

METHODIST HEALTHCARE

“Serving Humanity to Honor God”

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Methodist Healthcare System, Clinical Trials Office

MHS is committed to promoting professional growth and experiences in all aspects of healthcare, including clinical research. We are very pleased to announce to our medical

community the creation of a new service, the MHS Clinical Trials Office (CTO). The CTO supports the medical research community by facilitating timely and efficient implementation and execution of clinical trials in a research-friendly environment at all MHS inpatient and outpatient facilities.

The CTO employs standardized and uniform processes to assist you with the initiation and implementation of clinical trials in a quick and efficient manner. This will help ensure that proper contractual, regulatory, financial and other requirements are met.

Increasing concerns about regulatory compliance issues have prompted both facilities and investigators to more closely evaluate high risk areas such as billing, referral sources, fair market value and HIPAA compliance. The CTO is

designed to ensure compliance with FDA regulations, local laws and cost recovery regulations.

We are excited to offer this new service to investigators and sponsors in our research community. For more information on the services we can offer, please feel free to contact Sherri Shade, RN, Clinical Research Director at, (210) 575-4238 or sherri.shade@mhshealth.com.

What is research?

The Federal Health & Human Services Department, Offices of Human Research Protections defines research as being:

A means of systematic investigation including development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are supported under a program which is considered research for other purposes.

45CFR46.102 (d)

What does it mean to be “engaged in research?”

An institution is engaged in human subjects research when the institution’s employees or agents

1. Obtain data about living individuals for research purposes through intervention or interaction with them or
2. Obtain individually identifiable private information for research purposes.

***MHS Clinical Trials Office
7711 Louis Pasteur, Suite 706
San Antonio, TX 78229
Telephone: (210) 575-4238***