

University of Michigan
FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS
FWA 00004969

FWA Expiration: Date changes frequently; check the OHRP FWA database for the expiration date (<http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>)

1. Human Subject Research Will be Guided by Ethical Principles

With regard to federally-conducted or -sponsored research, all of the University's activities and all activities of the Institutional Review Boards (IRBs) designated under this Assurance will be guided by the ethical principles in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subject of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

2. Applicability

These terms apply whenever the University becomes engaged in federally supported* (i.e., conducted or supported) human subjects research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects. The University becomes so engaged whenever:

- a. The University's employees or agents intervene or interact with human subjects for purposes of federally-supported research;
- b. The University's employees or agents obtain individually identifiable private information about human subjects for purposes of federally-supported research; or
- c. The University receives a direct federal award to conduct human subject research, even where a subcontractor or collaborator carries out all activities involving human subjects.

*"Federally supported" is defined in this document and in the FWA as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves U.S. Government employees.

3. Compliance with the Federal Policy for the Protection of Human Subjects

In its conduct of federally-supported human subjects research, the University and the IRB(s) designated under this Assurance will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subjects research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D). The reference in the Code of Federal Regulations is shown below for each Agency which has adopted the Common Rule:

7CFR 1c Department of Agriculture
10 CFR 745 Department of Energy
14 CFR 1230 National Aeronautics and Space Administration
15 CFR 27 Department of Commerce
16 CFR 1028 Consumer Product Safety Commission
22 CFR 225 Agency for International Development
24 CFR 60 Department of Housing and Urban Development
28 CFR 46 Department of Justice
32 CFR 219 Department of Defense
34 CFR 97 Department of Education
38 CFR 16 Department of Veterans Affairs
40 CFR 26 Environmental Protection Agency
45 CFR 46 Department of Health & Human Services
45 CFR 690 National Science Foundation
49 CFR 11 Department of Transportation
By Exec. Order Central Intelligence Agency
By Statute Social Security Administration

4. Written Procedures

- a. The University has established, and will provide a copy to OHRP upon request, written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any:
 1. Unanticipated problems involving risks to subjects or others,
 2. Serious or continuing noncompliance with the Federal Regulations or IRB requirements, and
 3. Suspension or termination of IRB approval.
- b. The designated IRBs have established, and will provide a copy to OHRP upon request, written procedures for:
 1. Conducting IRB initial and continuing review (not less than once per year), approving 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;
 3. Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

5. Responsibilities and Scope of IRB(s)

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, all federally supported human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRBs. The IRBs will have authority to approve, require modifications in, or disapprove the covered human subject research.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, in federally supported studies, informed consent will be:

- a. Sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the Common Rule;
- b. Appropriately documented, in accordance with, and to the extent required by Section 117 of the Common Rule.

7. Requirement for Assurances for Collaborating Institutions/Investigators

The University will ensure that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

8. Written Agreements with Non-Affiliated Investigators

The University will ensure that engagement in human research activities of each independent investigator who is not an employee or agent of the University may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. The University will maintain commitment agreements on file and provide copies to OHRP upon request.

9. Institutional Support for the IRB(s)

The University will provide the IRBs that it operates with meeting space and staff sufficient to support each IRBs review and recordkeeping duties.

10. Compliance with the Terms of Assurance

The University accepts and will follow items 1 through 9 above with respect to federally supported research and is responsible for ensuring that the IRBs:

- a. Designated under the Assurance agree to comply with these terms; and
- b. Possess appropriate knowledge of the local research context for all research covered under the Assurance

Any designation under this Assurance of another Institution's IRB or an independent IRB for review of federally-supported research will be documented by a written agreement between the University and the IRB organization outlining their relationship and will include a

commitment that the designated IRB will adhere to the requirements of this Assurance. The Authorization Agreement will be kept on file and made available to OHRP upon request.

11. Assurance Training

The University will ensure that the Institutional Signatory Official, key Human Protection Program Administrators, and the IRB chairs are familiar with the contents of the OHRP Assurance Training Modules.

12. Educational Training

The University has establish training opportunities and oversight mechanisms to ensure that research investigators on federally-sponsored research, IRB members and staff, and other appropriate personnel maintain continuing knowledge of the relevant ethical principles, relevant Federal Regulations, OHRP guidelines and other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. The University provides training to IRB members and staff before they begin reviewing human subjects research and research investigators complete educational training before conducting human subjects research.

13. Renewal of Assurance

All information provided under this Assurance must be updated at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active Assurance.