You are a subscriber to the Good Clinical Practice/ Human Subject Protection e-mail update service provided by the U.S. Food & Drug Administration (FDA). The following information is important for all IRBs that review FDA-regulated research. If you are not associated with an IRB, this message may not be of concern to you.

**REMAINDER: IMPORTANT NOTICE REGARDING REGISTRATION OF IRBs REVIEWING FDA-REGULATED RESEARCH - COMPLIANCE DATE OF SEPTEMBER 14, 2009**

We believe there may be some confusion in the IRB community regarding IRBs currently reviewing FDA-regulated research who were registered in the OHRP database before July 14, 2009. If those IRBs had voluntarily provided information concerning FDA-regulated studies, it will be visible when their information is accessed in the modified database, but that does not mean the IRB is registered with FDA. All previous IRB records were migrated as "OHRP only" into the new registration database, which was activated on July 14, 2009. This designation must be updated to read "OHRP/FDA" (or "FDA only," if that is the case) to register the IRB with FDA. In addition, any existing FDA-specific information should be reviewed to determine if an update is necessary. (FDA-specific information includes an estimate of the number of active FDA-regulated studies and a checklist for choosing the type of FDA-regulated research - drugs, biologics, devices, etc.)

To determine if a recent update accomplished the required change, you can search for your IRB information at [http://ohrp.cit.nih.gov/search/](http://ohrp.cit.nih.gov/search/). An IRB search with your IRB # will display basic information including "type" near the far right. If it does not read "OHRP/FDA" or "FDA only" you need to submit a new update (see below).

If you are updating your information to provide/update the FDA-specific information, use the electronic submission system page for updating registrations at [http://ohrp.cit.nih.gov/efile/IrbRnwStart.aspx](http://ohrp.cit.nih.gov/efile/IrbRnwStart.aspx). After obtaining a submission number from the system, you will begin the update process. To enter information for each separate IRB, **access the pull-down list of IRB type** and select "OHRP/FDA" or "FDA only." If you had already registered, the information previously entered will appear when you "save and continue," along with data-entry fields to enable you to enter or update the FDA-specific information required by the new IRB registration rule.

For further information on FDA’s IRB registration requirements contact Jean Toth-Allen, Ph.D., Office of Good Clinical Practice, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, HF-34, Room 16-85, Rockville, MD 20857, telephone (301) 827-1585, e-mail [jean.toth-allen@fda.hhs.gov](mailto:jean.toth-allen@fda.hhs.gov).

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