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

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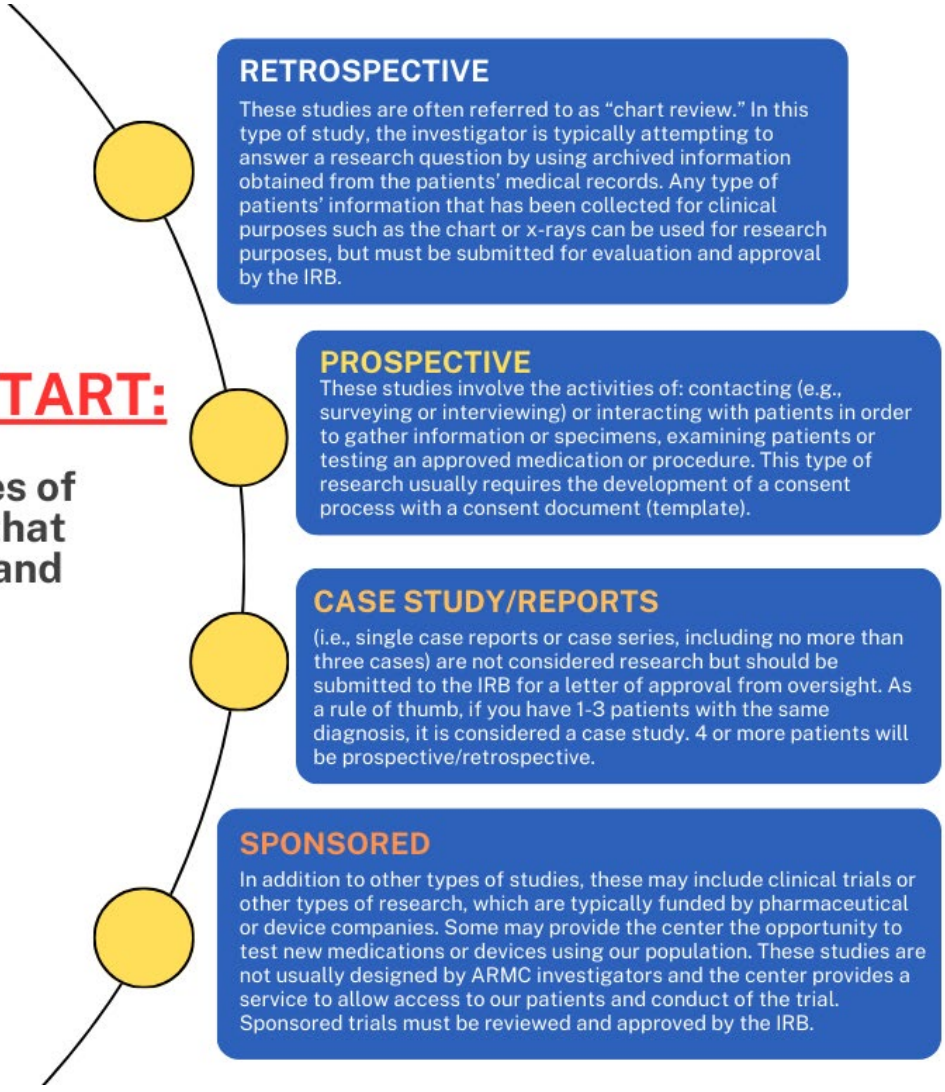
PLEASE READ BEFORE SUBMITTING:

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)**.

BEFORE YOU START:

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



INSTRUCTIONS:

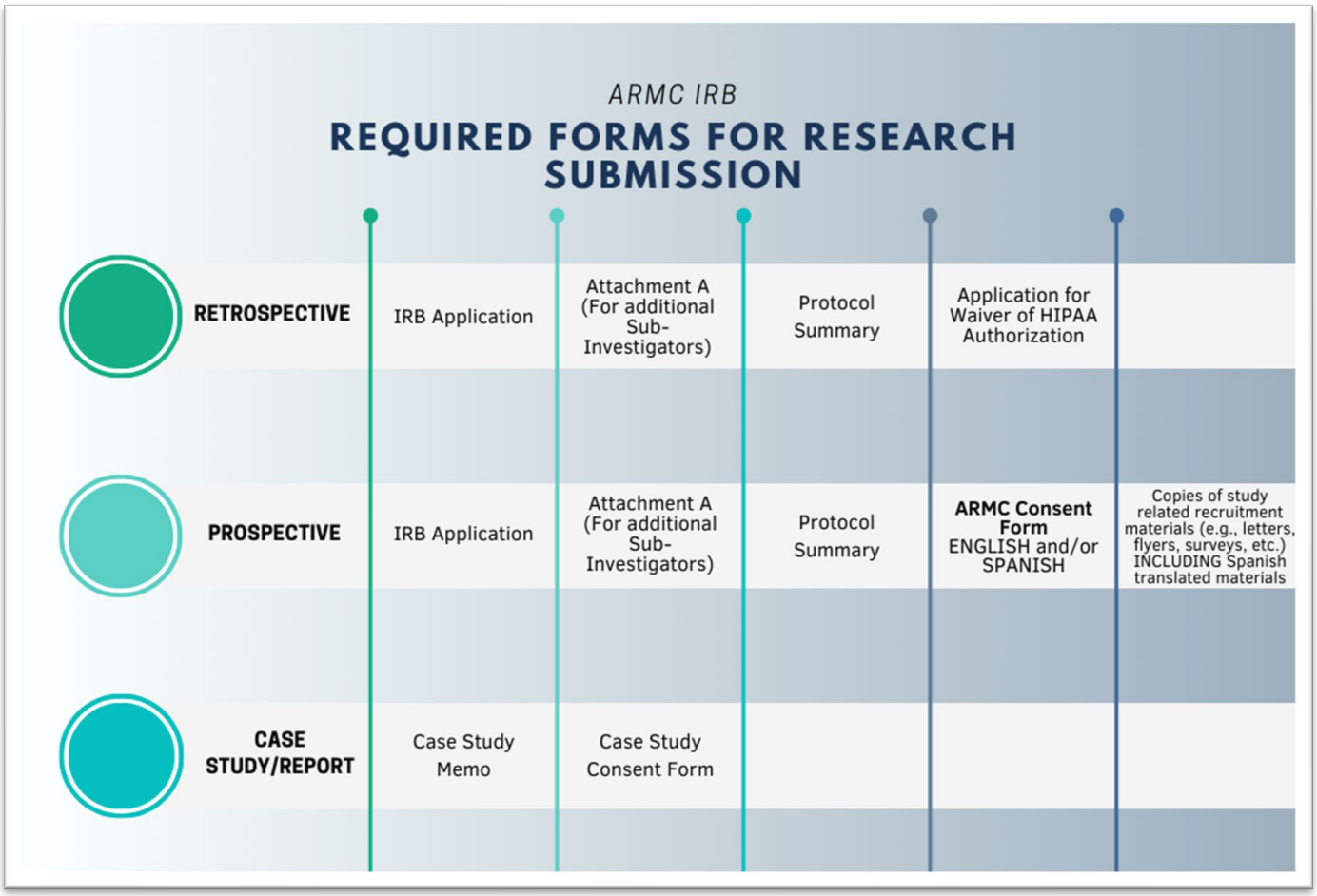
The IRB will NOT review your proposal and application unless ALL requirements below are met.

1. 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:
   a. **Observational Research**
   b. **Retrospective Research**
   c. **Biomedical Research**
   d. **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

2. 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:**



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).