OHRP IRB Registration Frequently Asked Questions (FAQs)

Question 1: When is an Institutional Review Board (IRB)/Independent Ethics Committee (IEC) registration required?

Answer: Any Institutional Review Board (IRB) or Independent Ethics Committee (IEC) that reviews HHS-supported or –conducted human subjects research—or any of the federal departments or agencies that have signed on to the Common Rule (45 CFR part 46) and accepts an OHRP-approved FWA to cover research it is conducting or supporting—must designate on the FWA the IRB/IEC(s) that will perform initial and continuing review of the research. Each IRB/IEC must be registered with OHRP before it may be designated on an FWA.

Question 2: What if my institution does not have an internal Institutional Review Board (IRB)

or Independent Ethics Committee (IEC)?

Answer: There are several possible options for institutions that do not have an internal IRB/IEC:

- Your institution could negotiate an agreement with an external IRB/IEC to review research under your institution's FWA. For example, you might be collaborating with someone at an institution that has an internal IRB/IEC, and that institution might be willing to allow its IRB/IEC to conduct reviews for your institution. Another option could be to contact an institution in your geographical area that has an Office for Human Research Protections (OHRP)-registered IRB/IEC and talk to them about possibly conducting reviews for your institution (please see http://ohrp.cit.nih.gov/search/asearch.asp#ASUR for a list of all IRB/IECs registered with OHRP).
- You may want to consider establishing your own IRB/IEC.
- You may want to negotiate an agreement with a commercial or independent IRB/IEC to review your research.

In all cases the IRB/IEC(s) would need to be designated under your assurance.

As stated in the Terms of Assurance:

> "Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request."

OHRP provides an example of an IRB/IEC Authorization Agreement at http://www.hhs.gov/ohrp/humansubjects/assurance/iprotsup.rtf. The agreement may be written, for example, to cover one research project, or to cover research projects on a case-by-case basis, or to cover a program of research. The agreement or separate institutional operating procedures should include a description of which regulatory requirements each party will be responsible for; e.g., reporting unanticipated problems involving risks to subjects or others (45 CFR 46.103). When an FWA institution relies on an external IRB/IEC, the IRB/IEC must have knowledge of the local research context [please see item (C) of OHRP's guidance document at http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm].

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

Question 3: Does a Federalwide Assurance (FWA) have to be updated if an institution later

relies on an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) not included in the original FWA submission?

Answer: Yes, the institution must list all Institutional Review Boards (IRB) or Independent Ethics Committees (IEC) that it will rely upon for the review of any research covered by its assurance (45 CFR 46.103). Therefore, the designation of additional IRBs/IECs requires an update of the FWA, if the research to be reviewed by the IRB(s)/IEC(s) is covered by the assurance. In addition, reliance on the IRB/IEC of another institution or organization, or an independent IRB, must be documented by a written agreement that is available for review by the Office for Human Research Protections (OHRP) upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose (see http://www.hhs.gov/ohrp/humansubjects/assurance/iprotsup.rtf) or the parties involved may develop their own agreement.

Question 4: What are the procedures for Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration?

Answer: To expedite the review and processing of an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration, as well as any update/renewal you may make in the future, you should use the Office for Human Research Protections (OHRP) Electronic Submission System. When a registration is submitted electronically, no hard copy needs to be sent to OHRP. You may also complete the form in hard copy and fax OR mail it (please do not do both) to OHRP. The instructions on both of these procedures can be found at http://www.hhs.gov/ohrp/assurances/index.html.

You may wish to also view the following related questions and answers:

What is the time period of the IRB/IEC registration?

Where can I find the IRB/IEC instructions and registration form?

Who can I contact with questions about IRB/IEC registration?

How can I track receipt of my registration submission?

How will I know when my IRB/IEC registration has been processed?

Question 5: What is the time period of an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration, and how quickly does the information on file with OHRP need to be updated?

Answer: The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration is effective for 3 years and must be renewed at the end of that period of time to remain effective. If the information on record with the Office for Human Research Protections (OHRP) for the IRB/IEC registration needs to be changed, those changes should be submitted within 90 days of the change. All updates of the IRB/IEC registration using the electronic system automatically renew the IRB/IEC registration for another 3 years. Complete updates (the

Federalwide Assurance (FWA) is fully completed) submitted in hard copy renew an FWA for another 3 years, while limited updates (the FWA is partially completed) submitted in hard copy will not change the FWA expiration date. For additional information you may want to visit: http://www.hhs.gov/ohrp/humansubjects/assurance/renwirb.htm

Question 6: Where can I find the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) instructions and registration form?

Answer: Links to the instructions and the form for submitting an IRB/IEC registration can be found on the Office for Human Research Protections's website at http://www.hhs.gov/ohrp/assurances/index.html.

Question 7: Who can I contact with questions about an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration?

Answer: If you have questions about submitting an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration, you should contact an IRB Coordinator listed at http://www.hhs.gov/ohrp/humansubjects/assurance/regirbi.htm.

Question 8: How can I track receipt of my Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration submission?

Answer: You can track the receipt of an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration submission on OHRP's website at http://ohrp.cit.nih.gov/search/logqry.asp. Here you will find information about when the IRB/IEC registration was received, as well as which IRB/IEC Coordinator is reviewing it and how to contact that person.

Question 9: How will I know when my Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration has been processed?

Answer: If the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) registration (both new and updates/renewals) is submitted electronically, the submitter, the Head Official, and the IRB/IEC Chair will receive an automatically generated e-mail informing them of the registration of the IRB/IEC immediately upon processing. Of course, this is dependent upon e-mail addresses being provided in the IRB/IEC registration. If the IRB/IEC registration (both new and updates/renewals) is submitted in hard copy, you will have to monitor OHRP's website to determine that processing has been completed or contact OHRP. After processing, all IRB/IEC registrations both new registrations and updates/renewals are listed on the OHRP website (http://ohrp.cit.nih.gov/search/asearch.asp#ASUR).

Question 10: What are the requirements for Institutional Review Board (IRB) or Independent Ethics Committee (IEC) membership?

Answer: The requirements for Institutional Review Board (IRB) or Independent Ethics Committee (IEC) membership are addressed in the Department of Health and Human Services (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/IEC 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/IEC.

Question 11: How do I determine the various categories of members for the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) roster?

Answer: The following are some general guidelines to assist you in composing the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) 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/IEC 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/IEC (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/IEC. An individual that has no affiliation with the organization registering the IRB/IEC, other than as an IRB/IEC member, is considered unaffiliated with the entity operating the IRB/IEC. Unaffiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution. Paying an unaffiliated member a reasonable market value 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 - HHS regulations at 45 CFR part 46 do not address the designation of alternate IRB/IEC members. However, for many years, the Office for Human Research Protections (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 be documented in the minutes.

Question 12: How does 45 CFR part 46 relate to the human subjects regulations used by non-HHS federal funding agencies?

Answer: The current U.S. system of protection for human research subjects is heavily influenced by the Belmont Report, written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, HHS and FDA revised and made as compatible as possible—under their respective statutory authorities—their existing human subjects regulations. With leadership

from HHS, the Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies, as listed below (each agency includes in its chapter of the Code of Federal Regulations [CFR] section numbers and language that are identical to those of 45 CFR part 46, subpart A).

- Department of Agriculture (7 CFR part 1c)
- Department of Commerce (15 CFR part 27)
- Department of Defense (32 CFR part 219)
- Department of Education (34 CFR part 97)
- Department of Energy (10 CFR part 745)
- Department of Health and Human Services (45 CFR part 46 subpart A)
- Department of Housing and Urban Development (24 CFR part 60)
- Department of Justice (28 CFR part 46)
- Department of Veterans Affairs (38 CFR part 16)
- Department of Transportation (49 CFR part 11)
- Consumer Product Safety Commission (16 CFR part 1028)
- Environmental Protection Agency (40 CFR part 26)
- Agency for International Development (22 CFR part 225)
- National Aeronautics and Space Administration (14 CFR part 1230)
- National Science Foundation (45 CFR part 690)

In addition, the Central Intelligence Agency must comply with all subparts of 45 CFR part 46 under Executive Order 12333.

For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. HHS has developed additional regulations for the human subjects research it conducts or supports that apply to particular special populations: 45 CFR part 46 subparts B-D apply to research involving pregnant women, human fetuses, and neonates (subpart B), prisoners (subpart C), and children (subpart D).

Several non-HHS federal departments and agencies have additional regulations in place for research involving special populations or for human subjects research in general.

Question 13: Do the human research regulations apply to non-U.S. institutions?

Answer: Yes, whenever non-U.S. institutions are engaged in non-exempt HHS-supported or –conducted human subjects research, the regulations apply. Please see: http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm#sectionb .