

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH Title: Protocol Feasibility Assessment	Last Revised: 12/2018 Prior Version: 12/2017
SOP NUMBER: SP-201	Page 1 of 4

1. PURPOSE:

This Standard Operating Procedure (SOP) describes the standards for assessing the feasibility of implementing a research protocol at University Hospitals.

2. SCOPE:

This SOP provides instruction and sets minimum standards regarding the process for reviewing the feasibility of implementing a research protocol throughout University Hospitals Health System (UHHS) with emphasis on recruitment, site logistics, and financial resources for implementation and completion of the study.

It is mandatory that all research projects across all departments that meet the criteria defined in section 3 below complete a protocol feasibility assessment prior to submitting to the IRB for review.

Departments must utilize and complete the UH Clinical Research Center (UHCRC) Protocol Feasibility assessment and internal study start-up processes prior to grant, IRB, or FDA submission.

3. RESPONSIBLE INDIVIDUALS:

This SOP applies to all Investigators who would like to implement a research study that prospectively enrolls human subjects. Research projects including sponsored research, clinical trials, and FDA regulated studies (including investigator initiated) are subject to this policy. Retrospective chart reviews, biorepositories, tissue and blood sample banking, exempt research, questionnaire studies, and behavioral research are all exempt from this requirement. If research design includes elements that span both exempt (chart review) and non-exempt (FDA regulated), then this SOP would apply to that research protocol.

It is encouraged that senior research members within the department mentor any new Investigator conducting research.

4. DEFINITIONS:

Requester - The REDCap user submitting the UH CRC Protocol Feasibility. This may be a study coordinator, department administrator, Investigator etc.

5. POLICY STATEMENT:

All research protocols detailed above are subject to the UH Clinical Research Center (UHCRC) Protocol Feasibility assessment and internal study start-up processes prior to implementation at UH.

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH	Last Revised: 12/2018
Title: Protocol Feasibility Assessment	Prior Version: 12/2017
SOP NUMBER: SP-201	Page 2 of 4

6. PROCEDURES:

Feasibility is an ongoing process broken into two parts and completed in REDCap®.

Part 1 focuses on assessing the number of eligible participants available for recruitment within UHHS. To obtain the number of potentially eligible participants for the study, a query of the electronic medical record (EMR) is conducted through TriNetX Software based on the information provided in *Part 1* by the Requester.

Part 2 is the study start-up process that captures information needed by UH CRC Cores and ancillary services. This is necessary to continue reviewing feasibility within each core and service, and also capture important information required to conduct a trial at UH.

6.1 Part 1: UH CRC Protocol Feasibility Assessment

Purpose: Information needed in this section pertains to study and site accrual goals and key inclusion and exclusion criteria as specified in the study protocol. To complete *Part 1*, the Requester populates information directly from the protocol relating to accrual requirements (i.e., study accrual, site accrual, estimated recruitment start and stop date) as well as inclusion and exclusion criteria.

1. Requesters select or follow the following link to the survey to complete Part 1.
 - a. Link: <https://redcap.uhhospitals.org/redcap/surveys/?s=AP7KJ97PTA>
 - b. Requesters enter the following information:
 - i. Study Team Information
 - ii. Study Information
 - iii. Enrollment Information
 1. Three inclusion criteria and three exclusion criteria are required for submission. More criteria may be entered as necessary.
 2. Information entered under the “Study Classification” section of the Project Feasibility survey will help the CRC make the determination of whether or not the protocol is exempt from meeting the feasibility query requirements (ex. rare disease, healthy volunteer, etc.), they should preemptively indicate the reason for the exemption (See Study Classification section of Part 1).
 - c. Requesters upload a Protocol or Protocol Synopsis (optional).
 - d. Requesters Submit *Part 1*.
2. After submission of *Part 1*, a notice is sent to the Clinical Research Center (CRC) through REDCap for a prompt to enter the information into the TriNetX system.
3. A member of the CRC will enter information into TriNetX **exactly** as provided by the Requester in *Part 1* to obtain the number of eligible participants within UHHS for the research trial.
4. TriNetX query results are provided to the Requester and study team by the CRC within **3 business days**; results include a query screenshot detailing outcomes from the UHHS

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH	Last Revised: 12/2018
Title: Protocol Feasibility Assessment	Prior Version: 12/2017
SOP NUMBER: SP-201	Page 3 of 4

database. For a study to qualify as feasible, there must be 5 times the number of required participants available in the UH systems (5 x Anticipated Accrual at Local Site).

5. Email notifications from the CRC alert Requesters regarding the outcome for the Feasibility review within **3 business days**:
 - a. Feasible (query returns ≥ 5 times Anticipated Accrual at Local Site) for implementation and are prompted to complete *Part 2*.
 - b. Not feasible (query returns < 5 times Anticipated Accrual at Local Site) due to the low number of eligible participants in the UHHS database.
 - c. Exempt (query returns < 5 times Anticipated Accrual at Local Site) due to special considerations including rare disease or specific patient population that cannot be queried. Protocol exemptions will be reviewed by the Associate Chief Scientific Officer and an exemption notice will be sent when applicable.
6. Studies deemed feasible or exempt in Part 1 can proceed to Part 2: Study Start-Up Process within the REDCap “UH CRC Research Study Database” in parallel with their IRB submission.
7. Studies deemed not feasible may NOT proceed with IRB submission or Study Start-Up Process.

6.2 Part 2: UHCRC Study Start-up Process

Purpose: *Part 2* is the UHCRC Study Start-up Process within the “UH CRC Research Study Database” which captures all information required by the Pre-Award Grants & Contracts Core, Research Finance, and ancillary cores and services such as Investigational Drug Services, Radiology, DCRU, Coordinator Core, FDA/Regulatory Support Core, etc.

Information required in this section pertains to site logistics to conduct protocol, additional UH resources needed, contractual/financial questions relating to overhead, investigational drugs and/or devices. Part 2 may be completed in parallel with IRB submission.

1. Study Team logs in to REDCap “UHCRC Research Study Database” and provide information for *Part 2*.
 - a. Link:

https://redcap.uhhospitals.org/redcap/redcap_v8.6.5/DataEntry/record_home.php?pid=510
 - b. Study Team completes the following forms:
 - i. Study Info for UH Website
 - ii. Protocol Information
 - iii. Study Contact Info (*optional*)
 - iv. Study Approvals & Milestones (*optional*)
 - v. Drug & Device Info (*if applicable to protocol*)
 - vi. PI Information Form
 - vii. Investigational Drug Services (*if applicable to protocol*)

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH	Last Revised:12/2018
Title: Protocol Feasibility Assessment	Prior Version: 12/2017
SOP NUMBER: SP-201	Page 4 of 4

- viii. Radiology Information & Review (*if applicable to protocol*)
2. Study Team will complete information on each required form (when applicable) and then send completed forms to each research core or service to begin the study start-up process.
 3. Each individual research core or service is responsible for reviewing and completing information on each start-up form and responsible for communicating potential issues to the PI and study team.
 - a. Examples of potential issues could include reduced overhead rates, purchase/payment details relating to investigational drug/device product, lack of appropriate resources to conduct study visits or procedures, etc.
 - b. It is the responsibility of the study team to resolve these issues with each research core or service prior to implementation of the protocol, but should not preclude investigators from submitting their study to the FDA and/or IRB.

6.3 Protocol Feasibility Outcome

The Associate Chief Scientific Officer reviews and signs-off on all Project Feasibility outcomes and a member of the CRC will return the signed document to the Requestor and the study team listed on the UH CRC Protocol Feasibility survey. The signed document should be retained by study team and attached for reference to the corresponding IRB submission.

7. REFERENCES

Link to Part 1- *UH CRC Protocol Feasibility*:

<https://redcap.uhhospitals.org/redcap/surveys/?s=AP7KJ97PTA>

Link to Part 2 *UH CRC Research Study Database*:

https://redcap.uhhospitals.org/redcap/redcap_v8.6.5/DataEntry/record_home.php?pid=510

APPROVALS

Approved by Dr. Grace McComsey, Vice President of Research and Associate Chief Scientific Officer,
University Hospitals Health System, Director, UH Clinical Research Center – December 14, 2018