

# U. S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP)

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## FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS

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

#### 1. **Human Subject Research Must be Guided by Ethical Principles**

All of the Institution's human subject activities and all activities of the Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by the ethical principles in: (a) 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, or (b) other appropriate ethical standards recognized by Federal Departments and Agencies that have adopted the Federal Policy for the Protection of Human Subjects.

#### 2. **Applicability**

These terms apply whenever the Institution becomes engaged in federally-supported\* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects. The Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of federally-supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects 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.

[\*Federally-supported is defined throughout the FWA and the Terms of Assurance 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

Institutions conducting federally-supported human subject research and the IRB(s) designated under the Institution's 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 subject 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 123	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 Energy
By Executive Order	Central Intelligence Agency
By Statue	Social Security Administration

### 4. Written Procedures

a) The Institution should establish, and should provide a copy to OHRP upon request, written procedures for:

- 1) ensuring prompt reporting to the IRB, appropriate 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, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

2) Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the Common Rule;

b) The designated IRB(s) has 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 human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s). The IRB(s) 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, 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 Institution is responsible for ensuring 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 engagement in human research activities of each independent investigators who is not an employee or agent of the Institution 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. OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the Institution may develop its own commitment agreement. Institutions must maintain commitment agreements on file and provide copies to OHRP upon request.

## **9. Institutional Support for the IRB(s)**

The Institution will provide the IRB(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively.

## **10. Compliance with the Terms of Assurance**

The Institution accepts and will follow items 1-9 above and is responsible for ensuring that (a) the IRB(s) designated under the Assurance agree to comply with these terms; and (b) the IRB(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP guidance on IRB Knowledge of Local Research Context on the OHRP website).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request.

## **11. Assurance Training**

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator, and the IRB Chair(s) that must be fulfilled under the Assurance. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these modules, prior to submitting the Assurance.

## 12. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject 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. Failure to update this information may result in restriction, suspension, or termination of the Institution's FWA for the protection of human subjects.

## **DOMESTIC INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS**

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## **B. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INTERNATIONAL (NON-U.S.) INSTITUTIONS**

### **1. Human Subject Research Must Be Guided by Ethical Principles**

All of the Institution's human subject activities and all activities of the Institutional Review Boards (IRBs) or independent ethics committees (IECs) designated under the Assurance, regardless of funding source, will be guided by one of the following statements of ethical principles: (a) The World Medical Association's Declaration of Helsinki (as adopted in 1996 or 2000); (b) 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 (c) other appropriate international ethical standards recognized by Federal Departments and Agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects.

### **2. Applicability**

These terms apply whenever the Institution becomes engaged in U.S. federally-supported\* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the U.S. Federal Policy for the Protection of Human Subjects. The Institution becomes engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of U.S. federally-supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of U.S. federally-supported research; or (c) the Institution receives a direct award to conduct U.S. federally-supported human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

If a U.S. Department or Agency Head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided by the U.S. Federal Policy, 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 101(h) of the U.S. Federal Policy.

[\*Federally-supported is defined throughout the Assurance document and the Terms of Assurance 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 Regulations, Policies, or Guidelines**

All U.S. federally-supported human subject research will comply with the requirements of any applicable U.S. Federal regulatory agency as well as one or more of the following:

a) The U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule (e.g., Subpart A) or the U.S. Department of Health and Human Services (DHHS) regulations at 45 CFR 46 and its Subparts A, B, C, and D;

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 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.

#### 4. **IRB/IEC Written Procedures**

a) The Institution should establish, and should provide a copy to OHRP upon request, written procedures for:

1) ensuring prompt reporting to the IRB/IEC, appropriate 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, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

2) Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the U.S. Common Rule;

b) The designated IRB(s)/IEC(s) should establish, and should provide a copy to OHRP upon request, written procedures for:

1) Conducting IRB/IEC initial and continuing review (not less than once per year), approving research, and reporting IRB/IEC 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/IEC review;

3) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB/IEC review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

#### 5. **Responsibilities and Scope of IRB(s)/IEC(s)**

Except for research exempted or waived in accordance with sections 101(b) or 101(i) of the U.S. Common Rule, U.S. federally-supported research should be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s)/IEC(s). The IRB(s)/IEC(s) should 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 U.S. Common Rule, informed consent should 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 U.S. Common Rule;

b) appropriately documented, in accordance with, and to the extent required by Section 117 of the U.S. Common Rule.

## **7. Considerations for Special Class of Subjects**

For DHHS-supported human subject research, this Institution will comply with 45 CFR 46 Subparts B, C, and D prior to the involvement of pregnant women or fetuses, prisoners, or children, respectively. For non-DHHS U.S. federally-supported human subject research, the Institution will comply with any human subject regulations and/or policies of the supporting Department or Agency for these classes of subjects.

## **8. Requirement for Assurances for Collaborating Institutions/Investigators**

The Institution is responsible for ensuring 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.

## **9. Written Agreements with Non-Affiliated Investigators**

The engagement in human research activities of each independent investigator who is not an employee or agent of the Institution 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. OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the Institution may develop its own commitment agreement. Institutions must maintain commitment agreements on file and provide copies to OHRP upon request.

## **10. Institutional Support for the IRB(s)/IEC(s)**

The Institution should provide the IRB(s)/IEC(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively.

## **11. IRB(s)/IEC(s) Compliance with the Terms of Assurance**

The Institution accepts and will follow items 1-10 above and is responsible for ensuring that (a) the IRB(s)/IEC(s) designated under the Assurance agree to comply with these terms, and (b) the IRB(s)/IEC(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP posted guidance on IRB Knowledge of Local Research Context).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be

documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request.

## **12. Assurance Training**

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator and the IRB Chair(s) that must be fulfilled under the Assurance. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB/IEC Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these Modules, prior to submitting the Assurance.

## **13. Educational Training**

OHRP strongly recommends that the Institution and the designated IRB(s)/IEC(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB/IEC members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant U.S. regulations; procedural standards under the Assurance; OHRP guidance; other applicable guidance; national, state and local laws; and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB/IEC members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

## **14. Renewal of Assurance**

All information provided under this Assurance should be updated every 36 months (3 years), 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 for the protection of human subjects.

**INTERNATIONAL INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS**

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