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# Office for Human Research Protections

## Step-by-Step Instructions for Filing a Federalwide Assurance

The Federalwide Assurance (FWA) is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS). The FWA is also approved by OHRP for federalwide use, which means that other U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects (also know as the Common Rule) may rely upon the FWA for the research they conduct or support.

A FWA is the only type of assurance currently accepted and approved by OHRP. It is required whenever an Institution becomes engaged in human subjects research conducted or supported by any U.S. 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 U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. For guidance on the meaning of "engaged" see OHRP's guidance at http://www.hhs.gov/ohrp/policy/engage08.html

Each institution must complete and submit its FWA(s) (new submissions, updates, and renewals) using the electronic submission system available through the OHRP Web site at http://ohrp.cit.nih.gov/efile/Default.aspx, unless it lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email (see http://www.hhs.gov/ohrp/assurances/contact/index.html) and explain why it is unable to submit its FWA electronically. Any institution that is unable to submit its FWA electronically after consultation with OHRP must send its FWA information in writing to OHRP by fax at (240) 453-8202, by email as a pdf scanned document, or mail it to the Office for Human Research Protections, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

An Institution's first step for submitting its FWA application should be to read and understand the Terms of Assurance at http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html.

**ITEM #1 - Institution Filing Assurance**

Type the legal name of the institution that is providing the Assurance and city, state or province, and/or country where the institution is located.

**ITEM #2 - Institutional Components**

Type the names of all components over which the Institution has legal authority that operate under a different name that will be covered by this FWA. For each component listed, type the city and state or country where the component is located.

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.

**ITEM #3 - Statement of Principles**

Indicate by an [x] the statement of ethical principles that govern your institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. If selecting"Other" please submit a copy to OHRP with this Assurance.

**ITEM #4 – Applicability**

(a) This assurance applies whenever your institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (known as 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.

(b) *Optional for U.S. institutions*: (does not apply to Non-U.S. institutions) This section provides each U.S. institution the option of voluntarily electing to apply either the Common Rule or the Common Rule and subparts B, C, D, and E of the HHS regulations at 45 CFR part 46 to all of its non-exempt human subjects research regardless of source of support, except for research that is covered by a separate assurance issues by another U.S. federal department or agency that has adopted the Common Rule.

**ITEM #5 – Assurance of Compliance with the Terms**

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

(b) *Non-U.S. institutions Only:* (does not apply to U.S. institutions) This section asks for the procedural standards that each non-U.S institution applies to human subjects research to which the FWA applies.

Indicate with an [x] at least one of the listed procedural standards. If selecting "Other standards(s) for the protection of human subjects recognized by U.S. federal departments or agencies which have adopted the Common Rule", please submit a copy to OHRP.

**ITEM #6 - Designation of Institutional Review Board(s)**

This Institution assures that it will rely upon only Institutional Review Boards (IRBs) registered with OHRP to review the research to which this FWA applies. Designate all of your institution's internal IRBs that review research under this FWA. If your institution has no internal IRBs, designate the external IRB that reviews all of the research to which this FWA applies or, if multiple external IRBs are relied upon, list the external IRB that reviews the largest percentage of research to which this FWA applies.

*Note:* Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

**ITEM # 7- Human Protections Administrator (e.g., Human Protections Administrator or Human Subjects Contact Person)**

Type the name, degree(s) or suffix, institutional title (e.g., administrative title such as manager or director of a given office), telephone number, email address, and mailing address, of the human protection administrator (i.e., the person who serve as primary point of contact for your institution's system for protecting human subjects).

The human protection administrator (HPA) should have comprehensive knowledge of all aspects of your institution's system of protections for human subjects, as well as be familiar with the institution's commitments under the FWA, and play a key role in ensuring that the institution fulfills its responsibilities under the FWA.

**ITEM #8- Signatory Official (i.e., Official Legally Authorized to Represent the Institution)**

Type the name, degree(s) or suffix, institutional title (e.g., President, CEO, Provost, Vice President, Dean for Research, etc.), institutional title, institution name, telephone and fax numbers, e-mail address, and mailing address of the Signatory Official (i.e., the institutional official legally authorized to represent the institution).

The Signatory Official assures that human subjects research to which the FWA applies is conducted in accordance with the terms of assurance. The Signatory Official must electronically sign and date the FWA using the electronic submission system available through the OHRP Web site at http://ohrp.cit.nih.gov/efile/, unless your institution lacks the ability to submit its FWA electronically. If your institution believes it lacks the

ability to submit its FWA electronically, it must contact OHRP by telephone or email and explain why it is unable to submit its FWA electronically.

Generally, the Signatory Official is someone at the level of President, Chief Executive Officer (CEO), or Vice President of a company, or at the level of President, Provost, Chancellor, Vice President, or Dean of an academic institution, unless another official has been specifically delegated with this authority.

**ITEM #9 - FWA Approval**

Leave this item blank. This section is for use by OHRP for approval of the FWA. Notification of Approval of an FWA

**Additional Information**

Once an electronically submitted FWA has been reviewed and approved by OHRP, the person submitting the electronic FWA, the Human Protections Administrator, and the Signatory Official on the FWA will receive an automatically generated e-mail notifying them of the approval of the FWA. The email will also include a copy of the approved FWA.

Each Institution must renew its FWA every 5 years, even if no changes have occurred, in order to maintain an active FWA.

The Institution must update its FWA within 90 days after changes occur regarding the legal name of the Institution, the Human Protections Administrator or the Signatory Official.

Any electronically submitted FWA renewal or update that is approved by OHRP begins a new 5-year effective period. Failure to renew or update an FWA appropriately may result in restriction, suspension, or termination of OHRP's approval of the Institution's FWA.

If you have questions, please do not hesitate to contact the Division of Policy and Assurances, OHRP, at (240) 453-6900 or within the U.S., 1-866-447-4777.