**GUIDANCE: Feasibility Assessment**

**Policy:** Researchers should assess the feasibility of conducting a research study before preparing for submission to CPHS for review and approval. The researcher must consider the scientific, ethical and financial aspects of conducting the research study.

**Invitation to Conduct Feasibility Assessment** – Sponsors may contact faculty and staff directly with an invitation to conduct a feasibility assessment. The faculty and staff assessing feasibility should review the protocol and determine the scientific, ethical and financial merits of conducting the study at this institution. Faculty and staff may be asked to sign confidentiality agreements with the sponsor prior to receiving material for review. Confidentiality agreements must be submitted to the Office of Sponsored research. The researcher is not authorized by the university to agree to any budgetary figures proposed by the sponsor at this point.

**Invitation to Participate in a Clinical Trial / Research** – The sponsor or a researcher from another institution may contact researchers directly with invitation to participate in a research study. The researcher should review the protocol and assess feasibility at this institution.

Researchers may use the pre-study checklist as a guide in determining whether or not they can and should participate or initiate a new research study. Researchers are strongly encouraged to work with their research team to make decisions about participation in a new research study or initiating a new research study.

The sponsor may visit at an early stage of the process in order to see if facilities are adequate (pharmacy/drug storage, clinic space, laboratory, etc.) and to gauge the interest and qualifications of proposed study personnel

All tests and procedures required by the protocol for each patient encounter should be considered. Departments such as Pathology, Radiology, Pharmacy, etc. should be contacted if their services will be required in order to determine if they can perform the tests.

**Applicable Regulations and Guidelines**

* None

**Applicable Institutional Policies and Procedures**

* None

**Attachments**

* Feasibility Questionnaire

**If you find errors in this document, contact** [**clinicaltrials@uth.tmc.edu**](mailto:clinicaltrials@uth.tmc.edu)

|  |  |
| --- | --- |
| **Document Number:** | 402-004 |
| **Author:** | Clinical Trials Resource Center |
| **Effective:** | June 1, 2011 |
| **Revision History:** | None |
|  |  |
|  |  |