IRB Registration Process
Frequently Asked Questions:

Question 1: What IRBs must be registered?

The HHS regulations at 45 CFR part 46, subpart E, require all IRBs to register with HHS if they will review human subjects research conducted or supported by HHS and are to be designated under an assurance of compliance approved for federalwide use (i.e., an FWA) by OHRP.

Question 2: When must an IRB be registered?

An IRB must be registered before it can be designated under an OHRP-approved FWA. IRB registration becomes effective when reviewed and accepted by OHRP. The registration is effective for 3 years.

Question 3: How must an IRB be registered?

Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile/ unless an institution or organization lacks the ability to register its IRB electronically. If an institution or organization believes it lacks the ability to register an IRB electronically, it should contact OHRP by telephone or email (see http://www.hhs.gov/ohrp/assurances/status/contact/index.html) and explain why it is unable to register its IRB electronically. Any institution or organization that is unable to register electronically after consultation with OHRP must send its IRB registration information in writing to OHRP by fax at (240) 453-8202, by email as a pdf scanned

document, or mail it to the Office for Human Research Protections, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Question 4: Where can I find the IRB registration instructions and registration form?

Links to the instructions and the form for submitting an IRB registration can be found on the OHRP website at http://www.hhs.gov/ohrp/assurances/forms/index.html. Additional instructions for electronic submission of a new IRB registration or for updating or renewing the registration of an IRB already registered with OHRP can be found at http://ohrp.cit.nih.gov/efile/

Question 5: Who can I contact with questions about an IRB registration?

If you have questions about submitting an IRB registration, you should contact an IRB Coordinator listed at http://www.hhs.gov/ohrp/assurances/status/contact/index.html.

Question 6: How can I track receipt of my IRB registration submission?

You can track the receipt of an IRB registration submission on the OHRP website at http://ohrp.cit.nih.gov/search/. Here you will find information about when the IRB registration was received, which IRB Coordinator is reviewing it, and how to contact that person.

Question 7: How will I know when my IRB registration has been reviewed and accepted?

Once the OHRP has reviewed and accepted the registration, the contact person that provided the registration information, the senior officer or head official of the institution or organization and the IRB chairperson(s) will receive an automatically generated e-mail informing them of the IRB registration. A copy of the reviewed and accepted registration is also attached to the email. Of course, this is dependent upon correct e-mail addresses being provided for these individuals. All OHRP reviewed and accepted IRB registrations - both new registrations and updates/renewals - are listed on the OHRP website http://ohrp.cit.nih.gov/search/).

Question 8: When must an IRB registration be renewed or updated?

Each IRB must renew its registration every three years. An IRB registration also must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information and/or the IRB chairperson. The updated registration information must be submitted electronically unless an institution or organization believes it lacks the ability to register its IRB electronically. If an institution or organization believes it lacks the ability to register an IRB electronically, it should contact OHRP by telephone or email (see http://www.hhs.gov/ohrp/assurances/status/contact/index.html) and explain why it is unable to register its IRB electronically. Any institution or organization that is unable to register electronically after consultation with OHRP must send its IRB registration information in writing to OHRP by fax at (240) 453-8202, by email as a pdf scanned document, or mail it to the:

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Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

An institution's or organization's decision to disband a registered IRB that it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or –supported research.

Question 9: What are the requirements for providing information on the number of protocols being reviewed by the IRB?

The HHS regulations at 45 CFR 46.502 (e) require institutions or organizations to provide the approximate number of all active protocols and approximate number of active protocols conducted or supported by HHS when registering an IRB. For the purpose of these requirements, an "active protocol" is any protocol for which the IRB conducted an initial or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

If the IRB reviews protocols regulated by both OHRP and the Food and Drug Administration (FDA), the institution or organization also must provide the approximate number of active protocols involving FDA-regulated products and a description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

Question 10: What are the requirements for providing information on the number of full time equivalent positions?

The HHS regulations at 45 CFR 46.502 (f) require institutions or organizations to provide information on the number of full time equivalent positions devoted to the IRB's administrative activities when registering an IRB.

Question 11: What are the requirements for IRB membership?

The requirements for IRB membership are addressed in the HHS regulations at 45 CFR 46.107[Note: 45 CFR 46.304 requires a specialized IRB composition when research involving prisoners is being reviewed, including the presence of a prisoner representative].

An IRB must:

i. have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
ii. make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;

iii. include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
iv. include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
v. not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Please see the regulations at 45 CFR 46.107 for complete information on all of the required qualifications to properly compose an IRB.

Question 12: How do I determine the various categories of members for the IRB roster?

The following are some general guidelines to assist you in composing the IRB membership roster.

Scientist/Nonscientist - Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation - An employee or agent of the organization registering the IRB (or a member of that person's immediate family) is considered affiliated. Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB. An individual that has no affiliation with the organization registering the IRB, other than as an IRB member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution. Paying unaffiliated members for their services would not make the member "otherwise affiliated" as stated in the regulations, or cause the member to have a conflicting interest.

Alternate Members – The HHS regulations at 45 CFR part 46 do not address the designation of alternate IRB members. However, for many years, the OHRP has permitted organizations submitting IRB registrations to OHRP to identify alternate members for primary members. When reviewing rosters that include alternate members OHRP assumes that, in general, with respect to the capacity in which the primary IRB member was intended to serve, each alternate IRB member has experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate would replace. The minutes of an IRB meeting should document the attendance of all primary and alternate IRB members who attended any part of the IRB meeting. If both a primary IRB member and his or her alternate(s) attend the same IRB meeting, OHRP assumes that the primary member is acting as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting.

Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member. OHRP recommends that the reason for the substitution of the alternate IRB member also should be documented in the minutes.

Question 13: Does a FWA have to be updated if an institution later relies on an IRB not included in the original FWA submission?

Yes, if that IRB is an internal IRB, because all internal IRBs that review research covered by the institution's FWA must be designated on that FWA. In addition, if the institution has no internal IRBs and has designated one external IRB, but decides to rely on a second external IRB that will review the largest percentage of research covered by its FWA, the institution must update its FWA to replace the first external IRB with the second IRB.

Reliance on an external IRB, i.e. an IRB of another institution or organization, or an independent IRB, must be documented by a written agreement that is available for review by the OHRP upon request.

OHRP's sample IRB Authorization Agreement may be used for this purpose (see http://www.hhs.gov/ohrp/assurances/forms/iprotsup.rtf) or the parties involved may develop their own agreement.

Question 14: Does registration mean that an IRB is in full compliance with the HHS regulations, 45 CFR part 46, or is otherwise meeting a particular standard of competence or expertise?

No, IRB registration is not a form of accreditation or certification by the HHS. An IRB that reviews human subjects research conducted or supported by HHS, and that is designated under an assurance of compliance approved for federalwide use by the OHRP under 45 CFR 46.103(a), must be registered with OHRP. However, the fact that an IRB is registered with OHRP does not mean that OHRP has determined that the IRB reviews research in accordance with the requirements of the HHS Protection of Human Subjects regulations, and does not mean that the IRB has the appropriate competence or expertise to review a particular research project.