OFFICE FOR
HUMAN RESEARCH PROTECTIONS (OHRP) FEDERAL WIDE ASSURANCE (FWA), IRB ORGANIZATIONS (IORG) IRB REGISTRATION

DESCRIPTION

An institution must update its FWA and IORG-IRB within 90 days after changes occur. The FWA is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, in order to maintain an active FWA. Any renewal or update that is submitted electronically, and approved by OHRP, begins a new-5-year effective period. At a minimum, an IRB registration must be renewed every 3 years.

RESPONSIBILITY

The University of Cincinnati (UC) IRB must continually update OHRP with any changes to the established FWA and/or IORG-IRB as required. OHRP requires that a single individual be designated as the Human Protections Administrator. The Human Protections Administrator, or designee, is responsible for updating the FWA and/or IORG-IRB with all IRB Authorization Agreements, changes in the Board membership, and additions or deletions of Boards.

PROCESS

Update/renewal to an FWA

- When an external IRB is designated on an FWA, there must be an agreement in place between the IRB and the FWA institution outlining the roles and responsibilities of each party. A copy of this agreement must be maintained by each party and available to OHRP upon request.
- If a part of the FWA update/renewal is to designate an additional IRB that will review the human subjects research covered by UC IRB’s FWA, that IRB must be registered with OHRP.
- An electronic submission to OHRP must be completed and is found at http://ohrp.cit.nih.gov/efile/. The OHRP-assigned registration number for each IRB designated on UC IRB’s FWA must be known in order to complete the submission and are listed at http://ohrp.cit.nih.gov/search/asearch.asp#ASUR.
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- A submission number for each electronic submission must be requested and is only good until OHRP approves the FWA associated with that submission. After approval of an electronically submitted FWA, a new submission number must be requested for subsequent electronic updates/renewals. The changes requested are not transferred to OHRP’s database until the FWA is approved.
- The Human Protections Administrator and the Signatory Official/Institutional Official will be notified automatically by e-mail as soon as OHRP has approved the update/renewal the FWA.
- If the update/renewal of the FWA includes designating an external IRB, the information provider and the Chair on that IRB will be notified and informed of the designation of their IRB on UC IRB’s FWA.
- Once the update is completed the FWA expiration date on the IRB website must be modified to reflect the current date.

**Update/renewal to an IRB**

- The Human Protections Administrator will be notified of any changes that are to be made to IRB membership or addition(s) and/or deletion(s) of existing IRB(s).
- After obtaining the submission number, changes to the registration of the IORG-IRB will be able to be made.
- With electronic submission, the submitter, the IRB Chair(s), and the Institutional Official will be notified by e-mail as soon as OHRP has processed the submission.
- A submission number must be requested for each electronic IORG/IRB registration. The submission number is good only until OHRP processes the IORG/IRB registration associated with that submission. After processing the electronic submission, a new submission number for subsequent updates/renewals must be requested. Changes to the request with each electronic submission are not transferred to OHRP’s database until the IORG/IRB registration has been processed.
- Once the update is completed the IRB website must be updated with the new information.
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Applicable Regulations, Document(s):
45 CFR 46

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<th>Adoption Date:</th>
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Date June 2014 Signature __signed copy on file________________________

Procedure Number: 328
FWA & IORG Submissions to the Office for Human Research Protections (OHRP)
Adopted: 11/2008 Revised: 06/2014
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