SETON: Request for Use of an External IRB

Instructions: An Investigator should complete this form to request approval from the Seton Office of Research Administration (ORA) to accept the one-time use of an external IRB on a research study. If the External IRB Use Request is accepted, the Investigator will be notified and a **one-time IRB Authorization Agreement is required to be executed <u>prior to study initiation</u>.**

Project Information	
Date of Submission to ORA	
Principal Investigator	
Project Title	
Study Sponsor, if applicable	
Primary Contact Information	

External IRB Information		
Name of External IRB		
Type of IRB (i.e. Commercial, Central, Institutional)		
Federal Wide Assurance (FWA) Number, if applicable		
OHRP IRB Registration Number(s)		
Is the External IRB aware of this request?	☐ Yes	☐ No
Is the External IRB accredited by AAHRPP?	☐ Yes	☐ No

Research Eligible for Use of an External IRB **Please check any that apply.**	
☐	The research is a major multi-center clinical trial and the Seton PI is not the overall PI of the trial.
☐	The research is a multi-center research consortium project.
☐	The research is a multi-center clinical trial with a central IRB.
☐	The research is a Phase III or IV clinical trial utilizing a central IRB.
☐	The research is an industry-initiated protocol.
☐	The research is an industry-funded clinical trial.
☐	Seton is engaged in the human research solely because it is receiving federal funds (employees or agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain consent of the subjects).

☐	Other (please explain reason for utilizing an External IRB):

Research Ineligible for Use of an External IRB **Verify (by checking the appropriate boxes below) that the research does not fall under any of the following categories of research ineligible for use of an external IRB.**		
Phase I Clinical Trials	☐ Yes	☐ No
Clinical Trials involving any of the following vulnerable populations: prisoners, HIV patients, fetuses, neonates, pregnant women, or mentally incapacitated	☐ Yes	☐ No
Exception from Informed Consent (EFIC) Trials	☐ Yes	☐ No
Humanitarian Use Device (HUD) Trials	☐ Yes	☐ No
Investigational Device Exemption (IDE) Trials	☐ Yes	☐ No

CERTIFICATION OF PRINCIPAL INVESTIGATOR

As the Principal Investigator of the above-referenced project, I agree to:

1. Maintain a regulatory file with all IRB and study related documentation.
2. Execute the research plan as described in protocol, including obtaining informed consent from all subjects as deemed appropriate by the IRB.
3. Conduct this research in accordance with the policies and procedures of Seton Healthcare Family (including obtaining all necessary approvals from the Clinical Research Operational Review) and the IRB who has reviewed this research.
4. Comply with applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this application.
5. Report immediately to this Institution any unanticipated problems involving risks to subjects or others in research covered under this protocol.
6. When responsible for enrolling subjects, obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative, as required under HHS regulations, 45 CFR part 46, and as stipulated by the IRB.
7. Report to sponsors and agencies as required.
8. Maintain records of research, including consent documents, for a minimum of six (6) years beyond the termination of the study or, if longer, as specified by the funding agency/sponsor of the project.

Failure to comply with any of the above regulations may result in **closure of the study** by this Institution**.** I hereby assure compliance to the above and assume responsibility for all activities involved in this project.

_____ _____

Signature of Principal Investigator **Date**

Office Use Only

I have reviewed this application and have determined that all departmental requirements are met. Use of the above-specified External IRB is appropriate for this project.

_____ _____

Signature of Designated Department Official **Date**