

**Arrowhead Regional Medical Center
Institutional Review Board**

**Instructions for Research Study
Submissions to ARMC IRB**



***Arrowhead Regional Medical Center
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Email: ARMC-IRB@armc.sbcounty.gov

PLEASE READ BEFORE SUBMITTING:

The contents of this document will assist you in the preparation and submission of your research proposal and forms required to conduct human studies research at Arrowhead Regional Medical Center (ARMC). **Please read this document prior to starting and submitting your proposal and application to the ARMC Institutional Review Board (IRB).**

PROSPECTIVE

These studies involve the activities of: contacting (e.g., surveying or interviewing) or interacting with patients in order to gather information or specimens, examining patients or testing an approved medication or procedure. This type of research usually requires the development of a consent process with a consent document (template).

CASE STUDY/REPORTS

(i.e., single case reports or case series, including no more than three cases) are not considered research but should be submitted to the IRB for a letter of approval from oversight. As a rule of thumb, if you have 1-3 patients with the same diagnosis, it is considered a case study. 4 or more patients will be prospective/retrospective.

RETROSPECTIVE

These studies are often referred to as "chart review." In this type of study, the investigator is typically attempting to answer a research question by using archived information obtained from the patients' medical records. Any type of patients' information that has been collected for clinical purposes such as the chart or x-rays can be used for research purposes, but must be submitted for evaluation and approval by the IRB.

BEFORE YOU START:

There are 4 basic types of approvable research that need to be evaluated and reviewed by the IRB:

SPONSORED

In addition to other types of studies, these may include clinical trials or other types of research, which are typically funded by pharmaceutical or device companies. Some may provide the center the opportunity to test new medications or devices using our population. These studies are not usually designed by ARMC investigators and the center provides a service to allow access to our patients and conduct of the trial. Sponsored trials must be reviewed and approved by the IRB.

INSTRUCTIONS:

The IRB will NOT review your proposal and application unless ALL requirements below are met.

- CITI TRAINING REQUIREMENTS:** All personnel involved with the study **MUST** complete the **CITI HUMAN SUBJECT RESEARCH** training prior to submission. If this module is not available, you can fulfill this requirement by completing one of the following courses:

- Observational Research**
- Retrospective Research**
- Biomedical Research**
- Survey Research**

NOTE: If you are affiliated with a different institution that subscribes to the Collaborative Institutional Initiative (CITI) program (<https://www.citiprogram.org>) and have completed or will complete the CITI training, you may, alternatively, submit your CITI completion certificate from that institution. **Your Human Subjects Research training is valid for 2 years.**

ATTACH CERTIFICATES OF ALL RESEARCH PERSONNEL TO EVERY IRB SUBMISSION

- REQUIRED FORMS:** The ARMC Research website (<https://www.arrowheadregional.org/education-research/office-research-and-grants/research/>) has all of the required forms for IRB submissions. Depending on the type of study submission, forms may vary. **PLEASE SEE CHART BELOW:**



REQUIRED FORMS FOR RESEARCH SUBMISSION

CV/Resume (for PI ONLY) & CITI Certificates MUST also be included with ALL submissions

RETROSPECTIVE	IRB Application	Attachment A (For additional Sub-Investigators)	Protocol Summary	Application for Waiver of HIPAA Authorization		
PROSPECTIVE	IRB Application	Attachment A (For additional Sub-Investigators)	Protocol Summary	ARMC Consent Form ENGLISH and/or SPANISH	PHI Authorization Form	Copies of study related recruitment materials (e.g., letters, flyers, surveys, etc.) INCLUDING Spanish translated materials
CASE STUDY/REPORT	Case Study Memo	Case Study Consent Form				

3. **RESUME/CV REQUIREMENT:** Please submit an up-to-date **resume/CV** of the **Principal Investigator**.
 - a. **NOTE:** Students, residents and fellows **MUST** have a designated ARMC faculty member as the PI (principal investigator). The ARMC faculty advisor holds ultimate responsibility for the study's conduct. The protocol, developed in conjunction with the PI, requires their **APPROVAL AND SIGNATURE** before submission.

4. **SUBMISSION:** Once all documents have been completed, filled, and signed by the appropriate people, please submit to the IRB Coordinator, wellss@armc.sbcounty.gov. The coordinator will advise if anything is missing or needs editing.

WHAT HAPPENS NEXT?

1. Once the coordinator has reviewed your documents, it is then sent to the IRB committee for official review.
2. If approved, the IRB committee chair will sign a letter of approval. The IRB coordinator will send that letter of approval to the study team.

Turnaround Time: On average, approval can take anywhere from 2-4 weeks. Depending on the level of patient risk involved, the turnaround time may be more or less.

FINAL NOTES

Changes in your Protocol

Amendments: If you need to make revisions or changes to your protocol, you must submit the **Protocol Amendment form** to the IRB for their review and approval prior to making the changes.

Adding Sub-Investigators: To notify the IRB about study personnel additions or deletions please use the **Add Investigator Memo** and attach all appropriate documentation needed.

Breach of Confidentially

If you suspect any protected health information (PHI) as designated in the IRB Application has been released in an unauthorized manner, you must immediately suspend your study and contact the ARMC Compliance Officer- Collin Goodrum (goodrumc@armc.sbcounty.gov; 909-580-3530). You may also contact the IRB Coordinator at (armc-irb@armc.sbcounty.gov; 909-580-6263).