Office for Human Research Protections (OHRP)

Step-by-Step Instructions for Registering an Institutional Review Board (IRB) or Independent Ethics Committee (IEC)

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NOTE: Only institutions or organizations that have their own Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) should submit an IRB/IEC Registration form. Institutions that do not have their own IRB/IEC but rely on the IRB/IEC of another institution should not submit an IRB Registration.

Follow the instructions below for each item on the IRB/IEC Registration form. If you have further questions, **after reading these instructions**, please go to the staffing guide on the OHRP website at http://www.hhs.gov/ohrp/daqi-staff.html (bottom of page), to determine the name and phone number of the staff member assigned to your region to contact.

PLEASE TYPE OR PRINT THE IRB REGISTRATION FORM LEGIBLY

TOP RIGHT-HAND CORNER - New Filing,Update or Renewal

Indicate by an [X] whether this is a "New Filing" or an "Update or Renewal" of an **already existing** IRB/IEC Registration. Also indicate by an [X] if the update or renewal includes the "Addition of New IRB(s)." If the IRB/IEC is already registered with OHRP, please provide your institution's/organization's IRB Organization (IORG) number. If you do not know your institution's/organization's IORG number, you may obtain this number from this website at **http://ohrp.cit.nih.gov/search/asearch.asp#IORG**. (See Update and Renewal instructions at **http://www.hhs.gov/ohrp//humansubjects/assurance/renwirb.htm**)

***ITEM #1* - Organization Operating the IRB(s)/IEC(s)**

Type or print the full legal name of the institution or organization that is registering the IRB/IEC and full mailing address, including country if outside the United States. Also, include the street address if it is different than the mailing address.

***ITEM #2* - Senior or Head Official of Organization Operating the IRB(s)/IEC(s)**

Type or print the full name, degree(s), organizational title (e.g., President, Provost, Chief Operating Officer), telephone number, fax number, e-mail, and full mailing address for the senior or head official of the organization operating the IRB/IEC [i.e., the person in your organization who is ultimately responsible for the performance and conduct of the IRB(s) or IEC(s)].

***ITEM #3* - Person Providing this Information**

Type or print the name, title, telephone number, fax number, and e-mail for the person providing the information submitted on the IRB/IEC Registration form. For electronic submissions, the person providing the information must have an e-mail address.

***ITEM #4* - Information on Each IRB/IEC to be Registered, Updated, or Renewed**

a. Indicate how many IRBs/IECs are to be registered, updated or renewed with your submission.

   Type or print the following information [items 4(b) through 4(f)] for each IRB/IEC to be registered. If you are registering more than one IRB/IEC, provide the information requested in item #4 for each IRB/IEC and clearly identify the information for each IRB/IEC.

b. **IRB Number -** If your submission is an update or renewal, type or print the IRB Registration number of the IRB/IEC. The IRB Number assigned by OHRP (e.g., IRB0000xxxx) can be found at **http://ohrp.cit.nih.gov/search/asearch.asp#IORG** .

   For each new IRB/IEC, provide the sequence number (e.g., IRB#1, ... IRB#4) of the IRB.

c. **IRB Name - For first time submissions of an IRB/IEC Registration,** OHRP will name each IRB/IEC using the name of the IRB/IEC Organization in item #1 followed by a sequential number (e.g., IRB#1, IRB#2) for each IRB/IEC registered. For example, if ABC University registers three IRBs, OHRP will name the IRBs: ABC University, IRB#1; ABC University, IRB#2; ABC University, IRB#3.

   If you would like to customize or add a descriptive Suffix (e.g., Behavioral, Biomedical) to the name given by OHRP, then provide your entry or additional name in this section of the IRB Registration form.

   For an update or renewal of an IRB Registration, the IRB name registered with OHRP (or modification of the name) should be entered in this section of the IRB Registration form. The IRB name as registered with OHRP can be found at **http://ohrp.cit.nih.gov/search/asearch.asp#IORG** .

   Provide the city and state or country for each IRB/IEC, if different from the location in item #1.

d. In this section you are asked to provide optional information related to the IRB/IEC. If you choose to answer these questions, indicate your choice with either an [x] or a check mark. The responses to these questions will not appear on the OHRP website that lists all registered IRBs.

1. Indicate whether or not the IRB or its parent organization has been accredited by a human subject protection accrediting organization. If yes, also provide the name of the accrediting organization and the date of accreditation.

2. Provide the approximate total number (none = 0; small = 1-25; medium = 26-99; or large = 100 or more) of currently active protocols. An active protocol is defined as any protocol or study for which an IRB conducted an initial review or a continuing review during the preceding calendar year.

3. Provide the approximate number of full-time positions devoted to the IRB's administrative activities. This number should include the sum of all full-time and part- time positions, to include professional, administrative, and support staff.

4. Respond with whether or not the IRB reviews or intends to review (within the 3-year period covered by the IRB Registration) research supported by the U.S. Government.

5. Provide the approximate number of currently active protocols supported by the U.S. Department of Health and Human Services (DHHS). DHHS includes the National Institutes of Health (NIH), Centers for Disease Control (CDC), Public Health Service (PHS), Agency for Healthcare Research and Quality (AHRQ), Substance Abuse and Mental Health Services Administration (SAMHSA), Health Research Services Administration (HRSA), and Center for Medicare Services (CMS)].

6. Provide the approximate number of currently active protocols supported by other Federal Departments and Agencies [(i.e., Department of Defense; Department of Energy; Education Department; National Science Foundation; Environmental Protection Agency; Department of Justice; International Development Cooperation Agency, Agency for International Development; Department of Veterans Affairs; National Aeronautics and Space Administration; Department of Agriculture; Department of Commerce; Consumer Product Safety Commission; Department of Housing and Urban Development; Department of Transportation).

7. Indicate whether or not the IRB reviews or intends to review (e.g., within the 3-year period covered by the IRB Registration) research that is regulated by the Food and Drug Administration (FDA) (e.g., research involving investigational drugs, biologics, or devices).

8. Provide the approximate number of currently active protocols involving products regulated by the FDA (e.g., research involving investigational drugs, biologics, or devices). An active protocol is defined as any

protocol or study for which an IRB conducted an initial review or a continuing review during the preceding calendar year.

9. Check the categories of products that are studied in active FDA-regulated protocols that are reviewed by the IRB. An active protocol is defined as any protocol or study for which an IRB conducted an initial review or a continuing review during the preceding calendar year.

e. Type or print the full name, degree(s), organizational title, telephone number, fax number, e-mail and full mailing address for the IRB/IEC Chairperson. Please make sure to include an e-mail address to facilitate future correspondence (e.g., regarding the registration, forwarding of new or revised OHRP guidance documents, etc.).

f. ***IRB Roster Form:***

General Information **- Completion of the IRB Roster form is required if your IRB/IEC is designated on an assurance submitted to OHRP.** Otherwise, completion and submission of the IRB Roster form is optional. If more space is needed, you may attach additional pages.

If the IRB/IEC is designated under an OHRP assurance, be sure your IRB/IEC meets the minimum requirements for membership. As detailed at 45 CFR Part 46, an IRB shall:

1. Have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

2. Be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

3. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

4. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

5. Include at least one member who is not otherwise affiliated with the institution operating the IRB and who is not a part of the immediate family of a person who is affiliated with it.

6. Make every nondiscriminating effort to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

7. Have no member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

   An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Instructions - At the top of the IRB Roster form, please include the name of the IRB Organization designated in item #1 and the IRB Registration Number and/or Sequence Number [see instructions for item 4(b) on page 2].

For each listed IRB/IEC member:

8. Type or print the list of members on your IRB/IEC. Primary members should be listed in the top section of the form and alternate members in the lower section. Note: Do not list non-voting individuals who attend IRB meetings. Their attendance may be documented in minutes of the meeting.

9. Type or print the "Gender" [e.g., male (M) or female (F)] and the highest "Earned Degree(s)" (e.g., Ph.D., M.D., MSW, B.A.).

10. Type or print the IRB/IEC member's "Primary Scientific or Nonscientific Specialty" (e.g., Sociology, Internal Medicine, Library Services). Also, either in the "Primary Scientific or Nonscientific" field or in "Comments" indicate if a given member provides special representation for the IRB (e.g., prisoner representative, advocate)

11. Type or print the IRB/IEC member's "Affiliation with Institution(s)" (e.g., employees, students, board members, alumni, etc., should be listed as "Y" or "Yes"; members with no affiliation or relationship with the institution operating the IRB other than being an active IRB member should be listed

as "N" or "No").

12. Type or print any additional relevant information regarding a given IRB/IEC member in the "Comments" section (e.g., prisoner representative, advocate).

When listing the alternate members, designate the corresponding number or name of the regular member(s) which a given alternate member represents. This information may be entered in the comments section.

SUBMITTING AN IRB/IEC REGISTRATION TO OHRP -

Please review and proofread all materials to be submitted and ensure that all parts of the registration form are complete and accurate. **Incomplete or incorrect documents may delay processing and registration of your IRB/IEC**.

Manually completed IRB/IEC registrations should be mailed, faxed, or e-mailed, single-sided, to OHRP. The mailing address is below. Registrations may be faxed to (240) 453-8202. If you would like to e-mail your registration, please go to the staffing guide on the OHRP website at http://www.hhs.gov/ohrp/daqi-staff.html (bottom of page), and e-mail the IRB registration to the staff member assigned to your region.

Electronically submitted IRB/IEC registrations should NOT be mailed or faxed to OHRP. Once you have clicked the "Submit" button, there is nothing more to do. The electronic submission area is monitored by OHRP, and if there are any questions about the registration, someone from OHRP will contact the submitter of the electronic document. Submissions are processed as they are received.

Once you have submitted an IRB/IEC registration, you may track the progress of your document until the IRB/IEC is registered. Once your institution's IRB/IEC registration has been processed, it will be listed on the OHRP website at http://ohrp.cit.nih.gov/search/asearch.asp#ASUR.

IRB Registration
Division of Policy and Assurances
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Sample IRB Registration Document [RTF - 361KB]
Sample IRB Registration Document [HTML]

Return to IRB Registration & Assurance Filing Main Page

If you have questions about human subject research, notify **ohrp@ hhs.gov**.
If you have questions/suggestions about this web page, notify Glen.Drew@hhs.gov