Version Date: [04/29/2025]

TERMS OF THE FEDERALWIDE ASSURANCE
FOR THE PROTECTION OF HUMAN SUBJECTS

[1]U. S. Department of Health and Human Services
Office for Human Research Protections

This document delineates the terms of the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP) Federalwide Assurance (FWA) for the protection of human subjects.

1. Applicability

These terms apply whenever the institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule, 1unless the research is otherwise exempt from the requirements of the Common Rule, or a U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

For information on the meaning of “engaged,” see OHRP’s guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

For the purposes of the FWA, federally supported research generally refers to research for which the U.S. Government is providing funding or other material support. For assistance in determining whether a particular research project is "supported," please consult with the federal department or agency involved in the research.

For a list of U.S. federal departments and agencies that have adopted or otherwise follow the Common Rule, see Appendix.

2. Compliance with Laws, Regulations, and Guidelines

(a) U.S. Institutions:

When a U.S. institution becomes engaged in research to which the FWA applies, the institution and the institutional review boards (IRBs) upon which it relies for review of such research will comply with 1the Federal Policy for the Protection of Human Subjects, also known as the Common Rule. The reference in the U.S. Code of Federal Regulations (CFR) is shown in the Appendix for each U.S. federal department and agency which has adopted the Common Rule.

(b) Non-U.S. Institutions:

When a non-U.S. institution becomes engaged in research to which the FWA applies, the institution and the IRBs upon which it relies for review of such research will comply with the Common Rule. The reference in the U.S. CFR is shown in the Appendix for each U.S. federal department and agency which has adopted the Common Rule. If a U.S. federal department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided by the Common Rule, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the Common Rule, consistent with the requirements of 45 CFR 46.101(h).

(c) U.S. and non-U.S. Institutions:

For any research to which the FWA applies, the institution also will comply with any additional applicable human subjects regulations of the U.S. federal department or agency that conducts or supports the research.1

When an institution is engaged in nonexempt human subjects research conducted or supported by HHS, the institution will comply with the requirements of these subparts of 45 CFR part 46:

- Subpart A – Basic HHS Policy for Protection of Human Research Subjects
- Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- Subpart D – Additional Protections for Children Involved as Subjects in Research
- Subpart E – Registration of Institutional Review Boards

IRBs upon which the institution relies for review of research conducted or supported by HHS to which the FWA applies must be registered with OHRP.

Human subjects research conducted or supported by each U.S. federal department or agency listed (see Appendix) will be governed by the regulations as implemented by the respective department or agency. The head of the U.S. federal department or agency retains final judgment as to whether a particular activity conducted or supported by the respective department or agency is covered by the Common Rule. If an institution needs guidance regarding implementation of the Common Rule or other applicable U.S. federal regulations, the institution should contact appropriate officials at the U.S. federal department or agency conducting or supporting the research.

For U.S. federally conducted or supported research covered by the FWA, the U.S. federal department or agency that conducts or supports the research retains final authority for determining whether the institution complies with the Terms of Assurance. If HHS receives an allegation or indication of noncompliance related to research to which the FWA applies and that is conducted or supported solely by a U.S. federal department or agency other than HHS, HHS will refer the matter to the other U.S. federal department or agency for review

and action as appropriate.

3. Reliance on IRBs Unaffiliated with an Institution Holding an FWA

Whenever an institution relies upon an IRB operated by another institution or organization for review of research to which the FWA applies, the institution and the organization operating the IRB must document the reliance and the responsibilities that each entity will undertake to ensure compliance with the requirements of the Common Rule. This documentation can occur, for example, through a written agreement between the relying institution and the reviewing IRB, by implementation of an institution-wide policy that identifies the reliance and the respective responsibilities of each party, or through a description of the reliance and respective responsibilities of the relying institution and reviewing IRB that is included in a research protocol. This documentation must be kept on file at both institutions or organizations and must be made available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.

4. **Renewal or Update of the Assurance**

In order to maintain a satisfactory written assurance, OHRP requires that an institution renew its FWA every 5 years, even if no changes have occurred.

OHRP also requires that an institution update its FWA within 90 days after changes occur regarding the legal name of the Institution, the Human Protections Administrator, or the Signatory Official.

Any renewal or update that is submitted to, and accepted by, OHRP begins a new 5-year effective period.

Failure to renew or update an FWA while continuing to engage in research subject to the Common Rule may constitute noncompliance.

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Appendix
Common Rule Federal Departments or Agencies

No.	Dept. or Agency	CFR Citation (2018)	Authority	Status under Pre-2018 Requirements	Status under 2018 Requirements
1	Department of Homeland Security	6 CFR Part 46	5 U.S.C. 301; P.L. 107-296, sec. 102, 306(c); P.L. 108-458, sec. 8306.	Follows Common Rule and all subparts per statute (Pub. L. 108-458, title VIII, section 8306)	Common Rule Signatory
2	Department of Agriculture	7 CFR Part 1c	5 U.S.C. 301; 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
3	Department of Energy	10 CFR Part 745	5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
4	National Aeronautics and Space Administration	14 CFR Part 1230	5 U.S.C. 301; 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
5	Department of Commerce (National Institute of Standards and Technology)	15 CFR Part 27	5 U.S.C. 301; 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
6	Social Security Administration	20 CFR Part 431	5 U.S.C. 301; 42 U.S.C. 289(a).	SSA and HHS split in 1995. Pursuant to the transition rules provided in Section 106 of title 1 of Pub.L. 103-296, SSA has been required to apply the CR to its research.	Common Rule Signatory
7	Agency for International Development	22 CFR Part 225	5 U.S.C. 301; 42 U.S.C. 300v-1(b), unless otherwise noted.	Common Rule Signatory	Common Rule Signatory
8	Department of Housing and	24 CFR Part 60	5 U.S.C. 301; 42 U.S.C. 300v-1(b) and 3535(d).	Common Rule Signatory	Common Rule Signatory

No.	Dept. or Agency	CFR Citation (2018)	Authority	Status under Pre-2018 Requirements	Status under 2018 Requirements
	Urban Development				
9	Department of Justice (National Institute of Justice)	28 CFR Part 46		Common Rule Signatory	Intends to become an official signatory
10	Department of Labor	29 CFR Part 21	5 U.S.C. 301; 29 U.S.C. 551.	Not a Common Rule Signatory	Common Rule Signatory
11	Department of Defense	32 CFR Part 219	5 U.S.C. 301.	Common Rule Signatory	Common Rule Signatory
12	Department of Education	34 CFR Part 97	5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474.	Common Rule Signatory	Common Rule Signatory
13	Department of Veterans Affairs (Office of Research Oversight) (Office of Research and Development)	38 CFR Part 16	5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
14	Environmental Protection Agency (Research and Development)	40 CFR Part 26	5 U.S.C. 301; 7 U.S.C. 136a(a) and 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); sec. 201, Pub. L. 109-54, 119 Stat. 531; and 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
15	Department of Health and Human Services	45 CFR Part 46	5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b)	Common Rule Signatory	Common Rule Signatory
16	National Science Foundation	45 CFR Part 690	5 U.S.C. 301; 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
17	Department of Transportation	49 CFR Part 11	5 U.S.C. 301; 42 U.S.C. 300v-1(b).	Common Rule Signatory	Common Rule Signatory
18	Office of the Director of National Intelligence	None	EO 12333 (1981), amended by EO 13284 (2003), EO 13355 (2004), and EO 13470	Follows CR because of EO 12333, as amended.	Follows CR because of EO 12333, as amended.

No.	Dept. or Agency	CFR Citation (2018)	Authority	Status under Pre-2018 Requirements	Status under 2018 Requirements
			(2008)		
19	Central Intelligence Agency	None	EO 12333 (1981), amended by EO 13284 (2003), EO 13355 (2004), and EO 13470 (2008)	Follows CR because of EO 12333, as amended.	Follows CR because of EO 12333, as amended.
20	Consumer Product Safety Commission	16 CFR Part 1028	5 U.S.C. 301; 42 U.S.C. 300v-1(b)	Common Rule Signatory	Common Rule Signatory
21	Corporation for National and Community Service (operating as AmeriCorps)	45 CFR 2584	42 U.S.C. 12651c(c)	Not a Common Rule Signatory	Common Rule Signatory