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The Clinical Coordinator

Clinical Research News You Can Use

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Informed Consent and Non-English Speaking Participants – Excerpt from FDA Guidance

Individuals who do not understand English may ask, or be asked, to participate in a clinical trial in locations where English is the predominant language. The investigators and the IRBs that review such research should carefully consider the ethical ramifications of enrolling or excluding potential subjects when a language barrier may exist between the investigator(s) and some or all of the potential subjects. Consistent with the requirement that selection of subjects be equitable, individuals should not routinely be excluded from participating in research simply because they do not understand English.

When individuals who do not understand English are to be enrolled in a clinical study, IRBs and investigators must ensure that the information given to such prospective subjects or their legally authorized representatives is in language understandable to the subjects or their representatives.

> Prospective participants should be given consent documents in a language understandable to them.

"Understandable" means that the information presented to potential subjects is in a language and at a level that they can comprehend and includes an explanation of scientific and medical terms.

The IRB must review and approve all English and non-English language versions of any consent documents (long form or short form with written summary) that are to be used by investigators to document the informed consent of subjects (21 CFR 50.27(a) and 21 CFR 56.111(a)(4) and (5)). When reviewing proposed informed consent procedures involving translation of written and oral information that is to be presented to subjects, FDA recommends that the IRB review and, if appropriate, approve procedures for ensuring that the translations will be prepared by a qualified individual or entity.

A protocol amendment in which the investigator proposes to include use of translated informed consent documents for a study already approved by the IRB with English language consent documents may be considered no more than a minor change to the research and may qualify for an expedited review procedure under FDA regulations at 21 CFR 56.110(b).

FDA notes that informed consent should be viewed as an ongoing process throughout the course of a subject's involvement in the research. Therefore, FDA recommends that whenever subjects who do not understand English are involved in research, appropriate interpreter services be made available throughout the course of the research.

For more information, read the FDA Information Sheet on Informed Consent.

Clinical Research Education

The Clinical Research Education course is designed to share best practices for managing clinical trials based on the principles outlined in the GCP guidelines.

This educational program is designed and conducted by experienced clinical trial research professionals from within UTHealth. The program examines the entire clinical trial process, from study feasibility to trial close-out activities, and provides practical recommendations for increasing the efficiency of clinical trial conduct. This course combines didactic presentations and interactive group sessions. Specific topics include human subject protections, GCP principles, institutional compliance, the informed consent process, study initiation, study conduct, FDA inspection, source documentation, investigational devices and drugs, and reporting requirements, among others.

This course is geared towards new research nurses, clinical research coordinators, and clinical research assistants; however, many experienced research staff have attended in the past to refresh their knowledge and to network with other research staff. This course has been offered at UTHealth since 2007 and has received positive feedback from participants.

Dates:	**October 22 – 23, 2019**
Location:	Cooley University Life Center
	7440 Cambridge St, Houston 77054
Fees:	$100
Register here:	Clinical Research Education

Informed Consent When Subject is Unable to Write

A person who can understand and comprehend spoken English, but who is physically unable to talk or write, can be entered into a study if he or she is competent and able to indicate approval or disapproval by other means. For example, an individual who has just had a stroke might not have the ability to sign the consent document.

If the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and is able to indicate approval or disapproval to study entry, then they may be entered into the study.

A person who speaks and understands English, but who does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law.

The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document.

A video tape recording of the consent interview is recommended.

For more information, read the FDA Information Sheet on Informed Consent.

Congratulations to Dr. Lucci and Team Upon a Successful NRG Audit!!!

NRG Oncology is a non-profit research organization formed to conduct oncologic clinical research and to broadly disseminate study results for informing clinical decision making and healthcare policy. It brings together the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG)—each recognized internationally as a research leader. NRG Oncology receives funding from NIH's National Cancer Institute (NCI) as a member of the NCI National Clinical Trials Network (NCTN).

Dr. Lucci's team conducts several NRG studies and was recently audited by NRG. Carol Robazetti and Konny Chang were very proactive in making sure everything was ready and in perfect condition before the auditor was scheduled to arrive. The team first reached out to UTHealth's Clinical Trials Resource Center (CTRC) as soon as they received notification of the audit, and Research Compliance Specialist Shwetha Pazhoor was assigned the role of helping the study team to prepare for the audit. Shwetha conducted several visits with the study team and, along with CTRC's Graduate Research Assistant Jessica Martinez, carefully reviewed all patient charts for studies that could possibly be audited. Carol and Konny were very receptive to the suggestions, worked overtime (even on weekends) to make the necessary changes, and achieved perfectly organized and well-documented study charts to present to the auditor, which resulted in a no-findings perfect audit and showed that hard work and dedication pays off!

Congratulations again to Dr. Lucci, Carol, and Konny for doing a fantastic job!!!

Test your Good Clinical Practice Knowledge

1. IND stands for _____.
2. An _____ is a request for authorization from the FDA to administer an investigational drug or biological product to humans.
3. IDE stands for _____.
4. An _____ allows an investigational device to be used in a clinical study to collect safety and effectiveness data.
5. The FDA form _____ is the cover sheet for all types of IND submissions.
6. The FDA shall provide a written determination within _____ after FDA receives an IND application.
7. For INDs and IDEs, an _____ must be submitted every year.

Answers:
1. Investigational New Drug, 2. IND application, 3. Investigational Device Exemption, 4. IDE, 5. 1571, 6. 30 calendar days, 7. annual progress report.

Upcoming Training

iRIS Training

Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth's CPHS and AWC.
Date: October 9, 2019
Time: 1:30 pm - 4:00 pm
Location: UCT 1160 (parking will be validated)
Registration is required. Register here.

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management. More information here.
Date: October 23, 2019
Time: 11:30 am – 1:00 pm
Topic: Billing Process by Kristen Parks, Director, Clinical Research Finance & Administration
Location: MSB B.645
Lunch will be provided for the first 40 participants.
Registration is not required.

TMC – SoCRA METS

Objective: Monthly training and educational event for clinical research professionals.
Date: October 2, 2019
Time: 3:30 pm – 4:30 pm
Topic: Stem Cell Research – Ethical Issues by Elizabeth Gendel, PhD
Location: Third Coast Restaurant, 6th Floor Room II, 6550 Bertner Avenue
Registration is required. Register here.

Clinical Research Education

Objective: Good clinical practice guidelines and clinical trial management.
Date: October 22-23, 2019
Time: 8:30 am – 4:00 pm
Location: Cooley Life Center (parking will be validated). Lunch will be provided.
Registration is required. Register here.

IRB Office Hours

If you would like help submitting an iRIS application or writing a protocol or consent form, or if you want to learn more about IRB reciprocity agreements, then consider taking advantage of IRB office hours.
MSB hours: 2nd and 4th Thursdays from 1:00 pm – 4:00 pm at MSB B.640
SOD hours: 1st Thursdays from 1:00 pm – 4:00 pm at SOD 4416 (Research Office conference room).
An appointment is not necessary

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 suite 1840. Please visit https://www.uth.edu/ctrc/ for more information.

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We would love to hear from you.
Please send your comments, suggestions and feedback to clinicaltrials@uth.tmc.edu