

# **FEDERAL WIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS**

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

### **A. TERMS OF THE FEDERAL WIDE ASSURANCE (FWA) FOR INSTITUTIONS WITHIN THE UNITED STATES**

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

All of the Institution's human subjects research activities, regardless of whether the research is subject to federal regulations, 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, known as the Common Rule.

#### **2. Applicability**

These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported\* by any 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 department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. In general, the Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of federally-conducted or –supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of federally-conducted or –supported research; or (c) the Institution receives a direct federal award to conduct human subjects 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.]

#### **3. Compliance with the Federal Policy for the Protection of Human Subjects and Other Applicable Federal, State, Local, or Institutional Laws, Regulations, and Policies**

When the Institution becomes engaged in federally-conducted or -supported human subjects research to which the FWA applies, the Institution and the institutional review boards (IRBs) designated under the Institution's Assurance will comply with the Federal Policy for the Protection of Human Subjects.

The reference in the Code of Federal Regulations is shown below for each 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 part 1230	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	Department of Health and Human Services
45 CFR part 46 (by Executive Order 12333)	Central Intelligence Agency
45 CFR part 690	National Science Foundation
49 CFR part 11	Department of Transportation

For any federally-conducted or -supported human subjects research to which the FWA applies, the Institution also will comply with any additional human subjects regulations and policies of the 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 human subjects research conducted or supported by the Department of Health and Human Services (HHS), the Institution will comply with all subparts of the HHS regulations at Title 45 Code of Federal Regulations part 46 (45 CFR part 46, subparts A, B, C, and D).

Human subjects research conducted or supported by each federal department or agency listed above will be governed by the regulations as implemented by the respective department or agency. The head of the 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 other applicable federal regulations, the Institution should contact appropriate officials at the department or agency conducting or supporting the research. For federally-conducted or –supported research covered by the FWA, the 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 human subjects research that is covered by the FWA and is conducted or supported solely by a Common Rule department or agency other than HHS, HHS will refer the matter to the other department or agency for review and action as appropriate.

Please note that if the Institution voluntarily extends the Common Rule or the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46 to all research regardless of support, OHRP will have the authority to ensure that the Institution complies with this commitment for all research to which the FWA applies that is not federally-conducted or –supported.

#### **4. Written Procedures\***

a) The Institution submitting the FWA has written procedures\* for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any department or agency conducting or supporting the research (or designee), 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 the requirements or determinations of the IRB(s); and
- 3) suspension or termination of IRB approval.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

b) The Institution must ensure that the IRB(s) designated under the FWA 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.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

[\*For HHS-conducted or -supported human subjects research, see [OHRP guidance on written IRB procedures](http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm>.]

## **5. Scope of IRB(s)'s Responsibilities**

All human subjects research to which the FWA applies, except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, will be reviewed, prospectively approved, and subject to continuing 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 subjects research. For research approved by the IRB(s), further appropriate review and approval by any department or agency conducting or supporting the research or by officials of the institution holding the FWA may be required.

## **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 for research to which the FWA applies 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; and
- 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**

When the Institution holding the FWA is either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.

An institution holding an FWA may collaborate with another institution that does not have an FWA. In such circumstances, a collaborating institution may operate under the FWA with the approval of the department or agency conducting or supporting the research and the institution holding the FWA.

For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining which institutions are engaged in the research and need to hold an assurance for the protection of human subjects.

## **8. Written Agreements with Independent Investigators Who are not Otherwise Affiliated with the Institution**

When the Institution holding the FWA is either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating independent investigators engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.

The engagement in federally-conducted or –supported human subjects research activities to which the FWA applies by each independent investigator who is not otherwise 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 review. OHRP’s sample [Individual Investigator Agreement](http://www.hhs.gov/ohrp/humansubjects/assurance/unafisup.rtf) (see <http://www.hhs.gov/ohrp/humansubjects/assurance/unafisup.rtf>) may be used or adapted for this purpose, or the Institution may develop its own commitment agreement in coordination with the department or agency conducting or supporting the research. Institutions must maintain commitment agreements on file and provide copies upon request to OHRP and any department or agency conducting or supporting the research.

For federally-conducted or –supported research covered by the FWA, the department or agency that conducts or supports the research retains final authority for determining which independent investigators are engaged in the research and need to be covered by a written commitment agreement with the institution holding the FWA.

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

The Institution will ensure that each IRB designated under the FWA has meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.

## **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 FWA agree to comply with these terms; and (b) the IRB(s) possess appropriate knowledge of the local research context for all research to which the FWA applies (please refer to the [OHRP Guidance on IRB Knowledge of Local Research Context](http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm>).

Any designation under the FWA of the IRB of another institution or organization must be documented by a written agreement between the Institution holding the FWA and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of the FWA. OHRP’s sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. This agreement should be kept on file at both institutions/organizations and made available upon request to OHRP and any department or agency conducting or supporting research covered by the FWA.

## **11. Assurance Training**

The [OHRP Assurance Training Modules](http://137.187.172.153/CBTs/Assurance/login.asp) (see <http://137.187.172.153/CBTs/Assurance/login.asp>) describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) that must be fulfilled under the FWA. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator, 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 FWA.

## **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, the following: relevant ethical principles; relevant federal regulations; written IRB procedures; 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 subjects research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research.

## **13. Renewal of Assurance**

All information provided under the FWA must be renewed or updated at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active FWA. 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 Subjects Research Must Be Guided by Ethical Principles**

All of the Institution's human subjects research activities, regardless of whether the research is subject to U.S. federal regulations, 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 U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.

## **2. Applicability**

These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported\* by any U.S. 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. In general, the Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of U.S. federally-conducted or –supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of U.S. federally-conducted or –supported research; or (c) the Institution receives a direct award to conduct U.S. federally-supported human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

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 U.S. Federal Policy for the Protection of Human Subjects, 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 U.S. Federal Policy for the Protection of Human Subjects.

[\*Federally-supported is defined throughout the Assurance document and the Terms of Assurance as the U.S. Government providing any funding or other support.]

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

When the Institution becomes engaged in U.S. federally-conducted or –supported human subjects research to which the FWA applies, the Institution and institutional review boards (IRBs) or independent ethics committees (IECs) designated under the FWA at a minimum will comply with one or more of the following:

- a) The U.S. Federal Policy for the Protection of Human Subjects (see section 3 of the Terms of the FWA for Institutions within the United States for a list of U.S. federal departments and agencies that have adopted the Common Rule);
- b) The Common Rule and subparts B, C, and D of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46;
- c) The U.S. Food and Drug Administration (FDA) regulations at 21 CFR parts 50 and 56;
- d) The May 1, 1996, International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6), Sections 1 through 4;

- e) The 1993 Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects;
- f) The 1998 Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans;
- g) The 2000 Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or
- h) 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.

All U.S. federally-conducted or -supported human subjects research to which the FWA applies will also comply with any additional human subjects regulations and policies of the U.S. federal department or agency which conducts or supports the research and any other applicable U.S. federal, international, state, local, or institutional laws, regulations, and policies.

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 human subjects research that is covered by the FWA and is conducted or supported solely by a Common Rule 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. IRB/IEC Written Procedures\***

a) The Institution submitting the FWA has established written procedures\* for ensuring prompt reporting to the IRB/IEC, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research (or designee), any applicable regulatory body, 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)/IEC(s); and
- 3) suspension or termination of IRB/IEC approval.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.



b) The Institution must ensure that the IRB(s)/IEC(s) designated under the FWA has established written procedures\* for:

- 1) conducting IRB/IEC initial and continuing review (not less than once per year), of 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; and
- 3) ensuring prompt reporting to the IRB/IEC of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB/IEC approval has already been given, may not be initiated without IRB/IEC review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

Upon request, the Institution will provide a copy of these written procedures to OHRP and any department or agency conducting or supporting research covered by the FWA.

[\*For HHS-conducted or -supported human subjects research, see [OHRP guidance on written IRB procedures](http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm>.]

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

All U.S. federally-conducted or -supported research to which the FWA applies, except for research exempted or waived in accordance with sections 101(b) or 101(i) of the U.S. Common Rule, will be reviewed, prospectively approved, and subject to continuing review at least annually by the designated IRB(s)/IEC(s). The IRB(s)/IEC(s) shall have authority to approve, require modifications in, or disapprove the covered human subjects research. For research approved by the IRB(s)/IEC(s), further appropriate review and approval by any U.S. federal department or agency conducting or supporting the research or by officials of the institution holding the FWA may be required.

## **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 for research to which the FWA applies 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 U.S. Common Rule; and
- 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 HHS-conducted or supported human subjects research, the Institution will comply with the HHS regulations at 45 CFR part 46, subparts B, C, and D, prior to the involvement of

pregnant women, fetuses, or neonates; prisoners; or children, respectively. For non-HHS U.S. federally-supported human subjects research, the Institution will comply with any human subject regulations and/or policies of the supporting U.S. federal department or agency for these classes of subjects.

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

When the Institution holding the FWA is either a) the primary awardee under a U.S. federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for U.S. federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other U.S. federally-approved assurance for the protection of human subjects.

An institution holding an FWA may collaborate with another institution that does not have an FWA. In such circumstances, a collaborating institution may operate under the FWA with the approval of the U.S. federal department or agency conducting or supporting the research and the institution holding the FWA.

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 which institutions are engaged in the research and need to hold an assurance for the protection of human subjects.

## **9. Written Agreements with Independent Investigators Who are not Otherwise Affiliated with the Institution**

When the Institution holding the FWA is either a) the primary awardee under a U.S. federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for U.S. federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating independent investigators engaged in such research operate under an appropriate OHRP-approved or other U.S. federally-approved assurance for the protection of human subjects.

The engagement in U.S. federally-conducted or –supported human subjects research activities to which the FWA applies by each independent investigator who is not otherwise 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/IEC review. OHRP's sample [Individual Investigator Agreement](http://www.hhs.gov/ohrp/humansubjects/assurance/unafisup.rtf) (see <http://www.hhs.gov/ohrp/humansubjects/assurance/unafisup.rtf>) may be used or adapted for this purpose, or the Institution may develop its own commitment agreement in coordination with the U.S. federal department or agency conducting or supporting the research. Institutions should maintain commitment agreements on file and provide copies upon request to OHRP or any 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 which independent investigators are engaged in the research and need to be covered by a written commitment agreement with the institution holding the FWA.

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

The Institution will ensure that each IRB(s)/IEC(s) designated under the FWA has meeting space and sufficient staff to support the IRB's/IEC's review and recordkeeping duties.

## **11. 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 FWA agree to comply with these terms, and (b) the IRB(s)/IEC(s) possess appropriate knowledge of the local research context for all research to which the FWA applies (please refer to the [OHRP Guidance on IRB Knowledge of Local Research Context](http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm>).

Any designation under the FWA of the IRB/IEC or another institution or organization should be documented by a written agreement between the Institution holding the FWA and the IRB/IEC organization outlining their relationship and include a commitment that the designated IRB/IEC will adhere to the requirements of the FWA. OHRP's sample IRB Authorization Agreement may be used for such purpose, or the parties involved may develop their own agreement. This agreement should be kept on file at both institutions/organizations and made available upon request to OHRP and any U.S. federal department or agency conducting or supporting research covered by the FWA.

## **12. Assurance Training**

The [OHRP Assurance Training Modules](http://137.187.172.153/CBTs/Assurance/login.asp) (see <http://137.187.172.153/CBTs/Assurance/login.asp>) describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB/IEC Chair(s) that must be fulfilled under the FWA. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator, 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 FWA.

## **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 the following: relevant ethical principles; relevant U.S. regulations; written IRB/IEC procedures; 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 subjects research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research.

## 14. Renewal of Assurance

All information provided under the FWA should be renewed or updated every 36 months (3 years), even if no changes have occurred, in order to maintain an active FWA. Failure to update this information may result in restriction, suspension, or termination of the Institution's FWA for the protection of human subjects.

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

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