Federalwide Assurance (FWA)
Spokes

The SIREN-NETT's first preference is for Spokes to have their own FWA or to be considered a component of a larger institution's FWA (e.g., their Hub's). Since some Spokes will not have their own IRBs, it is acceptable to defer to another institution's IRB provided written documentation verifying permission to do so is obtained. Please see below for specific details and examples of these documents.

PLEASE NOTE: All Spokes are responsible for adhering to the Federalwide Assurances regardless of whether they have their own FWA, are a component of another institution's FWA or defer to the IRB of another institution.

Background

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.

Individuals/Institutions Covered by an Existing FWA

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.

If your Spoke is a legal entity of a larger institution, it may already be covered as a component on that institution's FWA. Please check the status of your Spoke before continuing. Institutions holding FWAs can be found on the following website http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc . If your Spoke already has an FWA or is a component of another institution's FWA, please skip to page 3 of this document (Pulling FWA Required Documents for WebDCU).

Obtaining an FWA

It is SIREN-NETT's first preference for Spokes to obtain their own FWAs. You can obtain an FWA via the OHRP Electronic Submission System.

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.

FWA Forms and Instructions

Find links to the instructions and the forms for submitting an FWA at http://www.hhs.gov/ohrp/assurances/assurances/file/index.html.

Obtaining Authorized Signature

The FWA Signatory Official should be a high-level institutional official who has the authority to represent the institution named in the 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 Signatory Official cannot be the chair or member of any IRB designated under the FWA.

Tracking FWA Submission

You may track the receipt of an FWA at http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc.

FWA Approval

An automatically generated e-mail informing of the approval of the FWA will be sent immediately upon approval. Alternatively, institutions holding OHRP-approved FWAs are listed at http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc.

FWA Questions

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/assurances/contact/index.html). An Assurance Coordinator will also be assigned to newly submitted applications, and is listed with other tracking information at http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc.

Institutions with an Existing FWA Deferring to Another Institution's IRB or Independent Ethics Committee (IEC)

For institutions that do not have an internal IRB/IEC, your institution can negotiate an agreement with an external IRB/IEC to review research under your institution's FWA. To do so, 2 steps need to be completed:

1. Update FWA The institution must list all IRBs or IECs that it will rely upon for the review of any research covered by its assurance. To update the existing FWA to reflect the IRB being deferred to, please visit http://www.hhs.gov/ohrp/assurances/assurances/update/index.html.

2. Written Documentation of Agreement In addition, reliance on the IRB/IEC of another institution or organization, or an independent IRB, must be documented by a written agreement, which includes a commitment that the designated IRB will adhere to the requirements of this Assurance. The IRB/IEC Authorization Agreement (see page 4 of this document) or a similarly outlined document can be used for this purpose. The agreement should include a description of the regulatory requirements for which each party will be responsible.

OHRP does not require a copy of this documentation. However, please retain a copy at both locations (in addition to uploading into WebDCU) so that it is easily retrievable in the event OHRP requests it.

Please note, the institution holding the FWA retains ultimate responsibility for the protection of human subjects in all covered research in which the institution engages.

FWA Renewal

The FWA is effective for 5 years and must be renewed at the end of that period of time in order to remain effective. If the information on record 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 renew the FWA for another 5 years. For more information you may want to visit http://ohrp.cit.nih.gov/efile/FwaRenew.aspx.

Pulling FWA Required Documents for WebDCU

Proof of FWA should reflect the FWA number along with its components (if applicable) and IRBs linked to the assurance.

FWA's can be looked up using the following link: http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc.

Search for FWA proof by FWA number first, if you know it. This will put you on the page that is most relevant for upload into WebDCU. If you don't know the FWA number, search by Institution Name. It may also be helpful to search by state, as institution names/abbreviations are different on this website than what you may be familiar with.

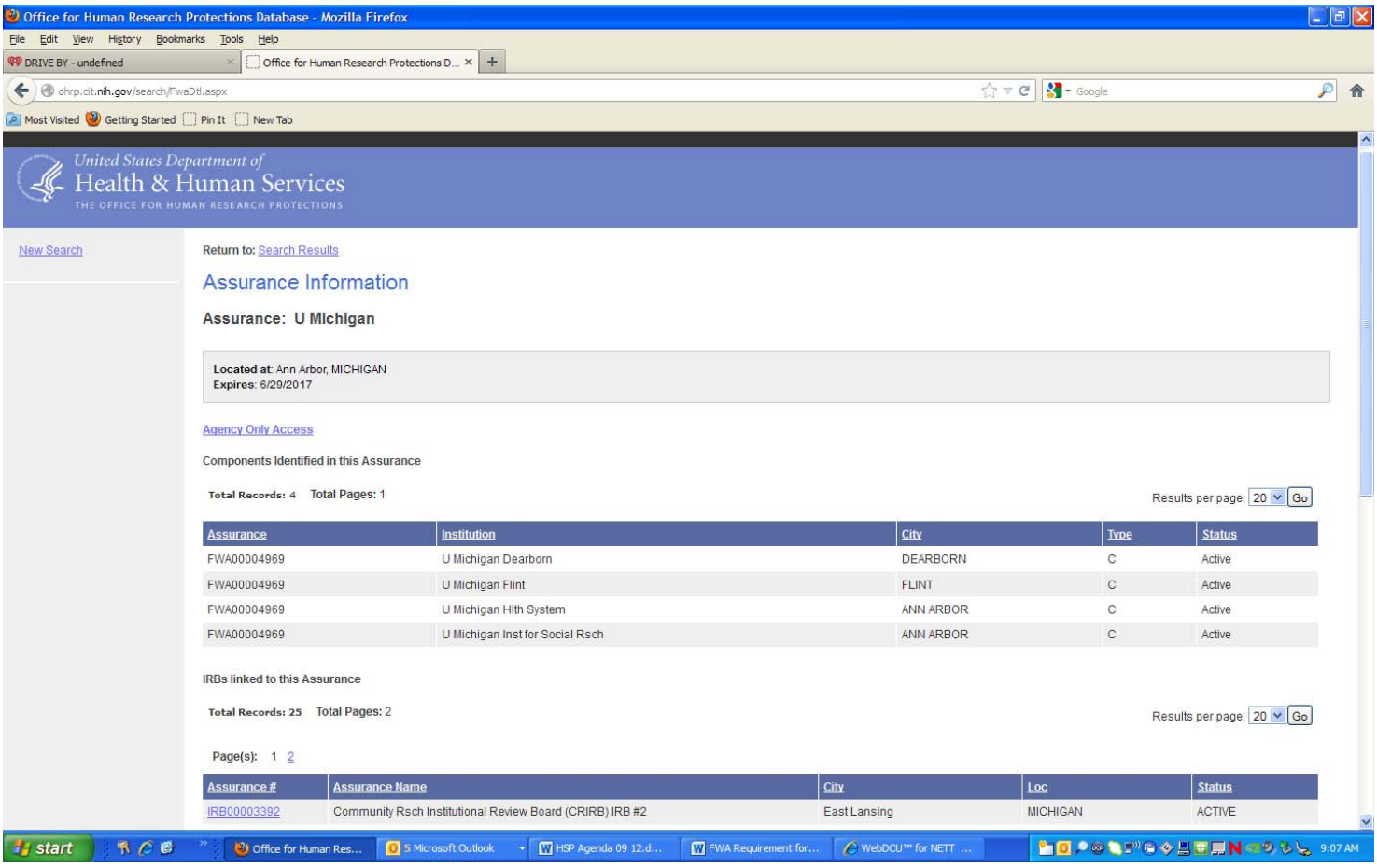
Once you do this, the page should look similar to the example provided below, which indicates the FWA number, along with the expiration date and IRB(s) linked to the assurance. This is what is required for FWA documentation. If the FWA number is not listed directly on this page, please add the FWA number to the "Notes" section of the entry in WebDCU (line 17).

Uploading Documents into WebDCU

For Spokes with their own FWA: Please upload the FWA documentation that reflects the FWA number, any applicable components, and the IRB(s) linked to the assurance.

For Spokes covered under the same FWA as the Hub: Please upload the FWA documentation for the Hub, which reflects the Hub FWA number, all the Spoke hospitals as "components" of the larger FWA, and the IRB(s) linked to the assurance. Please apply to all Spokes listed as components.

For Spokes deferring to another institution's IRB: The Spoke's FWA should list that IRB under "IRBs linked to this assurance." Please upload the FWA, displaying the FWA number and the IRB(s), and the IRB/IEC Authorization Agreement, and select the institution being deferred to.



Sample text for an Institution with a Federalwide Assurance (FWA) to rely on the IRB/IEC of another institution (institutions may use this sample as a guide to develop their own agreement).

Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):
_____

IRB Registration #: _____ Federalwide Assurance (FWA) #, if any: _____

Name of Institution Relying on the Designated IRB (Institution B):
_____

FWA #: _____

The Officials signing below agree that ____(*name of Institution B)*____ may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects research covered by Institution B's FWA.

(___) This agreement is limited to the following specific protocol(s):

Name of Research Project:_____
Name of Principal Investigator:_____
Sponsor or Funding Agency: _____ Award Number, if any: _____

(___) Other (*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):
_____ Date: _____

Print Full Name: _____ Institutional Title: _____

NOTE: The IRB of Institution A must be designated on the OHRP-approved FWA for Institution B.

Signature of Signatory Official (Institution B):
_____ Date: _____

Print Full Name*:* _____ Institutional Title*:* _____