Application for Review of Study

Please complete the following form and assemble all necessary documents required to complete submission. Failure to provide any required document(s) will result in an incomplete submission and will delay operational review.

SUBMISSION CHECKLIST -- All Submissions

Please check all applicable and not applicable items below.

Included	Not Applicable	DOCUMENTS
✔		Submission Form
✔		Research Protocol or Proposal
		Research Budget Worksheet
		IRB-Approved Informed Consent Form(s)
		IRB-Approved Assent Form(s)
		Waiver of Informed Consent
		Authorization to Use/Disclose Protected Health Information
		HIPAA Waiver
		Form 1572
		FDA IDE Approval Letter
		Centers for Medicare and Medicaid (CMS) Approval Letter
		IATA Training Certificate (*For All Personnel Shipping Biological and/or Infectious Specimens*)
		Data Collection Tool/Questionnaire
		Investigator Brochure/Product Brochure
		Recruitment Material
		Reimbursement & Coverage Guide
		Other:

FOR OFFICE USE ONLY

ADDITIONAL DOCUMENTS

The Seton Office of Research Administration (ORA) allows research investigators to seek institutional review board (IRB) approval from AAHRPP accredited, non-Seton IRBs. If you plan to seek approval or have received approval from an AAHRPP accredited, non-Seton IRB, please be sure to provide the additional documents below. Check all applicable and not applicable items below.

Included	Not Applicable	DOCUMENTS
		Institutional Review Board (IRB) Approval Letter
		Principal Investigator Curriculum Vitae (CV) (Signed/Dated)
		Co-Investigator(s) Curriculum Vitae (CV) (Signed/Dated)
		Human Subjects Protection Training (*For All Study Personnel*)
		Good Clinical Practice Training (*For Research Coordinators Only*)

Financial Disclosure & Conflict of Interest -- All Submissions

Please contact the Conflict of Interest Manager (512-324-7000 ext. 88225) in the ORA in order to ensure that all financial disclosure and conflict of interest requirements have been met. Each must be completed prior to receiving approval from the Clinical Research Operational Review (CROR).

I. STUDY OVERVIEW

A. Title of Research/Project

B. Study Objectives: If additional space is necessary, please use the **Study Objectives Continuation Page**.

C. Study Period		Month	Year
	Estimated Start Date	January	
	Estimated End Date	January	

D. Study Duration		Years
E. Duration of Each Subject's Participation		Years

F. Type of Study

- ☐ Treatment
- ☐ Prevention
- ☐ Diagnostic
- ☐ Screening
- ☐ Quality of Life
- ☐ Other
- ☐ Retrospective Chart Review
- ☐ Clinical Trial, Phase I
- ☐ Clinical Trial, Phase II
- ☐ Clinical Trial, Phase III
- ☐ Clinical Trial, Phase IV

II. INSTITUTIONAL REVIEW BOARD (IRB)

Designated IRB	STATUS		Reference Number
	Pending	Approved	
☐ Seton IRB			IRB #
☐ University of Texas (UT) at Austin IRB			IRB #
☐ UT Southwestern IRB			IRB #
☐ Quorum IRB			IRB #
☐ Central IRB			IRB #
☐ Western IRB			IRB #
☐ Other			IRB #

III. SPONSOR INFORMATION ☐ N/A

A. Sponsor Name

B. Sponsor Address

	City			
	State		**Zip Code**	

C. Sponsor Contact Name

Job Title			
Phone		**Email Address**	

IV. FUNDING SOURCE ☐ N/A

A. Is the above-listed Sponsor also the funding source for this study? ☐ Yes ☐ No

B. If not, please specify the funding source below.

V. STUDY SITE(S)

Please check all sites that will be involved in the study. Additionally, please provide the estimated number of subjects/records/study participants that will be enrolled at each site.

SITE	Number of Subjects	Number of Records (*Chart Review Only*)
☐ Seton Family of Hospitals – Network (SFH)		
☐ University Medical Center at Brackenridge (UMCB)		
☐ Seton Medical Center Austin (SMCA)		
☐ Dell Children's Medical Center (DCMC)		
☐ Seton Highland Lakes Hospital (SHL)		
☐ Seton Southwest Hospital (SSW)		
☐ Seton Edgar B. Davis Hospital (SEBD)		
☐ Cedar Park Regional Medical Center		
☐ Seton Northwest Hospital (SNW)		
☐ Seton Medical Center Williamson (SMCW)		
☐ Seton Medical Center Hays (SMCH)		
☐ Seton Shoal Creek Hospital (SSC)		
☐ Central Texas Rehabilitation		
☐ Other Seton Clinics Enter clinic name(s) here.		
TOTAL NUMBER	0	0

VI. STUDY ACTIVITIES

Describe the method and location for each phase of the study. Please also indicate who (e.g. individuals or groups) will be responsible for each phase. Regarding treatment and follow-up, be sure to indicate the number of visits planned for each subject. If the activity requires a "research only" visit, charges will be incurred. Please contact the Clinical Trials Specialist (512-324-7000 ext. 77330) in the Seton Office of Research Administration for pricing. If additional space is necessary, please use the **Study Activities Continuation Page**.

RECRUITMENT ☐ **N/A**	
Method	
Location	
Who	

ENROLLMENT ☐ **N/A**	
Method	
Location	
Who	

TREATMENT ☐ **N/A**	
Method	
Location	
Who	

FOLLOW-UP ☐ **N/A**	
Method	
Location	
Who	

VII. STUDY PERSONNEL

A. Principal Investigator					Degree (s)/Certification(s)
Job Title					
Institutional Affiliation					
Address		City			
		State	TX	Zip Code	
Phone		Fax			
Email Address					

Role/Responsibility: Please provide a detailed description of the research activities and/or procedures to be conducted by the principal investigator.

B. Research Coordinator ☐ N/A					Degree (s)/Certification(s)
Job Title					
Institutional Affiliation					
Address		City			
		State	TX	Zip Code	
Phone		Fax			
Email Address					

Role/Responsibility: Please provide a detailed description of the research activities and/or procedures to be conducted by the research coordinator.

VIII. OTHER STUDY PERSONNEL ☐ N/A

Name		**Degree (s)/Certification(s)**	
Phone		**Email Address**	

Role/Responsibility: Please describe research activities and/or procedures to be conducted.

Research Staff

Name		**Degree (s)/Certification(s)**	
Phone		**Email Address**	

Role/Responsibility: Please describe research activities and/or procedures to be conducted.

Research Staff

Name		**Degree (s)/Certification(s)**	
Phone		**Email Address**	

Role/Responsibility: Please describe research activities and/or procedures to be conducted.

Research Staff

Name		**Degree (s)/Certification(s)**	
Phone		**Email Address**	

Role/Responsibility: Please describe research activities and/or procedures to be conducted.

Research Staff

Name		**Degree (s)/Certification(s)**	
Phone		**Email Address**	

Role/Responsibility: Please describe research activities and/or procedures to be conducted.

Research Staff

Name		**Degree (s)/Certification(s)**	
Phone		**Email Address**	

Role/Responsibility: Please describe research activities and/or procedures to be conducted.

Research Staff

Name		**Degree (s)/Certification(s)**	
Phone		**Email Address**	

Role/Responsibility: Please describe research activities and/or procedures to be conducted.

Research Staff

IX. ADDITIONAL STUDY INFORMATION ☐ N/A

Please provide any additional information that should be considered by the Clinical Research Operational Review (CROR) and may be useful in further assessing operational impact on the Seton network. If additional space is necessary, please use the **Additional Information Continuation Page**.

X. CREDENTIALING ☐ N/A

In the section below, please specify all patient-related services in which each non-Seton study staff member is credentialed to perform at each Seton site(s) of the proposed study. If additional space is necessary, please use the **Credentialing Continuation Page**.

PLEASE NOTE: All non-Seton study personnel are required to be credentialed through Seton Medical Staff Services prior to participation in research at any Seton Healthcare Family site. If there is any concern regarding credentialing, it is strongly encouraged that the Clinical Research Operational Review be contacted as soon as possible. Otherwise, for more information about the credentialing process, please contact Seton Medical Staff Services (512-324-1111).

Name	**Degree(s)/Certification(s)**
Procedures/Research Activities	
Name	**Degree(s)/Certification(s)**
Procedures/Research Activities	
Name	**Degree(s)/Certification(s)**
Procedures/Research Activities	

XI. PRINCIPAL INVESTIGATOR'S ASSURANCE

During the research, if there are any changes in the information provided above (including a change of principal investigator), documentation of these changes must be submitted to the Seton Office of Research Administration (ORA) within 5 business days. As Principal Investigator, I am responsible for ensuring the completion of a Seton Patient Load Form for every subject for whom billing services will be required prior to the services being rendered. For patient safety, 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

Reset Form

Print Form