PRESBYTERIAN

PHS Interventional Study
Operational Approval Request

Operational approval is required for all interventional studies in which the protocol includes patient care provided in a PHS facility, to PHS patients, or by a PHS employee.

Section 1: Study Information

Date of Request:

Study Name:

Study Sponsor:

Other sources of funding (including funding to Sponsor, if known):

If not sponsored, is this an investigator initiated study? ☐ Yes ☐ No

Is this study registered at clinicaltrials.gov? ☐ Yes ☐ No NCT#**:**

Objective and Hypothesis

Primary Study Objective

Study Hypotheses

How does the study support the Triple Aim (Better Health, Exceptional Experience, Cost Leadership)?

Investigational item

Item name and description:

This item is a:

☐ Drug ☐ Device ☐ Other

Expected Duration of Study:

Expected Enrollment (of PHS patients):

Protocol *Please attach protocol synopsis with this form.*

1. If the PI is affiliated with an organization other than PHS, has the study been approved by that organizations IRB?

   ○ Yes ○ No ○ I don't know ◉ N/A

2. Does the study provide access to treatments, tests or technologies not otherwise available to PHS patients?

   ○ Yes ◉ No

3. Is the study question clinically meaningful? What is the expected benefit over the current standard of care?

Section 2: Operational Impact and Feasibility

Patient Population

4. Does PHS have a patient base that can fulfill the eligibility requirements of the study and meet the enrollment goal?

   ○ Yes ○ No

5. Does the study compete with other studies seeking the same patient population? ○ Yes ○ No

   - If so, how will this overlap be managed?

Staffing

Role	Name	Organization	Email	Phone
Principal Investigator (PI) *				
Clinical Research Coordinator (CRC) *				
Clinical Research Coordinator (CRC)				

** required*

If the PI is not employed or contracted by PHS, a PHS-employed or contracted clinician will be required to act as a Sub-I and assume *responsibility for oversight* of all study activities performed within PHS facilities. If the independent PI's organization will be performing CRC functions related to the study, a separate PHS Clinical Research Coordinator is not required. However, a PHS employee must be assigned to coordinate research activities that affect other PHS departments such as patient billing and sponsor invoicing. **Enter below:**				
PHS Sub-I				
PHS CRC *or*				
Other PHS Staff				

6. Is the individual identified above as the CRC **experienced / trained** in clinical trial management? ◯ Yes ◯ No **Comments**:

7. Does the PHS PI/ Sub-I have adequate capacity (time and sufficient patient access) to devote to the protocol? ◯ Yes ◯ No

8. What will be the impact on patient access?

9. Does the PHS Research Staff have adequate capacity to devote to the study? ◯ Yes ◯ No

Areas Impacted by this study

10. List the PHS facilities and departments where the study will be conducted:

11. What PHS departments will be expected to provide services under the protocol *(including ancillary)*?

Department	Services in Protocol?		Services Required
	Yes	No	
Laboratory	◯	◯	
Radiology	◯	◯	
Pharmacy	◯	◯	
Other:	◯	◯	
Other:	◯	◯	
Other:	◯	◯	

12. List the PHS business partners that will be impacted by this study *(e.g. RAA, Tricore) and nature of impact:*

13. Can all PHS departments impacted meet their responsibilities in the protocol? *(consider increases in volumes, special handling of drugs or devices, etc.).* ◯ Yes ◯ No

Compliance Considerations

Note: The PI / Research Staff is responsible for ensuring a Coverage Analysis is performed prior to enrolling patients on a study with billable services and coordinating with Finance and Patient Financial Services for special handling of participants' claims. Please work with your Research Coordinator to complete this section.

14. Will this study require **purchase** of drugs, devices, supplies or equipment from a specific vendor?(Note: any new vendors will require approval by Materials Management). ◯ Yes ◯ No

15. Will drugs or devices be provided free of charge by the study sponsor? ◯ Yes ◯ No
If yes, list items provided:

16. Has a Coverage Analysis been performed? ◯ Yes ◯ No ◯ N/A (If N/A, explain why below)

- Based on the Coverage Analysis, does the study protocol require patient services that would not be provided as routine care absent the clinical trial? ◯ Yes ◯ No
  - If so, will those non-routine services be paid for by the study sponsor? ◯ Yes ◯ No
    (consider not only types of services but frequency of services above routine care)

- Will the patient likely incur additional out of pocket expense due to study participation (e.g. copays related to new or more frequent procedures or visits)? ◯ Yes ◯ No
  - If so, what steps will be taken to ensure that the patient will have an understanding of their financial responsibility before services are provided?

- If "N/A", explain why:

Financial Considerations / Budget Information

Please attach supporting budget materials, if available.

17. Has a preliminary budget been proposed by the Sponsor? ◯ Yes ◯ No

18. Is the budget information below based on a preliminary budget proposal or a negotiated budget?

◯ Preliminary ◯ Negotiated

19. Budget based on enrollment of:

20. Gross revenue:

21. Costs for Patient Services not billable to Patient or Insurance (paid for by Sponsor or by Research Department):

22. Costs for Research and Administrative Staff (including benefit expense):
23. Net Income:
24. Is the proposed budget adequate? ◯ Yes ◯ No
25. If not, will additional negotiations occur? ◯ Yes ◯ No
26. If the negotiated study budget results in a net loss, has that been authorized? ◯ Yes ◯ No ◯ N/A

Section 3: Risks and Benefits of Participation

1. What are the benefits of participation?
   For Patients and Members:

   For PHS:

2. What are the potential risks or concerns due to participation, and what is the plan to mitigate them?
   For Patients and Members:

   For PHS:

Section 4: Contact Information

Contact Information (for follow up questions)

Notification of final approval will be sent to this individual unless otherwise requested.

Name and title:

Phone #: E-mail address:

Section 5: Conflict of Interest

Principal Investigator

Do you, or any member of your family, now have, or might reasonably within the next 12 months acquire, a financial interest in, or enter into a transaction or arrangement with

the entity directly funding this study (study sponsor)? Yes ○ No ◉

an entity providing funding to the study sponsor for this study? Yes ○ No ◉

If you answered yes to either question, please provide:

a) the name of the family member (or "self") and relationship to you
b) the name of the business or organization
c) the nature of your or your family member's relationship with the business or organization

Principal Investigator signature:

Medical Director of business unit conducting the study

Do you, or any member of your family, now have, or might reasonably within the next 12 months acquire a financial interest in, or enter into a transaction or arrangement with

the entity directly funding this study (study sponsor)? Yes ○ No ◉

an entity providing funding to the study sponsor for this study? Yes ○ No ◉

If you answered yes to either question, please provide:

a) the name of the family member (or "self") and relationship to you
b) the name of the business or organization
c) the nature of your or your family member's relationship with the business or organization

Medical Director signature:

Other potential COIs

List below any other potential COIs which you are aware of that may require review. *(Example, PHS employees who may have governance roles or financial interests with any of the funding sources related to this study)*

Section 6: Interdepartmental Coordination Approvals

The purpose of departmental coordination is to obtain the support, permission, and approval of ancillary departments or entities that may be impacted by the research. If a department listed is not impacted by the study, indicate "N/A" in date field.

	Approves	Has Concerns	Discussed	On Date
Pathology: Dr. Alexei Bakhirev (Pathology Associates)	○	○	☐ In Person ☐ Phone ☐ Email	
Laboratory: Dr. Robert Casias (Tricore)	○	○	☐ In Person ☐ Phone ☐ Email	
PHS Pharmacy: Erica Downing, PharmD	○	○	☐ In Person ☐ Phone ☐ Email	
Radiology/ Imaging / Nuc Med: Paula Lenane	○	○	☐ In Person ☐ Phone ☐ Email	
OR/ Procedural Suites: Brenda Gonzales	○	○	☐ In Person ☐ Phone ☐ Email	
Departmental Quality/ Safety Committees:	○	○	☐ In Person ☐ Phone ☐ Email	
Other:	○	○	☐ In Person ☐ Phone ☐ Email	

Section 7: Approvals

Clinical/ Operations Approvals

Obtain and document approvals from the individuals in the "Clinical / Operations" section.

	Approves	Has Concerns	Discussed	On Date
Program Administration				
	○	○	☐ In Person ☐ Phone ☐ Email	
Program Medical Director				
	○	○	☐ In Person ☐ Phone ☐ Email	
CDS Administration				
	○	○	☐ In Person ☐ Phone ☐ Email	

Remaining approvals will be obtained by the Research Department after you have submitted your request.

Please submit completed form and supporting documentation to Ebany Martinez-Finley, Director, Research at emartinez41@phs.org. For questions, call (505) 923-7854.

Administrative Approvals (to be obtained by the Research and Sponsored Awards Dept.)

	Approves	Has Concerns	Discussed	On Date
Medical Records/ HIM				
Tamara Hidalgo	○	○	☐ In Person ☐ Phone ☐ Email	
Patient Financial Services				
Laura Calkins	○	○	☐ In Person ☐ Phone ☐ Email	
Contracting				
Jason Sharp	○	○	☐ In Person ☐ Phone ☐ Email	
Health Plan				
	○	○	☐ In Person ☐ Phone ☐ Email	
	○	○	☐ In Person ☐ Phone ☐ Email	

Final Operational Approval (for Clinical Research Subcommittee use only)

Representative Committee Member	Signature	Date

Review Comments:

Clear Form