UTHealth Houston

Title: Feasibility Assessment	Version Number: 1.0	Effective Date: 1 Jun 2011	Page 1 of 2

1. **Purpose**
   To outline the procedures for assessing the feasibility of conducting a clinical research study at UTHealth Houston.

2. **Scope and Responsibility**
   This SOP applies to all the clinical studies being considered for conduct at UTHealth Houston.

3. **Definitions**
   3.1 Feasibility Assessment: To evaluate the possibility of conducting a clinical trial in a proposed location based on a list of questions. The answers will allow the qualified PI to make an informed decision regarding the feasibility of the study at his/her site.

   3.2 **Sponsor:** An individual, company, institution, or organization that takes responsibility for and initiates a clinical research trial.

   3.3 **Investigator Initiated Trial:** Clinical trials in which an investigator develops the study protocol and is responsible for study initiation and conduct.

4. **Policy**
   Investigators should assess the feasibility of conducting a research study. This assessment should consider scientific, ethical and financial aspects of conducting the research study.

5. **Procedures**
   5.1 **Invitation to Conduct Feasibility Assessment** – Sponsors or contract research organizations may invite investigators and research staff to conduct a feasibility assessment. Investigators and research staff assessing feasibility should review the protocol and any other relevant information such as protocol, consent document, lab manual, pharmacy manual, imaging protocol, device information, startup packet etc. Investigators and research staff should consider logistical and operational issues and evaluate the scientific, ethical and financial merits of conducting the study at this institution.

   All confidentiality agreements must be submitted to the Office of Sponsored Administration. Investigators are not authorized by the University to agree to any contract terms proposed by the sponsor.

   5.2 **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 any other pertinent information and assess feasibility at this institution.

5.3 Investigators should use the feasibility questionnaire as a guide in evaluating whether they should participate or initiate a new research study. Investigators are strongly encouraged to work with their research team to make decisions about participation in a research study or initiating a new research study.

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

5.5 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. This visit is also known as Site Qualification Visit (SQV) or Pre-Site Qualification Visit (PSQV).

6. Applicable Regulations and Guidelines

6.1 None

7. Applicable Institutional Policies and Procedures

7.1 None

8. Attachments

8.1 Feasibility Checklist

If you find errors in this document, contact clinicaltrials@uth.tmc.edu

Document Number:	401-004
Document Name:	Feasibility Assessment
Developed by:	Good Clinical Practice SOP Workgroup
Approved by:	AVP, Research Compliance
Revision History:	1 Jun 2011 1 Jun 2023