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Protocol #

PRMC Research Application

Instructions: This form serves as application to the Research Review Committee (RRC) to perform a review of any new research being conducted through Peninsula Regional Medical Center. This form, supporting documents and required signatures must be submitted to the Research Office to initiate the approval process.

1. What Type of Review Are You Seeking?

☐ **Limited – For protocols meeting IRB review category of "exempt" or "expedited"; JHCRN studies; University/College studies already approved by school's IRB; and identical trials recently reviewed for a different Investigator.** A limited review submission is conducted by a minimum of two members of the RRC. The reviewers will provide determination of protocol endorsement within two (2) weeks of submission to the RRC Administrative Specialist.

- **A reviewer may determine that the protocol needs to undergo full committee review at which time the Investigator would be notified**.
  Submission Requirements: Complete Research Application**,** Research Application Signature page, Principal Investigator Acknowledgement of Responsibilities form, Protocol, Abstract or schema, Consent form template (if applicable), IRB certification of approval (if applicable), and any other study related documents (questionnaires, assessment tools, etc.).

☐ **Full Committee – Required for all studies that do not fall under the limited category.**

- **Submission Requirements:** Complete Research application, Research application signature page, Principal Investigator Acknowledgement of Responsibilities form, Protocol, Abstract or schema, Consent form template, and any other study related documents (questionnaires, assessment tools, etc.), Budget and contract if applicable should be sent by e-mail to Research Office.

☐ **Waiver of Jurisdiction –** Studies conducted at PRMC but approved by an external IRB

- **Submission Requirements:** Complete Research application, Research application signature page, Principal Investigator Acknowledgement of Responsibilities form, Protocol, Abstract or schema, Consent form template, and any other study related documents (questionnaires, assessment tools, etc.), IRB of record certificate of approval and other documents as noted above for full committee review. Budget and contract if applicable should be sent by e-mail to Research Office

☐ **Administrative Review -** Research studies defined as quantitative research, which does not involve human subject contact, may qualify for an administrative review i.e., any study involving data collection exclusively.

- **Submission Requirements:** Complete Research application, Research application

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signature page, Principal Investigator Acknowledgement of Responsibilities form, Abstract, Schema/Protocol, Data Use Agreement form signed by the Principal Investigator and HIPPA Compliance Officer. Data Use Agreement must accompany all research study applications requesting use of Peninsula Regional Medical Center data. **Principal Investigators who wish to publish research findings may be required by their publisher to obtain full Institutional Review Board (IRB) approval rather than an administrative review.**

2. General Protocol Information

Protocol Number (Sponsor-assigned)	
Full Protocol Title	
Short Title (for office use only)	

Indicate IRB reviewing study:

☐ WIRB ☐ Copernicus ☐ JHMIRB ☐ CIRB ☐ Other:_____

Are you seeking Waiver of Jurisdiction? ☐ Yes ☐ No

The PI is the same on all supplemental forms

Principal Investigator		
Physician PI ☐ Yes ☐ No PI has medical staff privileges to perform study? ☐ Yes ☐ No ☐ N/A	Dept/Div/Organization:	Phone: Fax: Address:
PRMC Employee ☐ Yes ☐ No		E-mail:

Primary Study Contact	Name:
	Phone: Fax:
	Address:
	E-Mail:

Co-Investigators & Sub-Investigators. List all co-investigators and sub-investigators:

The names listed here go in section 3.2 of the DUA

Name/Title	Role

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3. Conflict of Interest (COI)	
The Principal Investigator, Sub-Investigator(s) and research staff are responsible for assuring that any real or potential conflicts of interest that might affect the relationship with the research participant or the outcome of the research are identified, disclosed, and appropriately managed, reduced, or eliminated. Significant financial interest is defined as meaning anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).	**COI forms submitted to the Sponsor & IRB** ☐ **Yes** ☐ **No; if No explain:**
4. Human Subject Training	
Have you completed human subjects training in the last four years?	☐ **Yes** ☐ **No;** **if No explain:**

5. Design & Study Origin

Phase	☐ Phase I	☐ Feasibility/Pilot
	☐ Phase II	☐ Prevention
	☐ Phase III	☐ Other-Explain:
	☐ Phase IV	
Trial Source	☐ National Cooperative Group Trial	
	☐ JHCRN	
	☐ Other externally peer-reviewed trial (NIH, ACS, Komen, etc.) Name:_____	
	☐ Industry Trial (design and implementation by the pharmaceutical or device company) Sponsor:_____	
	☐ Institutional Trial – Investigator Initiated	
	☐ Other	

Study Design or Schema – Attach a copy of the study schema, abstract or protocol to the bottom of the application.

Estimated Start Date:

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6. Clinical Trial Agreement & Budget

Note: All PRMC employed investigators must complete this section. Non-employed investigators must complete this section if there will be study-related services or care provided at PRMC.

How will this study be funded?	☐ Sponsor: _____ ☐ Grant: _____ ☐ Other: _____ ☐ N/A – move on to next section ☐ Budget/Contract

Will payments be made to participants? ☐ Yes ☐ No

If yes, will PRMC be responsible for payments? ☐ Yes ☐ No

If yes please review Administrative Policy Manual Subject: Research Studies – Payments to Participants

Review and complete the necessary steps indicated in the following PRMC Administrative Policies:

- Research Studies – Financial and Administrative Operations
- Research Studies – Payments to Participants

Include separate attachments as indicated in the attached policies.

Link to policies

https://www.peninsula.org/rahri (*see Forms and Information*)

If there is a budget or any contractual agreement affiliated with your research study, to maintain confidentiality, please forward copies to research@peninsula.org. Do not attach to this application.

7. Facilities Where The Study Will Be Conducted (Mark All That Apply)

Is your research being conducted onsite at PRMC?	☐ Yes ☐ No
☐ Richard A. Henson Cancer Institute ☐ Guerrieri Heart & Vascular Institute ☐ PRMC In-Patient Unit(s) – List: _____ _____ ☐ PRMC Surgery – On Campus ☐ Other: _____	☐ PRMC Diagnostic/Treatment Area(s) List: _____ _____ ☐ PRMC Practice(s)Peninsula Regional Medical Group(PRMG) - List: _____ _____

8. Study Participants

Gender	☐ Both ☐ Male Only ☐ Female Only ☐ N/A
Age Groups (Check all that apply)	☐ Infants or Children under age 6 ☐ Children aged 6 – 10 ☐ Children aged 11 – 16 ☐ Children aged 17 ☐ Adults 18 – 64 ☐ Adults 65 +

Indicate which of the following populations will be included in the research (mark all that apply) * indicates vulnerable population

Cognitively impaired	☐ Poor/uninsured	☐ Pregnant women
Prisoners	☐ Students of PI or study staff	☐ Employees of research site or sponsor
Limited or non-readers	☐ Students to be recruited in their educational setting, i.e., in class or at school	☐ Employees directly supervised by PI or sub-investigator
Institutionalized	☐ Wards of the state (e.g., foster children)	☐ Nursing home residents recruited in the nursing home
Minors (WIRB requires that subjects enrolled as minors be re-consented if they reach legal age of consent during their participation in the research. See the www.wirb.com FAQ on this topic for more information.)	☐ Adult subjects who cannot consent for themselves; i.e., requiring consent by a legally authorized representative	☐ Others vulnerable to coercion (specify):

If research involves PRMC Employees, please explain the data collected:

9. Accrual

Note: The RRC monitors accrual to open trials at least annually and prior to study renewal.

If a multi-center study, what is the total number of subjects to be enrolled at all sites:	_____ total subject enrollment target

	☐ N/A
How many subjects do you expect to enroll at your site annually?	
Expected duration of accrual: (months or years)	
Please explain how you will recruit participants:	*Any patient or provider directed advertising must be IRB-approved*
Estimated Site First Enrollment:	
Estimated Site Final Enrollment:	

10.HIPAA

Please explain how the study is HIPAA compliant:	☐ You will obtain authorization from the participant for the use and disclosure of Personal Health Information (PHI) through obtaining informed consent ☐ The data will be completely de-identified and therefore the need of authorization from the individual is waived. ☐ This is a Limited Data Set and you are seeking a Data Use Agreement. ☐ This study involves only the use of decedent data. ☐ Other – Explain in an attachment.

11. Drugs

Are drugs used in this protocol? Include all drugs, whether FDA approved or investigational	☐ Yes ☐ No if No go to section 13	
Name of Protocol-Specific Drug(s) Use attachment if more space is needed	Generic:	Trade (if available):
Who supplies protocol-required medication(s)? **Note:** Describe the reimbursement process for drug(s) not provided free of charge by sponsor:	☐ Physician ☐ PRMC ☐ Sponsor will provide free of	

	charge ☐ Other:_____ ☐ N/A
Where will the investigational drug be stored?	☐ Physician ☐ PRMC Pharmacy: ☐ Other:_____ ☐ N/A
What temperature range will the drug be stored at?	_____
Who will administer the investigational agent(s)?	☐ PRMC Employee ☐ Non-PRMC Employee

12. Pharmacy

Will PRMC Pharmacy services be required to perform any tasks associated with this study; check all that apply?	☐ Preparation ☐ Dispensing ☐ Oral ☐ Bulk ☐ IV Preparation ☐ Injection ☐ Chemo preparation ☐ Compounding/Placebo ☐ Randomization ☐ Blinding ☐ Dosing ☐ Inventory Management Ordering/Accountability ☐ Other (Order development, destruction, etc.) ☐ N/A

13. Devices

A link to define devices http://www.fda.gov/AboutFDA/Transparency/Basics/ucm211822.htm

Are devices used in this protocol?	☐ Yes ☐ No if No go to section 14 Name:_____
Is the device investigational or commercially available?	☐ Investigational ☐ Commercially available
Is the device provided free of charge by sponsor?	☐ Yes ☐ No If No please describe reimbursement process:_____
Who will supply the protocol required device(s)?	☐ Physician ☐ PRMC ☐ Other:_____
Where will the device be stored during the study?	☐ Physician ☐ PRMC Department. List department name: _____

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Anything used for placement of the device into the patient

	☐ Other: _____ ☐ N/A
14. Kits & Supplies	
Are you bringing kits/supplies to PRMC not provided by the hospital?	☐ Yes ☐ No if no go to section 15 List: _____
Who will supply the protocol required kits?	☐ Physician ☐ PRMC ☐ Sponsor will provide free of charge ☐ Other: _____ ☐ N/A
Where will the kits be stored during the study?	☐ Physician ☐ PRMC Department. List Department name: _____ ☐ Other_____ ☐ N/A
Who will be using the kits or supplies?	☐ PRMC employee ☐ Study Coordinator or PI
Are kits and supplies provided free of charge by sponsor?	☐ Yes ☐ No If No please describe reimbursement process:_____

Biomedical Equipment will require approval for use by the Biomedical Department. Any device that is to be plugged in requires an electrical safety check by the Facilities Management Department.

15. Equipment	
Do you have any biomedical equipment involved in this protocol?	☐ Yes ☐ No If No go to section 16 List: _____
Do you have any electrical equipment that you will be bringing on to the campus of PRMC or any other location owned/operated by PRMC?	☐ Yes ☐ No List: _____
16. Radiation	
Is radiation used in this project?	☐ Yes ☐ No if No go to section 17
If yes, what forms of radiation?	☐ Diagnostic x-rays ☐ Radiation therapy ☐ Radioisotopes
If yes, approval required by the Radiation Safety Officer	
17. Biosafety	

Does the study involve:	Recombinant DNA? ☐ Yes ☐ No Biological Toxins? ☐ Yes ☐ No Infectious Agents? ☐ Yes ☐ No
If you have answered yes to any of these questions, this study requires approval and additional review by the Research Committee	

18. Laboratory

Are PRMC Laboratory services required to perform any tasks associated with this study; check all that apply? **Note:** Please complete this section even if phlebotomy is being performed off-site but samples will be sent to PRMC for processing, shipping and or storage.	☐ Phlebotomy ☐ Processing ☐ Shipping ☐ Storage ☐ Tissue ☐ Laboratory Specimen ☐ N/A

19. Mandatory Attachments

1. **Signature Form:** This form needs to be signed by the PRMC Department Director where the study will be held as well as the Principle Investigator. The form should then be scanned as a PDF and submitted.

2. **Acknowledgement of Responsibility Form:** PI needs to complete, sign and date the "Acknowledgement of Responsibility Form". This document should be scanned and submitted.

3. **Data Use Agreement Form:** If you will be collecting data in any form, you will need to complete the Data Use Agreement Form. The document should be scanned as a PDF and submitted.

4. **Study Design Schema/Abstract and Protocol**

20. Supplemental Attachments