

Facilitating the FWA Process for Non-OHSU Research Partners

The following guidance is provided to help you assist your non-OHSU research partners in the FWA filing process. If you are unsure about whether or not an FWA is needed, see: The Federalwide Assurance (FWA): What is it and when is it needed?

1. Download the Form and Step-by-Step instructions for filing an FWA:

Domestic institution:

http://www.hhs.gov/ohrp/assurances/assurances_index.html#domestic

International institution:

http://www.hhs.gov/ohrp/assurances/assurances_index.html#international

2. The Institution will need to designate a Human Protections Administrator and a Signatory Official who is legally authorized to represent the Institution. The duties of each of these individuals (in some organizations an individual may fill both roles) are articulated in the Step-by-Step instructions for filing an FWA (see above).
3. OHRP provides an online tutorial on the protection of humans in research. This training is not required, but both OHRP and OHSU strongly recommend that all Signatory Officials, Human Protections Administrators, and IRB chairs complete this training. The tutorial can be found at: http://137.187.172.152/cbttng_ohrp/cbts/assurance/login.asp.
4. In many cases the OHSU IRB will provide IRB services for the non-OHSU facility. This can be limited to specific projects conducted by OHSU faculty members or it can include all human subjects research conducted at the non-OHSU facility. Contact the OHSU IRB Manager (503-494-7887) to verify that OHSU will serve as the IRB of record and to complete documentation of the agreement between OHSU and the non-OHSU entity.
5. If your collaborators need help with interpreting the instructions for filing, refer them to the OSHU IRB Manager (494-7887).
6. OHRP is accepting electronic filings. Instructions for electronic filing of an FWA can be found at: <http://ohrp.cit.nih.gov/efile/>.