

Clinical Research News You Can Use...

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Mandatory Good Clinical Practice Training

A message from Peter Davies, M.D., Ph.D., Executive Vice President for Research

A new program that has been developed by some of our institutions most accomplished clinical researchers to provide our investigators with access to information on the best practices in clinical research, (GCP-Good Clinical Practice guidelines derived from the International Conference on Harmonization). Good Clinical

Good Clinical Practice is an internationally accepted standard for the design, conduct, record keeping and reporting of clinical trials.

Practice (GCP) is an internationally accepted standard for the design, conduct, record keeping and reporting of clinical trials. The goal of GCP is to provide an assurance of the protection of the rights, safety and wellbeing of subjects and that the information generated by the research is accurate, credible and reflects the current best practices in the field of clinical trials research.

The new program that is being implemented at UT-Houston has been developed in recognition of the fact that the conduct of clinical trials in accord with GCP is the surest way to insure that the trials conducted under the auspices of our institution and under the direction of our faculty meet all the expectations and requirements associated with excellence in the conduct of clinical research.

In order to ensure that all investigators who are involved in conducting clinical trials research at UTHSC-H are fully familiar with their requirements of GCP, the University is instituting a new GCP training program.

Mandatory GCP training for Principal Investigators conducting clinical trials from January 2010.

Completion of this training program will be required of all faculty who will serve as the Principal Investigator of new clinical trials submitted to CPHS as of January 1, 2010. While there are good reasons to also recommend that all key study personnel involved in clinical research projects become familiar with the principles and practices of GCP, completion of GCP training will only be required of the PI's and not of the other key personnel or research staff. This requirement is only for investigators involved in clinical trials i.e. any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

To provide GCP training for our faculty, the GCP Advisory Committee has recommended that we use the excellent on-line training course developed by the Collaborative Institutional Training Initiative (CITI) at the University of Miami . This training program is comprised of a series of specific GCP modules that have been designed to review the basic component of GCPs as they apply to many aspects of clinical research.. CITI is the same group that developed the on-line Human Subjects Training Program that is used by our university to provide human subjects research certification. The CITI GCP training program is available for all UT faculty and staff at www.citiprogram.org. As with the human subjects training, completion of the GCP training will result in the generation of a certificate that can be either

Researchers and research staff can take the GCP certification online at www.citiprogram.org

appended to the research protocol in iRIS or forwarded to the CPHS. The investigator will have their CPHS investigator profile updated to reflect their completion of the CITI training, a status that will be valid for three years. As mentioned previously, after January 1, 2010, demonstration of satisfactory completion of the CITI GCP training program will be required of all investigators intending to serve as the PI of a clinical trial.

The staff of the Center for Clinical and Translational Sciences (CCTS) are developing a

series of on-line training modules that will supplement the CITI Training program by providing additional information on specific aspects of clinical research and clinical trials management. These modules will include two additional mandatory modules, one on Safety Reporting and one on Quality Management in Clinical Trials, that will be required of PI's of clinical trials after June 2010. In addition, investigators who hold their own INDs / IDEs will be required to complete an online module on responsibilities of Sponsor-Investigators from June 2010 onward. In addition to these mandatory training modules, the CCTS will be offering a number of optional educational classes on specialized topics in best practices in clinical research such as responsibilities of a lead investigator in a multi-site study, validation of electronic systems, creating clinical research databases, designing case report forms (for examples see Appendix). These specific classes will be designed to enhance the opportunity of researchers to become familiar with the increasingly complex process of conducting specialized clinical research projects.

The leadership of University of Texas Health Science Center at Houston recognizes the commitment and dedication of our clinical researchers and the importance of the work that they carry out in advancing clinical care through research. The development of these new training programs, both those that are mandatory and those that are elective, reflect our shared commitment to the concept of excellence in the conduct of clinical research.



Investigator Responsibilities

Excerpts from new FDA Final Guidance release

FDA released the final guidance titled “**Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects**” on October 26, 2009. The goal of this guidance is to help investigators better meet their responsibilities with respect to protecting human subjects and ensuring the integrity of the data from clinical investigations and to clarify for investigators and sponsors FDA’s expectations concerning the investigator’s responsibility (1) to supervise a clinical study in which some study tasks are delegated to employees or colleagues of the investigator or other third parties and (2) to protect the rights, safety, and welfare of study subjects.

Principal Investigators routinely delegate study-related tasks to co-investigators, research nurses, coordinators and others. The Principal

The PI should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated.

Investigator is responsible for providing adequate supervision of those to whom tasks are delegate and is accountable for regulatory violations resulting from failure to adequately supervise the

conduct of the clinical study. The investigator should develop a plan for the supervision and oversight of the clinical trial at the site. Supervision and oversight should be provided even for individuals who are highly qualified and experienced.

Investigators are responsible for protecting the rights, safety and welfare of subjects under their care during a clinical trial.

The investigator is responsible for providing reasonable medical care for study subjects for medical problems arising during participation in the trial that are, or could be, related to the study intervention. The

The PI is responsible for protecting the rights, safety, and welfare of subjects under their care during a clinical trial.

investigator should ensure that the research subjects have reasonable access to needed medical care. During any period of unavailability, the investigator should delegate responsibility for medical care of study subjects to a specific qualified physician who will be readily available to subjects during that time.

There are occasions when a failure to comply with the protocol may be considered a failure to protect the rights, safety, and welfare of subjects because the non-compliance exposes subjects to unreasonable risks. For example, failure to adhere to inclusion/exclusion criteria that are specifically intended to exclude subjects for whom the study drug or device poses unreasonable risks. Investigators should adhere to the protocol so that study subjects are not exposed to unreasonable risks. To read the guidance document please click [here](#).



Data and Safety Monitoring Plans

By Dr. Sujatha Sridhar
Clinical Trials Resource Center

An appropriate data and safety monitoring plan is one of the regulatory criteria for CPHS approval. Applications to the CPHS should include adequate provisions for monitoring of data collected for scientific validity and safety of research subjects. The monitoring plan for a research study is created based on the complexity of the research study and the possibility of potential harm to subjects.

For research involving no more than minimal risk, special provisions for data and safety monitoring may not be needed to protect research subjects. Clinical trials that involve more than minimal risks to subjects should have a data and safety monitoring plan.

Not all trials require a DSMB, but all clinical trials require a safety monitoring plan.

This plan should state how often monitoring will be performed. Monitoring may be planned at specific points in time, after a specific number of subjects have been enrolled, or upon recognition of harm. The plan should state what data will be reviewed for safety monitoring.

This plan should also state who will perform safety monitoring – the Principal Investigator, an independent person with expertise in the field, a safety monitoring committee or a formal data and safety monitoring board (DSMB).

DSMBs have generally been established for large, randomized multisite studies that evaluate treatments intended to prolong life or reduce risk of a major adverse health outcome

such as a cardiovascular event or recurrence of cancer. DSMBs are made up of multidisciplinary members who are knowledgeable in the conduct of research, and should include those with backgrounds in biostatistics, experimental design, bioethics, and experts in the medical field of concern.

DSMBs are usually established for large, randomized, multisite trials that evaluate treatments intended to prolong life or reduce a risk of a major health outcome.

DMCs typically operate under a written charter that includes well-defined standard operating procedures. Such charters are important for the same reason that study protocols and analytical plans are important—they document that procedures were prespecified and thereby reduce concerns that operations inappropriately influenced by interim data could bias the trial results and interpretation. An effective data and safety monitoring plan should be able to detect signals to decide when the research study should be stopped. Usually stopping criteria are based on one or more reasons such as efficacy, futility and safety.

For more information on DSMBs, visit:
<http://www.uth.tmc.edu/ctrc/datasafety.html>

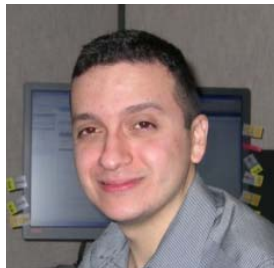


Office of Sponsored Projects Update

By Jodi Ogden
Director, Contracts

Wow, once again we have started the new fiscal year with a bang! The Contracts Section in the Office of Sponsored Projects is currently negotiating more contracts than ever before. Our office negotiates all sponsored contracts for the University including Clinical Trial Agreements, incoming Confidential Disclosure Agreements, Sponsored Research Agreements, Material Transfer Agreements, Subcontracts, Federal Contracts, Salary Reimbursement Agreements, and Interagency Contracts for Research. Our six specialists are currently negotiating more than 375 agreements! As a reminder, I recommend that you stay in touch with your Contracts Administrator. For those of you who have multiple agreements under negotiation, it is important for you to let your Contracts Administrator know when there are agreements that take priority. Although we negotiate many agreements simultaneously, it helps us a great deal if we are able to prioritize our workload based on your needs.

Over the summer we filled our two vacant positions and I would like you to join me in welcoming Daniel Deleon and Karen Niemeier! Daniel replaced Kiana Epps and is handling those departments that were assigned to her. Before joining the Office of Sponsored Projects at The University of Texas Health Science Center at Houston, Daniel worked in grants and contracts administration



in the Pediatrics and OBGYN departments at our Medical School. He started his career working in financial compliance at Harrah's Entertainment in Las Vegas. Daniel earned his Bachelor of Business Administration and his Master of Business Administration from Texas A&M University at Corpus Christi and is continuing his education by working on his Master of Health Administration at Texas Women's University.

Karen Niemeier replaced Sylvia Cabrera and is handling those departments that Sylvia



handled. Prior to joining UTHSC-H, Karen spent 10 years directing operations for an international litigation management company, where she managed contract negotiation and execution, client relations, and day-to-day operations for the firm. She also recently served as the senior assistant to the Chief Executive Officer of national restaurant chains, Pappas Restaurants and Luby's, Inc., where she coordinated community relations and legislative affairs efforts. A resident of historic Eastwood, and a past-president of the neighborhood's civic association, Karen earned her Bachelor of Science from The University of Texas at Austin.

You can access the new Workload Distribution chart in the Contracts section on the OSP website:

<http://www.uth.tmc.edu/osp/index.htm>.

Office of Sponsored Projects Update (contd.)



In addition to the changes in the Contracts Section, we now have our new Grants Director: Whitney C. Houston, MSW,

PMP®. Whitney is a seasoned grant professional with twenty years experience in the nonprofit and public health arenas. Whitney received a B.A. in Psychology and a Masters in Social Work both from the University of Houston. Additionally, Whitney completed post-graduate work at Brandeis University and served as a fellow at the CDC/ASPH Institute for HIV Prevention Leadership. Upon completion, she dedicated eight years in Miami, FL, working with HIV/AIDS grass-roots and public health organizations in numerous capacities, including grant writer, program evaluator, research

assistant and HIV/AIDS Grant Manager for Miami Dade County's Public Hospital. In 2004, Whitney returned to her hometown of Austin, TX, where she continued her work in public health with the Texas Department of State Health Services as a Project Officer for Federally Qualified Health Centers seeking federal and state funding. Whitney joined UTHSC-H Office of Sponsored Projects in November 2008 and is excited about working with the research community in her new role as Grants Director.

For those of you attending either the Grants 101 class or the Clinical Nurse Coordinator Education Training in October, I will be presenting at both sessions and I look forward to seeing you or meeting you. As always, feel free to contact me at 713-500-3968 or Jodi.Ogden@uth.tmc.edu. I welcome all suggestions and comments!

Featured Activity

IRB sessions are huge success!



On September 15, we launched a new series called Demystifying the IRB Process with the aim to help researchers understand the CPHS review and approval process, to enhancing the quality of interaction with CPHS and to

discussing strategies for improving timelines for approval. The first of these series, titled, An Introduction to the UTHSC-H Human Subjects Protection Program started with a bang with over 50 participants. Dr. Robert Nobles, Assistant Director of the Office of Research Support Services

gave a very inspired presentation on the responsibility that all of us share in protecting human subjects who volunteer in research projects.

Come and chat with the folks who staff the IRB every third Tuesday of the month. We have a variety of topics lined up for discussion, such as what the IRB looks for in a consent document, to insider tips on getting your protocol through the process faster.

To sign up for these sessions, log onto <https://mytrc.uth.tmc.edu>, select the function "course catalog", enter keyword "CTRC". The available IRB sessions will appear.

Upcoming Training

Clinical Research Budgeting/Billing Course

Objective: To simplify and clarify the clinical research billing processes, ensure full cost recovery of clinical research studies, and reduce the risks of inappropriately billing patients and/or third parties.

Date: Nov.10, 2009. **Time:** 8:30 a.m. – 11:30am

Location: UT Professional Building, 1100.55

Pre-registration is required. Please visit:

<http://www.uth.tmc.edu/research/clinical/training/ClinBudgeting.html>

Research Coordinator Monthly Forum

Objective: To discuss various topics of interest to research staff including research nurse, coordinators and administrators.

Date: Every 4th Tuesday of the month

Time: 11:30 a.m. - 1p.m.

Location: MSB 2.135

Next forum:

Lunch provided to the first 50 participants

November Topic:

Pre-registration is not required. Please email clinicaltrials@uth.tmc.edu to be added to the email distribution list.

Clinical Research Education

Objective: To provide a model of practice in conducting clinical research based on the principles of Good Clinical Practice focusing on human subjects protection and data integrity.

Dates: April 2010

Time: 8 a.m. - 4 p.m.

Location: UT Medical School Building

Registration will open in March 2010. Please visit:

<http://www.uth.tmc.edu/ctrc/training/clincoord.html>

Demystifying the IRB Process

Objective: To help researchers understand the CPHS review and approval process, to enhancing the quality of interaction with CPHS and to discussing strategies for improving timelines for approval..

Date: Every 3rd Tuesday of the month

Time: 11:30 a.m. - 1p.m

Location: MSB 2.135 (subject to change)

Pre-registration is required. Register at

<http://www.uth.tmc.edu/ctrc/training/irbtrain.html>. Registration will be open on the first of every month.

Accolades



From the Division of Oncology, congratulations to Susan Cooper (Regulatory Manager) and Jacqueline Shaw, LVN (Research Coordinator) who

just received their CCRP certifications from SoCRA.

Sheri Skinner, research manager, says “We are very proud of them. They are central to our efforts here in UT Physicians Oncology and both give generously of their talents and extensive experience to make our initiative a successful one. “

Q & A Corner

Have a question? We've got the answer.

How long do I need to keep my research records?

The investigational devices regulations (21 CFR 812.140(d)) require that the investigator or sponsor maintain the records required during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

We know from experience that investigators are not always notified of the date that records are no longer required for supporting a premarket approval application or notice of completion of product development protocol. Most institutions start calculating the retention period from the time the study was completed at their site. At UTHSC-H, our records retention policy requires storage of essential documents for at least 15 years from the time the study was completed. If you would like to read our policy, please visit - http://records.uth.tmc.edu/retention_schedule.htm

For industry sponsored research, please always refer to the study contract to find out what was agreed upon by the sponsor and institution.

Need some help reducing the readability of your consent? Making a budget? Developing your DSMP? Check out the CTCRC's Quick Reference page for helpful templates and links!"
<http://www.uth.tmc.edu/ctrc/quickreference.html>

We'd like to hear from you!

Please send newsletter submissions, questions or comments to:
clinicaltrials@uth.tmc.edu

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.

Director:

[Sujatha Sridhar](#)

713-500-7909

Clinical Trial Support: (Training, Budgets, Billing)

[Madelene Ottosen](#)

713-500-7910

Regulatory Specialist: (IND, IDE, Clinicaltrials.gov)

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