

Seton Clinical Research Steering Committee (CRSC) Purpose & Scope



- **Purpose:**

To assess impact of research studies upon Seton facilities and resources, assess safety and risk issues, and assess impact on Seton staffing.

- **Scope:**

All clinical research or other research activities which utilize Seton staff, facilities, or other resources including patient or organizational data.

Seton Clinical Research Steering Committee (CRSC) Submission Form

Please check appropriate box(s) to indicate site(s) where the study will be performed:

- UNIVERSITY MEDICAL CENTER AT BRACKENRIDGE (UMCB)
- SETON MEDICAL CENTER AUSTIN (SMCA)
- DELL CHILDRENS MEDICAL CENTER (DCMC)
- List Other Seton Facility(s) or Locations: _____

Please consult the Seton Office of Research Administration (ORA) while in the planning stages of your research study or clinical trial. This consultation is particularly important prior to engaging in budget negotiations with the sponsor funding the study as pricing for all services must be approved through the Seton Director of Managed care or other responsible parties.

The CRSC submission is required only for studies which will require Seton resources (staff, equipment, facilities, or services) including patient data extracted from Seton owned/managed data warehouses/databases/registries, etc.

Please provide 2 complete copies of all requested materials with this form including: IRB approval letter, protocol or description of the study, consent/assent, study budget, procedures/services pricing request, sponsor contract template, investigator and/or product brochure.

I. STUDY INFORMATION

Title Research/Project:		IRB # <input type="checkbox"/> pending <input type="checkbox"/> approved
Principal Investigator / Affiliation:		Phone: _____ Fax: _____ Pager: _____ Email: _____
Key Collaborator(s) / Affiliation (If applicable):		Phone: _____ Fax: _____ Pager: _____ Email: _____
Research Coordinator:		Phone: _____ Fax: _____ Pager: _____ Email: _____
Sponsor / Funding Source (Name):		
Number of subjects approved for enrollment:	Time to complete enrollment: (# months to years)	Duration of Each Subject's Participation (Month/Year – Month/Year)

II. LOCATION OF SUBJECTS (recruitment through follow-up) If study involves only medical record review- skip to section III <input type="checkbox"/> N/A If requesting data only – skip to section IV							
Indicate the location of study activities and if they will occur during standard of care visits or will be research only visits. Estimate the number of visits that will be required for each activity. If the activity calls for a “research only” visit and there will be no billed services provided, Patient Access must be informed at time of registration.							
Phase of study activity	Location: inpatient units, same-day surgery, outpatient clinics (please name)	Will occur during Standard care visit	Will occur as research only visit	# visits per activity per patient	Cost Coverage (N/A, sponsor or patient/insurance)		
					Sponsor	Patient/Insurance	N/A
RECRUITMENT		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ENROLLMENT		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TREATMENT		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FOLLOW-UP		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PLEASE NOTE: ANY RESEARCH PARTICIPANTS ENROLLED ON THE STUDY MUST BE DOCUMENTED ON THE SETON PATIENT LOAD FORM (PLF). IF YOU CANNOT ACCESS THE ELECTRONIC PLF FORMS USE THE ATTACHED PLF FORM & SUBMIT VIA EMAIL OR FAX AS DIRECTED.							
III. MEDICAL RECORDS (HIM*) <input type="checkbox"/> N/A	# Records	Frequency (how often requested)	Total # (#records x frequency)	PRINT NAMES OF RESEARCH PERSONNEL THAT WILL BE REVIEWING RECORDS			
records for proposal development							
records pulled for recruitment							
records pulled for data extract							
records pulled for sponsor audit							
		Is funding available? <input type="checkbox"/> yes <input type="checkbox"/> no		Are you obtaining informed consent? <input type="checkbox"/> yes <input type="checkbox"/> waived			
		HIPAA authorization <input type="checkbox"/> obtained <input type="checkbox"/> waived <input type="checkbox"/> both					
FOR PROPOSALS INVOLVING ONLY MEDICAL RECORD REVIEW – STOP HERE – PRINT OUT AND ATTACH COMPLETED LAST PAGE WITH SIGNATURES. Submit to Seton CRSC c/o Seton Office of Research Administration, CEC Suite 320; 512-324-7991(phone); 512-324-7792 (fax)							
*For studies which require medical records access and review, a letter of support must be obtained from the HIM (Health Information Management) manager located at the Seton facility/site from which records will be accessed / pulled.							

NOTE FOR IMAGING, LABORATORY & CARDIOPULMONARY REQUESTS: The following persons must be contacted (via phone or email) to establish a research account for services requested from these areas: Imaging – Chad Waggoner; Laboratory – Dee Houston; Cardiopulmonary – Stephen Sundquist

Reminder: The Seton/ORA Procedures & Services Pricing Request form must be completed for all procedures/services which are research-related & not standard of care.

VI. IMAGING List all radiographic procedures involved with this study & where performed. Interpretation fees are charged separately from procedure fees.
 N/A Interpretation fees will need to be negotiated with Austin Radiological Asssoc's. If no interpretation is required, please note in proper column.

Procedure	Total # per patient	Total # for All patients	# standard care	# research only	Performance site	# of copies	Interpreter (if not requesting ARA interpretation) Name of PI or designate	Cost Coverage		
								sponsor	Patient/insurer	N/A
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[ADD GENERIC ATTACHMENT FOR ADDITIONAL PROCEDURES]

VII. LABORATORY List all laboratory tests included in study protocol, individually (do not use profiles).
 N/A

Test/procedure	Total # per patient	Total # for All patients	# standard care	# research only	Collected by		Processed by		Lab involved in shipping ?		Cost Coverage		
					Research Staff	Hospital Lab	Sponsor Lab	Hospital Lab	yes	no	Sponsor	Patient/insurer	N/A
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[ADD CLINICAL LABORATORY ATTACHMENT FOR ADDITIONAL LABS]

What are the requirements for lab result turnaround time? N/A (state time period)

Are there format requirements for reporting? (e.g. units of measurement, quantitative, qualitative) no yes (describe)

Will you require a list of normal values prior to receiving lab results? no yes (place * next to listed lab requiring values)

Individual to receive lab results: Name: _____ Pager#: _____ Office address: _____

VIII. CARDIOPULMONARY / BLOOD GASES List all procedures individually and who will be responsible for interpretation. All research-only procedures require the PI to make arrangements for interpretation.
 N/A

Procedure	Total # per patient	Total # for all patients	# standard care	# research only	Performance site	Interpreter (Name of PI or designate)	Cost Coverage		
							sponsor	Patient/insurer	N/A
							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[ADD GENERIC ATTACHMENT FOR ADDITIONAL PROCEDURES]

IX. INVESTIGATIONAL DEVICES If the study involves an implantable or other device, please describe the device and procedure
 N/A

Name of Device & Description: Name of Device Manufacturer: IDE Number 501K Number For post-marketing approval studies PMA No. <input type="checkbox"/> Copy of signed FDA approval letter for IDE <input type="checkbox"/> Copy of Investigator Product Brochure Has Medicare Part A, IDE approval been obtained for Seton site(s) involved in study? <input type="checkbox"/> Yes ; <input type="checkbox"/> No <input type="checkbox"/> Manufacturer or Provider Supply Chain contact information Describe how Investigational Device will be provided to Seton:	Cost Coverage		
	Sponsor	Patient/insurer	N/A
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

X. ADDITIONAL RESEARCH RESOURCES NOT LISTED: Additional expenses may include staff time (e.g. nursing, respiratory, etc.) required to support any procedures or assessments that would not be standard of care. Indicate if funding is available for these services.
 N/A

Describe	Cost Coverage		
	sponsor	Patient/insurer	N/A
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

XI. Non-physician Credentialing: Are your non-physician research staff who will perform research-related patient procedures credentialed at the site of the proposed research?

Yes No

For information about research staff credentialing please contact:

Seton Medical Staff Services	512-324-1111	Monique Johnson mmjohnson@seton.org

XII. SUBMISSION:

Items to Submit:	Protocol	Budget & Pricing Forms	Other Related Study Documents	IRB Approval
Submit To: Seton CRSC (Steering Committee) c/o Office of Research Administration 1400 North IH-35, CEC, Ste. 320 Austin, TX 78701 512-324-7991 (phone) 512-324-7792 (fax) http://www.seton.net/medical_services_and_programs/clinical_research/	Two (2) Copies	Two (2) Copies	Two (2) Copies	Two (2) copies of approval letter and final consent with stamped date approved.

PRINCIPAL INVESTIGATOR'S ASSURANCE: During the research, if there are any substantive changes in the information provided above (including a change of principal investigator), documentation of these changes will be submitted to the Seton Office of Research Administration (ORA) within 24 hours. A list of subjects enrolled in the study will be provided every three months to the ORA. A copy of the signed consent will be placed in each subject's medical record unless the study involves genetic research, the subject is a member of a protected population or a Certificate of Confidentiality has been provided for the subjects.

Principal Investigator Signature:	Date
Research Coordinator Signature:	Date

CLINICAL TRIAL BUDGET TEMPLATE

Principal Investigator: _____
 Study Title: _____
 Sponsor: _____

PER PATIENT BUDGET

PROCEDURES	Single Event Charge to Sponsor	# Of Events Per Subject	Per Patient Charge to Sponsor	Screening Visit	Visit 1	Visit 2
Personnel Allowance	\$550	7	\$3,850	1	1	1
Subject Recruitment & Consent	\$100	1	\$100	1	0	0
Inclusion/Exclusion Criteria	\$100	1	\$100	1	0	0
Test1	\$175	1	\$175	1	0	0
Test2	\$150	7	\$1,050	1	1	1
Test3	\$50	7	\$350	1	1	1
Demographic Information	\$100	1	\$100	1	0	0
Management of Concomitant Meds and Adverse Events	\$100	7	\$700	1	1	1
Physical Exam	\$100	7	\$700	1	1	1
Vital Signs (BP, pulse rate, resp. rate)	\$45	2	\$90	0	2	0
Administer study drug in clinic	\$100	3	\$300	0	1	0
Phone Call	\$10	2	\$20	0	1	0
Questionnaire	\$100	4	\$400	1	0	0
CBC (Full Blood Count) - local lab	\$85	3	\$255	1	0	0
Hepatic Panel (AST, ALT, total bilirubin and alkaline phosphatase, GGT and indirect bilirubin and BUN (blood urea nitrogen) + creatine - local lab	\$277	3	\$831	1	0	0
Treatment-Induced collection	\$50	2	\$100	0	1	0
Qualitative Microbiology (Pathology Processing)	\$185	7	\$1,295	1	1	1
Preparation of Sample for Quantitative microbiology - central lab	\$70	3	\$210	1	0	1
Patient Reimbursement (travel, meals)	\$75	9	\$675	1	1	1
Pharmacy Dispensing Fee & CT materials management	\$125	6	\$750	0	1	1
PATIENT DIRECT CHARGES			\$12,051	\$2,217	\$1,651	\$1,496
PATIENT INDIRECT CHARGES			\$3,013	\$554	\$413	\$374
TOTAL PATIENT CHARGES			\$15,064	\$2,771	\$2,064	\$1,870

One-Time Charges	Charge to Sponsor
Start-up Fees - IRB, Steering Committee, pharma set-up, dry ice	\$5,000
	0
Close-Out Fee - File clean-up, close-out letter to IRB, final query resolution, archiving	\$3,000
	\$0
Total One-Time Charges	\$8,000

Invoiced Charges	Charge to Sponsor
IRB Amendments	300
Chest Xray - 2 view	450
CT Scan	1200
Screen Failures (per patient) without assay	500
Screen Failures (per patient) with assay	1200
SAE's (per event)	25

	Charge to Sponsor Per Subject	Total Number of Subjects	Total Charge To Sponsor
PATIENT DIRECT CHARGES	\$12,051	5	\$60,255
PLUS ONE-TIME CHARGES			\$8,000
EQUAL TOTAL DIRECT CHARGES	\$12,051		\$68,255
PLUS INDIRECT CHARGES (25%)	\$3,013		\$15,064
EQUAL TOTAL CHARGES	\$15,064		\$83,319

Principal Investigator/Program Director (Last, First, Middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY						FROM	THROUGH	
<i>PERSONNEL (Applicant organization only)</i>		Months Devoted to Project			INST.BASE SALARY	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Sum. Mnths		SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator							
SUBTOTALS								
CONSULTANT COSTS								
EQUIPMENT <i>(Itemize)</i>								
SUPPLIES <i>(Itemize by category)</i>								
TRAVEL								
PATIENT CARE COSTS		INPATIENT						
		OUTPATIENT						
ALTERATIONS AND RENOVATIONS <i>(Itemize by category)</i>								
OTHER EXPENSES <i>(Itemize by category)</i>								
CONSORTIUM/CONTRACTUAL COSTS					DIRECT COSTS			
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD <i>(Item 7a face page)</i>								\$
CONSORTIUM/CONTRACTUAL COSTS					FACILITIES AND ADMINISTRATIVE COSTS			
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD								\$

SETON RESEARCH PATIENT LOAD FORM (PLF)

Please complete the form as soon as you have scheduled a research participant and FAX it to the Seton Office of Research Administration (FAX: 512- 324-7792)

Date Completed: ___ / ___ / ___

Last Name		First Name, MI		Medical Record Number
Medical Record Number		Gender	Ethnicity	Social Security Number
This visit requires services which are:		Standard of care only	Research Only	Both SOC & Research
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This visit requires no billable services	Visit Start Date	Visit End Date		Total No. of Visits
<input type="checkbox"/>	/ /	/ /		
Project Title/Short Title		PI Dept. / Affiliation		PI Cost Center
Principal Investigator	PI Phone Number	PI Pager Number	PI Fax Number	PI Pager Number
Study Coordinator	Coordinator Phone Number	Coordinator Pager Number	Coordinator Fax Number	Coordinator Pager Number
Administrative Staff Who Manage PI Account:				

Seton CRSC study no. (CR-XX-XXX)	Seton Admitting Site/Facility	Comments

Admission Type:	<input type="checkbox"/> Inpatient	<input type="checkbox"/> Outpatient "One-time Only"	<input type="checkbox"/> Outpatient "Recurrent Visit"
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IRB Number	Primary IRB

Outpatient clinics or departments that will provide research procedures/services:	
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Investigational Device Included?	<input type="checkbox"/> No <input type="checkbox"/> Yes: If "yes," please provide IDE#:
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Seton CRSC & ORA

CRSC links and Research Resources for investigators, coordinators and others involved in clinical research or research administration:

Seton Internet:

- http://www.seton.net/medical_services_and_programs/clinical_research/
- **Seton Intranet: (Must be Seton-affiliated & registered)**
- <http://sharepoint.seton.org/sites/CRSC/default.aspx>

Additional Resources to assist in proposal development

Clinical Trials.gov

- https://www.clinfosource.com/common/external_link.asp?url=http://www.clinicaltrials.gov/ct/info/glossary

Johns Hopkins Medicine

- <http://www.hopkinsmedicine.org/Research/>

National Institutes of Health

- http://grants.nih.gov/grants/grant_basics.htm

Seton Office of Research Admin: 512-324-7991 (phone) 512-324-7792 (fax)