

Clinical Research Operational Approval Determination Form

In order to evaluate and mitigate certain legal and compliance risks, as well as resource utilization and financial impact, operational review and approval is required for certain studies.

*Please answer the following questions to determine if Operational Approval is required for your study. **Any "Yes" answer indicates that Operational Approval is required.** Note that ALL studies require IRB approval. You must include this form in your IRB submission, even if an Operational review is not required.*

Name of Study:

	Yes	No
1. Does the protocol require patient care that will be provided:		
a. In a PHS facility?	<input type="checkbox"/>	<input type="checkbox"/>
b. Specifically to PHS patients?	<input type="checkbox"/>	<input type="checkbox"/>
c. By a PHS employee?	<input type="checkbox"/>	<input type="checkbox"/>
2. Is PHS receiving funds for this study?	<input type="checkbox"/>	<input type="checkbox"/>
3. Does the research require disclosure of PHP data?	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the assistance of another PHS department needed to obtain data that will be reported (e.g. Medical Records/HIM, Data & Analytics, Revenue Cycle, Epic)	<input type="checkbox"/>	<input type="checkbox"/>

Name and title of PI/ CRC completing this form

Date