

<b>No./Title:</b> UTHSC Oversight of Clinical Trials	<b>Resp. Office:</b> Sponsored Programs	<b>Effective Date:</b> 9/8/21
<b>Category:</b> Sponsored Programs	<b>Last Review:</b> NEW	<b>Next Review:</b> 9/7/24
<b>Contact:</b> Sarah White, Associate Vice Chancellor Office of Sponsored Programs	☎ 901.448.2359	✉ swhite82@uthsc.edu
<b>Related Policies:</b> FIO205 – Sponsored Projects		

## PURPOSE

The University of Tennessee requires that (1) UTHSC faculty research be appropriately supervised by UTHSC; and (2) UTHSC faculty receive institutional credit for the research they perform. To accomplish these goals, this procedure provides written guidance to UTHSC faculty, regarding the proper routing of their clinical trial and research related agreements. This policy applies to all UTHSC full time faculty for all clinical trials.

## BACKGROUND

Fundamental missions of the Office of Research are to support clinical investigation, to increase UTHSC faculty involvement in clinical trials, and to secure research award credit for the University for conducting clinical research activities. There is substantial clinical trial expertise among UTHSC faculty in Memphis and in the academic medical centers where UTHSC faculty practice across the state of Tennessee. Further, there is a robust network of resources that have been created by UTHSC’s Office of Research linking these clinical trial experts statewide. This network connects faculty through a number of domains that include, but are not limited to: (1) the Office of Sponsored Programs (all campuses); (2) the Clinical Trials Governance Board, (which includes clinical trials offices in Memphis and elsewhere in the State of TN through UTHSC’s affiliated hospitals and large practice groups); (3) the Clinical Trials Network of Tennessee (CTN2)\*, and its participating institutions (which include hospitals and practice groups where UTHSC faculty practice); and (4) the TN Clinical and Translational Science Institute, that also links all UTHSC sites and partner hospitals, and investigators throughout Tennessee.

- \* CTN2 is a legally separate 501(c)(3) subsidiary of the UT Research Foundation that was created to enhance Tennessee state-wide, multi-site, multi-institutional clinical trials, involving UTHSC, and Tennessee hospitals and large practice clinics in the CTN2 network where UTHSC faculty practice. UTHSC, as well as many of its partner hospital and practice plans, have entered into a Master Clinical Trial Agreement with CTN2.

## PROCEDURE

In order to fulfill the UT Board of Trustee’s mandate described, above, there are several conduits for clinical trial and clinical research related contracting and processes that have been

established. The contracting process an investigator must use will be dependent on the funding source and the genesis of the research.

### 1. Federally and Foundation Sponsored Trials

For **all** federally or foundation (e.g., American Heart Association) sponsored clinical trials performed by UTHSC faculty, the university must be the contractor (either prime- or sub-awardee) and funds flow manager. As such, all federally or foundation sponsored clinical trials and clinical research agreements, or any such activity with federal flow-through, must be processed through the UTHSC Office of Sponsored Programs. This includes, for example, non-disclosure or confidentiality disclosure agreements (NDA and CDA, respectively), clinical trial agreements (CTA), data use agreements (DUA) which may be necessary for a particular clinical trial, and subawards from another institution that has the prime federal award.

### 2. Industry Sponsored Clinical Trials

#### a. Site Initiated Trials

These trials may be contracted through the UTHSC Office of sponsored programs with clinical research agreements extended as needed to participating hospitals, clinics, and other sites. They can also be contracted via CTN2 as described in section 2b.

#### b. CTN2 Initiated Industry Sponsored Network Clinical Trials

The execution of Master Clinical Trial Agreements between CTN2 and its partner hospitals and practices has provided a mechanism by which UTHSC faculty can meet all UT requirements by using this organization for three way contracting between the Hospital, Sponsor and CTN2.

c. UTHSC faculty at Le Bonheur Children's Hospital are permitted to contract through Children's Foundation Research Institute (CFRI) for non-government trials while UTHSC and CFRI are working to create an affiliation/alignment that allows UTHSC the required oversight of faculty research and Higher Education Research and Development survey (HERD) credit for UTHSC faculty's research. The current pathway will time out two years from the date of the Chancellor's approval of this procedure for UTHSC Oversight of Clinical Trials.

The UTHSC Office of Sponsored Programs should be engaged by the site PI to establish the necessary clinical research agreements, for any trials conducted at UTHSC itself, and if otherwise applicable.