New FDA Guidance on INDs – Sep 2013


The IND regulations define *clinical investigation* as: an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of the IND regulations, an experiment is any use of a drug, whether approved or unapproved, except for the use of a marketed drug in the course of medical practice.

A clinical investigation of an approved drug is exempt from IND requirements if it meets all the following criteria:

- The drug is approved for use in the US.
- The research is not intended to be reported to FDA as a well-controlled study in support of a new indication or change in labeling of the drug.
- The research is not intended to support a significant change in the advertising for the drug.
- The research does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk or decreases the acceptability of the risk associated with the use of the drug.
- The research is approved by an IRB and follows informed consent requirements.
- The research is not intended to promote or commercialize the drug product.

The guidance also addresses research involving dietary supplements. Although a dietary supplement is not considered a drug, if the clinical investigation is intended to evaluate the dietary supplement’s ability to diagnose, cure, mitigate, treat or prevent a disease, an IND is required under 21 CRF 312. For example, there is an ongoing clinical trial at UTHealth involving mango that is being conducted under an FDA IND.

The sponsor or sponsor-investigator of clinical trials using approved drugs is responsible for determining whether the trial meets the IND exemption criteria. When there are doubts, contact the CTRC and we will work with you to seek advice from FDA on the applicability of the IND regulations. To read the entire guidance click here.
Preparing Your Patient for a Research Visit at the CRU
Kathy Franco, Nurse Manager, Clinical Research Unit

Some of the aspects of your patient having a successful clinical research visit can be completed by pre-visit preparation.

- If the patient is coming to the CRU, provide our phone number, 713-704-4137. If the patient gets lost in the hospital, he or she can call. We can also provide a map of the hospital, to indicate how to get from the Valet parking to the CRU.
- If the CRU is validating parking, the patient should park at Memorial Hermann Valet. If you want the patient to park in one of the other garages, this should be negotiated in your budget before your study starts.
- Any special patient instructions for the visit can be added to the patient demographic sheet. Email the demographic sheet as an attachment to or fax a demographic sheet to 713-704-6417. Special instructions can include any Memorial Hermann services that are required, amount of compensation that the patient will be receiving, and a description of any special assistance the patient will need in the unit.
- If your patient will be requiring an EKG, or RRL test, instructing them not to use body lotion or powder, can help in getting good contact with the electrodes.
- If your patient is going to have blood work done, verify with the protocol and lab manual if the patient needs to be “fasting” for the visit. Some studies only want to know if the patient has been fasting. It’s not a requirement for the labs to be completed.
- If there aren’t any dietary restrictions, we recommend that patients have a “hearty” meal the night before, this usually helps the veins pop-up. Also instructing the patient to stay warm, by wearing a sweater, jacket, or long sleeves, can aid in obtaining the necessary blood sample.
- The patient’s hydration status is one of the most important things in completing a successful venipuncture. If the patient does need to be fasting, he or she should still be able to have water. If someone hasn’t had anything to drink for over 12 hours, veins can be flat and it becomes more difficult to obtain the sample. Dehydration can also lead to a hemolyzed sample or bruising to the patient’s arm.
- If the patient has a tendency to feel very anxious or to faint during a blood draw, we will assist the patient to lie down during the blood draw. If the patient does have a vagal response, lying down is safer. We can also give the patient juice and crackers afterwards.
- We only allow each CRU nurse or phlebotomist to attempt 2 venipunctures on a patient. If unsuccessful after 2 attempts, another nurse will need to try to obtain the blood sample.
- Patients, who come to the CRU for timed PK visits, requiring several samples, will have a saline lock placed. For these visits, we suggest that patients leave minor children at home if possible. The length of these visits tends to be challenging for both the patient and young children. Also, safety is a concern.
- If your study requires discharge instructions for the patient, such as not driving for a specific period of time, or side effects that the patient will need to report immediately, we can help coordinators to develop these.

We hope that this information is helpful and we are happy to assist you with your patients in the CRU. For more information send us an email.
Representatives from the Center for Clinical Investigations (CCI) will be presenting the new budget tool at the Coordinator Forum on October 22, 2013. Christopher Denman was instrumental in developing this template.

The template is being piloted by various groups within the School of Medicine. The CCI team is now ready to make the new budget template available throughout UTHealth via the CTRC and OSP websites. At the forum this month, Christopher will talk about his approach in developing this template. Kimberly Lofton, Sr. Contracts and Grants Analyst, who has been using the new template for several months now, will talk about her experience using the template and walk us through the template. Kathy Franco, Nurse Manager, CRU will talk about obtaining CRU prices. A representative from MHH will discuss the process for obtaining MHH prices. The forum will be held at MSB 2.134 from 11:30 am to 1 pm on October 22, 2013.

### New Faces and Changing Places

We are pleased to announce that Marilyn Perry, CCRP, has accepted a position as Program Manager for the clinical research administration. Marilyn graduated from the University of Detroit-Mercy College with a Bachelor of Science and is a Certified Clinical Research Professional. She has been working in the clinical research field since 1998. In her new role, Marilyn will work with researchers and research staff within Internal Medicine with clinical reviews of research budgets, financial management of trials and serve as a resource for best practices in clinical trial conduct. Congratulations and good luck on your new position within our institution!

**Kara Kime** graduated from New Mexico State University with a Bachelor of Science in Biology then attended Texas State University to obtain a Master of Health Services Research degree. She has previously worked as a Research Coordinator for Phase I Drug Trials at PPD. Later, she took a position as an IRB coordinator at Seton Family of Hospitals. While working for Seton, she transferred to the Epilepsy Program and held the positions of Project Coordinator then Research Coordinator before moving to Houston. Kara is currently working in the CRU as a Senior Regulatory and Compliance Specialist. Welcome to UTHealth, Kara!
Revised OHRP Guidance on Compensating Research Subjects

Research subjects are often given some payment for participation in research in addition to compensation for out of pocket expenses such as parking. CPHS reviews the plan for payment to subjects to determine if the payment may be considered undue influence.

OHRP had deleted the following sentences from the guidance: “In no case should remuneration be viewed as a way of offsetting risks; that is, it should not be considered a benefit to be weighed against study risks. The level of remuneration should not be so high as to cause a prospective subject to accept risks that he or she would not accept in the absence of the remuneration.”

The revision clarifies that payment to subjects may include compensation for risks associated with their participation in research and that compensation may be an acceptable motive for some individuals agreeing to participate in research. It has also been revised to focus more specifically on issues related to consent. More information here.

Clinical Trials Registration
Thea Troetscher, RN, Regulatory Specialist

Is your trial registered? If you are conducting a sponsored clinical trial, the study sponsor is required by federal law to register the trial at clinicaltrials.gov. However, if the trial is investigator initiated, you may be legally responsible for registration. FDAAA 801 requires registration of all “applicable clinical trials.” Loosely, “applicable clinical trials” are prospective, controlled clinical trials comparing drugs or devices, other than phase I/pilot, or small feasibility studies. More information here.

If you are considering publication of your research, be aware that the member journals of ICJME will also require, as a condition of consideration for publication in their journals, registration in a public trials registry. More information here.

If your trial is already registered, and your PI is the Responsible Party for that registration, your study team is required to keep the registry up to date with any significant changes or information within 30 days of the changes, and verify the record as being up to date at least every 6 months. More information here.

For assistance, help, support, a lifeline, do not hesitate to email or call 713-500-3583

CRP 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: Thu, Oct 10 - 01:30 pm – 04:00 pm
Tue, Oct 29 – 01:30 pm – 04:00 pm
Location: UCT 1160 (subject to change).
Register here.

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/cctr for more information.

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