

# Additional Requirements for Research Involving the Environmental Protection Agency (EPA)

## Purpose:

---

The information in this guidance is for investigators conducting human subjects research involving the Environmental Protection Agency (EPA). While the EPA is a signatory to the 2018 Revised Common Rule which took effect January 21, 2019, research conducted or supported by the EPA requires compliance with additional federal regulations codified at [40 CFR 26](#) and additional policy and procedures contained in [EPA Order 1000.17A](#).

## In this document:

---

[Applicability](#)

[Definitions](#)

[Notification requirements](#)

[EPA-specific requirements](#)

[Additional Information](#)

## Applicability:

---

Human Subject Research involves the EPA when any of the following apply:<sup>1</sup>

- The research conducted or supported by the EPA.
- The research occurs in EPA facilities by any person.
- The research is conducted by EPA employees in any facility.
- Research solicited by an EPA office or department.<sup>2</sup>
- Research on any substance or pesticide, if anyone conducting or sponsoring the research intended, at any point, for submission of the research results to the EPA for consideration or inspection.<sup>3</sup>

---

<sup>1</sup> 40 CFR 26.101, 40 CFR 26.201, 40 CFR 26.301, and 40 CFR 26.401

<sup>2</sup> EPA Order 1000.17A Section 4.(E)

<sup>3</sup> 40 CFR 26.1101(a)(1)-(2)

## Definitions:

---

Additional subparts within the EPA regulations at 40 CFR 26 and EPA Order 1000.17A provide definitions beyond those included in the Common Rule. Some of these definitions expand those detailed within the Common Rule, while others provide interpretation or clarification of terms that are not explicitly defined as part of the Common Rule.

**Child** - A person who has not attained the age 18 years<sup>4</sup>

**Intentional Exposure Research** – 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.<sup>5</sup> For example, research in which the subject's exposure to a substance is artificially manipulated or controlled through intentional dosing of the study substance or by controlling the subject’s behavior to bring them into contact with a substance.

**Observational Research** - Any human research that does not meet the definition of research involving intentional exposure of a human subject.<sup>6</sup> Studies that involve naturally occurring environmental exposures with no alterations to subject behavior or environmental conditions may meet this definition.

**Observational Human Exposure Studies** - 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.<sup>7</sup>

## Notification Requirements

---

### Prior Approval

All human subjects research involving the EPA must be reviewed and approved by, or determined to be exempt by, the EPA Human Subjects Research Review Official (HSRRO) before human subjects work may begin.

After obtaining approval or determination of exemption from the ISU IRB, Principal Investigators submit approved IRB applications and approval/determination letter to the EPA HSRRO for review. Policy regarding this requirement is contained in [EPA Order 1000.17A](#).

Information submitted to EPA HSRRO should include:

- a) discussion of:
  - (1) The potential risks to human subjects;
  - (2) The measures proposed to minimize risks to the human subjects;

---

<sup>4</sup> 40 CFR 26.202(b)

<sup>5</sup> 40 CFR 26.202(a)

<sup>6</sup> 40 CFR 26.302

<sup>7</sup> [Scientific and Ethical Approaches for Observational Exposure Studies \(SEAOES\)](#), National Exposure Research Laboratory (NERL) | U.S. Environmental Protection Agency

- (3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;
  - (4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and
  - (5) The balance of risks and benefits of the proposed research.
- b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.
  - c) Information about how subjects will be recruited, including any advertisements proposed to be used.
  - d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.
  - e) All correspondence between the IRB and the investigators or sponsors.
  - f) Copy of the IRB approval letter.

### Prompt Notification

Investigators must notify the EPA Human Subjects Research Review Official (HSRRO) and EPA Project Officer promptly of any:

- IRB suspension or termination of the research
- Unanticipated Problems Involving Risks to Subjects or Others that the IRB deems reportable
- Any event significant enough to result in the removal of a subject of the study<sup>8</sup>
- Any instance of serious or continuing noncompliance<sup>9</sup>

## EPA-specific Requirements

---

- The EPA regulations **prohibit *intentional exposure research with any human subject who is pregnant (and therefore her fetus), a nursing woman, and/or a child.***<sup>10</sup> The regulations do not allow exceptions to this ban.
- Children may only be included in *observational research* that is minimal risk, or if more than minimal risk, there must be prospect of direct benefit to the individual subject. The relation of the benefit to risk must be at least as favorable to subjects as that presented by available alternative approaches. Adequate provisions must be made for soliciting the assent of the child and permission of parents/guardians.<sup>11</sup>
- All *human observational exposure studies* conducted or supported by EPA must adhere to the principles set forth in EPA document: [Scientific and Ethical Approaches for Observational Exposure Studies \(SEAOES\)](#).<sup>12</sup>

---

<sup>8</sup> DOE Order 1000.17A Section 6.(A)4

<sup>9</sup> 40 CFR 26.108 and 40 CFR 26.1108

<sup>10</sup> 40 CFR 26.1203

<sup>11</sup> 40 CFR 26.404-406

<sup>12</sup> EPA Order 1000.17A

## Additional information:

“Basic Information about Human Subjects Research” *U.S. Environmental Protection Agency*

<https://www.epa.gov/osa/basic-information-about-human-subjects-research-0>

Environmental Protection Agency 40 CFR 26 – Protection of Human Subjects

[https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40cfr26\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40cfr26_main_02.tpl)

EPA Order 1000.17A

[https://www.epa.gov/sites/production/files/2016-06/documents/2016\\_policy\\_order\\_revision\\_6-10-16.pdf](https://www.epa.gov/sites/production/files/2016-06/documents/2016_policy_order_revision_6-10-16.pdf)

EPA Protections for Subjects in Human Research with Pesticides

<https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/protections-subjects-human-research-pesticides>

EPA Pesticide regulatory statutes:

Federal Insecticide, Fungicide, and Rodenticide Act (U.S.C. 136 et seq.)

<https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities>

408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)

<https://www.govinfo.gov/app/details/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapIV-sec346a>

“Scientific and Ethical Approaches for Observational Exposure Studies” *National Exposure Research Laboratory (NERL) | U.S. Environmental Protection Agency*

[https://cfpub.epa.gov/si/si\\_public\\_record\\_report.cfm?Lab=NERL&dirEntryId=191443&simpleSearch=1&searchAll=scientific+and+ethical+approaches+for+observational+exposure](https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NERL&dirEntryId=191443&simpleSearch=1&searchAll=scientific+and+ethical+approaches+for+observational+exposure)

### Document History

---

---

*Created/Approved:* 12/17/2019

---

---