

**Clinical Research Proposal registration form**

**Purpose**

The purpose of this document is to establish defined standard operating procedures for human specimen collection, storage and transportation.

**Applicability**

This standard operating procedure applies to all the research project involving human specimen collection, storage and transportation within University of North Texas Health Science Center laboratories.

**Please provide the following information for preliminary review by safety office**

1. Title of the project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Principal investigator: Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact information: Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone number\_\_\_\_\_\_\_\_\_\_\_\_

1. Summary of the project
2. UNTHSC facilities will ONLY be used only for sample collection, storage and transportation. Yes \_\_\_\_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_\_

If the answer is ”No” please explain the other activities

1. Location of sample collection and storage

**Personnel (Please provide the list) and training completed**

*The proposed research project is a pharmaceutical company-sponsored clinical trials, samples are only drawn according to and in furtherance of the respective protocols. No other research is performed, and no other use is permitted. The sponsor and its agents may make future use of stored samples, provided that the intent to perform such research is specified in the study protocol.*

*Study personnel are certified in the collection, storage, and shipping of these samples which, depending on the protocol, may be processed either by a local lab (Quest, Lab Corp., etc.) or by the sponsor’s central lab. These labs are CLIA and CAP certified.*

*At no time and in no way would the Principal Investigator of one of these trials perform independent research on samples collected for one of these trials. Such activity would be considered an actionable violation of both the protocol and the contract.*

Office of Clinical Research

Responsible official

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***For safety office use only:***

The project has been reviewed and recommended to adhere with the SOP to work with the human specimen.

Need additional IBC review: Yes \_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_

Safety Director/ Biosafety officer

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_