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 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 the Department of Health and Human Services**

This form is to be used for the following purposes:

a. To register an IRB if an institution or organization has not previously registered an IRB.
b. To renew the registration of an IRB previously registered by an institution or organization.

c. 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).
d. To add another IRB to those previously registered by an 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 seven-digit number was assigned to your institution or organization by OHRP the first time it registered an IRB. 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.

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

   *Name of Institution or Organization (i.e., full legal name):

   *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 <u>separately</u> for each IRB being renewed or updated, or newly registered)

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

[ ] Yes. Provide the eight-digit IRB registration number previously assigned to this IRB panel by OHRP: _____ (This number was provided by OHRP the first time the IRB panel was registered with OHRP. If you do not know the IRB registration number, search for the IRB 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)

[ ] No, this is a new IRB registration.

B. Provide the IRB name (i.e., the full name of the IRB panel or committee), 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 (i.e., the IRB panel or committee)

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

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

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

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

*Phone: *FAX *E-Mail

D. ♦Approximate (i.e., nearly correct, or exact) number of full-time equivalent positions devoted to the IRB's administrative activities: _____

E. ♦Approximate (i.e., nearly correct, or exact) number of <u>all active protocols</u> (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 (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 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 FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act (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 (i.e., nearly correct, or exact) number of active protocols involving FDA-regulated products reviewed: _____

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

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

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:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0279. Public burden for this collection of information is estimated to average thirty minutes for an initial IRB registration, and twenty minutes for updating or renewing the registration of a previously registered IRB. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human

Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer