

Section: Clinical Research Center

Date Created: August 28, 2018

Title: Intake Form

Date Last Reviewed/Modified: April 1, 2019

SOP Number: SOP- 52

Version Number: 1

PURPOSE: The purpose of this standard operating procedure (SOP) is to explain the intake process for services from the Clinical Research Center (CRC).

SCOPE: This SOP applies to sponsored clinical trials and that the tools the Clinical Research Center (CRC) offers for investigators to assess feasibility that can be applied to any clinical research study being considered at University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM).

PERSONNEL RESPONSIBLE: CRC Manager, Director of Clinical Research Operations, Study Coordinators and/or other staff are knowledgeable of and can facilitate investigators accessing available resources to assist with protocol feasibility.

PROCEDURES: The purpose of this form is to gather information regarding the study that is being requested for CRC services. Whether using the Clinical Research Center or needing your study built in the Clinical Trials Management System (CTMS) there is a centralized intake process to aid in building studies.

1. Download and complete the Study Intake Form from the CRC website <https://www.unmc.edu/cctr/resources/crc/intakeform.html>
2. Email completed Study Intake Form and the following documents to StudyIntake@unmc.edu :
 - Protocol
 - Consent Template
 - Budget Template
 - Editable Contract
 - Contract Questionnaire
 - Investigators Brochure/Instructions for Use for Devices
 - Patient Facing Documents

If any of the above documents are not applicable to your study, please explain why in the body of your intake form email.

3. Questions should be addressed by email to StudyIntake@unmc.edu

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ASSOCIATED FORMS:

Study Intake Form

SOP-52
Study-Intake-form_2



RESOURCES:

UNMC: [Center for Clinical & Translational Research](#)

Staff Accountability:

Developed By: Manager, Clinical Research Center
Director of Clinical Research Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center
Reviewed By: Director of Clinical Research Operations, Clinical Research Center

Department Approval

Signed  Director of Clinical Research Operations	Signed  Medical Director of Clinical Research Center
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Study Intake Form			
Study Information			
Title:		IRB# (If available):	
Pet Name:		Accrual Goal for UNMC/NM:	
PI:		Overall Study Accrual:	
Department:		Phases/Stages/Arms that UNMC/NM is participating In:	
Department Contact:			
Other Study Staff:		Funding Source:	
Management Group:		Protocol Type:	
Study Coordinator:		CTMS Shell Created:	
Sponsor:		Forté EDC Requested (IIT):	
Sponsor Contact:			

Ancillary Departments Approvals (designate with approval date or 'N/A')		Requested CRC Services (attn: StudyIntake@unmc.edu , pick appropriate services from drop down)	
Pathology (attn: Tim Greiner (Hem/Liquid))		Calendar/Matrix Determination	
Pathology (attn: Geoffrey Talmon + Salma Elhag (Solid, Archival))		Coverage Analysis	
Pharmacy (attn: Jon Beck, Erin Iselin)		Budget	
Radiation Treatment certification (attn: Amy Filler-Katz)		Regulatory Submission	
Radiology - Imaging Manuals, Other Special Forms (attn: Tiffany Tunney and Bev Hamman)		Clinical Services	
Biological Production Facility (attn: Charlie Branson)	Other (Specify):		
Nuclear Medicine (attn: Neil Hansen, Frank Rutar, Mark Theis)		Contract Negotiation (designate appropriate negotiator by selecting 'X' from drop down)	
External Groups [Ex: Home Health Care]		Sponsored Programs Administration (attn: Shannon Robinson)	
[Ex: Red Cross (e.g. leukapheresis. attn: Carri Harford)]			
Other (Specify)		UNHealth (attn: Amanda Leingang)	

Documents (Attach required documents and designate field with 'X' or explain why 'N/A'. Attach or map location of files for preferred documents)			
	Required		Preferred
	Approved Internal Feasibility Questionnaire (If required by Department)		1572
	Protocol (Full)		Financial Disclosure
	Consent Template		Lab Manual
	Budget Template		Manual of Operations
	Editable Contract		CRFs (Highly Desired)
	Completed Contract Questionnaire		External Feasibility Questionnaire
	Investigator's Brochure/Instructions for Use		Other (Specify)
	Patient Facing Documents (Only if CRC is submitting Regulatory)		

Please copy the table and paste with source formatting in an email to StudyIntake@unmc.edu and copy the appropriate Contract and Ancillary Department Staff (listed next to department as attn:)