Arrowhead Regional Medical Center

Institutional Review Board

Instructions for Research Study Submissions

Arrowhead Regional Medical Center

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Welcome! 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

A. There are four basic types of approvable research that need to be evaluated by the IRB:

- **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.
- **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).
- **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.
- **Case Study/Reports** (i.e., single case reports or case series, including no more than three cases) are not considered research and should be submitted to the IRB for a letter of exemption from oversight. The process for submitting case studies are located on the Research website.

B. The vast majority of research projects submitted by ARMC staff, residents, interns, nurses, and other affiliates are **retrospective studies**. Retrospective studies must be submitted to the IRB using a submission package which consists of **a research proposal** (see protocol summary template for instructions on preparation) and a short list of required forms listed in the section of this document entitled IRB: Document Submission. Please note all forms and templates are downloadable from the Research at ARMC website (https://www.arrowheadmedcenter.org/pResearch.aspx).

C. **Prospective and sponsored research-** You **are encouraged to make an appointment with the IRB Coordinator** to discuss your project prior to submission (this is best done while still in the preparation phase). We will assist you in proposal development, identification of necessary resources, and a preliminary list of necessary IRB submission package contents**.** If you are planning a prospective study, contact the IRB Coordinator (ARMC-IRB@armc.sbcounty.gov) **and** cc Teckah Lawrence (Lawrencete@armc.sbcounty.gov) in your email to arrange a meeting.

D. All submissions must be **typed with original signatures** and **submitted in person to the Office of Research and Grants or via email (armc-irb@armc.sbcounty.gov).** Documents requiring signatures should be printed, signed, scanned, and then, uploaded if being emailed. **The Office of Research and Grants is not responsible for completing incomplete forms or obtaining signatures, and we will return the forms to you, if not complete.**

E. Finally, research is serious business and not adhering to the instructions and regulations can result in serious consequences for you and ARMC. However, most importantly research should be educational and FUN! Hopefully, your project will directly result in improving health care outcomes at ARMC and in general.

F. Do NOT begin without approval! You cannot begin recruitment, consent, collecting data, reviewing charts, etc. until your IRB approval. **Submission of materials for review is not sufficient**—you must wait for approval. **The IRB cannot issue retroactive approval for research**.

Let's get started

Step 1. All personnel that will be involved with the study **MUST** complete their human studies research training prior to submission. You may complete your training through the National Institute of Health's Protecting Human Research Subjects website (http://phrp.nihtraining.com/). If you are affiliated with an 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. Your human research subjects protection training is valid for 4 years.

If these requirements are not met, **the IRB will NOT review your proposal and application for research.**

Step 2. Pose a research question and write the proposal- The website has the protocol summary template to guide the development and writing of your proposal. This is the most important part of any clinical study. You and/ or your research mentor should pose an important and relevant question related to clinical practice. **Students, residents and fellows MUST have a designated ARMC faculty member as the PI (principal investigator). This ARMC faculty advisor will be ultimately responsible for the conduct of the study.** The proposal should be prepared in collaboration with your faculty advisor and must be approved by them for submission.

Some examples of research questions are, "What risk factors predict poor outcomes in ankle surgery?" or "Why do patients miss their follow up appointments?" Answers to these questions improve health outcomes! Unlike basic scientists, we, as clinicians, focus on what is directly relevant to clinical care and improving outcomes. The research question must be both practical and relevant. You should be able to answer it in a reasonable time frame, and it should not be, simply, a reproduction of other, earlier studies.

Step 3. Writing the research proposal is the next step and requires time and effort! It usually requires 1-2 months to prepare a solid proposal, so please allow sufficient time. The protocol summary template was designed to assist you in the development of a complete and well-structured proposal. Once the proposal is written, it is very easy to then complete and submit the IRB forms.

Please contact the IRB Coordinator early for direct guidance in initiating and completing your research proposal. She will guide you towards key staff at ARMC for assistance.

Step 4. The IRB process- All members of the ARMC IRB have signed and are bound by a confidentiality agreement. All discussions within the IRB are confidential and any material submitted to the IRB is privileged information.

As previously stated, once the proposal is written, it is very easy to complete the IRB application and forms. It is also important that you review each document and form, and you complete the various required applications entirely. If you do not understand either the rationale behind completing the form, or how to complete the forms, please contact the Office of Research and Grants for assistance. Incomplete applications will not be processed.

IRB: Document Submission

After your proposal and forms are submitted to the IRB, your study will undergo one of three levels of review: Exempt, Expedited or Full Committee review. The level of review will be determined by the IRB Coordinator.

- **Exempt:** The initial review for exempt studies is typically performed by an IRB Coordinator. Following the initial review, studies deemed exempt do not require further IRB regulatory review. However, this determination must be made by the IRB Office. No determinations can be made retroactively.

- **Expedited:** The expedited review process is carried out by a subcommittee composed of the IRB chairperson or by one or more experienced reviewers. In other words, these types of reviews do not require the convening of the full committee, and occur on a continuous basis throughout the year as studies are submitted. These types of reviews are reserved for retrospective chart reviews.

- **Full Committee** review is the most rigorous level of review. The full committee meets once a month to review new and continuing protocol applications and modification requests.

Retrospective Studies

The following documents are a part of the submission package for retrospective studies. For the initial submission, you must submit the following items for IRB review

1. **Your protocol summary.** This should be submitted in the recommended format.
2. **IRB Application**. This form must be completed filled out, typed, and have original signatures.
3. **NIH Training Certificate.** If you have completed this training as part of your residency, the IRB Coordinator should have a copy of the certificate on file. If the training is over 3 years old, you will be asked to update it. If you have never completed the training or the IRB Coordinator does not have a copy of it, you will be asked to submit this document.

The following form must be completed and submitted if there are any changes in your study protocol.

4. **Request to Approve Updates/Revisions—**This form should be submitted with any changes that occur in the conduct of your study protocol, consent or process. The changes must be IRB approved. (If you have changes in study personnel, please submit an IRB memo to add the sub-investigators)
5. **Memo—**This form must be submitted to the IRB should any changes in study personnel occur.

At the time of project renewal- usually yearly- you must complete the following form.

6. **Request for Annual Review** (or Continuing Review Application) **-** This form will be used if you wish to renew your study**. Renewal of a study is NOT automatic and must be approved by the IRB.** For most studies the IRB requires a yearly review unless otherwise stipulated in your approval letter. This form must be completed and submitted in advance of your renewal date and failure to do so will result in suspension of your study. If a study is not submitted for renewal you and your faculty co-pi will be notified that your study will be closed out and no further active research can be conducted.

The following forms are used when the study is finished.

7. **Request to Close Protocol-** This form will be completed when you have finished your study and is self- explanatory. If you continue to conduct data analysis you will not fill out this form but submit the Annual Review form. Once you have filed this report, the IRB will issue a final study closure notification.

Finally, the following document is an important informational and educational tool so please read it!

Researcher Self-Evaluation Worksheet—This form is for your benefit in determining if your proposal is ready to be submitted to the IRB. Reviewing it will assist you in understanding how the IRB will assess your proposal.

Prospective Studies

The contents of the prospective research study package will vary from study to study. But, a partial list of potential documents that might be submitted as a part of your prospective study package is listed below.

For the initial submission, you may submit the following items in addition to your human research subjects training certificates for IRB review:

1. **Protocol Summary-**This should be submitted in the recommended format.
2. **IRB Application Form—**typed with original signatures
3. **Informed Consent Form**—use template on Research Website. If you would like to request a waiver of consent, document and justify this in the protocol summary
4. **Copies of Study Related Recruitment Materials** (e.g., letters, flyers, radio script/commercial)
5. Any additional documents as requested by the ARMC IRB

The following form must be completed and submitted if there are <u>any changes in your study protocol.</u> These changes will be reviewed for approval and you will be notified by the IRB of the decision.

6. **Request to Approve Updates/Revisions—**This form should be submitted with any changes that occur in the conduct of your study protocol, consent or process.
7. **IRB Memo—**Complete this form for all personnel changes

During your study, if any <u>serious adverse events, adverse events, or protocol deviations</u> occur, these must be reported to the IRB using the following form.

8. **IRB Memo**—Complete this form stating the event that has occurred and provide any necessary documentation

At the time of <u>project renewal</u>- usually yearly- you must complete the following form.

9. **Request for Annual Review** (or Continuing Review Application) **-** This form will be used if you wish to renew your study**. Renewal of a study is NOT automatic and must be approved by the IRB.** For most studies the IRB requires a yearly review unless otherwise stipulated in your approval letter. This form must be completed and submitted in advance of your renewal date and failure to do so will result in suspension of your study. If a study is not submitted for renewal you and your faculty co-pi will be notified that your study will be closed out and no further active research can be conducted.

The following forms are used when the study is finished.

1. **Request to Close Protocol-** This form will be completed when you have finished your study and is self- explanatory. If you continue to conduct data analysis you will not fill out this form but submit the Annual Review form. Once you have filed this report, the IRB will issue a final study closure notification.

Sponsored Studies

Although additional documentation may be required, the initial submission package for sponsored research will likely include at least the following items:

1. A Study Proposal (or Protocol).
2. Application form
3. Investigator's Brochure (if applicable)
4. Informed Consent Form(s) (if applicable)
5. ORG Research Financials Form

Please contact the IRB Coordinator directly at ARMC-IRB@armc.sbcounty.gov or the Office of Research and Grants at 909-580-6336 for more information about conducting a sponsored study at ARMC.

IRB Review Process

What should I submit to the IRB?

1. **Initial submission-** You must submit your proposal and noted forms above and also submit your human studies certificates if not on file with IRB Coordinator. **Failure to submit these documents will result in your project not being reviewed!**
2. **Research Renewal-** Forms must be submitted 30 days in advance from your annual renewal**.** Include the **Annual Review form** and any **necessary memos such as personnel changes.**
3. **Study Closure-** If you are requesting to close your study, you will submit a request to close form.

What happens once I submit my forms and proposal to the IRB, and when should I expect a decision?

1. Now that you have carefully reviewed the documents and forms, and you have completed and written a well thought out proposal that has been reviewed and approved by your faculty advisor (if applicable).
2. You may now submit your completed forms, human research subjects certificates and protocol summary to the Office of Research and Grants IRB.
3. **IRB action**
   - The IRB is striving to review and notify the investigator within 72 hours of submission if the application is complete and ready for review.
   - On receipt of the forms, we will first check for completion and accuracy.
   - If the submission is complete, it will then be assigned for review and action and you and your faculty advisor will be informed when the review will occur (whether via IRB Chair or full IRB Committee).
   - If the forms are not complete, there is missing information or there is no proposal, you and your faculty advisor will be notified by e-mail with a check list for completion. Incomplete projects will be kept for 10 business days (i.e., 2 weeks); if all information or documents are not submitted prior to this time period, the project will be “Withdrawn” and no IRB review will occur. The PI will need to contact the IRB, if they plan to resubmit and obtain approval.

The three most common omissions are not providing the human research subjects training certificates, not obtaining your advisor’s and chairman’s signatures (if applicable), and not providing a complete protocol summary.

What will happen during the review?

1. For Prospective Studies, your proposal and forms will be assigned to at least two independent members of the IRB. They will complete their reviews prior to the next scheduled meeting of the IRB. They will send their critiques to the IRB Coordinator for review. All prospective studies will be discussed and action taken at the monthly IRB meeting. If a majority of the IRB members vote to approve the study, the IRB Coordinator will send out an approval letter.

If your study is a retrospective chart review, the submission packet will be sent to the IRB Chair for review and action. If the IRB Chair approves your study, the IRB Coordinator will send out your approval letter.

YOU CANNOT START ANY RESEARCH UNTIL YOU RECEIVE THE IRB APPROVAL LETTER. If you start any research activity related to the submitted project prior to IRB approval and delivery of the approval letter you will be conducting unapproved research and your project will be suspended by the IRB.

2. **If your study is approved-** The approval letter will be sent to you and your faculty advisor (if applicable). Specifically, if you are doing a study involving the review of medical records, the approval letter will need to be taken to Medical Records in order to access charts. Advise them of what diagnosis or procedure you will need to review and the time frame. Medical Records will create a query to identify the medical records that qualify. A date will be agreed upon on which you will come to the Medical Records department and access the charts.

3. **If your Study is Not Approved-** The IRB will notify you after the review that your study is not approved with specific actions that must be addressed prior to a re-review. We will endeavor to assist you directly to correct any and all issues in the review, but you must first consult with your faculty advisor, if applicable. NO RESEARCH CAN BE CONDUCTED WITHOUT RESOLUTION OF IRB CONCERNS AND ISSUANCE OF AN APPROVAL LETTER FROM THE IRB.

    - **Requests for revisions or other information must be completed within 20 working days or the study submission will be "Withdrawn"** from the review process. Studies that have been withdrawn can only be re-submitted after consultation with the ARMC IRB.

Final Notes

Changes in your protocol

If you want to make revisions or changes to your protocol, you must submit the **Request to Approve Update/Revisions to Current Protocol** to the IRB for their review and approval prior to making the changes. To notify the IRB about study personnel additions or deletions, adverse events, serious adverse events, or protocol deviations, please use the IRB Memo template 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*).