# Federalwide Assurance (FWA) for the Protection of Human Subjects

## Terms

### 1. Human Subjects Research Must Be Guided by a Statement of Principles

All of the Institution's human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. This statement of principles may include (a) an appropriate existing code, declaration (such as the World Medical Association's Declaration of Helsinki), or statement of ethical principles (such as the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research), or (b) a statement formulated by the institution itself.

### 2. 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, unless 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

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

[*For the purposes of the FWA, federally-supported means the U.S. Government providing any funding or other support.]

## 3. Compliance with Laws, Regulations, Policies, and Guidelines

**(a) U.S. Institutions:**

When the Institution becomes engaged in research to which the FWA applies, the Institution and institutional review boards (IRBs) upon which it relies for review of such research will comply with the Common Rule.

The reference in the U.S. Code of Federal Regulations is shown below for each U.S. federal department and agency which has adopted the Common Rule:

7 CFR part 1c – Department of Agriculture

10 CFR part 745 – Department of Energy

14 CFR part1230 – National Aeronautics and Space Administration

15 CFR part 27 – Department of Commerce

16 CFR part 1028 – Consumer Product Safety Commission

22 CFR part 225 – Agency for International Development

24 CFR part 60 – Department of Housing and Urban Development

28 CFR part 46 – Department of Justice

32 CFR part 219 – Department of Defense

34 CFR part 97 – Department of Education

38 CFR part 16 – Department of Veterans Affairs

40 CFR part 26 – Environmental Protection Agency

45 CFR part 46, subpart A – Department of Health and Human Services

45 CFR part 46, subpart A – Central Intelligence Agency (by Executive Order 12333)

45 CFR part 46, subpart A – Department of Homeland Security (by federal statute)

45 CFR part 690 – National Science Foundation

49 CFR part 11 – Department of Transportation

**(b) Non-U.S. Institutions:**

When the Institution becomes engaged in research to which the FWA applies, the Institution and IRBs upon which it relies for review of such research at a minimum will comply with one or more of the following:

- The Common Rule;
- The U.S. Food and Drug Administration regulations at 21 CFR parts 50 and 56;

- The current International Conference on Harmonization E-6 Guidelines for Good Clinical Practice;
- The current Council for International Organizations of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects;
- The current Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;
- The current Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or
- Other standard(s) for the protection of human subjects recognized by U.S. federal departments and agencies which have adopted the U.S. Federal Policy for the Protection of Human Subjects.

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 above, consistent with the requirements of section 101(h) of the Common Rule.

**(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 and policies of the U.S. federal department or agency which conducts or supports the research and any other applicable federal, state, local, or institutional laws, regulations, and policies. When the Institution is engaged in non-exempt human subjects research conducted or supported by HHS, the Institution will comply with the requirements of subparts B, C, D, and E of the HHS regulations at Title 45 Code of Federal Regulations part 46, when applicable, for research involving pregnant women, fetuses, and neonates; prisoners; and children, respectively.

Human subjects research conducted or supported by each U.S. federal department or agency listed above 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 the Institution needs guidance

regarding implementation of the Common Rule and/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.

## 4. Written Procedures

(a) The Institution submitting the FWA has established written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research (or designee), and OHRP of any:

1. unanticipated problems involving risks to subjects or others;

2. serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB(s); and

3. suspension or termination of IRB approval.

(b) The Institution will ensure that the IRB(s) that reviews research to which the FWA applies has established written procedures for:

1. conducting IRB initial and continuing review (not less than once per year), of research, and reporting IRB findings to the investigator and the Institution;

2. determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and

3. ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate

apparent immediate hazards to the subjects.

(c) Upon request, the Institution will provide a copy of these written procedures to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.

## 5. Institutional Support for the IRB(s)

The Institution will ensure that each IRB upon which it relies for review of research to which the FWA applies has meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

## 6. Reliance on an External IRB

Whenever the Institution relies upon an IRB operated by another institution or organization for review of research to which the FWA applies, the Institution must ensure that this arrangement is documented by a written agreement between the Institution and the other institution or organization operating the IRB that outlines their relationship and includes a commitment that the IRB will adhere to the requirements of the Institution's FWA. OHRP's sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. This agreement must be kept on file at both institutions/organizations and made available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.

## 7. Renewal or Update of the Assurance

The Institution must renew its FWA every 5 years, even if no changes have occurred, in order to maintain an active FWA.

The Institution must 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 appropriately may result in restriction, suspension, or termination of OHRP's approval of the Institution's FWA.

[ Return to OHRP Assurance Main Page (/ohrp/register-irbs-and-obtain-fwas/fwas/index.html) ]

*If you have questions about human subjects research, click*IRBorFWA@hhs.gov (mailto: IRBorFWA@hhs.gov)

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