

Welcome to TidalHealth Research Institute

Below are some guidelines to help navigate TidalHealth's Research Review Committee approval process. Please contact The Research Office at **(410) 543-7285** or research@peninsula.org if you have any questions.

Guidelines for Research Approval

TidalHealth Research Institute utilizes an internal Research Review Committee (RRC) to review and grant preliminary approval for research conducted at TidalHealth Peninsula Regional. This is not Institutional Review Board oversight, but a committee appointed by TidalHealth to ensure the study meets the mission and goals of TidalHealth.

TidalHealth outsources Institutional Review Board (IRB) approval and oversight responsibilities in a contractual relationship with Western Institutional Review Board (WIRB) www.wirb.com and Copernicus Group Independent Review Board (CGIRB) www.cgirb.com. If you desire to have TidalHealth provide IRB oversight utilizing one of its IRB partners, please be advised there are fees which will be incurred by the principal investigator for use of these services. Fee schedules are available on the websites of each of the respective IRBs.

Waiver of Jurisdiction

If you are obtaining IRB approval through an IRB agency not affiliated with TidalHealth and wish to request a waiver of jurisdiction from TidalHealth and WIRB to your chosen IRB, you may qualify for a "waiver of jurisdiction". All requests for waiver of jurisdiction must be submitted to TidalHealth and, subsequently, WIRB with a letter of approval from the IRB chosen to provide oversight. Following review and approval by the RRC and WIRB written documentation noting waiver of jurisdiction to an alternate IRB will be provided by WIRB. The study may not begin until confirmation of approval is received by the Research Review Committee. Currently, WIRB does not charge for these services.

Submission Process

Below are the submission steps:

1. Please complete the Research Submission Application form in its entirety and include appropriate additional documents at the end of the application.

2. Please include the following study specific documents:
 - Abstract, Synopsis or schema
 - Informed Consent Form (ICF)
 - Budget and Contract (if applicable)
 - Grant (if applicable)
 - Institutional Review Board approval letter if not WIRB or CGIRB and you are requesting an IRB Waiver of Jurisdiction. TidalHealth Research Application (see example)
 - TidalHealth Research Application (see example)
 - Research Application Signature Page (see example)

- PI Acknowledgment of Responsibilities (see example)
- Data Use Agreement (1 form, list everyone involved in study) see example

Each individual involved in the study must complete the following training:

- Human Subject Training* (see instructions)
- Financial Conflict of Interest Training* (see instructions)
- GCP Training* (see instructions)
- Data Use Agreement (1 form, list everyone involved in study) see example

Processing of Application/Final Approval

TidalHealth will provide a protocol tracking number upon receipt of the research application. Please use this number to reference your project for all future correspondence.

TidalHealth will request approval of all departments listed on the RRC application who will need to provide resources or support to the research project that have not already endorsed the project prior to RRC approval.

Once the RRC reviews the research project, a letter of their findings will be forwarded to the Principal Investigator (PI).

- If the RRC requires additional information, the PI will be asked to provide the additional information to complete the review process.
- If the RRC endorses the study, it becomes eligible for submission to the IRB. A letter of endorsement will be issued by the RRC and must be included in the IRB submission packet. You are eligible to conduct your research once you have full IRB approval.
- If you are requesting a waiver of jurisdiction, upon approval by TidalHealth's Research Review Committee we will submit a request for waiver of jurisdiction to WIRB on your behalf and you will be notified by WIRB when the waiver has been granted. Upon receiving that notification you would be eligible to begin your research project.

Please feel free to contact the Research Office at **410-543-7285** or email at research@peninsula.org with any questions.