EPA
ORDER

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Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research

1. Purpose

The purpose of this document is to establish Environmental Protection Agency (EPA) procedures and responsibilities for implementing the requirements set forth in Title 40 Code of Federal Regulations (CFR) Part 26.

This Order supersedes EPA Order 1000.17 A1 *Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research*, approved May 27, 2011 and amended on July 27, 2011.

2. Applicability

This Order applies to all research involving human subjects conducted or supported by EPA and covered by 40 CFR Part 26. It also addresses the oversight process for research involving human subjects that is exempt from 40 CFR Part 26. Furthermore all other EPA policies and other official EPA actions involving EPA conducted or supported research with human subjects shall cross-reference or include this Order.

3. Definitions

A. **Research**. Research means a systematic investigation, including research, development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Note that some demonstration and service programs may include research activities. [40 CFR 26.102(d)].

B. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. [40 CFR 26.102 (f)]

C. **Exempt research.** Research studies that may be found to be exempt are identified in 40 CFR 26.101(b). An example of such exempt research is that involving the analysis of existing research materials if they are publicly available or recorded in a manner such that the subjects cannot be identified.

D. **Intentional exposure research**. Research involving intentional exposure of a human subject means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study. [40 CFR 26.202(a)]
E. **Observational research.** Observational research means any human research that does not meet the definition of research involving intentional exposure of a human subject in 40 CFR 26.202(a). [40 CFR 26.302]
F. **Observational Human Exposure Studies.** As defined in Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES), observational human exposure studies are studies that involve the collection of environmental samples, data, and information from study participants in their everyday environments as they go about their normal activities. They involve neither the deliberate exposure of participants nor the control of environmental conditions in a way that impacts the participants' naturally occurring exposures (SEAOES, pp. 7-8).

4. Policy

In dealing with human subjects research it is EPA policy that:

A. All research shall comply with 40 CFR Part 26 and with this Order.
B. All human observational exposure studies conducted or supported by EPA will adhere to the principles set forth in SEAOES.
C. All human subjects research conducted or supported by EPA must either be approved or be acknowledged as exempt research by the EPA Human Subjects Research Review Official (HSRRO) before any work involving human subjects research can begin. Approval will be given only to research that complies with subsections 4.A. and B. above. Preliminary review by the HSRRO can be requested for any research project, contract, grant application, cooperative agreement, cooperative research and development agreement (CRADA), interagency agreement or any formal agreement involving EPA support of such studies. However, preliminary review is not required for any project, and if provided does not substitute for approval following IRB review.
D. In laboratories/centers/offices/regions where there is a HSRRO-approved Human Subjects Officer (HSO), projects must first be reviewed by the on-site HSO before projects are presented to the HSRRO. In absence of an HSO, projects must be submitted directly to the HSRRO.
E. Any solicitation issued by an EPA office or department for research involving human subjects shall require compliance with this order and 40 CFR Part 26.
F. This policy extends to all EPA employees, regardless of the location of the employee or the human subjects research activity. This policy, however, does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research (40 CFR 26.101 (g)). Procedures followed in

foreign countries to protect human research subjects may differ from those set forth in 40 CFR Part 26. See section 40 CFR 26.101(h) for information about research involving human subjects that is performed in foreign countries.

5. Requirements

Research involving human subjects provides important medical and scientific benefits to individuals and to society. The need for this research does not, however, outweigh the need to protect individual rights and interests.

To obtain approval or a concurrence of exemption by the HSRRO, researchers must submit the IRB-approved research package or documentation of exemption, including evidence of IRB approval and any correspondence between the IRB and the researchers.

Researchers must also provide evidence of a Federalwide Assurance (FWA) on file with the U.S. Department of Health and Human Services (HHS) or other agency that their institution or organization will comply with regulatory provisions in the Common Rule (codified by EPA at 40 CFR 26, Part A). In special circumstances where there is no such assurance, EPA will advise the institution or organization on the process for obtaining an assurance from HHS or another source. For EPA investigators, no proof of assurance is required (EPA is covered by FWA #12755).

6. Responsibilities

All EPA employees, contractors, grant recipients, and parties to other EPA agreements share the responsibility to protect the rights and welfare of human research subjects.

A. **Principal Investigator.** The Principal Investigator, as the person directly implementing the research, has specific responsibilities related to that research project. These responsibilities include:

1. Complying with this Order, 40 CFR Part 26 and other applicable policies and regulations.

2. Ensuring the rights and welfare of subjects are protected.

3. Submitting all necessary documents to the IRB and making all appropriate modifications as required by the IRB.

4. Notifying EPA and the HSRRO (and HSO where applicable) of IRB suspension or termination of the research, of Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) that the IRB deems reportable, and any event that is significant enough to result in the removal of a subject from the study. In addition,

for grantees of EPA, the PI must notify his/her Project Officer (described below) promptly, according to the terms specified by the IRB of record for the project.

B. **Human Subjects Research Review Official (HSRRO).** The HSRRO is responsible for reviewing all EPA conducted or supported research studies involving human subjects. The HSRRO determines compliance with this Order and reviews all EPA conducted or supported research studies involving human subjects covered by 40 CFR Part 26. The outcome of HSRRO review will be in writing. Ordinarily, the HSRRO's decision is expected in 30 days or fewer.

1. The HSRRO may withhold approval of any proposal if it does not adequately protect the rights and welfare of human subjects. The HSRRO will provide a written explanation to the requestor for such withholding. Such letter will contain an explanation of the applicable appeal rights. The Principal Investigator (PI) may revise the proposal to address the concerns of the HSRRO and resubmit the proposal. The decision to withhold approval may be appealed as set out below.

2. Studies that have been suspended or terminated by an IRB are automatically suspended or terminated by the EPA.
    a. The HSRRO also has the authority to suspend or terminate any study (i) if it is found to be in material noncompliance with the assurance or with the IRB approved methods and procedures; (ii) if the assurance is withdrawn by the approving organization; (iii) if there is good reason to believe that the rights and welfare of the human research subjects are not being adequately protected; or (iv) if there has been unexpected serious harm to one or more human subjects.

    b. If a non-EPA institution is involved, the HSRRO informs the Human Subjects Officer and/or the Project Officer (or equivalent) in writing of the reason for the suspension or termination. If the study has been suspended, the suspension shall remain in effect until the deficiencies have been corrected and the HSRRO has approved resumption of work. Decisions to suspend or terminate a study may be appealed as set out in subsection 6.E. below. Studies affected by a suspension or termination shall remain in suspended or terminated status pending conclusion of the appeal.

3. The HSRRO may establish and maintain an appropriate group or groups to advise and assist him/her in carrying out these responsibilities.

C. **Human Subjects Officer (HSO)**

1. Some laboratories/centers/offices/regions have a Human Subjects Officer (HSO). Generally, the HSO should serve as a liaison for the HSRRO, laboratory/center/office/regional senior management, Project Officers, and researchers regarding human subjects research.

2. The HSO may provide advice, recommendations, and information to the HSRRO and laboratory/center/office/region senior management on human subjects research related issues within the laboratory/center/office/region. The HSO may also help to ensure that researchers meet regulatory requirements by facilitating and coordinating researcher and staff education and training in HSR.

3. The HSO may also assist researchers and Project Officers regarding the preparation and review of research projects for oversight by IRBs and the HSRRO. After appropriate training and approval by the HSRRO, the HSO may also make determinations that a project does not constitute human subjects research.

D. **EPA Program Office, Regional Office, Project Officer**

1. The EPA program or regional office that conducts or supports research covered by this Order is responsible for compliance with it. In the first instance the office will decide whether the project involves "research" and "human subjects" as per 3.A. and 3.B. above and hence is subject to this Order. While the HSO is authorized to make the determination of what constitutes human subjects research once he or she is approved by the HSRRO, a courtesy consultation with the HSRRO is available upon request. Each research project will have a Project Officer from or reporting to the responsible office.

2. The program or regional office supporting extramural research involving human research subjects is responsible for notifying the EPA Award Official/Contracting Officer that human subjects are involved.

3. The Project Officer is responsible, inter alia, for monitoring the conduct of the study for compliance with the agreed upon procedures and methods for the protection of the rights and welfare of human subjects. Such monitoring may involve various management techniques such as site visits, review of documentation and communication with the researchers. Should the Project Officer discover material noncompliance with the assurance or with the IRB approved methods and procedures, the Project Officer shall notify his/her management, the Award Official/Contracting Officer (when applicable) and the HSRRO at once.

E. **EPA Award Official/Contracting Officer**

1. The EPA Award Official/Contracting Officer is responsible for including with the contract, grant, cooperative agreement, CRADA or other formal agreement, except interagency agreements, a programmatic or administrative term or condition requiring compliance with EPA's regulations, policies and procedures for the protection of human research subjects as described or referenced in this Order. For interagency agreements, he/she is responsible for including a clause or special condition requiring protection of human research subjects as per their own version of the Common Rule. Should the department or agency not be a signatory to the Common Rule, the clause or special condition will require compliance with EPA's regulations, policies, and procedures as described or referenced in this Order.

2. The Award Official/Contracting Officer will immediately notify the institution in writing when a study is terminated or suspended and include in such notification a statement of the basis for the termination or suspension.

F. **The Administrator**

1. If an institution or individual wishes to appeal the withholding of approval for a new study or activity in a study (paragraph 6.B.(1)), the suspension of a study because of deficiencies (paragraph 6.B. (2)) or the termination of a study because of deficiencies (paragraph 6.B.(2)), the institution may do so by delivering a written appeal within thirty (30) days of the date of receipt of notification of the action to the Administrator or his/her designee, U.S. Environmental Protection Agency, Washington, DC 20460. The appeal shall set forth in detail the decision being appealed and the basis of the appeal and may include supporting materials.

2. The Administrator or his/her designee will respond in writing within thirty (30) days of receipt of the appeal, which time can be extended for good cause by the Administrator or his/her designee.

7. Saving Provision

Any and all modifications to 40 CFR Part 26 will automatically become part of this Order on the effective date of such modifications.

8. Supersession

This Order supersedes EPA Order 1000.17 A1 *Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research*, approved May 27, 2011 and amended on July 27, 2011.

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