IRBshare, a New System for Joint Review of Multisite Studies

Elizabeth Massey Gendel, PhD

UTHealth has recently joined IRBshare, which is a new joint IRB review model for streamlining the review of multisite studies.

In this model (Fig 1), a temporary reliance is created between IRBs. The IRB of only one of the study sites conducts a full board review, and once this review is complete and the study is approved, the full board review documents are shared with all other sites via a secure, web-based document-sharing system. Local subcommittees from the shared sites can then perform a review for local context issues. Thus, the IRB review process is accelerated.

IRBshare launched in October 2012. Currently, 45 institutions participate (listed here) and 11 studies are enrolled (listed here).

So far, UTHealth has used IRBshare in the review and approval of one multicenter clinical trial in which UTHealth is a secondary site. This trial typically would have gone to UTHealth’s full board for review. However, with the use of IRBshare, the study was reviewed administratively by a UTHealth IRB chair within a few days. After minor changes to the consent document, the study was approved. Note that the speediness of this process is dependent upon approval of the study by the lead site’s IRB prior to submission to UTHealth’s CPHS. Also note that UTHealth study teams that take advantage of IRBshare are still required to submit an application and typical supporting documents to UTHealth’s CPHS.

Conversely, UTHealth investigators who are leads on multisite studies can submit their protocols for full board review at UTHealth and then use IRBshare to expedite the reviews at other sites.

IRBshare is operated by Vanderbilt University and is acknowledged by OHRP, FDA, and AARPP. There is no cost to use the service.

If you are interested in using IRBshare, please contact a UTHealth IRBshare liason: Audrey Ester (713-500-7914) or Sujatha Sridhar (713-500-3622).

Further information can be found at IRBshare.org.
Coverage Analysis Launch Update
Clinical Research Finance Team

The launch of coverage analysis began relatively smoothly. The Clinical Research Finance (CRF) team made a few updates to the forms to address questions and concerns. Additional training courses were also provided to ensure adequate training opportunities for the clinical research community.

Effective 09/09/2014, the billing risk questions (which help to determine if a coverage analysis is required) can be accessed via iRIS. However, only new protocol applications started after 09/09/2014 will have access to the billing risk questions, so please continue to use the questionnaire on the CRF website for all studies that started before 09/09/2014.

Please be sure to thoroughly complete each form prior to submission, including any required signatures. The completed forms are used to determine how to proceed with the coverage analysis, so it is important to include all of the required information.

Also, note that the review process cannot occur until protocol documents have been loaded in iRIS. The coverage analysis requires review of this material, so there may be a delay in review if the iRIS application is not completed.

Please also remember that an NCT number is required so that the CRF team can add the number to the GE Centricity dictionary.

Information on coverage analysis, including procedures and forms, as well as helpful hints and resources, can be found on the Clinical Research Finance team’s website here.

Feel free to contact the CRF team with any questions. The team can offer additional training as needed and is happy to walk through individual questions.

CRF team:
Trae Rohan, 713-500-3583
Heather Cody, 713-500-3983
Amaris Ogu, 713-500-3984

AS OF SEPTEMBER 1, 2014, A COVERAGE ANALYSIS IS REQUIRED FOR ALL CLINICAL STUDIES WITH BILLABLE CHARGES.

For a summary of coverage analysis procedures, see the story on page 1 of the August 2014 issue of The Clinical Coordinator, found here.

Apple May Limit Data Sharing on New Health Platform

Twelve years after the U.S. Department of Health and Human Services removed patient consent as a requirement for the release and disclosure of patient information for most common uses, it looks as if Apple is laying down a big bet in the opposite direction. Apple is placing consent-management restrictions on developers who plan to use its HealthKit mobile application platform. Read about it here.
Harris Health System requires the inclusion of Spanish-speaking only participants
Adapted from a Harris Health System Memorandum

The staff and management of Harris Health System Research and Sponsored Programs work to ensure that all Harris Health patients who are likely to benefit from research participation have the ability to do so.

In FY2012, 57.4% of Harris Health System patients were Hispanic. Thus, in order to ensure the equitable selection of potential research participants, Harris Health requires the inclusion of Spanish-speaking only participants in all research conducted within their facilities, unless a scientific rationale precludes their inclusion.

Harris Health System requires a fully translated, Spanish informed consent document to provide potential participants with the necessary protocol details during the informed consent process.

To accommodate studies for which approved translated documents are not available at the time that the initial application is submitted to Harris Health for administrative review, Harris Health System Research and Sponsored Programs will grant a 3-month approval. This will allow time for translation and approval of the documents by the affiliate IRB. Upon approval by the IRB, researchers will be expected to submit the translated documents via a Continuing Review form in Harris Health’s eProtocol Management System. Upon approval of the translated documents by Harris Health, an updated expiration date will be provided that matches the IRB expiration date.

For additional information, please contact Julie Thompson, PhD (713-566-6473).

Upcoming Certification Testing Dates

CCRP certification: For those of you interested in becoming a Certified Clinical Research Professional, the next test date in Houston, TX is at The Methodist Hospital on January 17, 2015 with a registration deadline of December 5, 2014. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in March 2015. Applications will open October 1, 2014, and you can find more information here.
Upcoming Training

**Study Coordinator Monthly Forum**
**Objective:** Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.
**Date:** September 23, 2014; October 28, 2014
**Time:** 11:30 am – 1:00 pm
**Location:** MSB 2.135
*Lunch provided for the first 40 participants.*
Registration is not required. Information [here](#).

**Clinical Research Education Program**
**Objective:** Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. Days 1 and 2 focus on clinical trial management, and day 3 focuses on clinical trial finance and contracting.
**Date:** October 14 – 16, 2014
**Time:** 8:00 am – 4:00 pm
**Location:** Cooley University Life Center
Registration is required. Register [here](#).

**iRIS Training**
**Objective:** Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth’s CPHS and AWC.
**Date:** October 7, 2014
**Time:** 1:30 pm – 4:00 pm
**Location:** UCT 1160
*Parking will be validated.*
Registration is required. Register [here](#).

**SPA Training Course**
**Objective:** The SPA Training Course is a biannual, three-day educational course taught by both departmental and central research administrators. This course will provide hands on experience and expert knowledge of subjects ranging from proposal submission to award closeout.
**Date:** October 21 – 23, 2014
**Time:** 9:00 am – 4:00 pm
**Location:** TMC Library (Jessie Jones Library)
Registration is required. Register [here](#).

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### About the Clinical Trials Resource Center

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Please visit [www.uthouston.edu/ctrc/](http://www.uthouston.edu/ctrc/) for more information.

**Sujatha Sridhar, MBBS**
Director
713-500-3622

**Catrina Coverdale, BS, CCRP**
Training Coordinator
713-500-3578

**Elizabeth Massey Gendel, PhD**
Regulatory Specialist
713-500-3587

**Elizabeth Meyer, BS**
Graduate Assistant
713-500-3551

**Ngozi Okafor, MPH**
Graduate Assistant
713-500-3551