PRESBYTERIAN

Observational / Data Study
Operational Approval Request

Operational approval is required for observational or data studies that involve the disclosure of data held by PHS to any third party. This data includes, but is not limited to: Patient, employee, or member information (including de-identified data), PHP claims data, PHS billing, cost, charge or other proprietary information.

Section 1: Study Information

Date of Request:

Study Name:

Study Duration: **Est volume (# of charts, enrollment, etc.):**

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

Study Staff	Name	Organization Name or PHS Dept	E-mail	Phone
Principle Investigator				
Research Coordinator				

If the PI is not employed or contracted by PHS, a PHS employee or contracted clinician will be required to act as a Sub-I and assume responsibility for oversight of study activities involving PHS data. Enter below:

PHS Sub-I or Co-I:

If the PI is not a PHS employee, provide the name of the institution / organization requesting access to PHS data:

Objective and Hypothesis

Primary Study Objective

Study Hypotheses

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

Study Type

Indicate Study Type:(choose from drop down)

For Data Collection studies, indicate type of data being collected.

For "Other", please explain:

Section 2: Operational Impact and Feasibility

PHP Data Considerations (only required for studies that include PHP claim data)

1. Will the study require the release of claims information? ☐ Yes ☐ No

   - If yes, has PHP agreed to release the requested data? (Some data may be proprietary and/or owned by other entities. Approval must be granted by PHP.) ☐ Yes ☐ No
   - Name of entity(ies) receiving the information:

PHS Data Considerations (e.g. patient data from Epic or other sources; proprietary cost, charge or other information)

Access to and / or transfer of patient information or proprietary data may be subject to approval by the following PHS bodies: Data Governance, Information Security, Revenue Management

2. Will the study require access to Epic by study staff for chart review? ☐ Yes ☐ No

   - Will access to Epic be requested for individuals who are not employed by PHS? ☐ Yes ☐ No
   - If yes, list individual(s) and roles:

3. Will data within Epic be captured in any manner and disclosed to a third party? ☐ Yes ☑ No

   - If yes, name of entity receiving data:
   - Will the data be de-identified? ☐ Yes ☐ No
   - Who else will have access to this data?
   - How will the data be transferred and stored?

4. If the PI is a contracted or independent provider, will the study be opened by PHS or through the independent provider's practice / or other organization (i.e. will PHS be a party to any study agreement)?

PHS Resource Considerations

5. Will assistance be needed to obtain the data? ☐ Yes ☐ No
   - If no, how will the data be obtained?

   - If yes, which PHS departments do you need help from to obtain required study data? *
     - ☐ Medical Records / HIM
     - ☐ Revenue Cycle (charge or payment information – will not be disclosed without prior approval)
     - ☐ Data and Analytics (e.g. Reports needed to determine data set for review)
     - ☐ Other(s):

   What is the nature of the assistance needed?
   - ☐ Copies of medical records data?
   - ☐ An aggregated report of patient data (Service Now Demand Request will be required)
   - ☐ Formal Data Analysis (Service Now Demand Request will be required)
   - ☐ Other (Explain):

**** A fee will be charged depending upon the nature and volume of services requested***

Financial Considerations

6. **Is the Study sponsored?** ☐ Yes ☐ No

   If yes:
   - **Study Sponsor Name**:
   - **Other sources of funding (including funding to Sponsor if known)**:

7. Will PHS be contracted directly with the study sponsor? ☐ Yes ☐ No
8. If PHS is not receiving funding directly from the sponsor, will the independent provider or organization receiving funding subcontract with PHS to provide and/or analyze the data? ☐ Yes ☐ No
9. Has a preliminary budget been proposed by the Sponsor or independent provider / organization?
   ☐ Yes ☐ No
   - Is the proposed budget adequate? ☐ Yes ☐ No
   - If the negotiated study budget results in a net loss, has that been authorized?
     ☐ Yes ☐ No ☐ N/A
   - Is the budget information below based upon a preliminary budget proposal or a negotiated budget?
     ☐ Preliminary ☐ Negotiated
   - Budget based on volume of:
   - Gross Revenue:
   - Costs for Research and Administrative Staff (including benefit expense):
   - Net income/(loss):

Clear Form

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

Section 3: Conflict of Interest

Principal Investigator *(for PHS employed or contracted PI's)*

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 4: 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: Approvals

PHS Department Approval (Department where research is being conducted)

Department / Facility Administration	Approves	Declines	Communicated	Date
Name:	☐	☐	☐ In Person ☐ Phone ☐ Email	

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

Review Notes / Comments

Administrative Approvals (to be obtained by the Research Dept.):

approvals needed will depend on the characteristics of each study	Approves	Declines	Communicated	Date (or N/A if approval is not applicable)
Medical Records/ HIM				
Tamara Hidalgo	☐	☐	☐ In Person ☐ Phone ☐ Email	
Data & Analytics				
Kalyani Gopalan	☐	☐	☐ In Person ☐ Phone ☐ Email	
Health Plan (Claims Data Requests)				
	☐	☐	☐ In Person ☐ Phone ☐ Email	
Data Sharing Agreement Creation / Review				
Sophia Collaros / Erica Chavez	☐	☐	☐ In Person ☐ Phone ☐ Email	
Data Access & Sharing Exchange (DASE)				
Andrea Kinsley	☐	☐	☐ In Person ☐ Phone ☐ Email	

Final Operational Approval (for Clinical Research Subcommittee use only)

Representative Committee Member	Signature	Date

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