U.S. Department of Health and Human Services (HHS)

Step-by-Step Instructions for Registering an Institutional Review Board (IRB)

Version Date: [INCLUDE WHEN APPROVED]

This form is used by institutions or organizations operating IRBs that review either or both of the following:

a) Research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research
b) Clinical investigations regulated by the Food and Drug Administration (FDA) of HHS

The IRB Registration form is to be used for the following purposes:

- To register an IRB if an institution or organization has not previously registered an IRB
- To renew the registration of an IRB previously registered by an institution or organization
- To update the registration of an IRB previously registered by an institution or organization (e.g., update the contact person providing the IRB registration information or the IRB chairperson)
- To add another IRB to those previously registered by an institution or organization.

NOTE: Only institutions or organizations that have their own IRB should submit an IRB registration form. Institutions that do not have their own IRB but rely on the IRB of another institution should not submit an IRB registration. Investigators seeking IRB review and approval for research should not submit an IRB registration.

ITEM #1 - Has your institution or organization previously registered an IRB with HHS

If yes, go to item #2; if no, go to item #3.

ITEM #2 – What is your institution or organization (IORG) number?

The institution or organization number, or IORG number, is a unique, seven-digit number that was assigned to your institution or organization by OHRP the first time it registered an IRB. This number should be used whenever your institution or organization subsequently updates or renews the existing registration or registers a new IRB panel or committee on the existing registration. If you do not know your IORG number, search for

your institution or organization on OHRP's public Search database at http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc or contact OHRP by Email at IRBorFWA@hhs.gov. or by phone at 1-866-447-4777.

ITEM #3 - Name of Institution or Organization Operating the IRB(s)

Provide the full legal name, spelled out correctly, of the institution or organization that is operating the IRB(s) being registered. Provide the full mailing address, including country if outside the United States. Also, include the street address if it is different from the mailing address. (The physical address of the institution or organization operating the IRB is to be provided in this section.)

ITEM #4 - Senior Officer or Head Official of Institution or Organization Responsible for Overseeing the Activities of the IRB(s)

Provide the full name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of the organization operating the IRB [i.e., the person in your organization who is ultimately responsible for overseeing the activities of the IRB(s)].

ITEM #5 – Contact Person Providing this Registration Information

Provide the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

***ITEM #6* – IRB Registration Information (to be completed separately for each IRB being renewed or updated, or newly registered)**

a. Indicate whether this is a renewal or update of a registration for an IRB already registered with HHS.

   If yes, select Yes and provide the eight-digit IRB registration number previously assigned to this IRB panel by OHRP. OHRP provided that unique, eight-digit number the first time the IRB panel was registered with OHRP. If you do not know the IRB registration number, search for the IRB on the OHRP's public Search database at http://www.hhs.gov/ohrp/assurances/status/index.html or contact OHRP by email at IRBorFWA@hhs.gov or by phone at 1-866-447-4777.

   If no, select No, this is a new IRB registration.

b. Provide the IRB Name (i.e., the full name of the IRB panel), if any, that has been assigned by your institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB#1).

c. Provide the location of this IRB panel, including the mailing and street addresses, if different from the mailing and street addresses of the institution or organization, phone number, facsimile number, and electronic mail address.

d. For IRBs regulated by OHRP, provide the approximate (i.e., nearly correct, or exact) number of full-time equivalent positions devoted to this IRB's administrative activities.

e. For IRBs regulated by OHRP, provide the approximate (i.e., nearly correct, or exact) number of all active protocols. (For the purpose of completing this field, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.)

f. For IRBs regulated by OHRP, provide the approximate (i.e., nearly correct, or exact) number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention), etc.). (For the purpose of completing this field, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.)

g. For IRBs regulated by FDA, provide the following information if this IRB reviews, or intends to review protocols involving products regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act. (For the purpose of completing this field, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.)

    i) Provide the approximate (i.e., nearly correct, or exact) number of active protocols involving FDA-regulated products reviewed; and

    ii) Provide a description (i.e., by checking and completing appropriate fields) 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.

h. Provide this IRB chairperson's full name, phone number, and electronic mail address.

(End form)

Administrative Considerations for Registering IRBs:

As detailed at 45 CFR Part 46, an IRB reviewing HHS-supported or conducted human subjects research shall:

1. Satisfy the requirements for IRB membership at 45 CFR 46. 107: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.107.
2. Prepare and maintain adequate documentation of a list of IRB members as provided at 45 CFR 46.108(a)(2): https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.108. The record is to be maintained and made available by the institution upon request, in that the list is accessible for inspection and copying by authorized representatives of OHRP at reasonable times and in a reasonable manner.

As detailed at 45 CFR part 46, subpart E an IRB shall:

1. Renew its registration every 3 years. IRB registration renewal is submitted electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP at IRBorFWA@hhs.gov.
2. Update the registration information for an IRB within 90 days after changes occur regarding the contact person that provided the IRB registration information or the IRB chairperson. Such updates must be submitted electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP at IRBorFWA@hhs.gov.
3. Report to OHRP in writing at IRBorFWA@hhs.gov the institution or organization's decision to disband a registered IRB it is operating within 30 days after permanent cessation of IRB's review of HHS-conducted or -supported research.

As detailed in 21 CFR 56.106(e), an IRB that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the act and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products shall revise its registration in the following circumstances:

1. If an IRB's contact or chairperson information changes, the IRB must revise its registration information by submitting any changes in that information within 90 days of the change.
2. An IRB's decision to review new types of FDA-regulated products (such as a decision to review studies pertaining to food additives whereas the

IRB previously reviewed studies pertaining to drug products), or to discontinue reviewing clinical investigations regulated by FDA is a change that must be reported within 30 days of the change.

3. An IRB's decision to disband is a change that must be reported within 30 days of permanent cessation of the IRB's review of research. All other information changes may be reported when the IRB renews its registration. The revised information must be sent electronically through *http://ohrp.cit.nih.gov/efile*. If an IRB lacks the ability to revise its registration electronically, it must send its registration information, in writing, to the Office of Good Clinical Practice, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993.

Note that *http://ohrp.cit.nih.gov/efile* does not permit institutions or organizations operating an IRB(s) to change names of currently registered IRB panels or committees on its IORG. In such circumstances, the institution or organization must send an IRB name change request in writing to OHRP at IRBorFWA@hhs.gov. OHRP staff will process the request and change the IRB panel or committee name(s) in the registry.