Office of Clinical Research
Annual Report 2017
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The mission of the Office of Clinical Research (OCR) is to maximize expertise in the field of clinical research by providing research support to University of Tennessee Health Science Center (UTHSC)-affiliated investigators to improve the quality, efficiency and regulatory compliance for the conduct of clinical research.

The UTHSC OCR is a premier research support center for clinical translational research within the Mid-South area conveniently located within the UTHSC Memphis campus.

The UTHSC OCR offers individualized fee-based research services for the development, set-up, initiation, quality control, financial management, and closeout of clinical research trials for investigators.

Objective: The OCR will provide research services to UTHSC affiliated investigators to improve the quality, efficiency, and regulatory compliance of the conduct of industry-sponsored clinical research trials and enhance the institution’s ability to fulfill its research mission.

Research Services: Services provided at the UTHSC campus, OCR Pauline Clinical Research, Methodist University Hospital, Methodist Germantown Hospital, Methodist South Hospital, Methodist North Hospital, Methodist Healthcare-Sutherland Cardiology Clinic (1211 Union Avenue and Methodist Germantown and Methodist North), Regional One Health, and Hamilton Eye Institute. OCR services have been contracted with investigators at Campbell Clinic, and St. Jude Children’s Research Hospital.

Services available to UTHSC affiliated investigators include:

- Education and training of new or inexperienced investigators in the conduct of clinical research
- Institutional Review Board submissions
- Guidance in regulatory compliance issues and adherence to federal regulations, assistance with completion and management of regulatory documents
- Budget preparation and negotiations
- Prospective reimbursement analysis
- Invoicing and tracking payments
- Liaison services as needed to sponsors and off-site clinical locations
- Coordinators available to attend investigator meetings with principle investigators
- Research nurse coordinator and non-nurse coordinator support to facilitate site management of day to day implementation of clinical trials
- Assist with development, training, and monitoring of existing department or new research personnel
- Coordination of pre-study setup visits and site initiation visit meetings for all new clinical trials
- Contract negotiation for each clinical trial (CDA, CDT, and amendment processing)
- Assist sponsors to locate investigators for new clinical trials and support facilitation of interaction with sponsors and contract research organizations
- Assess trial feasibility for interested investigators
- Coordination of site initiation and monitoring visits
- Access to appropriate clinical space, laboratory facilities, and equipment
- Use of clinical trial management system to facilitate clinical financial reporting
Research Highlights:

- MERGE software system for clinical trials management
- OCR research personnel increased to meet investigator demands
- Standard Operating Procedures available to investigators
- Further development of Manual of Operating Procedures
- Standardized personnel training documentation
- Monthly education and training for OCR personnel on relevant research topics
- Updated OCR work policies for multiple locations
- Assisted with the implementation of two new investigator initiated trials, including IRB, budget, personnel, and regulation.
- Offering Liaison services to assist sponsors’ location of qualified UTHSC investigators
- Assist investigators to identify opportunities to participate in new clinical trials
- Development and creation of new study related documents for investigator use (Site source documents, logs, etc.)

The following figures illustrate OCR activity from 2012 to the present:

Figure 1: The number of OCR supported active clinical trials has grown from two trials in 2013 to 43 trials in 2017, demonstrating an increase of activity every year since initiation.
**Figure 2:** OCR supported active clinical trials were implemented primarily at Methodist Hospitals through the fiscal year.

**Figure 3:** OCR supported pending clinical trials will also be primarily implemented at Methodist Hospitals.
Figure 4: There were eleven OCR supported clinical trials completed.

Figure 5: Most OCR supported active clinical trial were in cardiology (37%) during the fiscal year, with other fields minimally represented.
**Figure 6:** Upcoming OCR supported clinical trials are anticipated to be based in Cardiology and Hepatology.

**Figure 7:** OCR supported completed clinical trials through the fiscal year were from diverse therapeutic areas, ie primarily Cardiology.
Figure 8: OCR supports all Phases of clinical investigation including Interventional, Observational, Registry, PI initiated, and NIH studies

Figure 9: The majority of the OCR supported completed clinical trials were Phase 3
Figure 10: The number of subjects screened/pre-screened in OCR supported clinical trials have increased significantly.

Figure 11: The number of subjects enrolled into OCR supported clinical trials have grown each year.
Figure 12: The number of subjects visits into OCR supported clinical trials have substantially increased year over year.

Figure 13: The number of sponsor monitor visits had continued to increase. Fourteen new OCR supported clinical trials were initiated.