OHRP FWA Frequently Asked Questions (FAQs)

Question 1: What compliance assurance process for human subject protection is accepted by the Office for Human Research Protections (OHRP) and other Federal agencies?

Answer: HHS human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to OHRP. The Federalwide Assurance (FWA) is the only type of new assurance accepted and approved by OHRP. FWAs also are approved by the Office for Human Research Protections (OHRP) for federalwide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support. Institutions engaging in research conducted or supported by non-HHS federal departments or agencies should consult with the sponsoring department or agency for guidance regarding whether the FWA is appropriate for the research in question.

You may wish to view the following related questions:

What is an assurance of compliance with human subject protection regulations?

When is an institution considered to be engaged in research?

When do collaborating institutions need to obtain a Federalwide Assurance (FWA)?

Question 2: What is an assurance of compliance with human subject protection regulations?

Answer: An assurance of compliance is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46. The Federalwide Assurance is the only type of new assurance accepted and approved by OHRP.

Question 3: When does a research institution need to be covered by an assurance of compliance with human subjects research protections?

Answer: All institutions engaged in human subjects research that is not exempt from the regulations, and is conducted or supported by any HHS agency must be covered by an Office for Human Research Protections-approved assurance of compliance (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm). The

Federalwide Assurance (FWA) is the only new type of assurance accepted and approved by OHRP.

An institution may extend its FWA to cover a collaborating individual investigator under certain conditions using the sample Individual Investigator Agreement or a comparable agreement developed by the institution.

Question 4: When is an institution considered to be "engaged in research"?

Answer: In general, an institution is considered to be engaged in human subjects research when its employees or agents:

> (1) obtain data about living individuals for research purposes through intervention or interaction with them, or
>
> (2) obtain individually identifiable private information for research purposes (45 CFR 46.102(d),(f))
> http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

In general, an institution is considered to be engaged in human subjects research whenever it receives a direct HHS award to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution. For example, when the direct awardee institution subcontracts all human subjects activities to another institution the direct awardee institution would still be considered engaged in the research. In such cases, the awardee institution bears the ultimate responsibility for protecting subjects involved in the research conducted under the award. In general, simply informing potential subjects about a research study is not considered engagement in research. Also, providing written information about a research study, including how to contact the investigators for information and enrollment, and seeking and obtaining prospective subjects' permission for investigators to contact them are not considered engagement in research. However, seeking or obtaining informed consent from a research participant is considered engagement in research.

[For details, please see OHRP guidance on this topic at http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm; specifically, Section (B)(3).]

Question 5: What is a Federalwide Assurance (FWA)?

Answer: The Federalwide Assurance (FWA) is the only type of new assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements

set forth in 45 CFR part 46, as well as the Terms of Assurance.

FWAs also are approved by OHRP for federalwide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support. Institutions engaging in research conducted or supported by non-HHS federal departments or agencies should consult with the sponsoring department or agency for guidance regarding whether the FWA is appropriate for the research in question. There are two versions of the FWA and the Terms of Assurance, one of each for domestic (U.S.) institutions and for international (non-U.S.) institutions.

You may wish to view the following related questions and answers:

What research does the Federalwide Assurance (FWA) cover?

What time period does the FWA cover and when does it have to be updated?

Question 6: What research does the Federalwide Assurance (FWA) cover?

Answer: The FWA covers all non-exempt human subjects research at the submitting institution that is HHS-conducted or -supported or funded by any other federal department or agency that has adopted the Common Rule and relies upon the FWA. It is not project specific. Domestic institutions may voluntarily extend their FWA to cover all human subjects research at the submitting institution regardless of the source of support for the particular research activity.

Question 7: What time period does the Federalwide Assurance (FWA) cover and when does it have to be updated?

Answer: The Federalwide Assurance (FWA) is effective for 3 years and must be renewed at the end of that period of time in order to remain effective. If the information on record with OHRP for the FWA needs to be altered, those alterations should be submitted within 90 days of the change. All updates of the FWA using the electronic submission system automatically renews the FWA for another 3 years. Complete updates (the FWA is fully completed) submitted in hard copy renew an FWA for another 3 years, while limited updates (the FWA is partially completed) submitted in hard copy will not alter the FWA expiration date. For more information you may want to visit http://www.hhs.gov/ohrp/humansubjects/assurance/renwirb.htm.

Question 8: What are the key features of the Federalwide Assurance (FWA) for domestic (U.S.) institutions?

Answer: The key features of the Federalwide Assurance (FWA) for domestic (U.S.) institutions are the following:

a) the identifying information for the institution filing the FWA, the Human Protections Administrator (or a reliable point of contact) at the

institution, and the institutional official signing the FWA;

b) a list of the institution's legal components where human subjects research will be conducted (legal components are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the legal entity or institution, for example, ABC University can list its XYZ University Hospital, KLM School of Public Health, and EFG Institute for International Studies as components);

c) a statement of ethical principles to be followed in protecting human subjects of research;

d) an applicability statement indicating that the institution commits to comply with the Terms of the FWA for Institutions within the United States (see section A of the Terms of the FWA at http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm) for all federally conducted or supported human subjects research covered by the FWA; the institution also may voluntarily extend the Common Rule or 45 CFR part 46 to all research regardless of the source of support;

e) the designation of one or more IRBs that will review the research covered by the FWA (these IRBs must be registered [http://www.hhs.gov/ohrp/assurances/index.html#registernew] with OHRP before the FWA can be approved); and

f) the signature of an official authorized to represent the institution.

The FWA is signed by a high-level individual within the institution, for example, the Chief Executive Officer, Chief Operating Officer, President, or Chancellor, committing the institution to abide by the Terms of Assurance whenever it is engaged in human subjects research covered by the assurance. This person is considered to be the "signatory official" for the purposes of the FWA.

Question 9: What are the key features of the Federalwide Assurance (FWA) for international (non-U.S.) institutions?

Answer: The key features of the FWA for international (non-U.S.) institutions are the following:

a) the identifying information for the institution filing the FWA, the Human Protections Administrator (or a reliable point of contact) at the institution, and the institutional official signing the FWA;

b) a list of the institution's legal components where human subjects research will be conducted (legal components are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the legal entity or institution, for example, ABC University can list its XYZ University Hospital, KLM School of Public Health, and

EFG Institute for International Studies as components);

c) a statement of ethical principles to be followed in protecting human subjects of research;

d) an applicability statement indicating that the institution commits to comply with the Terms of the FWA for International (non-U.S.) Institutions (see section B of the Terms of the FWA at http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm#sectionb) and one or more procedural standards (see section 4 of the FWA for international institutions at http://www.hhs.gov/ohrp/assurances/assurances_index.html#international for a list of the procedural standards) for all U.S. federally conducted or supported research covered by the FWA;

e) the designation of one or more IRBs that will review the research covered by the FWA (these IRBs must be registered [http://www.hhs.gov/ohrp/assurances/index.html#registernew] with OHRP before the FWA can be approved); and

f) the signature of an official authorized to represent the institution.

The FWA is signed by a high-level individual within the institution, for example, the Chief Executive Officer, Chief Operating Officer, President, Director General, or Chancellor, committing the institution to abide by the Terms of Assurance whenever it is engaged in human subjects research conducted or supported by HHS. This person is considered to be the "signatory official" for the purposes of the FWA.

Question 10: Do international institutions seeking a Federalwide Assurance (FWA) have to comply with 45 CFR part 46?

Answer: OHRP is sometimes asked if, when an international institution selects a procedural standard under section 4.b of the FWA for International (non-U.S.) Institutions that has less stringent requirements than 45 CFR part 46, can the institution disregard the more stringent requirements of 45 CFR part 46?

It is current OHRP policy that in the absence of a determination of equivalent protections provided by a procedural standard other than 45 CFR part 46, the requirements of 45 CFR part 46 must be applied to research conducted or supported by HHS. Section 3 of the Terms of the FWA for International (Non-U.S.) Institutions (see section B of the document) state that 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 conducting or supporting the research and any other applicable U.S. federal, international, state, local, or institutional laws, regulations, and policies. It is OHRP's position that if an international institution selects a procedural standard under its FWA other than 45 CFR part 46, any

requirements of 45 CFR part 46 not stipulated by the selected procedural standard still must be satisfied for non-exempt human subject research that is conducted or supported by HHS.

For example, the International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6) do not specifically limit use of expedited review for research undergoing continuing review by the IRB. For research conducted or supported by HHS, if an international institution selected ICH-GCP-E6 as its primary procedural standard under section 4.b of its FWA, the IRB may only use an expedited review procedure to conduct continuing review of HHS-conducted or supported research if the research qualifies for expedited review as provided for under HHS regulations at 45 CFR 46.110.

Other U.S. federal departments or agencies may permit deviations from their regulations for research that they conduct or support that is covered by an FWA for international institutions. 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.

Question 11: Are there options other than the Federalwide Assurance (FWA) for HHS-conducted or -supported research?

Answer: No. In January 2005, the Office of Management and Budget approved the Federalwide Assurance (FWA) forms and related documents and the IRB or independent ethics committee (IEC) registration form. At that time, OHRP announced that the FWA will be the only new type of assurance accepted for review and approval by OHRP. Institutions holding an OHRP-approved Multiple Project Assurance (MPA) or Cooperative Project Assurance (CPA) are required to submit an FWA to OHRP for approval by December 31, 2005, if the institution is required to have an OHRP-approved assurance of compliance. Any Inter-Institutional Amendment between an OHRP-approved MPA and an affiliate institution will be deactivated on January 1, 2006 if the affiliate institution has not obtained its own FWA. Single Project Assurances (SPA) currently approved by OHRP will remain in effect for the duration of the project and through all non-competitive award renewals.

Question 12: Who is covered by a Federalwide Assurance (FWA)?

Answer: Employees and agents of the institution holding an approved FWA are covered whenever they are involved in the conduct of research covered by the FWA. Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

An institution holding an OHRP-approved FWA (hereafter referred to as the assured institution) may extend the applicability of its FWA to cover two types of collaborating individual investigators: collaborating independent investigators

and collaborating institutional investigators.

1. A collaborating independent investigator is:

    a. not otherwise an employee or agent of the assured institution;

    b. conducting collaborative research activities outside the facilities of the assured institution; and

    c. not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

2. A collaborating institutional investigator is:

    a. not otherwise an employee or agent of the assured institution;

    b. conducting collaborative research activities outside the facilities of the assured institution;

    c. acting as an employee or agent of an institution that does not hold an OHRP-approved FWA with respect to his or her involvement in the research being conducted by the assured institution; and employed by, or acting as an agent of, an institution that does not hold an OHRP-approved FWA and does not routinely conduct human subjects research.

The extension of an assured institution's FWA to cover a collaborating individual investigator should be documented using an Individual Investigator Agreement (IIA) or another similar agreement developed by the institution holding the FWA (see http://www.hhs.gov/ohrp/humansubjects/assurance/guidanceonalternativetofwa.htm for OHRP's guidance on the use of the IIA and the link to the sample IIA document).

If HHS-conducted or -supported human subjects research activities routinely occur at a non-assured institution, the institution should obtain an OHRP-approved FWA, and the IIA (or similar agreements) should not be used. Also, if the non-assured institution is the primary awardee for an HHS-supported award providing support for non-exempt human subjects research, the institution must obtain its own OHRP-approved FWA. If an institution is uncertain about the need for its own FWA, it should consult with OHRP.

NOTE: All previous types of sample agreements to cover an independent investigator—i.e., Agreement for Independent Investigators (AII), Non-Institutional Investigator Agreement (NIA), and Unaffiliated Investigator Agreement (UIA)—have been replaced by the sample Individual Investigator

Agreement (IIA). Previously executed AIIs, NIAs, and UIAs may remain in effect until all applicable research that has already been initiated is completed or until the previous agreement has been replaced by a new Individual Investigator Agreement modeled on the OHRP sample IIA, or by a comparable written agreement developed by an assured institution.

Question 13: What are the procedures for submitting a Federalwide Assurance (FWA)?

Answer: To expedite the review and approval of a Federalwide Assurance (FWA), as well as any update/renewal you may submit in the future, you should use the Office for Human Research Protections (OHRP) Electronic Submission System. Once an electronic file is "submitted" to OHRP, you must fax OR mail (please do not do both) a copy of the signature page to initiate the review process. You may also complete the FWA in hard copy and fax OR mail (please do not do both) it to OHRP. The instructions on both of these procedures may be found at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

The FWA application will only be considered complete by OHRP when it is completed in its entirety, signed by the Signatory Official, and dated. Additionally, the IRB/IEC(s) designated on the FWA must be registered with OHRP before the FWA can be approved.

You may also wish to view the following questions and answers:

Who may sign as the Signatory Official on a Federalwide Assurance (FWA)?

Where can I find the instructions and forms for submitting a Federalwide Assurance (FWA)?

Who can I contact with questions about submitting a Federalwide Assurance (FWA)?

How can I track OHRP's receipt of my Federalwide Assurance (FWA) submission?

How will I know when my institution's Federalwide Assurance is approved?

Question 14: Who may sign as the Signatory Official on a Federalwide Assurance (FWA)?

Answer: The FWA Signatory Official should be a high-level institutional official who has the authority to represent the institution named in the Federalwide Assurance (FWA), as well as all the institutional components listed in the FWA. Entities that the Signatory Official is not authorized to represent may not be covered under the FWA. This person is usually the President, Chancellor, Director General, Chief Executive Officer, or Chief Operating Officer. The intent in requiring that the Signatory Official be a high-level individual is two-fold. First, OHRP encourages institutions to promote a culture of conscience for the ethical conduct of human subjects research at the highest level within the institution. Second, the Signatory Official should be at a level of responsibility that would allow authorization of

necessary administrative or legal action should that be required. Finally the Signatory Official cannot be the chair or member of any IRB designated under the FWA.

Question 15: Where can I find the instructions and forms for submitting a Federalwide Assurance (FWA)?

Answer: Links to the instructions and the forms for submitting both a domestic and international FWA may be found on the OHRP website at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

Question 16: Who can I contact with questions about submitting a Federalwide Assurance (FWA)?

Answer: If you have questions about submitting an FWA, you should contact the Assurance Coordinator assigned to your state or international region (see the OHRP website at http://www.hhs.gov/ohrp/daqi-staff.html#staff).

Question 17: How can I track Office for Human Research Protection's (OHRP) receipt of my Federalwide Assurance (FWA) submission?

Answer: You may track the receipt of an FWA on the Office for Human Research Protections website at http://ohrp.cit.nih.gov/search/loggry.asp. Here you will find information about when the FWA was received, as well as which Assurance Coordinator is reviewing it and how to contact that person.

Question 18: How will I know when my institution's Federalwide Assurance (FWA) is approved?

Answer: If the Federalwide Assurance (FWA) (both new and updates/renewals) is submitted electronically, the submitter, the Human Protections Administrator, and the Signatory Official will receive an automatically generated e-mail informing them of the approval of the FWA immediately upon approval. Of course, this is dependent upon e-mail addresses being provided in the FWA. If the FWA (both new and updates/renewals) is submitted in hard copy, the institution will have to monitor the Office for Human Research Protections (OHRP) website for evidence of approval or contact OHRP. Institutions holding OHRP-approved FWAs are listed on the OHRP website at http://ohrp.cit.nih.gov/search/asearch.asp#ASUR.

Question 19: How will the Office for Human Research Protections (OHRP) respond to queries from an FWA institution about human subjects research conducted or supported by a non-HHS department or agency?

Answer: When the Office for Human Research Protections (OHRP) receives a request from an FWA institution for guidance regarding implementation of the Common Rule for human subjects research conducted or supported by another department or agency that has adopted the Common Rule, OHRP will direct the requestor to contact appropriate officials at the other department or agency. When the requestor seeking guidance regarding a specific research project does not identify the conducting or supporting department or agency, OHRP will qualify its response with a statement that if the research is supported by another department or agency the requestor should also consult with appropriate officials at the supporting department or agency. If the requestor at the FWA institution and

appropriate officials at the conducting or supporting department or agency mutually agree to seek OHRP input on the matter, OHRP staff will be available to provide guidance.

Question 20: When do institutions collaborating in non-HHS research need to obtain a Federalwide Assurance (FWA)?

Answer: If human subjects research conducted or supported by a non-HHS Common Rule department or agency involves collaborating institutions that do not hold an FWA or other applicable OHRP-approved assurance for federalwide use, OHRP does not require the collaborating institutions to obtain FWAs, but an FWA may be required by the non-HHS department or agency conducting or supporting the human subjects research.

For such situations, while obtaining an FWA would be one option for the collaborating institutions to comply with the assurance requirement of the Common Rule §__.103(a) [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103], obtaining an FWA would not be required by HHS. When requests for guidance on this topic are received by OHRP, OHRP will refer the requestor to appropriate officials at the conducting or supporting Common Rule department or agency for assistance in deciding on an appropriate assurance mechanism.

Question 21: Will the Office for Human Research Protections forward reports received from FWA institutions to non-HHS federal funding agencies or departments?

Answer: The Office for Human Researh Protections (OHRP) receives reports from institutions holding a Federalwide Assurance (FWA) of:

(i) unanticipated problems involving risks to subjects or others;

(ii) serious or continuing noncompliance with the Common Rule or the requirements or determinations of the IRB; or

(iii) suspension or termination of IRB approval.

If the human subjects research is conducted or supported by a Common Rule department or agency other than HHS, OHRP will not forward the report(s) to that other agency. However, OHRP will remind the FWA institution in writing of the institution's responsibility to notify the conducting or supporting department or agency head in accordance with the requirements of §46.103(b)(5) [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103] of the Common Rule.

Question 22: How does the Office for Human Research Protections (OHRP) handle allegations or indications of noncompliance when the research is not HHS-supported or conducted?

Answer: When the allegations or indications of noncompliance are limited solely to the research activities conducted or supported by another Common Rule department

or agency, for Human Research Protections (OHRP) will refer the matter to appropriate officials at the other department or agency for further investigation and action, as appropriate. OHRP's Division of Compliance Oversight (DCO) will not be involved in the conduct of the investigation unless the relevant department or agency requests OHRP's involvement. When the other department or agency completes its investigation without OHRP involvement, a report on the outcome of the investigation should be provided to OHRP.

Question 23: How does 45 CFR part 46 relate to the human subjects regulations used by non-HHS federal funding agencies?

Answer: The current U.S. system of protection for human research subjects is heavily influenced by the Belmont Report, written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, HHS and FDA revised and made as compatible as possible—under their respective statutory authorities—their existing human subjects regulations. With leadership from HHS, the Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies, as listed below (each agency includes in its chapter of the Code of Federal Regulations [CFR] section numbers and language that are identical to those of 45 CFR part 46, subpart A).

- Department of Agriculture (7 CFR part 1c)
- Department of Commerce (15 CFR part 27)
- Department of Defense (32 CFR part 219)
- Department of Education (34 CFR part 97)
- Department of Energy (10 CFR part 745)
- Department of Health and Human Services (45 CFR part 46 subpart A)
- Department of Housing and Urban Development (24 CFR part 60)
- Department of Justice (28 CFR part 46)
- Department of Veterans Affairs (38 CFR part 16)
- Department of Transportation (49 CFR part 11)
- Consumer Product Safety Commission (16 CFR part 1028)
- Environmental Protection Agency (40 CFR part 26)
- Agency for International Development (22 CFR part 225)
- National Aeronautics and Space Administration (14 CFR part 1230)
- National Science Foundation (45 CFR part 690)

In addition, the Central Intelligence Agency must comply with all subparts of 45 CFR part 46 under Executive Order 12333.

For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. HHS has developed additional regulations for the human subjects research it conducts or supports that apply to particular special populations: 45 CFR part 46 subparts B-D apply to research involving pregnant women, human fetuses, and

neonates (subpart B), prisoners (subpart C), and children (subpart D).

Several non-HHS federal departments and agencies have additional regulations in place for research involving special populations or for human subjects research in general.

Question 24: Do the human research regulations apply to non-U.S. institutions?

Answer: Yes, whenever non-U.S. institutions are engaged in non-exempt HHS-supported or –conducted human subjects research, the regulations apply. Please see: http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm#sectionb .