For Office Use Only –
Protocol #

TidalHealth 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 TidalHealth Peninsula Regional. 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 TidalHealth 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 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 TidalHealth Peninsula Regional 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.

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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		
Principal Investigator		
Physician PI ☐Yes ☐No PI has medical staff privileges to perform study? ☐Yes ☐No ☐ N/A	Dept/Div/Organization:	Phone: Fax: Address:
TidalHealth 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:		
Name/Title	**Role**	

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:

6. Clinical Trial Agreement & Budget

Note: All TidalHealth employed investigators must complete this section. Non-employed investigators must complete this section if there will be study-related services or care provided at TidalHealth.	
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 TidalHealth 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 TidalHealth 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
http://intranet.peninsula.org/sites/pi/research/researchcomp/Documents/Forms/AllItems.aspx?FilterField1=Categories0&FilterValue1=Finance

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 TidalHealth?	☐Yes ☐No
☐ Richard A. Henson Cancer Institute ☐ Guerrieri Heart & Vascular Institute ☐ TidalHealth In-Patient Unit(s) – List: _____ _____ ☐ TidalHealth Surgery – On Campus ☐ Other: _____	☐ TidalHealth Diagnostic/Treatment Area(s) List: _____ _____ ☐ TidalHealth Practice(s)TidalHealth 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 ☐ Adults 18 – 64	☐ Children aged 17 ☐ 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 TidalHealth 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 ☐ TidalHealth ☐ Sponsor will provide free of charge ☐ Other:_____ ☐ N/A	
Where will the investigational drug be stored?	☐Physician ☐TidalHealth Pharmacy: ☐Other:_____ ☐N/A	
What temperature range will the drug be stored at?	_____	
Who will administer the investigational agent(s)?	☐TidalHealth Employee ☐Non- TidalHealth Employee	

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12. Pharmacy	
Will TidalHealth 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	
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 ☐TidalHealth ☐Other:_____
Where will the device be stored during the study?	☐Physician ☐ TidalHealth Department. List department name: _____ ☐Other: _____ ☐N/A
14. Kits & Supplies	
Are you bringing kits/supplies to TidalHealth not provided by the hospital?	☐Yes ☐No if no go to section 15 List: _____
Who will supply the protocol required kits?	☐Physician ☐TidalHealth ☐Sponsor will provide free of charge ☐Other: _____ ☐N/A
Where will the kits be stored during the study?	☐Physician ☐TidalHealth Department. List Department name: _____ ____ ☐Other_____ ☐N/A
Who will be using the kits or supplies?	☐ TidalHealth 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 TidalHealth or any other location owned/operated by TidalHealth?	☐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 TidalHealth 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 TidalHealth 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 TidalHealth 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**