

U.S. Department of Health and Human Services Office for Human Research Protections

Step-by-Step Instructions for Filing a Federalwide Assurance for Institutions Within the United States

The Federalwide Assurance (FWA) is an assurance of compliance with the 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 Department of Health and Human Services (HHS). The FWA is also approved by OHRP for Federalwide use, which means that other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research that they conduct or support.

Institutions engaging in research conducted or supported by federal departments or agencies other than HHS should consult with the department or agency that is conducting or supporting the research for guidance regarding whether or not the FWA is appropriate for the research in question.

Each institution that is engaged in HHS-conducted or -supported human subjects research must submit an FWA to OHRP. In general, an institution is engaged in human subjects research whenever: (a) the institution's employees or agents intervene or interact with human subjects for research purposes; (b) the institution's employees or agents obtain individually identifiable private information about human subjects for research purposes; or (c) the institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. For more information to determine whether or not an institution may be engaged in HHS-conducted or -supported human subjects research, please review the [OHRP guidance on Engagement of Institutions in Research](http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>.

The FWA Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement.

Follow the instructions below for each item on the FWA form. If you have further questions **after reading these instructions**, please go to the staffing guide on the OHRP website at <http://www.hhs.gov/ohrp/daq-staff.html> (bottom of page), to determine the name and phone number of the staff member assigned to your region to contact.

If there are any changes to an FWA after it is approved by OHRP, the institution should submit an update of that information to OHRP by following the [instructions for updating or renewing an FWA](http://www.hhs.gov/ohrp/humansubjects/assurance/renwfw.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/assurance/renwfw.htm>.

TOP RIGHT-HAND CORNER - "New Filing" versus "Update or Renewal"

Indicate by an [x] whether this is either: 1) a “New Filing”, or 2) an “Update or Renewal” of an **already existing** FWA. Your FWA form is a “New Filing” if this is your institution’s initial filing for an FWA. If your institution already has an approved FWA, the form should be appropriately marked as an “Update or Renewal” and include your institution’s FWA number. (See the [instructions for updating or renewing an FWA](#) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/assurance/renwfwfwa.htm>.)

ITEM #1 - Institution Filing Assurance

- a. Type or print the legal name of the institution (or the name the institution uses in doing business) that is providing the Assurance. Please **do not provide both names in this section**. Any alternate name(s) or components of the institution filing the FWA or separate legal entities that will be covered by the FWA should be listed under Item #2 of the FWA form.

Any component that does business in its own name (e.g., applies for federal research funding in its own name and/or has its own IPF/EIN identifiers, described below in subparagraph c) may file its own FWA form if the organization’s administrative structure permits the component to make legally binding commitments to the Terms of Assurance independent of the “parent” institution. Such a decision may be appropriate if the component has its own human subjects protection program that is separate or distinct from the “parent” institution.

Each institution engaged in human subjects research conducted or supported by HHS must submit its own FWA form, except in the following situations:

1. The OHRP guidance entitled “[Guidance on Extension of an Assurance to Cover Individuals at Another Institution](#).”
2. A special exception is requested of, and approved by, OHRP. The request for an exception should be submitted to OHRP in writing. An example of circumstances under which OHRP may approve such a request is as follows:

Separate legal entities may be covered under one FWA, if there is one human subjects protection program that oversees the review and conduct of human subjects research at each entity or institution. In such cases, the Signatory Official who signs the FWA must have authority over the entire human subjects protection program and be ultimately responsible for the review and conduct of human subjects research at each component and separate legal entity covered under the FWA. A formal agreement between each separate legal entity should be prepared to outline the relationship between the institutions and document the authority granted to the Signatory Official with regard to the oversight of human subjects research at each institution. A copy of the agreement should be kept on file at each institution covered by the FWA and made available to OHRP upon request.

Do not hesitate to contact OHRP if consultation is needed on subparagraphs 1 and 2 above, or if you have general questions about completing the FWA form.

Institutions engaging in human subjects research conducted or supported by a federal department or agency other than HHS should consult with the department or agency that is conducting or supporting the research for guidance regarding which institutions need their own assurances.

- b. Type or print the city and state where the institution is located.
- c. Type or print the HHS Institution Profile File (IPF) code and the Federal Entity Identification Number (EIN; tax number), if known. OHRP does not assign these numbers; they are assigned by other federal departments or agencies for certain tracking purposes. OHRP requests these numbers to distinguish between similar institutions and to try to avoid approval of multiple assurances for a given institution. If you are not aware of your institution's IPF code or EIN, you may leave these items blank. These numbers are not required for FWA processing.
- d. Indicate whether your FWA will replace a Multiple Project Assurance (MPA; "M" number) or a Cooperative Project Assurance (CPA; "T" number), by providing the respective number of your current Assurance.

ITEM #2 - Institutional Components

Type or print the names of all components of the institution identified in item #1 that will be covered by the FWA, including any alternate names used by your institution or its components. 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. In order to keep the listing of components manageable, only list the major components of your institution that are likely to be represented as either the applicant organization or as a research performance site. Please do not list all departments of your institution, as their participation in a study is likely to be represented by the name of the institution or one of the major components.

For each component listed, type or print the city and state or country where the component is located.

ITEM #3 - Statement of Principles

Indicate by an [x] the statement of ethical principles that govern your institution in fulfilling its responsibilities for the protection of the rights and welfare of human subjects in research. OHRP recognizes The Belmont Report as an acceptable statement of ethical principles for the protection of human subjects in research. If "Other Statement of Principles" is selected, a copy of those principles must be submitted to OHRP at the time the FWA form is submitted, as required by the Common Rule.

ITEM #4 – Applicability

- a. Review the [Terms of the Federalwide Assurance \(FWA\) for Institutions Within the United States](http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm> to obtain an understanding of the regulatory requirements that will be applied to federally-conducted or – supported human subjects research.
- b. **Completion of this section is optional.** This section provides the institution with the option of voluntarily applying either 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 source of support. Indicate with an [x] whether your institution elects to apply the Common Rule or the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46 to **all** human subjects research regardless of source of support, unless an agency or department conducting or supporting the

research determines that the research shall be conducted under a separate assurance.

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 an institution voluntarily extends the Common Rule or the Common Rule and the HHS subparts (B, C, and D) 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.

ITEM #5 - Designation of Institutional Review Boards (IRBs)

Designate your institution's Institutional Review Boards (IRBs) of record for this Assurance. **You must indicate at least one IRB in this section. Please ensure that all designated IRBs are registered, or are in the process of registering, with OHRP prior to submitting an FWA form to OHRP. OHRP does not take action on an FWA form until at least one of the designated IRBs is registered and assigned an IRB Registration number.** If the registration of the IRB is in process when you submit your FWA, OHRP will insert the IRB Registration number. Any IRB relied upon by the institution for review of human subjects research to which the FWA applies must be registered with HHS and must be designated under the institution's FWA. An FWA may be updated at any time to designate additional IRBs.

To determine if an IRB is registered with OHRP, you should go to the OHRP website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> and search for it. If an IRB(s) needs to be registered, go to the [IRB Registration materials](http://www.hhs.gov/ohrp/assurances/) on the OHRP website at <http://www.hhs.gov/ohrp/assurances/>.

List on the FWA form the IRB Registration number for each designated IRB [not the IRB Organization number (IORG number)] and the name of the IRB(s) as registered on this website.

If your institution relies on the IRB of another institution or organization, this arrangement must be documented in writing between the two institutions/organizations. OHRP has a sample [IRB Authorization Agreement](http://www.hhs.gov/ohrp/humansubjects/assurance/iprotsup.rtf) on its website at <http://www.hhs.gov/ohrp/humansubjects/assurance/iprotsup.rtf> that may be used for this purpose, or the parties involved may develop their own agreement. The agreement must be kept on file at the institutions and available for review by OHRP upon request, but it should not be submitted with the FWA form.

If at any time your institution relies on an IRB not listed on your FWA to review research to which the FWA applies, you must update your FWA and list the additional IRB(s) (see the [instructions for updating or renewing an FWA](http://www.hhs.gov/ohrp/humansubjects/assurance/renwfw.htm) on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/assurance/renwfw.htm>).

ITEM #6 - Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

Designate the individual who will serve as the Human Protections Administrator (HPA) (i.e., the

primary contact person for human subjects protection issues) for your institution. The HPA would exercise operational responsibility for your institution's program for protecting human subjects in research. The 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. Please note that the HPA should be prepared to fulfill the responsibilities noted above for all research covered under the FWA.

Type or print the full name, degree(s) or suffix, institutional title (e.g., administrative title such as manager or director of a given office), institution name, telephone and fax numbers, e-mail address, and full mailing address for the HPA. The e-mail address is very important, as this will provide the means for effective communication from OHRP (e.g., sending of new information regarding the FWA or other guidance from OHRP). If any of these fields are not available, please indicate accordingly rather than leaving the field blank.

ITEM #7 - Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

The Signatory Official must be a senior institutional official who has the authority to commit the entire institution named in the FWA form, as well as all of the institutional components listed under Item #2, to a legally binding agreement. Entities that the Signatory Official is not legally authorized to represent may not be covered under the FWA. **This individual must also have the authority to assure compliance of the institution and all of its components to the Terms of the FWA.** Generally, this is someone at the level of President, Chief Executive Officer (CEO), of 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. **Typically, the Signatory Official is not a department chair, division director, or another official who only has authority over a portion of the institution.** OHRP recommends that an IRB Chairperson or an IRB member not serve as the Signatory Official.

The signature of the Signatory Official and the date of the signature must be provided on the FWA form. The FWA form with the original signature must be submitted to OHRP.

Type or print the full name, degree(s) or suffix, institutional title (e.g., administrative title such as President, CEO, Provost, Vice President, Dean for Research, etc.), institution name, telephone and fax numbers, e-mail address, and full mailing address for the Signatory Official. The e-mail address is very important, as this will provide the means for effective communication from OHRP (e.g., sending of new information regarding the FWA or other guidance from OHRP). If any of these fields are not available, please indicate accordingly rather than leaving the field blank.

ITEM #8 - FWA Approval

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

Submitting an FWA Form to OHRP

Please review and proofread all materials to be submitted and ensure that all parts of the FWA form are complete and accurate. Submitting FWA forms **that are complete will expedite review and approval by OHRP. Submission of an incomplete FWA form may delay processing and approval of the FWA.**

Please submit the FWA form on single-sided pages and with the signature of the Signatory Official by fax (240-453-8202), regular mail, express mail, or hand delivery to OHRP at:

Division of Policy and Assurances
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Notification of Approval of an FWA

When an institution submits an FWA electronically, the person submitting the electronic file, the Human Protections Administrator, and the Signatory Official will receive an automatically generated e-mail notifying them of the approval of the FWA and providing them with the FWA number assigned to the institution. This, of course, is dependent upon the electronic file submitted to OHRP providing e-mail addresses as requested. When an institution submits an FWA in hard (paper) copy, it will need to monitor the OHRP website (<http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>) to ensure that the FWA has been approved.

If you have any 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.