FDA issued a new guidance in August 2013 titled, “IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed.”

Many of the recommendations in this guidance have appeared in other FDA guidance documents. CPHS is already in compliance with the recommendations in this guidance document.

**Investigator Qualifications:** As part of its review of the qualifications of investigators, CPHS requires submission of CVs of the principal investigator and co-investigators. Submissions that do not include CVs are returned for corrections. This is one of the most common reasons for ‘return for corrections’. One way to avoid this problem is to upload the investigator CV to the investigator profile. Then one would not have to submit a CV for every new CPHS application. Before submitting the CPHS application, it is a good idea to review whether the study team has the collective experience, expertise and qualifications for conducting the research study.

**Adequacy of Research Site:** CPHS evaluates the adequacy of the research site to determine whether the proposed research meets the criteria for approval, so it is a good idea to include the information in the initial application. For example, when the research involves a new medical device, include information on training provided to healthcare providers for the use of the device. If the research involves working with a new research site for example, an outside clinic, include adequate information on the new research site and how the research protocol will be implemented at the research site.

**INDs and IDEs:** When the research is being conducted under an FDA approved IDE or IND, clearly include information on the IND/IDE in the CPHS application. For research involving drugs and biologics, if a determination has been made that an IND is not needed, include documentation from the sponsor or FDA or justification on why an IND is not needed. All significant risk device studies must have an IDE approved by FDA. If the sponsor determines that a device study is nonsignificant risk, submit justification or if FDA has agreed with the sponsor’s NSR determination, submit documentation from FDA with the initial CPHS application.

Read the guidance [here](#).
The Clinical Research Unit (CRU) currently has 100 active trials, 4 of which are new NIH funded multicenter trials in Pediatric, GI and Orthopedic Trauma Surgery.

This month we would like to highlight the CRU Laboratory.

CRU laboratory staff members at the University of Texas Health Science Center at Houston are available to assist in the processing, storage, and shipping of laboratory specimens including, but not limited to blood, stool, urine, and saliva. In addition to the laboratory staff, the CRU nurses and coordinators are also IATA certified in shipping and maintain their annual blood borne pathogen testing requirements.

There are 4 centrifuges available for ambient and refrigerated centrifugation, one of which is a micro centrifuge capable of 12,000G speeds. There are also 4 freezers and a refrigerator available for storing samples. Freezers include the standard -20°C, -30°C and -70°C temps as well as a liquid nitrogen freezer for more temperature sensitive specimens, such as stem cells or vaccines. In addition to the normal alarms in place, each freezer is hooked up to a data logger that will call selected CRU staff 24/7 in case of temperature fluctuations. Through collaboration with MHH, the CRU also has access to a laminar flow hood for cell reconstitution or other protocols that may require aseptic techniques.

The CRU lab falls under the MHH CAP and CLIA umbrella and therefore we are able to perform certain Point of Care Testing such as urine pregnancy tests and dipsticks, and Hemoglobin A1c testing.

In addition to the list of services described above, the CRU lab offers dry ice for shipping at $12.00 per shipment.

Please contact Monika Ruscheinsky at monika.ruscheinsky@uth.tmc.edu for more info and for any lab questions you may have.

**News:** Dr. Michael Fallon was recently highlighted in a Houston Chronicle article. In the article, he discusses the need for hepatitis C screening. Dr. Fallon’s clinical and research interests include diagnosis and therapy of hepatopulmonary syndrome and the prevention and treatment of complications of chronic liver disease as well as therapy for Hepatitis C, B and non-alcoholic fatty liver disease. To access the article click here.

**Internship Program:** The CRU is now offering a Research Nurse/Coordinator Internship Program. Call for information. The first intern is Catherine Thorstenberg RN.

**Reminder:** Just as a reminder, please don’t forget to use our new CRU Patient Registration Form. To request a copy you can contact Sheryl Fue via e-mail at Sheryl.L.Fue@uth.tmc.edu.

**Employee of the Month**

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The CRU invites investigators, research staff, and sponsors to tour the unit. To schedule a tour, contact Kathy Franco RN BSN, CCRC by phone at 713-704-4137, or via e-mail at Kathy.D.Franco@uth.tmc.edu.
Center for Clinical Investigations Update  
Team Leads

The Center for Clinical Investigation (CCI) was officially launched in January 2013 to guide, strengthen, and build clinical research at UTHealth while reducing the burden on individual research teams. The CCI hopes to achieve this goal by identifying best practices, streamlining clinical research processes, and providing education, training, and support. Three key teams were created: regulatory, clinical research operations, and finance.

Much progress has been made in the last several months. For example, the Finance Team has developed a new clinical trial budget template to help ensure all costs are adequately captured in study budgets. The template is being piloted by various groups within the School of Medicine. Once finalized, the budget template will be made available throughout UTHealth via the CTRC and OSP websites. The Finance Team also is working with University Administration to develop a policy on payment to research participants and with CPHS to make the process for billing IRB fees more efficient.

You are welcome to attend the Finance Team meetings at UTPB 1100:55 from 2 to 3 pm every third Monday.

The Regulatory Team is working on an easily accessible repository of commonly required documents, such as laboratory certification, IRB member rosters, and IRB registration information. These documents will be available under a new section in iRIS called Coordinator Tools. The Regulatory Team also is working on strategies to improve IRB time to approval.

You are welcome to attend the Regulatory Team meetings at UTPB 1100:55 from 2 to 3 pm every second Monday.

The Clinical Research Operations Team is developing a mentoring program for new clinical trial coordinators and research nurses.

You are welcome to attend Clinical Research Operations Team meetings at UTPB 1100:55 from 2 to 3 pm every fourth Monday.

Tips for Consent Documents Version Control  
Deborah Dowlin, CPHS Office

A document footer is an organizational tool that ties the consent document to a specific version of the protocol document (or investigator brochure, an amendment release, etc.). Document footers should be placed in the lower left corner of the document because the IRB approval stamp is always placed in the lower right corner. The CPHS staff does not update document footers on informed consent forms. We rely on the site to update their footers as needed. For industry sponsored studies, the Sponsor will update the document footer each time a new version of the consent is released. In these instances, the site should always use the footer provided by the Sponsor. Document footers are not a requirement on consent forms for investigator-initiated studies; but if you plan to use them to stay organized, do not place the iRIS generated IRB “version date” on the consent document. The iRIS generated IRB “version date” changes each time the submission is received (or returned) or modified. A better solution is to use the date that the protocol was updated or the date the amendment was released. If you have any questions or concerns do write to us at cphs@uth.tmc.edu.
A new release of the iRIS system was implemented in mid-July that included several new features. Unfortunately, along with “new versions” of software often come “new problems or bugs”. We have been documenting these issues and reporting them to the vendor so that they can send us an updated release of the system which will resolve these problems. Please be sure to report any “odd” behaviors of the system to Barbara Legate at 713-500-3470 or Barbara.S.Legate@uth.tmc.edu as soon as possible. In the meantime, here is a list of several issues that we are already aware of.

- The spellchecker function is not working in the text editors.
- The “Print Friendly – PDF option” is not working. Select the “HTML” option when using the “Print Friendly” button instead.
- There is a problem with REVIEW BOARD FORMS whereby the system is allowing people to “detach” them from submissions and also allowing you to “attach” them to a submission even when they have already been attached before – this is not supposed to work like this. There should be NO CHECKBOX next to any form that has been submitted before but this is not working correctly. Please pay attention to this issue when submitting revisions to submissions because if forms become “detached” from submissions, they are sometimes not visible on the board side on a returned response.
- Submissions sometimes appear on the Completed Tab even when they are not complete and vice versa, they sometimes appear on the INCOMPLETE tab even when they are complete. If you see a submission like this, please let me know because iMedRIS can move them to the appropriate tab for us until this issue is resolved.
- The Targeted enrollment Pre-defined field is not saving data correctly. After you enter numbers in the fields, it appears to save it but then if you go out of that panel and come back in, the system will take whatever number you put in the first field and put it in several of the fields. If you are using the CRU and this panel appears on your application, I suggest you leave that area blank until the problem gets fixed.
- From the Study side, the filters on the Study Document page are not working. There are fields called “Category” and “Sub-category” that are not active that should be.
- Study teams are no longer able to add Study Contacts on the Study Management page where they should have access to do this. If you need a person added as a Study Contact to a study, please contact either Barbara Legate or Paula Alexander to add the person for you until this issue has been resolved.

If you have more questions left unanswered please feel free to contact Barbara Legate at 713-500-3470.
NEW FACES

Cherrelle J. Duncan is a native of Lafayette, LA. There she attended the University of Louisiana at Lafayette and received her Bachelor of Art in Public Relations. She is a recent graduate from the Bush School of Government & Public Service at Texas A&M University and obtained her Master of Public Service & Administration. Cherrelle joined the Office of Sponsored Projects as a Sponsored Project Specialist in late July (two months after graduation). She enjoys cooking, attending concerts, all other entertainment, volunteering, planning events and playing with her puppy.

Daniel O’Neal completed his undergraduate studies at Southern Methodist University in Dallas before moving to Houston in 2007 to complete both his J.D. and LL.M graduate degrees. In his free time, he volunteers in the community by providing pro bono legal assistance in certain civil matters to indigent HIV/AIDS patients; and in non-legal capacities with entities such as the Food Bank and Planned Parenthood. Daniel’s current position at UTHealth is as a Sponsored Projects Specialist in the Office of Sponsored Projects. Welcome to UTHealth Science Center at Houston!

National Clinical Trials Number in Bills

NCT Number: Effective January 1, 2014, it will be mandatory to report the National Clinical Trial (NCT) number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination Manual. National Clinical Trial (NCT) number is the number issued by ClinicalTrials.gov registry that is unique to each trial registered. The format for the ClinicalTrials.gov registry number is “NCT” followed by an 8-digit number, e.g.: NCT00000419. More information here.

CERTIFICATION FOR CLINICAL RESEARCH PROFESSIONALS

CCRP certification: For those of you interested in becoming a certified research professional, the next test date at The Methodist Hospital in Houston, TX is November 2, 2013 with a registration deadline on September 20, 2013. More information here. CRC certification: The next test date for certified Clinical Research Coordinator is February 27 – March 22, 2014 and application deadline is October 1, 2013. More information here.
UPCOMING TRAINING

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management and network with research administrators and staff from various research groups within UTHealth.
Dates: Every 4th Tuesday of the month
Time: 11:30 a.m. – 1 p.m.
Location: MSB 2.135
Lunch provided to the first 40 participants
Registration is not required. More information here.

Clinical Research Education
Objective – Promoting excellence in clinical trial management for research nurses, study coordinators and other research staff. Day 1 focuses on clinical trial finances and contracting, day 2 and 3 focus on clinical trial conduct.
Time: 8 am to 4 pm
Location: Cooley University Life Center.
Registration is required. Register here.

Orientation for Clinical Research Staff
Objective – This educational program is designed to be a general overview of clinical trial research at UTHealth. This five hour program will cover basics of CPHS (UTHealth IRB) review and approval process, Memorial Hermann Hospital review and approval process, clinical trial financial management, and clinical trial management.
Time: 8 am to 1 pm
Location: UTPB 1100:55
Registration is required. Register here.

iRIS Training
Objective: Hands on training in the iRIS system to submit research protocols involving human subjects to the IRB.
Dates: Sep 10 and Sep 26, 2013.
Location: UCT 1160 (subject to change)

About Clinical Trials Resource Center
It is the mission of the Clinical Trials Resource Center to provide a single portal of expertise, and best practices for the study team to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Visit www.uthouston.edu/ctrcenter for more information.

Sujatha Sridhar, MBBS
Director
713-500-3622

Thea Troetscher, RN
Regulatory Specialist
713-500-3583

Marilyn Perry, CCRP
Regulatory Specialist
713-500-3587

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

Ngozi Okafor, MPH
Graduate Assistant
713-500-3551