1. **PURPOSE:**
This Standard Operating Procedure (SOP) describes the standards for fulfilling the scientific, regulatory, medical, and ethical requirements for assessing the feasibility of implementing a protocol at University Hospitals.

2. **SCOPE:**
This SOP provides instruction and sets minimum standards regarding the process for assessing protocol feasibility for all departments within University Hospitals involved in the conduct of research. This SOP is not intended to supersede existing systematic processes for assessing protocol feasibility by a department but is intended to set a minimum standard.

3. **RESPONSIBLE INDIVIDUALS:**
This SOP applies to all Investigators engaging in research at University Hospitals. In addition, the Department Review Committee and/or Department Chair or designee is charged with ensuring that this review is complete and thorough. It is encouraged that other individuals who may be involved in the execution of the protocol are included in the feasibility assessment.

4. **DEFINITIONS:**
Please reference the Glossary for complete definitions of terms found in this SOP.

5. **POLICY STATEMENT:**
All research protocols must be reviewed for scientific merit and ethical standards consistent with local, state and federal requirements and must be consistent with UH IRB Policy, Department Review of Protocols.

6. **PROCEDURES:**
For an investigator whose respective department does not already have an established process for systematically assessing protocol feasibility, the following procedures must be executed:

   The Principal Investigator (PI) will review the protocol to determine whether: 1) the protocol meets scientific and ethical merit; 2) the protocol is financially feasible; and 3) adequate resources are available to conduct the study.

   As the PI reviews the protocol, he/she should systematically consider and evaluate the protocol and document the evaluation. The systematic approach can be achieved by using any or all of the tools referenced in this SOP under Forms and Attachments (Examples: Protocol Feasibility Checklist, or Research Vetting Ticket) or other protocol feasibility assessment tools or processes. Regardless of the evaluation process (i.e. following established department procedures or investigator assessment.

Developed by the Center for Clinical Research and Technology Clinical Research SOP Committee
as noted above) or tools used for the assessment, the investigator must maintain documentation of this review.

The PI will clarify any questions with the Sponsor (if applicable).

If the PI finds that the protocol is feasible, the protocol as well as the documented assessment of feasibility is to be forwarded to the Department Review Committee and/or Department Chair for review. (See UH IRB Policy, Department Review of Protocols).

7. REFERENCES
UH IRB Policy, Department Review of Protocols

8. FORMS OR ATTACHMENTS
Protocol Feasibility Checklist
Research Vetting Ticket

APPROVALS
Approved by Carol Fedor, Director, HRPP– December 10, 2014
Approved by Philip Cola –VP, Research and Technology – December 10, 2014