It is often said that informed consent is not just a form but a process. However documentation of consent is also very important. In addition to getting the consent document signed and dated, it is also very important to document the consent process in the source documents.

According to the FDA GCP regulations (21 CFR 312.62(b), “the case history for each individual shall document that informed consent was obtained prior to participation in the study”. This requirement can be met by documenting the consent process in the source documents or by documenting the consent process within the case report form.

We recommend that the investigator or the study staff write a progress note about the consent process that includes how and when the consent discussion occurred. Some study teams have developed template language that they include in the medical records. Here is an example of language that can be used to document the consent process in the progress notes:

**15 May 2014**

_Discussed the TRYAL study with Mr. John Doe. Explained the study procedures and went over the consent document and answered his questions. I offered that he could take the consent document home and discuss with his family, but Mr. Jones said he would like to discuss with his wife. Mr. Doe returned in an hour and indicated interest in participating in the study. Mr. Doe and I signed the consent document. I gave a copy of the signed consent document to Mr. Doe._

_A. Smith, RN_

Remember, the oft repeated mantra in compliance circles, “if it is not documented, it didn’t happen.”

You can read more about informed consent process and documentation [here](#).

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**Upcoming Certification Testing Dates**

**CCRP certification:** For those of you interested in becoming a Certified Clinical Research Professional, the next test date at The Methodist Hospital in Houston, TX is July 19, 2014 with a registration deadline of June 6, 2014. You can find more information [here](#).

**CCRC certification:** The next exam dates for certification as a Clinical Research Coordinator are in September 2014. Applications for testing open May 1, 2014, and you can find more information [here](#).
UTHealth has developed an internal process for coverage analysis. The initial focus will be on industry-sponsored clinical trials, and **coverage analysis for certain industry-sponsored trials will be mandatory starting June 1, 2014.**

**What is coverage analysis?**
Coverage analysis is a review of all of the procedures listed in the study protocol’s schedule of events to determine which ones are eligible for billing to a third party, such as Medicare. This review is integral to ensuring clinical research billing compliance.

**Who will conduct the coverage analysis?**
UTHealth’s Clinical Trials Resource Center (CTRC) will ensure that a formal coverage analysis is completed when required. CTRC staff will assist the designated members of the research team or department in conducting coverage analysis.

**Does my clinical trial require coverage analysis?**
If the research sponsor is willing to pay for all of the procedures in the study schedule, then a formal coverage analysis is not needed. On the other hand, if some costs are billed to a third party payor, such as Medicare, then a formal coverage analysis is required. CTRC will work with researchers and research staff to assist them in making this determination.

**What is the basic process for coverage analysis?**
When studies are submitted via iRIS for CPHS review, CTRC will identify those that require coverage analysis and will then reach out to the study team to offer assistance. If you’d like to know more about this process or would like to learn how to conduct a coverage analysis for your research study, please contact CTRC at clinicaltrials@uth.tmc.edu.

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**Harris Health System Research Fee Schedule**

The Harris Health System has released an updated fee schedule for research protocol services. The updated schedule can be found [here](#). The new fees are effective for financial agreements created after May 15, 2014. Note that the Study Initiation Fee for the Investigational Drug Service has been increased to $1,500. Researchers are encouraged to request an initial financial review of a proposed protocol during the preparation of the protocol budget. Each service has 3 quoted rates:

- **The “Government Discount Rate”** applies to federally-funded research studies that cover Facilities & Administrative (F&A) costs (also known as Indirect Costs) in addition to fee-for-service costs.
- **The “Commercial Discount Rate”** applies to research studies funded by commercial sponsoring agencies that cover F&A costs in addition to fee-for-service costs.
- **The “Standard Non-Discount Rate”** applies to research studies that only pay for fee-for-service costs.

If you have any questions, please contact Sara Ruppelt at 713-566-6225.
To address concerns about IRB fee billing, a new billing process has been established. IRB fees for initial and continuing review, as well as the administrative fee for initial review of protocols by outside IRBs, will be billed directly by the IRB office to the sponsor.

**The Process**
Cristina Dyke, Administrative Services Officer in the Clinical Research Unit (CRU), will generate an invoice based on the submission received by the IRB office. The invoice will be sent to the sponsor contact who is listed on the application and will be copied to the UTHealth study team contacts.

Note that the IRB application for initial review has been revised to include sponsor contact information for IRB billing purposes. For existing research, Cristina will contact the study team to obtain the sponsor contact information.

**Process for Protocols Reviewed by Chesapeake IRB**
For protocols reviewed by Chesapeake IRB, please make arrangements with the sponsor to pay Chesapeake directly. If the sponsor does not agree to be billed directly by Chesapeake, ensure that the sponsor will pay for all Chesapeake IRB invoices plus 30% in indirect costs.

**Current IRB Fee Structure**
The current IRB fee structure is found [here](#). Note that IRB fees are charged for the initial and continuing review of industry-sponsored studies but not for investigator-initiated studies or for studies funded by federal agencies or non-profit foundations.

For questions about an IRB fee invoice, please contact Cristina Dyke. To share general comments or suggestions on the new IRB fee billing process, please contact [clinicaltrials@uth.tmc.edu](mailto:clinicaltrials@uth.tmc.edu).

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**CRU SERVICE – CLINICAL TRIAL MONITORING**
Kathy Franco, CRU Nurse Manager

The ICH Guidelines for Good Clinical Practice defines monitoring as an act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirements. In industry sponsored trials, monitoring is the sponsor’s responsibility. In an investigator initiated trial, the responsibility for monitoring lies with the Principal Investigator (sponsor-investigator) and in a multi-center federally funded trial, the coordinator center is responsible for the monitoring plan.

Some sponsor-investigators at UTHealth have met their responsibility for monitoring by contracting with commercial research companies. Others have hired individuals within their team to monitor trials. We have had several requests for other options for monitoring. We are very happy to announce that monitoring services are now available at UTHealth.

Monitoring will be conducted by Cary Warner. Cary has worked as a research coordinator for more than 20 years. She was with the University of Texas Health Science Center at San Antonio before joining the Clinical research Unit at UTHealth where she was the research coordinator and regulatory specialist for over 7 years. Cary is a certified clinical research coordinator. The cost of monitoring will depend on the complexity of the trial, the frequency and extent of monitoring. The CRU will evaluate the monitoring plan and offer an estimate based on the hourly rate of $65 an hour.

To request for monitoring services, contact Kathy Franco, RN, BSN, CCRC or call 713-500-4147.
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: May 27, 2014; June 24, 2014
Time: 11:30 am – 1:00 pm
Location: MSB 2.135
Lunch provided to the first 40 participants
Registration is not required.
More information here.

Clinical Research Budgeting and Billing
Objective: A hands-on workshop the clinical trial budgeting and billing process at UTHealth. The course will cover the process for coverage analysis, building a research budget, developing a billing grid and the process for creating EG accounts and Case Accounts.
Date: June 24, 2014; Aug 26, 2014
Time: 1:30 pm to 3:30 pm
Location: MSB B400
Registration is required. Register here.

iRIS Training
Objective: Hands-on training in the iRIS system to submit research protocols involving human subjects to UTHealth’s CPHS for review by the IRB.
Date: June 12, 2014
Time: 1:30 pm – 4:00 pm
Location: UCT 1160 (subject to change)
Parking will be validated.
Registration is required. Register here.

Orientation for Clinical Research Staff
Objective: This half day program provides an overview of clinical trial research at UTHealth. This course will cover CPHS review process and approval process, the MHH hospital review process, and a brief introduction to clinical trial management.
Date: June 24, 2014; Aug 26, 2014
Time: 8:00 am to 1:00 pm
Location: MSB 2.104B
Registration is required. Register here.

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 for more information.

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Registration for the October 2014
CLINICAL RESEARCH EDUCATION
will open mid Summer.