OMB No. 0990-0279
Approved for use through August 31, 2015

U.S. Department of Health and Human Services (HHS)
Registration of an Institutional Review Board (IRB)

This form is used by institutions or organizations operating IRBs that review:

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; and/or**
b) **Clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services**

This form is to be used for the following purposes:

a. To register an IRB if your institution or organization has not previously registered an IRB
b. To update or renew the registration of an IRB previously registered by your institution or organization
c. To add another IRB to those previously registered by your institution or organization

Fields with an * are required for OHRP IRBs and FDA IRBs

Fields with an ♦ are required for OHRP IRBs but are optional for FDA IRBs

Fields with an ‡ are required for FDA IRBs but are optional for OHRP IRBs

Fields with no symbol are optional for both OHRP IRBs and FDA IRBs

1. ***Has your institution or organization previously registered an IRB with the Office for Human Research Protections (OHRP)?**

   [ ] Yes, proceed to section 2 [ ] No, proceed to section 3

2. ***What is your institution or organization (IORG) number?** _____ (This number was provided by OHRP the first time your institution or organization registered an IRB. If you do not know your IORG number, search for your institution or organization on the OHRP website at http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc or contact OHRP using the contact information at http://www.hhs.gov/ohrp/daqi-staff.html or by phone at 1-866-447-4777.

3. **Name of Institution or Organization Operating the IRB(s)**

   *Name of Institution or Organization:

   *Mailing Address:

   *Street Address (if different from the Mailing Address above):

*City: *State/Province: *Zip/Postal Code:

*Country (if outside the U.S.):

4. Senior Officer or Head Official of Institution or Organization Responsible for Overseeing the Activities Performed by the IRB(s)

*First Name: Middle Initial: *Last Name:

Earned Degree(s): Title or Position:

*Mailing Address (if different from the Mailing Address in section 3:

*City: *State/Province: *Zip/Postal Code:

*Country (if outside the U.S.):

*Phone: *FAX: *E-Mail:

5. Contact Person*)* Providing this Registration Information

*First Name: Middle Initial: *Last Name:

Earned Degree(s): Title or Position:

Name of Institution or Organization (if different from the Name in section 3):

*Mailing Address (if different from the Mailing Address in section 3):

*City: *State/Province: *Zip/Postal Code:

*Country (if outside the U.S.):

*Phone: *FAX: *E-Mail:

6. IRB Registration Information (to be completed separately for each IRB being renewed/updated or newly registered)

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

[ ] Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: _____ (This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know the IRB registration number, search for the IRB on the OHRP website at http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc or contact OHRP using the contact information at http://www.hhs.gov/ohrp/daqi-staff.html or by phone at 1-866-447-4777)

[ ] No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

C. Location of the IRB

*Mailing Address (if different from the Mailing Address in section 3):

*Street Address of the IRB (if different from the Mailing Address of the IRB):

*City: *State/Province: *Zip/Postal Code:

*Country (if outside the U.S.):

*Phone: *FAX *E-Mail

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: _____

E. ♦Approximate number of all active protocols (for purposes of completing this registration, 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. ♦Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, 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 that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, 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) Approximate number of active protocols involving FDA-regulated products:_____

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

[ ] human drugs	[ ] food additives
[ ] medical devices	[ ] color additives
[ ] biological products	[ ] other
	Specify:_____

H. IRB Chairperson

*First Name: Middle Initial: *Last Name:

Earned Degree(s): Title or Position:

Name of Institution or Organization (if different from the Name in Section 3):

Mailing Address (if different from the Mailing Address in section 3):

City: State: Zip/Postal Code:

Country (if outside the U.S.):

*Phone: *E-Mail:

FAX:

I. ♦IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Attach additional pages if necessary

Member Name (Last, First)	**Sex M / F**	**Earned Degree(s)**	**Scientist (S) or Non-scientist (N)** [1]	**Primary Scientific or Nonscientific Specialty**	**Affiliation**[2] **with Institution(s) Y / N**	**Comments (e.g., prisoner representative, advocate, name of alternate member(s))**
IRB Chair: 1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
Alternative Members[3]						
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						

NOTES:

[1] 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.

[2] Affiliation: Please indicate whether or not each individual (**or** a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

[3] Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

When an institution or organization registers two or more IRBs, all alternate members for all IRBs may be listed on the roster of one IRB, or they may be listed separately with each IRB roster. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members on registered IRBs serving as alternate members do not need to be listed as an alternate on any roster. Each alternate IRB member who replaces a primary member at any given meeting should have experience, expertise, background, professional competence, and knowledge equivalent to that of the primary IRB member whom the alternate will replace. Whenever an alternate member substitutes for a primary member of the IRB, the combined requirements of § 46.107(a) and 46.108(b) shall remain satisfied. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member, and include the identity of the replaced primary and the alternate members. If multiple alternate members serve at an IRB meeting, the pairing of primary and alternate members should be indicated.