

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 known 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 information on the meaning of “engaged”, see OHRP’s guidance at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.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: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subject/index.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 Component Organizations

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

Component organizations are generally considered to be parts of the 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 component organizations.

ITEM #3 – Applicability

(a) This assurance applies whenever the 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.

ITEM #4 – Assurance of Compliance with the Terms

Read and note the following:

This institution assures that whenever it engages in research to which this Assurance applies, it will comply with the [Terms of the Federalwide Assurance](https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subject/index.html) (contained in a separate document on the Office for Human Research Protections (OHRP) website at <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subject/index.html>

ITEM #5 - Institutional Review Board(s)

Read and note the following:

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

ITEM # 6- 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 protections administrator (HPA) (i.e., the person who serves as primary point of contact for your institution's system for protecting human subjects).

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.

ITEM #7- 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.), institution name, telephone number, 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 website 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, contact OHRP by telephone or email and explain why the institution 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 #8 - FWA Approval

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

Additional Information

Once an electronically submitted FWA has been reviewed and approved by OHRP, the person that submitted the application, the Human Protections Administrator, and the Signatory Official on the FWA will receive an automated e-mail notification of approval that includes the institution's assigned FWA number and a PDF copy of the approved FWA.

In order to maintain a satisfactory written assurance, OHRP requires that an institution renew its FWA every 5 years, even if no changes have occurred.

OHRP also requires that an institution update its FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator or the Signatory Official.

An institution may update or renew its FWA using the Electronic Submission System (ESS) at <https://ohrp.cit.nih.gov/efile/FwaRenew.aspx>. ESS requires an applying

institution to create a submission number to access an application. A submission number is created by using the FWA number, the most recent Signatory Official last name on file with OHRP, and the most recent Human Protections Administrator last name on file with OHRP. This information is found on the institution's current approved FWA. An 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 while continuing to engage in research subject to the Common Rule may constitute noncompliance.

If you have questions, please contact OHRP at IRBorFWA@hhs.gov or by phone at (240) 453-6900 or 1-866-447-4777.