Step-by-Step Instructions for Filing a Federalwide Assurance for International (Non-U.S.) Institutions

Each institution that is engaged (see definition of "engaged" at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm) in Department of Health and Human Services (DHHS) supported or conducted human subject research must submit a Federalwide Assurance (FWA) to the Office for Human Research Protections (OHRP). 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 application. You should also review the Questions and Answers material found at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/afaq.htm. If you have further questions after reading these instructions and reviewing the Questions and Answers, please go to the staffing guide at http://ohrp.osophs.dhhs.gov/dpa-staff.htm#Table2, to determine the name and phone number of the staff member assigned to your region and contact them.

**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 application is a "New Filing" if this is your institution's initial filing for a 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 Update and Renewal instructions at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/renfwaw.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 application.

Institutions that are affiliated solely through professional or collaborative arrangements must submit their own FWA application, unless a special exception...
is requested and described in a cover letter submitted with the FWA application, and approved by OHRP. An exception may be made by OHRP as described in the following example.

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 and made available to OHRP upon request.

Do not hesitate to contact OHRP if consultation is needed on this issue.

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 paragraph c) may file its own FWA application, 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.

b. Type or print the city, country and mail code where the institution is located.

c. Type or print the DHHS 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. The numbers are not required for FWA processing.

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 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, a 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.

**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. International institutions may elect the Declaration of Helsinki as their statement of ethical principles for the protection of human subjects in research. If "Other" principles are named, as required by the human subjects protection regulations, a copy of those principles must be submitted with the FWA application.

**ITEM #4 - Applicability**

a. Review the Terms of the Federalwide Assurance (FWA) for International (non-U.S.) Institutions on the OHRP website at [http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm](http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm) to obtain an understanding of the regulatory requirement that will be applied to federally-supported or -conducted human subjects research.

b. This section asks about the regulatory standards that your institution applies to human subjects research. Indicate with an [x] the alternative regulatory standards available on the FWA application for International Institutions (non-U.S.) that your institution elects to apply for U.S. federally-supported or -conducted human subjects research.

Please note that the listed alternative regulatory standards are considered to be generally consistent to the U.S. Common Rule (i.e., U.S. Federal Policy for the protection of human subjects in research). However, for DHHS-supported or -conducted human subjects research item 7 of the Terms of the FWA for International (non-U.S.) Institutions may require additional protections for the involvement of pregnant women or fetuses, prisoners, or children.

If "Other" procedural standards are named, a copy of those standards must be submitted with the FWA application.

**ITEM #5 - Designation of Institutional Review Boards(s)/Independent Ethics Committee(s)**

Designate the Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) of record for this assurance. You must still indicate at least one IRB/IEC in this section.
Please ensure that all designated IRBs/IECs are registered, or are in the process of registering, with OHRP prior to submitting the FWA application. OHRP does not take action on a FWA application until all designated IRBs/IECs are registered and assigned IRB Registration numbers. If the registration of the IRB/IEC was in process when you submitted your FWA, OHRP will insert the IRB Registration number.

To determine if an IRB/IEC is registered with OHRP, you should go to the OHRP website at [http://ohrp.cit.nih.gov/search/asearch.asp#IORG](http://ohrp.cit.nih.gov/search/asearch.asp#IORG) and search for it. If an IRB(s) needs to be registered, go to the instructions on the OHRP website at [http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm](http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm) - with links to sample registrations in Rich Text and HTML Formats.

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

If your institution relies on another institution's IRB/IEC, this arrangement must be documented in writing between the two institutions. OHRP has a sample IRB Authorization Agreement on its website at [http://ohrp.osophs.dhhs.gov/humansubjects/assurance/irbasur.htm](http://ohrp.osophs.dhhs.gov/humansubjects/assurance/irbasur.htm) that may be used for this purpose, or the institutions 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 application.

If at any time your institution relies on an IRB/IEC not listed on your FWA, you must update your FWA and list the additional IRB(s)/IEC(s). (See Update and Renewal instructions on the OHRP website at [http://ohrp.osophs.dhhs.gov/humansubjects/assurance/renwfwa.htm](http://ohrp.osophs.dhhs.gov/humansubjects/assurance/renwfwa.htm))

**ITEM #6 - Human Protections Administrator** 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 should 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.

When considering who should be appointed as HPA, it is important to remember that the duration of an FWA is 3 years and that, at the institution's option, a FWA may cover all human subjects research at the filing institution, not just federally-supported or -conducted human subjects research. The HPA should be familiar with the institution's commitments under the FWA and that the HPA is responsible for assisting the institution in ensuring that it fulfills its responsibilities.

Type or print the full name, degree(s), institutional (e.g., administrative) title, institution, telephone and fax numbers, e-mail address, and full mailing address for the HPA. The e-
ITEM #7 - Signatory Official

The Signatory Official must be a senior institutional official who has the authority to commit the entire institution named in the FWA application, 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 Assurance. Generally, this is someone at the level of President or Chief Executive Officer (CEO) of a company or Provost or Chancellor of an academic institution, unless another official has been specifically delegated with this authority. **Thus, the IRB Chair and IRB members are not appropriate personnel to serve as the Signatory Official.**

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

Type or print the full name, degree(s), institutional (e.g., administrative) title, institution, 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). If any of these fields are not available, please indicate accordingly rather than leaving the field blank. NOTE, you may also obtain news items and new guidance from OHRP by signing up on the OHRP-L LISTSERV (instructions are found on the OHRP website at http://ohrp.osophs.dhhs.gov/list.htm)

ITEM #8 - DHHS Approval

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

**Submitting an FWA Application to OHRP -**

Please review and proofread all materials to be submitted and ensure that all parts of the FWA application are complete and accurate. **Applications that are complete will facilitate quicker review and approval by OHRP. Incomplete documents may delay processing and approval of the FWA.**

Please submit the FWA application single-sided and with the original signature of the Signatory Official by regular mail, express mail, or hand delivery to OHRP at:
FWA Submission
Division of Assurances and Quality Improvement
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

FWA applications may be submitted by fax to 011-301-402-0527, as long as the FWA with the original signature(s) follows by mail. (Note, IRB registrations are also acceptable via fax at the above number.)

Notification of Approval of a FWA -

Notice of approval of a FWA will be sent by e-mail to the Signatory Official and the Human Protections Administrator if e-mail addresses were provided for them on the FWA application. A copy of the approved FWA will be sent by regular mail to the Signatory Official.

If you have any questions, please do not hesitate to contact the Division of Assurances and Quality Improvement, OHRP, at 011-301-496-7005.