UNTHSC Investigator Guidance

National Institutes of Health (NIH)-Required Actions

Clinical Trial Research funded by NIH

NIH launched a series of initiatives to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research, by visiting this web site in depth: https://grants.nih.gov/policy/clinical-trials.htm

Note that these requirements are only for NIH-funded clinical trials.

Key Points to Consider:

UNTHSC Investigators who are planning to submit a grant application to NIH for a clinical trial must first contact the Office of Sponsored Programs (OSP) who will advise appropriate actions and document and co-ordinate relevant human subject (IRB) issues with the Office of Research Compliance (ORC).

Grant Application Form Changes / New Human Subjects & Clinical Trial Information Form

There will be a new Human Subjects and Clinical Trial Information form which will be included in grant application packages and contract for all human subjects and/or clinical trial research applications beginning for **January 25, 2018** due dates.

This form consolidates human subjects, inclusion enrollment, and clinical trial Information previously collected across multiple agency forms. The form collects information on human subjects and clinical trials at the study level.

This new form will be included in the new FORMS-E Application Packages.

Contact Office of Sponsored Programs (OSP) at the earliest stage of your research planning for guidance and advice regarding this form and process.

Single IRB Policy for Multi-site Research

The NIH “Single IRB Policy for Multi-site Research” applies only in situations where the research will be conducted at two or more distinct and separate institutions. For example, “multi-site” does not mean several clinics affiliated with UNTHSC; such a study would be a single site project.

In any case, notify Office of Sponsored Programs AND the Office of Research Compliance prior to developing a grant application if your research project will involve more than one academic institution, hospital, medical center, or research institute separate from UN

Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov

All NIH-funded clinical trials are expected to register and submit result information to Clinicaltrials.gov, as per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" for competing applications submitted on or after 1/18/2017.

The following website link provides resources for understanding and complying with this NIH policy and the federal regulations in Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) as implemented by 42 CFR Part 11:

https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Note that this NIH-mandated requirement to register at ClinicalTrials.gov is required only for NIH-funded Clinical Trials.

Further, it is the Principal Investigator's responsibility to register their NIH-funded trial and maintain the record throughout the research project. For additional information regarding Roles and Responsibilities, as well as Results and Reporting, see the FAQ web pages at: https://grants.nih.gov/policy/clinical-trials/reporting/faq.htm#A

Good Clinical Practice (GCP) Training

Researchers who are conducting clinical trials supported by funds from the National Institutes of Health (NIH) are required to complete training in "Good Clinical Practice (GCP)". *Note that this GCP training is separate and in addition to the required training in human subject research*. That is, GCP training is not a substitute for the CITI Human Subjects Research course.

The web link to the NIH site describing this requirements with additional guidance is here: https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

Some basic pointers for this GCP training requirement:

- The requirement only applies to NIH-funded Clinical Trials
- All investigative team members (not just the principal investigator) associated with an NIH-funded clinical trial must complete training in GCP
- This GCP training must be re-taken every three (3) years
- Each person is required to maintain appropriate documentation regarding their GCP training and be prepared to present it upon demand from any NIH official. It is the investigator's responsibility to complete GCP training and retain training records.

For more information on this NIH-mandated GCP requirement, see the NIH FAQ link at this site: https://grants.nih.gov/grants/policy/faq_nih_good_clinical_practice.htm#5162

Certificate of Confidentiality (COC)

If a NIH Certificate of Confidentiality (COC) is obtained for a study, please describe in the Confidentiality section of the Protocol Synopsis form. You may use language similar to the following:

- This study has a Certificate of Confidentiality (COC) coverage from the U.S. Department of Health and human Services due to the new NIH policy. This COC offers a layer of protection and further strengthens the confidentiality plan.

Please add the following language to the consent document:

- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose or use information that may identify you, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

  The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of federal agencies. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The protection offered by the Certificate does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threat of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities, and will do so without disclosing your participation in this study. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.