FDA Informed Consent Guidance

The Food and Drug Administration recently published draft guidance on Informed Consent intended for IRBs, clinical investigators and sponsors. This guidance, when finalized, will supersede the September 1998 “A Guide to Informed Consent”.

The guidance emphasizes that obtaining a subject’s signature on the consent form is only part of the informed consent process. The guidance reiterates that a good informed consent process should:

- Provide adequate information to make an informed decision
- Facilitate subject’s comprehension
- Provide opportunity to ask questions
- Observe voluntary agreement to participate
- Minimize possibility of coercion or undue influence.

The guidance document provides new recommendations in several areas.

The guidance clarifies when review of patient records would be considered part of the clinical investigation. Review of records to determine whether the patient may be eligible for a clinical investigation could be considered preparation for a clinical investigation and may be allowable before informed consent is obtained. However, only limited information to establish eligibility should be recorded.

The guidance addresses the issue of enrolling participants who do not understand English. The guidance states that when enrollment of non-English speaking subjects is expected, investigators should provide appropriately translated documents to the IRB along with a description of how information will be communicated to the subjects. When investigators are faced with non-English speaking subjects, the preferred option is to prepare a translated consent document, but if time does not permit, the investigator may consult with the IRB to determine if there is sufficient justification to enroll subjects without translated form or to use short form consent.

The guidance document describes at length additional protections for adults with impaired consent capacity and for children. The guidance strongly discourages subjects from enrolling in more than one clinical trial simultaneously or from enrolling in the same clinical trial multiple times.

The guidance emphasizes that subjects should be advised in the informed consent document that in the event of their decision to withdraw from a clinical investigation, data collected up to the time of withdrawal must remain in the study database.

Read the guidance document here. The guidance is open for comments and suggestions until September 15, 2014.
Informed Consent Focus group
Elizabeth Meyer, Graduate Assistant, CTRC

Experienced research nurses and research coordinators from various departments in UT Health shared their thoughts on the process of obtaining consent at a focus group was in June 2014. The focus group was a continuation of the discussion initiated at the Let’s Talk Ethics meeting earlier in the month. Paula Knudson, Member CPHS and Rebecca Lunstroth, IRB Chair Panel 1, moderated the discussion. Coordinators shared their experiences and concerns regarding recruiting participants, earning trust, working with investigators and more.

There was general consensus within the group that the informed consent process is extraordinarily important to building relationships with participants and their families. Coordinators indicated that patients respond more positively to a study when study professionals approach them modestly, with a relaxed and optimistic demeanor, and politely ask if family members should be involved in the discussion. Taking the time to “take off the white coat”, sit down and go through the entire consent document helps participants feel that they can ask questions and grasp their essential role in the study. Often these participants will reliably return for later study visits. It was agreed that building trust while obtaining informed consent leads to better engagement and retainer of participants throughout a study.

Though recruitment can be difficult at times, coordinators warned that patients who initially appear interested in a study may be enrolling solely to obtain an incentive. Dutifully screening and explaining risks to these patients helps deter those who do not fit or understand study criteria. Generally, participants deem parking vouchers to be the most important incentive.

Special circumstances addressed by the coordinators include language barriers, assent of children and informed consent in emergency research. Coordinators recommended that those obtaining consent act from a service perspective, and do whatever possible to ensure patient comfort and understanding during the consent process. Speaking with children separate from parents, allowing time for Legally Authorized Representatives to make an informed decision and holding consent conversations in clinics rather than in hospital settings were a few of the suggestions.

Coordinators felt that consent documents are usually too long for participants. Coordinators agreed that the document should be written in a more patient-friendly format and abbreviated to a few pages.

“These coordinators are doing an outstanding job. We should request them to teach all new coordinators.” said Paula Knudson.

Informed consent process has been the focus of several discussions at the Let’s Talk Ethics meetings. We will continue to talk about challenges in the informed consent process in our future meetings.
This and That – Updates for Research Coordinators

CPHS Report to Faculty and Research Staff

We’d like to remind you that the 2013 CPHS report to faculty and research staff is available on the CPHS website. Time to approval has been reduced steadily over the past several years. We are all very familiar with the fact that it takes both the IRB and the research team to reduce time to approval. The chart on Page 4 of this report breaks down the approval time into time taken by the IRB and the time taken by the research team to respond to the IRB.

We take your comments and suggestions very seriously. The CPHS executive committee reviews every comment you submit when you complete the CPHS Faculty Survey – a link to this survey is sent with each IRB Outcome Letter.

Researchers Handbook - MHHS

We congratulate the staff at the Center for Clinical Innovation and Research Institute for publishing the “Researcher’s Handbook – Guidelines for Research in Memorial Hermann Health System”. This handbook informs researchers and research staff about the policies and procedures for conducting human subjects research in Memorial Hermann Health System facilities including the review process, research credentialing process, budgeting and billing for clinical research and many other issues that researchers and research staff deal with on a daily basis.

The handbook has step-by-step guidance for requesting access to the medical records for research purposes. While it is primarily a handbook for researchers, it also describes the process for review of Quality Improvement or Performance Improvement projects.

You can access the handbook under Operating Procedures when you click My Assistant within iRIS. It will also be available via Physician’s Link.

Medical School Petty Cash Office Closing

Claire Brunson, Director, Management Services sent a notification last week that July 29th from 9:00 AM – 10:00 AM will be the last day the Medical School’s petty cash office will be open, as reimbursement requests have dwindled substantially. You may take your petty cash receipts to the Bursar’s Office at 7000 Fannin, 22nd floor to be reimbursed, or save your receipts until they accumulate to over $25.00 and a check or direct deposit may be requested/processed.

Clinical Research Budgeting and Billing

If you need to access the UTP price list or billing forms to send to McKesson, please note that the documents have been moved from the CTRC website to the new Clinical Research Finance website at OSP. You can access clinical research budgeting and billing documents here. You will need UTHealth user ID and password to access some of the documents.

The Clinical Research Finance team is working on organizing several sessions on the new coverage analysis process that will be implemented this fall. Dates and locations of these sessions will be disseminated widely.

Ophthalmological Exams

Marilyn Perry, Program Manager for the Clinical Research Administration in the Department of Internal Medicine called us recently to let us know about a new trend she has noticed. Many new studies include ophthalmological exams for research participants to test for drug side effects to the eye. To obtain pricing and get answers to other logistical questions, please contact Laura A. Baker, COA, Director, Clinical Trials Unit at the Robert Cizik Eye Clinic at laurbaker@cizikeye.og.
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:** July 22, 2014; August 26, 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](#).

**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:** July 29, 2014; August 20, 2014

**Time:** 1:30 pm – 4:00 pm

**Location:** UCT 1160 (subject to change)

*Parking will be validated.*

Registration is required. Register [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:** Aug 26, 2014; December 2, 2014

**Time:** 1:30 pm to 3:30 pm

**Location:** MSB B400

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:** Aug 26, 2014; December 2, 2014

**Time:** 8:00 am to 1:00 pm

**Location:** MSB 2.104B

Registration is required. Register [here](#).

Registration for the October 2014

**CLINICAL RESEARCH EDUCATION COURSE**

*will open next week.*

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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.

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