UM and Florida Department of Health Implement IRB Affiliation

Effective February 1st, 2010

The University of Miami and the Florida Department of Health recently signed and implemented an IRB affiliation agreement which will facilitate collaborative research within these organizations. ***Please note that at this time this affiliation does not apply to studies involving Jackson Health Systems and its affiliates.***

This agreement defines that studies in which investigators and/or sites of UM and the State of Florida are jointly engaged need only be approved by the Institutional Review Board (IRB) of the Florida Department of Health. Previously, such studies required review and approval both by the IRB of the Florida DOH and by the UM IRB.

Details of this agreement and the process which must be followed by UM investigators submitting studies to the Florida Department of Health IRB are defined in the "investigator guidance" document reprinted below. This guidance will be permanently available on the HSRO website at www.hsro.miami.edu

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Investigator Guidance
Studies being Reviewed by Florida Department of Health IRB

Effective February 1, 2010, the University of Miami (UM) will rely on the Florida Department of Health (FL DOH) Institutional Review Board (IRB) for the review, approval and continuing oversight of research involving UM investigators engaged in research at DOH.

University of Miami investigators are engaged in research at DOH if any of the following conditions exist:

(i) The research takes place at a DOH facility, including, but not limited to: County health departments, State laboratories, and the A.G. Holley State Hospital; or

(ii) The research involves DOH clients (except when community-based research only incidentally involves a DOH client or clients); or

(iii) The research involves the use of non-public information maintained by DOH.

In order for the University of Miami to properly account for and facilitate review of studies meeting the above criteria, the following process must be followed.

New Studies

1. Investigator/study team must complete a "new study" application in ePROST. To accomplish this, the applicant must:
    a. Indicate "External IRB" for Review Type at question 1.11 on the smart form
    b. Select "FL DOH IRB" at question #1.11.A
    c. Complete the short form ePROST application
    d. Submit the study through the eProst system which will route the application first through departmental review and any ancillary review (if required) and finally to the IRB through the HSRO
        i. Once received by the HSRO, the study will move into the "Pre-Board Review" state
        ii. During "pre-board review", the HSRO will:
            a) review all documentation for completeness and ensure that all needed ancillary approvals have been acquired
            b) ensure that all disclosed conflicts of interest are defined to the IRB
            c) ensure that all key study personnel are CITI certified
            d) ensure that all required HIPAA forms are included
            e) ensure that ICF documents contain all UM-required information and language
    e. When required documentation is complete, the HSRO will notify the IRB of the Florida Department of Health that the study is eligible for its review and approval.
    f. PI must print and upload this HSRO-issued, "permission" email when submitting the study via the DOH IRB electronic system for review

1. The IRB of the Florida Department of Health will notify the HSRO by email whenever a UM-DOH collaborative study is approved.
    a. The HSRO will update the ePROST system with this approval information
    b. eProst will shift the study status into the "Protocol at External IRB" state

Continuing Review

For studies that meet the above criteria but which are currently approved by both the UM and DOH IRBs, review authority will be transferred solely to the DOH IRB at the time of continuing review. The process of this transfer is as follows:

1. ePROST will automatically issue 90-, 60-, and 30-day reminders to PI and study contact prior to expiration of UM IRB approval

Scenario 1:

CRITERION -- There are no changes to the ongoing study being reported at the time of continuing review.

1. PI or study contact must notify the HSRO by email to transfer oversight solely to the DOH IRB. In this notification, the PI must attest that:
    a. There are no material changes to the study that would require review by UM (new COI disclosures, changes requiring ancillary committee review, etc.)
2. the HSRO will
    a. Issue a "permission" email to the Florida Department of Health IRB confirming that the study may be reviewed solely by the DOH IRB
    b. PI must print and upload this "permission" email when submitting the DOH IRB continuing report via the DOH IRB electronic system for review
3. The IRB of the Florida Department of Health will notify the HSRO by email whenever the continuing report of an UM-DOH collaborative study is approved.
    a. The HSRO will update the ePROST system with this approval information
    b. eProst will shift the study status into the "Protocol at External IRB" state

Scenario 2:

CRITERION - There **are** changes to the ongoing study being reported at the time of continuing review.

1. PI must submit an amendment to the HSRO defining the changes (new COI disclosures, changes requiring ancillary committee review, etc.)
    a. This amendment must be submitted via the eProst system which will route it first for departmental review and any ancillary review, if required and then to the HSRO
    b. Once received by the HSRO, the amendment will move into the "Pre-Board Review" state
        i. The HSRO will review all documentation for completeness to ensure that:
            a) All needed ancillary approvals have been acquired
                1) If not, the study will be routed back to appropriate ancillary committee(s) for review
            b) Any disclosed conflict of interest is appropriately reviewed
            c) All key study personnel are CITI certified
            d) Appropriate HIPAA forms are included
            e) Appropriate ICF templates are used
    b. When all documentation is complete, the HSRO will notify the IRB of the Florida Department of Health that the amendment and/or continuing report is eligible for its review and approval.
    c. PI must print and upload this HSRO-issued, "permission" email when submitting the study via the DOH IRB electronic system for continuing review

4. The IRB of the Florida Department of Health will notify the HSRO by email whenever the continuing report of an UM-DOH collaborative study is approved.
    a. The HSRO will update the ePROST system with this approval information
    b. eProst will shift the study status into the "Protocol at External IRB" state

IRB Fee Payment

Payment for IRB review of studies being sent to the Florida Department of Health IRB should be made directly to the Florida Department of Health IRB.