STUDY FEASIBILITY

PURPOSE: This Standard Operating Procedure (SOP) describes the procedures for assessing the feasibility of conducting a specific protocol at the CRC. Before agreeing to participate in a clinical research study, the Principal Investigator (PI) and the University of South Florida (USF) must agree to the scientific, clinical, and ethical merits of the study, the financial impact to the institution, compliance with regulations, and the operational feasibility of conducting the study at the CRC.

SCOPE: This SOP applies to all the clinical studies being considered for conduct at the CRC.

RESPONSIBILITY: The PI, Clinical Research Coordinator or delegate, Clinical Research Administrators (CRAs), Fiscal Managers, Department Chairs, and others who may be responsible for protocol review and study feasibility assessment at the CRC.

DEFINITIONS:

Confidentiality Disclosure Agreement (CDA): A legal document which ensures confidentiality of proprietary information that a sponsor gives to the investigator. A signed, study specific CDA may be required before a sponsor will provide its proprietary information, such as the study protocol, to an investigator. It is also referred to as a Non-Disclosure Agreement or Confidentiality Agreement.

Contract Research Organization (CRO): A person or an organization contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

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.

Protocol: A document that describes the objectives(s), design methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial.

Protocol Amendment: A written description of a change(s) to or formal clarification of a protocol.

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

PROCEDURE:

1. When a sponsor/ CRO contacts the study site about a potential study, the PI will assess whether or not it would be feasible to conduct the protocol with the existing staff and facility.

2. In order to obtain the protocol and study documents from the sponsor/ CRO for assessment review, the PI will be asked to sign a CDA.

3. The PI or study coordinator must send the CDA to ocr@health.usf.edu to facilitate an efficient review and execution of the agreement. The PI may not sign the CDA on behalf of the University of South Florida (USF).

4. The PI, study coordinator and other appropriate site personnel will review the protocol and assess feasibility at the CRC to ensure the following:

- The study objectives are clear
- The study design is feasible to enable the study objectives to be met
- The study will not expose subjects to undue risk
- The study is ethically acceptable and based on good medical science
- The study is financially and logistically feasible
- There are sufficient number of potential subjects available for the study to meet enrollment goals
- There are sufficient staff members to conduct the study
- The site has the appropriate resources and equipment to conduct the study
- All tests and procedures required by the protocol for each subject encounter are considered
- Other departments should be contacted if their services will be required in order to determine if they can perform the tests (e.g. pharmacy, radiology).

5. The research staff may use the Protocol Feasibility Checklist (Appendix P) as a guide in determining whether or not they can and should participate or initiate a new research study if the sponsor does not provide one.

6. 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).

7. The PI is strongly encouraged to collaborate with his/her research team to make decisions about participating in or initiating a new research study.

8. When it is determined that the protocol meets the above criteria, the PI or study coordinator will notify the sponsor/ CRO of their willingness to participate in the study.

REFERENCES:	21CFR 312.30 Protocol Amendments ICH Guidelines for Good Clinical Practice (E6) section 4.2- Adequate Resources ICH Guidelines for Good Clinical Practice (E6) section 5.6- Investigator Selection
RELATED POLICIES:	
APPENDICES:	Appendix P: Protocol Feasibility Checklist

REVISION HISTORY: Keep a running history of all revision dates

Approval Date	Effective Date	Review/Revision Date
01/01/2015	**06/01/2016**	