems of Records for which public health researchers are approved as Routine Users

DOE Privacy Act Systems of Records for which Public Health Researchers are Approved as Routine Users

- DOE-2, DOE-Personnel Supervisor Maintained Personnel Records
- DOE-5, Personnel Records of Former Contractor Employees
- DOE-10, Energy Employees Occupational Illness Compensation Program Act Files
- DOE-13, Payroll and Leave Records
- DOE-15, Intelligence-Related Access Authorization
- DOE-33, Personnel Medical Records (including industrial hygiene information)
- DOE-35, Personnel Radiation Exposure Records
- DOE-38, Occupational and Industrial Accident Records)
- DOE-71, The Radiation Accident Registry
- DOE-72, The DOE Radiation Study Registry
- DOE-73, The US-DTPA Registry
- DOE-86, Human Radiation Experiments Records
- DOE-88, Epidemiologic and Other Health Studies, Surveys, and Surveillance

Detailed descriptions of each of these systems of records can be found in the Federal Register, 74 FR 994 and 1. These systems are not found at every DOE site. Each system is subject to different record retention requirements.

A. Personally Identifiable Information (PII)

DOE has established requirements for the protection of PII in accordance with the Privacy Act of 1974 and Office of Management and Budget (OMB) requirements. OMB has defined PII as any information collected or maintained by the Department about an individual, including but not limited to, education, financial transactions, medical history, and criminal or employment history, and information that can be used to distinguish or trace an individual's identity, such as his/her name, Social Security number, date and place of birth, mother's maiden name, biometric data, and any other personal information that is linked or linkable to a specific individual.

Specifically, PII information provided by the U.S. Government or other U.S. Government contractors for use in the execution of work under this contract must be protected in accordance with the Department of Energy Privacy Program (DOE Order 206.1), the Official Use Only directive, the Physical Security Manual, the Information Security Manual, and

Cyber Security Manuals. For convenience, DOE has listed below the minimum requirements.

i. Table 3 - DOE CHECKLIST - For Researchers Using Personally Identifiable Information (PII)

DOE CHECKLIST		
For Researchers Using Personally Identifiable Information (PII)		
The following items need to be addressed in all protocols:		**Check if Applicable**
1.	Keeping PII confidential.	
2.	Releasing PII only under a procedure approved by the responsible IRB(s) and DOE, where required.	
3.	Using PII for approved health studies and public health activities, or with the consent of the participant.	
4.	Handling and marking documents containing PII as “containing PII or PHI (Protected Health Information).”	
5.	Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII.	
6.	Making no further use or disclosure of the PII except when approved by the responsible IRB(s) and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project; (d) when required by law; or (e) with the consent of the participant.	
7.	Protecting PII data stored on removable media (CD, DVD, USB Flash Drives, etc.) using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified.	
8.	Using passwords to protect PII used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1.	
9.	Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped.	

DOE CHECKLIST		
For Researchers Using Personally Identifiable Information (PII)		
The following items need to be addressed in all protocols:		**Check if Applicable**
10.	Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products.	
11.	Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file; i.e., separate encrypted e-mail, telephone call, and separate letter.	
12.	Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII.	
13.	Using two-factor authentication for logon access control for remote access to systems and databases that contain PII. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1_0_2.pdf).	
14.	Reporting the loss or suspected loss of PII immediately upon discovery to: 1) the DOE funding office Program Manager, if the project is funded by DOE; and 2) the applicable DOE IRB. If the DOE Program Manager is unreachable, immediately notify the DOE-CIRC (1-866-941-2472, http://www.doecirc.energy.gov/).	

B. Categories of Classified or Controlled Information

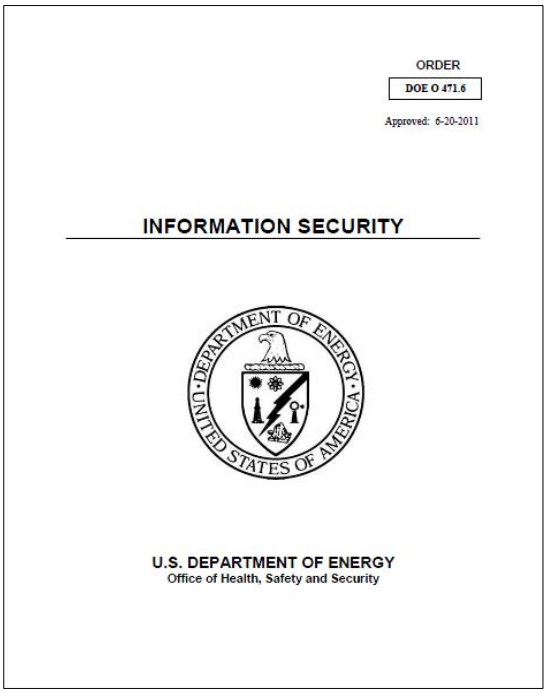
i. Classified Information

Classified Information			
Category	**Legal Basis**	**"Legal" Definition**	**Types of Information**
Restricted Data (RD) includes: ▪ Weapons data ▪ Nuclear material ▪ Production data of special nuclear material	Atomic Energy Act of 1954, as amended	All information concerning (1) design, manufacture, or utilization of atomic weapons; (2) the production of special nuclear material; (3) the use of special nuclear material in the production of energy.	▪ Nuclear weapon designs ▪ Nuclear material production ▪ Naval nuclear propulsion

Classified Information			
Category	**Legal Basis**	**"Legal" Definition**	**Types of Information**
Formerly Restricted Data (FRD) includes: ▪ weapons data ▪ nuclear materials ▪ production data	Atomic Energy Act of 1954, as amended	Information jointly determined by the Departments of Energy and Defense to relate primarily to the military utilization of atomic weapons.	▪ Stockpile size ▪ Yields ▪ Storage sites
National Security Information (NSI) includes special compartmentalized and intelligence data	Executive Order 12958	Information that has been determined by an Executive Order to require protection against unauthorized disclosure and that is so designated.	▪ Conventional weapons ▪ Security systems ▪ Foreign relations ▪ Intelligence

ii. Controlled Information, Which May Be Classified, or Unclassified

Controlled Information, Which May Be Classified, or Unclassified			
Category	**Legal Basis**	**"Legal" Definition**	**Types of Information**
Naval Nuclear Propulsion Information (NNPI)	42 U.S.C. 7158	Information concerning the propulsion plants of naval nuclear powered ships and associated nuclear support facilities.	May be classified or unclassified
Work for Others (WFO)	DOE Order 0481.1C	Work for others is the performance of work for non-DOE entities by DOE/contractor personnel and/or the utilization of DOE facilities that is not directly funded by DOE.	May be classified or unclassified

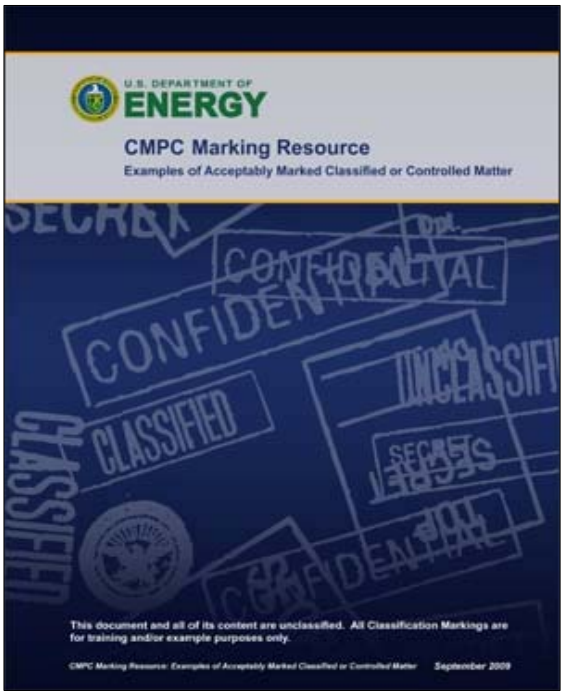

ORDER

DOE O 471.6

Approved: 6-20-2011

INFORMATION SECURITY

U.S. DEPARTMENT OF ENERGY
Office of Health, Safety and Security



iii. Unclassified Controlled Information

Unclassified Controlled Information			
Category	**Legal Basis**	**"Legal" Definition**	**Types of Information**
Unclassified Controlled Nuclear Information (UCNI)	▪ Atomic Energy Act of 1954, as amended ▪ 10 CFR 1017	Certain unclassified sensitive information related to production or utilization facility design, safeguards and security measures, or previously classified nuclear weapons information.	▪ Security plans ▪ Facility designs ▪ Certain isotope separation technologies
Official Use Only (OUO)	Freedom of Information Act exemptions	Certain unclassified but sensitive information that may be exempt from public release under the Freedom of Information Act.	▪ Privacy (PII) ▪ Predecisional ▪ Proprietary ▪ OPSEC

Export Controlled Information (ECI)	▪ Nuclear Non-proliferation Act ▪ Arms Export Control Act ▪ Atomic Energy Act of 1954, as amended ▪ Export Administration Act of 1979, as amended ▪ Office of Foreign Assets and Control (OFAC)	Information that may be of use to a nuclear proliferant.	▪ Technologies useful to nuclear proliferants

C. Requests for Security Clearances

A public health researcher may need a security clearance to enter a DOE/NNSA facility, access within a facility, or to access certain records at the site. The level of access authorization, either "L" or "Q", is based upon work performed at the site or level of classified matter to be reviewed and determined through an evaluation of the public health researcher's needs with the sponsoring Agency and with records managers at the DOE site. Applicants for "L" or "Q" access authorizations are subject to a Federal background investigation by the Office of Personnel Management or the Federal Bureau of Investigation. The time needed for a clearance may take up to 12 months or longer.

If the applicant has a HHS security clearance at the appropriate level, DOE's Personnel Security Office has a process for quickly granting a DOE "Q" security clearance. Public health researchers, whose work is funded by CDC or ATSDR, can apply for clearance through the HHS Security Office, which coordinates activities with the DOE Personnel Security Office to obtain the necessary clearance.

If there is an immediate need for a security clearance, the circumstances should be presented to DOE's Personnel Security Office to determine what actions may be appropriate.

Applicants who are not U.S. citizens cannot have access to certain categories and levels of classified matter.

D. Requests to Review Records

i. Unclassified Documents

To help public health researchers identify records most pertinent to their work, as well as to minimize the impact of the data collection phase on DOE records personnel, data nneeds should be discussed with DOE (and for NNSA sites, NNSA) and contractor records management staff prior to submitting formal written requests. The DOE/NNSA point of contact is responsible for coordinating such discussions. In general, public health researchers are permitted to review any unclassified DOE-owned records that contribute to the successful completion of a study.

Once these introductory discussions have taken place, public health researchers submit written requests for records to the DOE site records management staff. All requests for records review are in writing at the beginning of the study or at any time during the data collection period. The response is coordinated through the DOE site point of contact and a copy of the request is sent to HS-10. The written request should be in the form of itemized lists of specific records boxes or documents. Requests are made at least 10 to 15 working days prior to a site visit although the site may need additional time to make needed materials available. Unclassified environmental data for public health assessments does not require a written request but is provided after discussion with the DOE site point of contact.

Requests for worker rosters needed for ongoing health studies, including FWP projects, are coordinated by HS-10 through the appropriate PSO.

The DOE/NNSA site records staff coordinate each request with all relevant site organizations. The records staff notifies DOE and contractor staff if classified records are included in the request. Site records staff provide the public health researcher with a timely response to each request, confirming that the records are available for review or explaining why some or all of the requested information is unavailable.

Unclassified documents are made available at the site for review**.** Documents stored offsite at Federal Record Centers and other repositories are recalled to the site unless other arrangements are made through DOE records management staff.

DOE site records officials determine the status of records that have been checked out of a repository and provide the requested records as soon as possible. If requested records cannot be located, the DOE/NNSA site point of contact promptly notifies HS-10, and if an NNSA site, NNSA-SH-20, and the public health researcher.

If requested records have been destroyed according to approved procedures and authorized records disposition schedules, the requestor is informed in writing of the date of destruction**.**

iv. Classified or Controlled Documents

DOE and contractor organizations having custody of classified material are required to work within the appropriate laws, regulations, and DOE orders when providing access to site records and when declassifying records to meet the needs of public health researchers.

Public health researchers with security clearances are considered to have the necessary "need-to-know" status for access to most site records. "Need-to-know" status means that a cleared individual needs access to classified information in the performance of official duties or to satisfy contractual obligations. If necessary, HS-10 provides verification of this status to the DOE office with custodial responsibility for the records. Categories of records to which access may be restricted include Work for Others,

Special Compartmentalized and Intelligence Information, Weapons Data and Nuclear Materials Production Data Information, Export Controlled Information, Unclassified Controlled Nuclear Information and Naval Nuclear Propulsion Information (see Section "c" below for more information on these types of records).

Within 10 working days, the site point of contact notifies the public health researcher, the Office of Security, HS-10, and if an NNSA site, also NNSA-SH-20, of any potential delays pertaining to a request for access to classified documents.

Once a request to review classified documents has been processed by the site designee, the documents are made available for review**.** Public health researchers need to plan their work so that the number of individuals needing access to classified information is limited.

a) Document Declassification

Declassification activities for the study should be carried out according to DOE requirements. Periodic meetings should be held to evaluate progress and resolve problems.

Written requests to declassify, downgrade, or sanitize site documents are submitted by the public health researcher to the DOE site point of contact. Sanitizing a document means removing (redacting) sensitive portions of a document to make it unclassified and available to the public. HS-10 (and for NNSA sites, NNSA-SH-20) also should be notified of any declassification requests.

If a document is outside the purview of the site declassification staff (i.e., the classified information relates to another Agency), the DOE/NNSA site point of contact notifies HS-10 (and for NNSA sites, NNSA-SH-20) for coordination assistance. The DOE site point of contact also notifies the public health researchers in writing about the action and provide a time estimate for a decision.

The DOE/NNSA site point of contact provides a written explanation for any document that cannot be declassified to the public health researcher.

b) Review of Notes, Papers, and Other Information Prepared or Duplicated at a Site

All notes, papers, computer disks, recordings, photographs, copies, and other information prepared at a site by public health researchers may be reviewed for classified, sensitive unclassified, or PII information before the materials are allowed to leave the site. Such review should be completed within 10 working days unless the material requires declassification or redaction. Only materials containing nonsensitive, unclassified information are released to the public health researcher. Materials containing classified or sensitive information are retained.

Materials containing classified information are discussed with the public health researcher to determine whether it can be suitably redacted or declassified. The

DOE/NNSA point of contact is notified if it cannot. If a mutually satisfactory resolution cannot be reached, the DOE point of contact notifies and requests further assistance from HS-10.

v. Documents with Special Access Requirements

The following types of information may require special procedures before access is granted. If access is denied, the DOE point of contact provides written notification within 5 working days to the requester and to HS-10, explaining the reason for denial and available appeals processes or other possible solutions.

a) Work for Others (WFO)

A DOE/NNSA site cannot release information about work done for other agencies, countries, or other DOE sites without the data owner's approval. The DOE/NNSA site point of contact notifies the Office of Security and the Office of Document Reviews. The Office of Classified and Controlled Information Review coordinates and requests permission from other agencies or countries to grant access. For work performed for other DOE/NNSA sites, the point of contact is the classification officer or other appropriate management official. If other countries or agencies refuse to permit disclosure, the request is denied.

b) Sensitive Compartmented Information (SCI)

Access to sensitive compartmented and intelligence information, a category of classified National Security Information (NSI), must be authorized through DOE Headquarters and possibly through another Federal Agency. The public health researcher needs to limit the number of security-cleared individuals requesting access to this sensitive information.

c) Weapons Data and Nuclear Materials Production Data Information

Access to weapons data and nuclear materials production data information requires a security clearance through the Headquarters Support Division, NNSA. The DOE point of contact coordinates the completion of the required form and its submission and review by the Security Support Division, which should respond within 15 working days. If processing of the form is significantly delayed, the site point of contact notifies HS-10 to request further assistance.

d) Export Controlled Information (ECI)

ECI deemed relevant and necessary for the study or public health activity by the public health researcher is reviewed by the DOE program manager at the site to determine whether the value of the ECI to a country of national security concern or to a nuclear proliferant warrants that it be withheld from public disclosure. Every effort

is made to provide the information to public health researchers. The Export Control Division adjudicates any concerns or disputes about the identification and protection of ECI.

e) Unclassified Controlled Nuclear Information (UCNI)

Documents containing UCNI may have special access or handling requirements. The DOE records staff provides details to the requester and HS-10 point of contact with regard to access to and control of UCNI.

f) Naval Nuclear Propulsion Information (NNPI)

The Deputy Administrator for Naval Reactors must approve access to information regarding the Naval Nuclear Propulsion Program and naval nuclear powered vessels. If access is granted, it will be to U.S. citizens only.

8. ROLES AND RESPONSIBILITIES

A. DOE's Former Worker Medical Screening Program (FWP)

The U.S. Department of Energy (DOE) Former Worker Medical Screening Program, otherwise known as the Former Worker Program (FWP), supports the conduct of ongoing medical screenings for all former DOE Federal, contractor, and subcontractor workers from all DOE sites across the complex to identify adverse health conditions that may have resulted from working at DOE facilities.

Mandated by Congress in the Defense Authorization Act of 1993 (Public Law 102-484), the FWP provides medical screening and examinations to check for adverse health effects that could be related to radiation, noise, beryllium, asbestos, silica, lead, cadmium, chromium, solvents, and other occupational exposures.

FWP, managed by the DOE Office of Health, Safety and Security (HSS), uses independent occupational health experts through cooperative agreements held by consortia of universities, labor unions, and commercial organizations throughout the United States with expertise in administration of medical programs.

i. Goals of the FWP are:

a) To identify and contact DOE workers who may be at risk for occupational disease that may have resulted from working at DOE facilities.

b) To conduct appropriate medical screening of former workers who wish to participate in the program.

c) To provide information and assistance to affected workers in gaining medical care and compensation for work-related illnesses.

d) To use the collected information to implement controls for current operations in order to prevent or reduce negative health effects for current and future employees.

vi. Participants

The FWP identifies, notifies, and makes medical screening services available to the more than 600,000 former employees who worked in the weapons complex during the past 60 years for DOE or its predecessor agencies. One of the primary challenges is identifying and locating workers who no longer work within the DOE complex. In order to identify former workers who may be eligible to participate in this program, HSS works with DOE Headquarters program offices to obtain rosters of former employees from site contractors and DOE site offices.

vii. Program Information

All personal and medical information that is collected as part of this program is treated as confidential and is used only as allowed by the Privacy Act of 1974. All FWP activities are conducted with the approval of the IRBs of DOE and involved institutions. All individuals sign an informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization prior to participation.

For additional information about the FWP, refer to the website:
http://www.hss.energy.gov/HealthSafety/FWSP/formerworkermed/

B. Occupational Studies and Other Public Health Activities Funded by DOE and Conducted or Sponsored by HHS

The HHS/CDC energy-related research program seeks to create an interdisciplinary approach in which occupational and environmental health studies, exposure assessment and dosimetry, health communication, and community or worker-based involvement efforts work in unison to answer questions about the potential public health effects of DOE-related radiation and chemical exposures. The research and public health activity priorities have

been to address the historical operations of the nuclear weapons complex, to quantify community or worker exposures, and to study possible health effects of those exposures. The advancement of science in radiation and/or chemical exposure is aimed at quantifying the risk to population groups who were exposed to radiation and/or chemicals as a result of having lived around or having worked in the DOE nuclear weapons complex. The information gained may assist in the adjustment of radiation and chemical exposure standards by regulatory or advisory groups. This knowledge may also improve our capability for early detection and prevention of future radiation and chemically related cancers and other diseases.

i. National Institute for Occupational Safety and Health (NIOSH)

In 1970, Congress passed the Occupational Safety and Health Act "to assure, so far as possible, every working man and woman in the Nation safe and healthful working conditions." The Act created the National Institute for Occupational Safety and Health (NIOSH) to identify the causes of work-related diseases and injuries, evaluate the hazards of new technologies and work practices, create ways to control hazards so that workers are protected, and recommend occupational safety and health standards.

NIOSH, within its Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS), established the Occupational Energy Research Program (OERP) to conduct the occupational health research component of the program. NIOSH with DOE has developed a research agenda with input from a variety of sources, including experts from different research fields and representatives from labor and community organizations.

In general, NIOSH has authority, pursuant to 29 U.S.C. sec. 669(a), to conduct health hazard evaluations (Part 85). NIOSH regulations at 42 CFR 85 and 85a govern the conduct of such projects, including provisions for initiation and conduct of investigations, interviews of employees, use of space provided by the employer, and access to the employer's records and facilities. Although these regulations do not apply to DOE, DOE seeks to ensure NIOSH access to DOE facilities consistent with these regulations.

NIOSH health research and related activities at DOE facilities are organized into two broad categories: occupational health studies and site surveys.

viii. National Center for Environmental Health (NCEH)

In 1980, as an expression of its commitment to solving health problems related to the environment, CDC established the Center for Environmental Health to focus on preventing disability, disease, and death due to environmental factors. In 1991, "National" was added to the center's name to reflect the breadth of its activities. The National Center for Environmental Health (NCEH), located in Atlanta, employs personnel dedicated to carrying out a national environmental health program. In addition to ongoing research into the health effects of environmental hazards, NCEH provides immediate response to requests for assistance from States and countries throughout the world to investigate outbreaks of non-communicable diseases. It operates a world-class

laboratory that measures toxicants and their effects on people. NCEH is a leader in determining the health effects on humans of numerous environmental hazards, both technological and natural.

NCEH, within its Division of Environmental Hazards and Health Effects, established the Radiation Studies Branch (RSB) to conduct the environmental health research component of the program. The RSB is structured to ensure an interdisciplinary approach that links community involvement, environmental dosimetry, radiation epidemiology, health risk analysis, and health communication.

In general, HHS/Public Health Service/CDC has legislative authority under Section 301(a) of the Public Health Service Act (42 U.S.C. sec. 241) to conduct research into the health effects of a broad range of environmental hazards and to cooperate with other appropriate authorities in conducting this such of research. As an Agency within CDC, NCEH conducts health research and related studies at DOE facilities. The studies are organized into three general categories: community-based environmental dose reconstruction, risk analysis, and epidemiologic research.

ix. Agency for Toxic Substances and Disease Registry (ATSDR)

In 1980, Congress created the Agency for Toxic Substances and Disease Registry (ATSDR) to implement the health-related sections of laws that protect the public from hazardous wastes and environmental spills of hazardous substances. CERCLA, commonly known as the “Superfund” Act, provided the congressional mandate to remove or clean up abandoned and inactive hazardous waste sites and to provide Federal assistance in toxic emergencies. As the lead Agency within the Public Health Service for implementing the health-related provisions of CERCLA, ATSDR is charged under the Superfund Act to assess the presence and nature of health hazards at specific Superfund sites, to help prevent or reduce further exposure and illness that result from such exposures, and to expand the knowledge base about health effects from exposure to hazardous substances.

In 1984, amendments to the Resource Conservation and Recovery Act of 1976 (RCRA), which provides for the management of legitimate hazardous waste storage or destruction facilities, authorized ATSDR to conduct public health assessments at these sites when requested by the Environmental Protection Agency (EPA), States, or individuals. ATSDR was also authorized to assist EPA in determining which substances should be regulated and the levels at which substances may pose a threat to human health.

With the passage of the Superfund Amendments and Reauthorization Act of 1986 (SARA), ATSDR received additional responsibilities in environmental public health. This act broadened ATSDR’s responsibilities in the areas of public health assessments, establishment and maintenance of toxicological databases, information dissemination, and medical education.

Since 1986, ATSDR has been required by law to conduct a public health assessment at each of the sites on the EPA National Priorities List. The aim of these evaluations is to find out if people are being exposed to hazardous substances and, if so, whether that exposure is harmful and should be stopped or reduced. If appropriate, ATSDR also conducts public health assessments when petitioned by concerned individuals. Public health assessments are carried out by environmental and health scientists from ATSDR and from the States with which ATSDR have cooperative agreements.

C. DOE's Program of Independent Studies

HS-10 is committed to ensure that studies are conducted by independent public health researchers. This research includes public health activities that primarily focus on the examination of worker exposures to hazardous substances and to health outcomes that may have resulted from DOE operations, including, but not limited to, development and production of nuclear weapons and materials and other nuclear energy-related research. Other activities include assessments of offsite exposures, evaluations of community health risks, and risk communication.

This commitment is pursuant to the authorities in the Atomic Energy Act of 1954, as amended, section 31a (42 U.S.C. § 2051a) and the Energy Reorganization Act of 1974, section 103(3) (42 U.S.C. § 5813(3)), DOE is authorized to conduct and make arrangements to conduct research activities relating to the protection of worker health and the health of communities surrounding DOE sites, and to promote safety relevant to its research and production activities**.** To achieve these objectives and ensure the independence of the studies, DOE (which includes DOE/NNSA Headquarters, site offices, service centers, and laboratories) guides independent research with universities, national laboratories, and other resources that can assist in carrying out such studies (Atomic Energy Act, section 161 (42 U.S.C. § 2201); Energy Reorganization Act, section 104(i) (42 U.S.C. § 5814(i)); and the Economy Act of 1932, as amended (31 U.S.C. §§ 1535 and 1536)).

Appendix 1: DOE Institutional Review Boards (IRBs)

Below is information on contacts for DOE's Human Subjects Protection Program and DOE's IRBs. This information is current as of the date of the issuance of this Access Handbook. For the latest information, please see the DOE Human Subjects Protection Program website: http://humansubjects.energy.gov.

DOE's Human Subjects Protection Program:

DOE has 12 sites that engage in human subjects research. Nine of these sites have their own internal IRBs and 3 use external IRBs. There are two program managers at DOE Headquarters responsible for working with these 12 DOE sites, as well as DOE Headquarters program offices that fund human subjects research within and outside of DOE, and independent researchers

who conduct research on DOE employees and/or their data. For more information, see: http://humansubjects.energy.gov/ or contact:

- Elizabeth (Libby) White, *DOE Human Subjects Protection Program Manager*
  Email: elizabeth.white@science.doe.gov

- John Ordaz, *NNSA Human Subjects Protection Program Manager*
  Email: john.ordaz@nnsa.doe.gov

The **Central DOE IRB (CDOEIRB)** was established in January 2010 by four DOE Headquarters organizations: SC, HSS, NNSA, and the Office of Intelligence and Counterintelligence. The CDOEIRB serves as DOE's IRB of Record for purposes of satisfying the human subjects protection requirements of the DOE for study protocols that involve: 1) beryllium (Be)-related studies sponsored or conducted by DOE facilities or involving the DOE workforce; (2) the Former Worker Medical Screening Program; (3) multi-site research focused on the health and/or productivity of current workers at DOE sites; (4) human terrain mapping projects for DOE sites that do not manage or operate their own internal IRB; and (5) a portion of the energy efficiency studies sponsored by DOE. DOE has used a Central IRB since 2001, but the earlier IRB focused only on beryllium-related studies.

Contact:

- Becky Hawkins, *CDOEIRB Administrator*
  Email: mailto:becky.hawkins@orise.orau.gov
- Darcy Mallon, *CDOEIRB Associate Administrator*
  Email: mallon@bnl.gov

DOE Site IRBs

- **Argonne National Laboratory (ANL - uses the University of Chicago IRB):**
  Contact: Gail Van Gorp, *Human Subjects Protection Program Manager*
  Email: gvangorp@anl.gov

- **Ames Laboratory**
  Contact: Jim Withers, *Ames Laboratory, Office of Environment, Safety, and Health*
  Email: withers@ameslab.gov

- **Brookhaven National Laboratory (BNL - uses the Stony Brook IRB):**
  http://www.bnl.gov/ora/ora.asp
  Contact: Darcy Mallon, *Human Subjects Protection Program Manager*
  Email: mallon@bnl.gov

- **Fermi National Accelerator Laboratory (FNAL – uses the Oak Ridge Site-wide IRB)**
  Contact: John B. Dawson, *Human Subjects Protection Program Manager*
  Email: jbdawson@fnal.gov

- **Idaho National Laboratory (INL):**
  https://inlportal.inl.gov/portal/server.pt/community/inl_portal_support/547
  Contact: Dena Tomchak, *Human Subjects Protection Program Manager*
  Email: dena.tomchak@inl.gov

- **Lawrence Berkeley National Laboratory**
  Contact: Chris Byrne, *Human Subjects Protection Program Manager*
  Email: cebyrne@lbl.gov

- **Lawrence Livermore National Laboratory**
  Contact: Ann-Marie Dake, *LLNL Human Subjects Protection Program Manager*
  Email: dake1@llnl.gov

- **Los Alamos National Laboratory:**
  Contact: Donna Leshne, *LANL Human Subjects Protection Program Manager*
  Email: dleshne@lanl.gov

- **Oak Ridge National Laboratory, Oak Ridge Institute for Science and Education, Y-12, or K-25:**
  http://orise.orau.gov/orisehumansubjects/
  Contact: Becky Hawkins, *Human Subjects Protection Program Manager*
  Email: becky.hawkins@orise.orau.gov

- **Pacific Northwest National Laboratory (PNNL):**
  Contact: Kathy Ertell, *Human Subjects Protection Program Manager*
  Email: katherine.ertell@pnnl.gov

- **Sandia National Laboratory (SNL):**
  http:www.sandia.gov/health/hsb/index.html
  Contact: Terry Reser, *Human Subjects Protection Program Manager*
  Email: treser@sandia.gov

- **Savannah River Site (SRS):**
  Contact: Karen Brown, *Human Subjects Protection Program Manager*
  Email: karent.brown@srs.gov