

The Federalwide Assurance (FWA): What is it and when is it needed?

The federal Office for Human Research Protections (OHRP) requires that federally funded human subjects research only be conducted at facilities covered by a Federalwide Assurance (FWA). An FWA is a document that designates the Institutional Review Board that will review and oversee the research, specifies the ethical principles under which the research will be conducted, and names the individuals who will be responsible for the proper conduct of the research.

OHSU has its own FWA (FWA00000161) for research conducted at OHSU. However, the OHSU IRB is charged with the responsibility for assuring that all human subjects research conducted by OHSU investigators is conducted in compliance with federal law even if part or all of the research is conducted at a facility that does not belong to OHSU. In some cases, this means that the OHSU IRB cannot approve a research project to be conducted entirely or in part at a non-OHSU facility unless that facility has its own FWA.

The following guidelines are provided to assist OHSU investigators in designing protocols that do not require an FWA for a non-OHSU collaborator. Further instructions on obtaining IRB approval to conduct research at a non-OHSU facility are provided below.

An FWA is required whenever all three of the following conditions are met:

- the research is funded by a grant from the federal government;
- the research is not exempt from IRB oversight; and
- employees or agents of the non-OHSU site are engaged in the research.

Federal funding. All types of federal awards, including training grants and fellowships, are subject to the FWA requirement. The requirement also applies to federal grant money received by OHSU as part of a subcontract from another institution. Please check with the Research Grants and Contracts office if you have questions about funding sources.

Exemption from IRB oversight. The types of research that are exempt from IRB oversight are defined in [45 CFR 46.101](#). Designing studies that will qualify for exemption from IRB oversight will not only eliminate the FWA requirement, but significantly reduce other compliance requirements, including HIPAA requirements, and is therefore advisable wherever possible.
(45 CFR 46.101 website: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>).

Determining who is engaged in research. OHRP defines engagement in research according to the guidelines that can be found at the following website:
<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>. Some examples are provided here:

Institutions are “engaged” in research when their employees or agents:

- Perform invasive or non-invasive procedures for research
- Manipulate the environment for research purposes (light, sound, temperature) or make video or sound recordings
- Conduct interviews or other protocol-dictated communications
- Obtain private information from medical records in an individually identifiable form
- Carry out an informed consent process

Institutions **are not** “engaged” in research when their employees or agents:

- Permit the use of their facilities for intervention or interaction with subjects by research investigators

- Release contact information or other identifiable private information (such as medical records) to investigators with written permission of the subject
- Assist in recruiting subjects by providing information about studies
- Release information or specimens in non-identifiable form, when the materials were originally obtained for non-research purposes
- Draw blood as a professional service (for example for a genetic protocol)

Procedures for Studies Requiring an FWA

If an FWA is needed for a non-OHSU facility (either domestic or international) collaborating on your research project, first check the OHRP website located at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> to determine whether the institution already has an FWA on file. If the institution has an FWA on file, provide the FWA number along with the name of the institution you wish to collaborate with on the Initial Review Questionnaire and in the protocol for your study prior to submitting the study for IRB review. If the facility you wish to collaborate with has its own federally registered Institutional Review Board, it may be possible for the OHSU IRB to waive oversight to that IRB for protocols.

If an FWA is required and not already on file, go to **Facilitating the FWA Process for Non-OHSU Research Partners** <http://www.ohsu.edu/research/rda/irb/policies.shtml>.

Procedures for Studies NOT Requiring an FWA

Even when an FWA is not needed, OHSU requires that the collaborating facility agree to assist OHSU in the responsible conduct of the research. This agreement is documented by having the director of the facility with which you are collaborating sign an Agreement for the Protection of Human Subjects and Designation of Responsible Institutional Review Board. The text of the agreement can be found at <http://www.ohsu.edu/research/rda/forms.shtml#hsf>. If you need assistance in completing this agreement, please contact the ORIO at 503-494-7887 or e-mail irbinbox@ohsu.edu. The signed agreement must be submitted to the IRB before the research will be approved.