Office for Human Research Protections (OHRP)

FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS

A. TERMS OF THE FEDERALWIDE ASSURANCE FOR INSTITUTIONS WITHIN THE UNITED STATES

1. All of the institution's human subject activities, and all human subject activities of the Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by the ethical principles in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

2. The following terms apply whenever (a) IRBs operated by the institution provide review and oversight of Federally-supported human subject research, regardless of where the research takes place or by whom it is conducted; or (b) the institution becomes engaged in Federally-supported human subject research. The institution becomes so engaged whenever (a) the institution's employees or agents intervene or interact with living individuals for purposes of Federally-supported research; (b) the institution's employees or agents obtain, release, or access individually identifiable private information for purposes of Federally-supported research; or (c) the institution receives a direct Federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

3. Federally-supported human subject research for which the IRB provides review and oversight will comply with the Federal Policy* (Common Rule) for the Protection of Human Subjects. All human subject research supported by the Department of Health and Human Services (HHS) will comply with all Subparts of HHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46). All Federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All Federally-supported human subject research will comply with any human subject regulations and policies of any relevant regulatory Department or Agency.

* 7 CFR 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 and Human Services
45 CFR 690	National Science Foundation
49 CFR 11	Department of Transportation

By Executive Order	Central Intelligence Agency
By Statute	Social Security Administration

4. Except for research exempted or waived under Sections 101(b) or 101(i) of the Federal Policy, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight by the designated IRBs. The IRBs will have authority to approve, require modifications in, or disapprove the covered human subject research.

5. Except where specifically waived or altered by the IRB under Sections 101(i), 116(c) and (d), or 117(c) of the Federal Policy, all human subject research will require written informed consent, in nonexculpatory language understandable to the subject (or the subject's legally authorized representative), including the following basic elements per Section 116(a) and (b) of the Federal Policy: (a) Identification as research; purposes, duration, and procedures; procedures which are experimental; (b) Reasonably foreseeable risks or discomforts; (c) Reasonably expected benefits to the subject or others; (d) Alternative procedures or treatments, if any, that might be advantageous to the subject; (e) Extent of confidentiality to be maintained; (f) Whether compensation or medical treatment are available if injury occurs (if more than minimal risk); (g) Whom to contact for answers to questions about the research, subjects' rights, and research-related injury; (h) Participation is voluntary; refusal to participate, or discontinuation of participation, will involve no penalty or loss of benefits to which subject is entitled; and (i) When appropriate, additional elements per Section 116(b) of the Federal Policy.

6. The institution and the designated IRBs have established (or will establish within 90 days), and will provide to OHRP upon request, written procedures for (a) verifying whether proposed activities qualify for exemption from, or waiver of, IRB review; (b) conducting IRB initial and continuing review, approving research, and reporting IRB findings to the investigator and the institution; (c) 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; (d) ensuring that changes in approved research are reported promptly and are not initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject; and (e) ensuring prompt reporting to the IRB, institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any (i) unanticipated problems involving risks to subjects or others in any covered research; (ii) serious or continuing noncompliance with Federal, institutional, or IRB requirements; and (iii) suspension or termination of IRB approval for Federally-supported research.

7. The Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chairperson(s) will personally complete the relevant OHRP basic educational modules, or comparable training approved by OHRP, prior to submitting the Assurance. Members and staff of the IRBs will complete relevant training before reviewing human subject research. Research investigators must complete appropriate institutional training before conducting human subject research.

8. The institution and the designated IRBs have established (or will establish within 90 days), and will provide to OHRP upon request, education and oversight mechanisms (appropriate to the nature and volume of its research) to verify that research investigators, IRB members and staff, and other relevant personnel maintain continuing knowledge of, and comply with, relevant Federal regulations, OHRP guidance, other applicable guidance, State and local law, and institutional policies for the protection of human subjects. The institution and the designated IRBs will require documentation of such training from research investigators as a condition for conducting HHS-supported human subject research.

9. The institution is responsible for verifying that IRBs designated under the Assurance agree to comply with items (1) through (8) above and that the IRBs possess appropriate knowledge of

the local context in which research for which they are responsible will be conducted.

10. This institution is responsible for ensuring that all institutions and investigators collaborating in its Federally-supported human subject research operate under an appropriate Assurance of Protection for Human Subjects. All institutions engaged in such research, including subcontractors and subgrantees, must hold their own Assurance.

11. The institution will provide IRBs that it operates with resources, professional staff, and support staff sufficient to carry out their responsibilities efficiently and effectively.

12. The activities of individual research investigators who are not employees or agents of the institution may be covered under the Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. (OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the institution may develop its own such commitment agreement.) Institutions must maintain such commitment agreements on file and provide copies to OHRP upon request.

13. Information provided under this Assurance should be updated every 36 months, even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the institution's Federalwide Assurance of Protection for Human Subjects.

DOMESTIC INSTITUTIONS ACCEPTING THESE TERMS

MAY PROCEED WITH THE ASSURANCE PROCESS

Note: Terms of Assurance are negotiable. Please contact OHRP should you have questions about or which to negotiate these Terms.

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B. TERMS OF THE FEDERALWIDE ASSURANCE FOR INSTITUTIONS OUTSIDE THE UNITED STATES

Note: Terms of Assurance are negotiable. Please contact OHRP should you have questions about or which to negotiate these Terms.

1. All of the institution's human subject activities, and all human subject activities of the Independent Ethics Committees (IECs) or Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by one of the following statements of ethical principles: The World Medical Association's *Declaration of Helsinki (as adopted in 1996 or 2000); The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* of the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or other internationally recognized ethical standards.

2. The following terms apply whenever (a) IECs or IRBs operated by the institution provide review and oversight of human subject research supported by the United States (US) Government, regardless of where the research takes place or by whom it is conducted; or (b) the institution becomes engaged in human subject research supported by the US. The institution becomes so engaged whenever (a) the institution's employees or agents intervene or interact with living individuals for purposes of research supported by the US; (b) the institution's employees or agents obtain, release, or access individually identifiable private information for purposes of research supported by the US; or (c) the institution receives a direct award to conduct human subject research supported by the US, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

3. All US-supported human subject research will comply with the requirements of any applicable Federal regulatory agency as well as one of the following:

    a. the US Federal Policy (Common Rule) for the Protection of Human Subjects and/or the US Department of Health and Human Services (HHS) regulations at 45 CFR 46;

    b. the May 1, 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6) Sections 1 through 4;

    c. The 1993 Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects;

    d. the 1998 Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans;

    e. the 2000 Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or

    f. other internationally recognized standards for the protection of human subjects.

4. The activities of individual research investigators who are not employees or agents of the institution may be covered under the Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IEC/IRB oversight. (OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the institution may develop its own such commitment agreement.) Institutions will maintain such commitment agreements on file and provide copies of them to OHRP upon request.

5. All information provided under this Assurance should be updated every 36 months, even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the institution's Federalwide Assurance of Protection for Human Subjects.

6. US-supported research should be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IEC/IRB. The convened IEC/IRB, with a majority of its members present, should have authority to approve, require modifications in, or disapprove the covered human subject research. The IEC/IRB should possess appropriate knowledge of the local context in which research for which it is responsible will be conducted.

7. Unless authorized by the supporting US Agency, US-supported research should require written informed consent, in nonexculpatory language understandable to the subject (or the subject's legally authorized representative), including the following basic elements: (a) Identification as

research; purposes, duration, and procedures; procedures which are experimental; (b) Reasonably foreseeable risks or discomforts; (c) Expected benefits to the subject or others; (d) Alternative procedures or treatments; (e) Extent of confidentiality to be maintained; (f) Whether compensation or medical treatment are available if injury occurs (if more than minimal risk); (g) Whom to contact for answers to questions about the research, subjects' rights, and research-related injury; (h) Participation is voluntary; refusal to participate, or discontinuation of participation, will involve no penalty or loss of benefits to which subject is entitled; and (i) When appropriate, additional elements as determined by the IEC/IRB.

8. The institution and the designated IRB/IEC should establish written procedures for (a) verifying whether proposed activities qualify for exemption from, or waiver of, IEC/IRB review; (b) conducting initial and continuing IEC/IRB review, approving research, and reporting IEC/IRB findings to the investigator and the institution; (c) determining appropriate continuing review intervals and oversight mechanisms for all approved research; (d) ensuring that changes in approved research are not initiated without IEC/IRB approval, except when necessary to eliminate apparent immediate hazards to the subject; and (e) ensuring prompt reporting to the IEC/IRB, institutional officials, and the relevant US Agency Head, any applicable regulatory body, and OHRP of any (i) serious or continuing noncompliance with US, institutional, or IEC/IRB requirements; (ii) unanticipated problems involving risks to subjects or others in any covered research; and (iii) suspension or termination of IEC/IRB approval for US-supported research.

9. The institution should obtain the concurrence of the supporting US Agency prior to the involvement of pregnant women, prisoners, children, or fetuses in US-supported research.

10. The Institutional Signatory Official and the Institutional Human Subject Protection Administrator should complete appropriate education and training related to the protection of human subjects. The IEC/IRB Chairperson, members, and staff should complete appropriate education and training before reviewing human subject research. Research investigators should complete appropriate education and training before conducting human subject research. Educational modules available on the OHRP website may be used for such training, or the institution may utilize other appropriate educational materials of its own choosing.

11. The institution and the designated IEC/IRB should establish adequate education and oversight mechanisms (appropriate to the nature and volume of the research being conducted) to verify that its research investigators, IEC/IRB members and staff, and other relevant personnel maintain continuing knowledge of, and comply with, relevant policies and procedures for the protection of human subjects. The institution should require documentation of such training from research investigators as a condition for conducting US-supported human subject research.

12. The institution should provide IECs/IRBs that it operates with resources, professional staff, and support staff sufficient to carry out their responsibilities efficiently and effectively.

13. The institution accepts and will follow items (1) through (12) above and is responsible for ensuring that the IEC/IRB designated under the Assurance also follows them.

INTERNATIONAL INSTITUTIONS ACCEPTING THESE TERMS

MAY PROCEED WITH THE ASSURANCE PROCESS

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