

## **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 " studies; University/College studies already approved by recently reviewed for a different Investigator. A limited minimum of two members of the RRC. The reviewers will endorsement within two (2) weeks of submission to the R  • A reviewer may determine that the protocol need at which time the Investigator would be notified. Submission Requirements: Complete Research Applications of the Resear	school's IRB; and identical trials review submission is conducted by a l provide determination of protocol RRC Administrative Specialist. ds to undergo full committee review explication, Research Application ement of Responsibilities form, late (if applicable), IRB certification of
approval (if applicable), and any other study relate assessment tools, etc.).	ed documents (questionnaires,
<ul> <li>Full Committee – Required for all studies that do not fall</li> <li>Submission Requirements: Complete Research approached signature page, Principal Investigator Acknowledge Protocol, Abstract or schema, Consent form temp documents (questionnaires, assessment tools, etc. should be sent by e-mail to Research Office.</li> </ul>	oplication, Research application ement of Responsibilities form, late, and any other study related
<ul> <li>Waiver of Jurisdiction – Studies conducted at PRMC but at Submission Requirements: Complete Research apsignature page, Principal Investigator Acknowledge Protocol, Abstract or schema, Consent form templedocuments (questionnaires, assessment tools, etc. and other documents as noted above for full compaphicable should be sent by e-mail to Research Of</li> </ul>	plication, Research application ement of Responsibilities form, ate, and any other study related ), IRB of record certificate of approval mittee review. Budget and contract if
Administrative Review - Research studies defined as qualinvolve human subject contact, may qualify for an adminidata collection exclusively.  • Submission Requirements: Complete Research and	strative review i.e., any study involving



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	1						
Protocol Number (Sponsor-assigned)							
Full Protocol Title							
Short Title (for office use only)							
Indicate IRB reviewing study:							
WIRB Copernicus	]HMI	RB [	CIRB	Other:			
Are you seeking Waiver of Jurisdiction	?			Yes	□No		
Principal Investigator							
Physician PI Yes No	Dept/	Div/Or	ganizat	ion:	Phone:		Fax:
PI has medical staff privileges to					Address:		
perform study? YesNo N/A							
PRMC Employee Yes No					E-mail:		
Primary Study Contact	Name						
	Phone	•			Fax:		
	Addre	ss:					
	E-Mail	•					
Co-Investigators & Sub-Investigators.	List all	co-inv	estigat	ors and sub	o-investigato	rs:	
Name/Title				Ro	le		



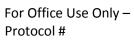
3. Conflict	of Interest (COI)				
The Principal Investigator, Sub-Investigator(s) and			COI forms submitted to the Sponsor		
research staff are responsible for assuring that any real			& IRB		
or potentia	I conflicts of interest that mig	ht	affect the	☐ Yes	
relationship	o with the research participan	ıt o	r the		
outcome of	f the research are identified, o	disc	closed, and	☐ No; if No explain:	
appropriate	ely managed, reduced, or elim	nina	ated.		
Significant	financial interest is defined as	m	eaning		
anything of	monetary value, including bu	ut n	ot limited to,		
salary or ot	her payments for services (e.	g., (	consulting		
fees or hon	oraria); equity interests (e.g.,	sto	ocks, stock		
options, or	other ownership interests); a	nd	intellectual		
property rig	ghts (e.g., stocks, stock option	ıs, (	or other		
ownership	interests); and intellectual pro	оре	erty rights		
(e.g., paten	ts, copyrights and royalties fr	om	such rights).		
4. Human S	Subject Training				
Have you co	ompleted human subjects tra	inir	ng in the last	□Yes	
four years?				□ No;	
,		if No explain:			
5. Design	& Study Origin				
Phase	Phase I		Feasibility/Pile	ot	
	Phase II		Prevention		
	Phase III		Other-Explain	:	
	Phase IV				
Trial	Trial National Cooperative Group Trial				
Source JHCRN					
	Other externally peer-rev	vie	wed trial (NIH,	ACS, Komen, etc.)	
Name:					
	Industry Trial (design and implementation by the pharmaceutical or device				
	company) Sponsor:				
	Institutional Trial – Inves	tiga	ator Initiated		
	Other				
Study Design	gn or Schema – Attach a copy	of	the study sche	ma, abstract or protocol to the bottom	
of the appli			•	·	
Estimated S	Start Date:				



c Clinical Trial Associated O Developer					
6. Clinical Trial Agreement & Budget Note: All PRMC employed investigators must complete must complete this section if there will be study-related.					
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 Su Participants	bject: 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 <a href="https://www.peninsula.org/rahri">https://www.peninsula.org/rahri</a> (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 <a href="maintain-research@peninsula.org">research@peninsula.org</a> . Do not attach to this application.					
7. Facilities Where The Study Will Be Condu	icted (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 Diagnostic/Treatment Area(s) List:				
□ PRMC Surgery – On Campus	☐ PRMC Practice(s)Peninsula Regional Medical Group(PRMG) - List:				
□ Other:					
1	•				

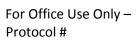


8. Study Participants							
Gender			☐ Both ☐ Mal	le Onl	У	☐ Female	Only 🗆 N/A
Age Groups (Check all that apply)  □ Infants or Children to 10				er age 6	_		
			☐ Children aged☐ Adults 18 – 64		10		☐ Children aged 17 ☐ Adults 65 +
Indicate which of the following	qoq	ulati			the	research	
apply) * indicates vulnerable po							•
Cognitively impaired		Poc	r/uninsured			Pregnant	women
Prisoners		Stu staf	dents of PI or stud f	dy		Employe or spons	es of research site or
Limited or non-readers		in t	dents to be recrui neir educational ing, i.e., in class o ool				es directly ed by PI or sub- tor
Institutionalized			rds of the state (e er children)	e.g.,		_	nome residents I in the nursing
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.		can the con	Ilt subjects who not consent for mselves; i.e., requ sent by a legally norized represent	uiring			ulnerable to (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:			e	nrollment	_ total subject : target		



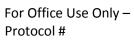


			□ N/A		
How many subjects do you expect to enroll at your site					
annually?					
Expected duration of accrual: (months o	r years)				
Please explain how you will recruit participants:			Any patient or provider directed advertising must be IRB-approved		
Estimated Site First Enrollment:					
Estimated Site Final Enrollment:					
10.HIPAA					
Please explain how the study is HIPAA compliant:	the use and dis (PHI) through of the data will therefore the nois waived.  This is a Limit Use Agreement	closure obtaining I be comeed of a ited Data t. volves o	orization from the port Personal Health In informed consent pletely de-identified uthorization from the Set and you are sently the use of decedant attachment.	nformation d and he individual eking a Data	
11. Drugs					
Are drugs used in this protocol? Include all drugs, whether FDA approved or investigational			☐No if No go to s	ection 13	
Name of Protocol-Specific Drug(s) Use attachment if more space is needed			c:	Trade (if available):	
Who supplies protocol-required medication(s)?  Note: Describe the reimbursement process for drug(s) not provided free of charge by sponsor:			ysician MC onsor will provide fr	ee of	



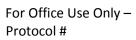


	charge Other: N/A				
Where will the investigational dr	Physician PRMC Pharmacy: Other: N/A				
What temperature range will the	e drug be stored at?				
Who will administer the investig	ational agent(s)?	PRMC Employee Non-PRMC Employee			
12. Pharmacy					
Will PRMC Pharmacy services be required to perform any tasks associated with this study; check all that apply?	Preparation  Dispensing  Oral  Bulk  IV Preparation  Injection  Chemo preparation  Compounding/Place	Other (Order development, destruction, etc.)			
13. Devices					
Are devices used in this protocol	Yes No if No go to section 14 Name:				
Is the device investigational or co	Investigational Commercially available				
Is the device provided free of ch	Yes No If No please describe reimbursement process:				
Who will supply the protocol rec	Physician PRMC Other:				
Where will the device be stored	Physician PRMC Department. List department name:				





	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:
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?	
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	
8	





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	Phlebotomy				
tasks associated with this study; check all that apply?	Processing				
<b>Note:</b> Please complete this section even if phlebotomy	Shipping				
is being performed off-site but samples will be sent to	☐ Storage				
PRMC for processing, shipping and or storage.	☐Tissue ☐ Laboratory Specimen				
	□N/A				
19. Mandatory Attachments					
1. Signature Form: This form needs to be signed by t	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.					
F Di ana submittea.					
2. Acknowledgement of Responsibility Form: Pl nee	eds to complete, sign and date the				
"Acknowledgement of Responsibility Form". This o	, , ,				
-	document should be scanned and				
submitted.					
3. Data Use Agreement Form: If you will be collectin	og data in any form, you will need to				
-					
complete the Data Use Agreement Form. The doc	ument should be scanned as a PDF and				
submitted.					
4 Study Docian Schoma/Abstract and Protocol					
4. Study Design Schema/Abstract and Protocol					
20. Supplemental Attachments					