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University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

Date Created: **November 1, 2010**

Title: **Assessing Protocol Feasibility**

Version Date: **January 1, 2023**

SOP Number: **SM01**

PURPOSE: The purpose of this standard operating procedure (SOP) is to outline how investigators determine that they are a suitable research site to conduct a proposed research plan effectively and completely per the requirements of the protocol with the available resources.

SCOPE: The tools the Clinical Research Center (CRC) offers for investigators to assess protocol feasibility can be applied to any clinical research study being considered at University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM).

PERSONNEL RESPONSIBLE: Principal Investigators (PI), Sub-Investigators and other supporting research staff should be responsible and willing to perform a protocol feasibility assessment in order to effectively evaluate if they have the resources needed to conduct a research study.

DEFINITIONS:

- **Feasibility** - an assessment used to determine whether a research study is likely to be delivered successfully, taking into account the practical aspects of managing the project.
- **Protocol -** A document that describes how a clinical trial will be conducted to include the objective(s), design, methodology, statistical considerations, and organization. It works to ensure the safety of study participants and integrity of the data collected.

PROCEDURES:

Items needed before an investigator can fully assess the feasibility of participating in a protocol are:

- Confidentiality Agreement (CDA) in place, so that the investigator can obtain a copy of the full protocol.
- A projected budget, from sponsor, or grant application.
- A full protocol.

There are many questions investigators must ask themselves before deciding to move forward with a study. A good way to start is to complete the Feasibility Survey worksheet to address possible barriers and address all issues to consider:

- Is the research question related to the patient population at the research site?
- Does the research offer intervention that will require a subject to forego standard of care?
- Is there a patient population that would be willing to participate and potentially benefit from participating in this research?

If approached, the CRC can assist investigators in the feasibility assessment process with the following tools:

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- Feasibility Survey, which asks questions that will assist in evaluating the protocol, resources and costs required
    - If CRC services are requested, CRC Start-Up Team can provide a budget for these services. Investigator will complete the Study/CTMS Intake Form and send it to StudyIntake@unmc.edu.
- The electronic access core can also complete a search of the Electronic Medical Record system to generate potential patient population available, based on study criteria.

ASSOCIATED FORMS:

SM01 Feasibility Survey Worksheet

RESOURCES:

Study

ACRP – Tools to help Clinical Research Sites Optimize Performance – Workshop 21 Workbook

SOP-52: Study Intake

UNMC CCTR website: Study Intake Form
https://www.unmc.edu/cctr/resources/crc/intakeform.html

UNMC CCTR website: Electronic Health Record Data Access Core
https://www.unmc.edu/cctr/resources/ehr/index.html

Department Approval:

Signed Katie Penas Signed: 2/21/2023
Clinical Research Manager

Signed Signed: 4/3/2023
Assistant Vice Chancellor for Clinical Research

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Study Feasibility Survey

Principal Investigator:		
Protocol Title:		
Name of Sponsor:		
Sponsor-Specific Study Information:	**Individual Responsible**	**Response**
• Total Number of Sites for Study	Project Manager	
• Number of Sites Actively Enrolling	Project Manager	
• Time Frame for Enrollment (beginning & end dates)	Project Manager	
• Total Enrollment Goal	Project Manager	
• Total Number of Patients Enrolled To Date	Project Manager	
UNMC-Specific Study Information:	**Individual Responsible**	
• Anticipated Total Number of Subjects	PI, Study Coordinator	
• Anticipated Number of Subjects/Year	PI, Study Coordinator	
• Estimated screen failure rate	Study Coordinator	
• Projected timeline for IRB submission	PI, Study Coordinator, Project Manager	
• Local or Central IRB	Study Coordinator, Project Manager	
• If known, where is UNMC on the sponsor's list to be selected as a site?	Project Manager	
• Is credentialling required for Radiology or Rad/Onc?	Study Coordinator, Project Manager	

Item	Answers	Individual Responsible/Comments	Scoring
I. Overall Feasibility			
Do the protocol objective, procedures, etc. agree with PI clinical judgment?		Physician	3=Yes 2=Yes, but some questions 1=No
Are there any competing trials in your department?		Physician, Study Coordinator	2=No 1=Yes
Is the protocol integrated with routine standard of care?		Physician, Study Coordinator	2=Yes 1=No
If imaging (PET, CT or MRI) is required, does the sponsor require site qualification?		Industry trials, project manager	2=No 1=Yes
If specialized equipment is required, is time available on that equipment?		Industry trials, project manager	3=Yes, readily available 2=Yes, but not readily 1=No
III. Subject Enrollment			
Are the inclusion/exclusion criteria reasonable to meet enrollment?		Physician	2=Yes 1=No
Is the trial likely to attract new patients to UNMC/NM?		Physician	2=Yes 1=No
Is the visit schedule likely to be acceptable for subjects?		Study Coordinator	2=Yes 1=No
IV. Resources			
Are there special pathology requirements?		Study Coordinator	2=No 1=Yes
Are there special pharmacy requirements?		Study Coordinator	2=No 1=Yes
Does the study include Rad/Onc services?		Study Coordinator	2=No 1=Yes
		Total Score	**0**
Additional Comments/Considerations:			

The higher the score, the better the fit. High scores do not necessarily guarantee approval.

Great fit score:	20 to 24
Fit ok, some issues noted:	15 to 19
Not a good fit for this site:	14 & less

Department Administrator

Department Chair

Research Coordinator