



**ARROWHEAD REGIONAL MEDICAL CENTER  
INSTITUTIONAL REVIEW BOARD**

**Investigator Guidelines for Research Protocol Submission**

Arrowhead Regional Medical Center (ARMC) Institutional Review Board (IRB) will review all research projects to ensure the protection of the rights and welfare of human research subjects.

As part of the ARMC-IRB deliberations, the Principal Investigator may be asked to clarify points in the proposed research and will be scheduled to present the study at a Board meeting prior to approval. In addition, the Principal Investigator is required to report to the Board, at intervals determined by the Board, on the progress of an approved project. Principal Investigators must report any unexpected deaths or adverse events to the IRB Office immediately. This includes events reported to the Investigator by the sponsor and/or manufacturer.

**NO RESEARCH PROJECT IS TO BE INITIATED AT THE MEDICAL CENTER WITHOUT APPROVAL OF THE ARMC-IRB**

**Liability:**

The County, on behalf of the Medical Center, is legally responsible for the acts and omissions of its employees and contract physicians while acting in the course and scope of their duties under the auspices of the County. In the event of a claim or lawsuit against an employee or contract physician, based on his or her actions in connection with an activity involving human subjects alleged to have resulted in injury to a participant therein, the County would be obligated to provide legal representation for said employee or contract physician if the research project was approved by the ARMC-IRB.

**If the Principal Investigator has knowledge of, or should have knowledge of, the applicable Medical Center and IRB policy which requires every research activity placing human subjects at risk to be reviewed by the ARMC-IRB and fails to obtain such approval prior to involvement of human subjects, then it would be the position of the County, the Medical Center, and the ARMC-IRB that the Investigator was acting independently and outside of the course and scope of his or her duties which otherwise would fall under the auspices of the County. The County of San Bernardino would not be obligated to defend or indemnify the Investigator in such situations should legal action be initiated by research subjects.**

The San Bernardino County Board of Supervisors has not authorized the Medical Center to compensate or provide medical treatment free of charge to research subjects who incur physical injury during the course of a research project. In the event that liability is imposed on the County of San Bernardino for injuries suffered by a research subject, the County shall seek indemnification from the Principal Investigator if the Investigator knew or should have known that Medical Center and ARMC-IRB policy requires all research activities placing human subjects at risk to be reviewed and approved by the ARMC-IRB and such review and approval was not obtained.

## THREE TYPES OF STUDIES

**Retrospective-** These are often referred to as a “chart review.” The investigator is typically seeking to answer a research question using data from archived or current medical records, without needing to directly interact with the patient.

**Prospective-** These often involve direct interaction with participants via patient care/procedures or questionnaires, surveys, educational material, etc. This type of research will require an Informed Consent and Patient Bill of Rights for every participant enrolled in the study. Additionally, the IRB will now require a Research Financials Form be completed to evaluate your study for any costs incurred by ARMC. Costs will not affect your IRB approval but will need further review.

**Sponsored-** These typically include clinical trials or other types of research funded by pharmaceutical or medical device companies. These studies are typically determined by the sponsor in direct collaboration with the Principal Investigator. Sponsored studies require a review of the Clinical Trial Agreement/contract and Financial Budget. If you are considering participating in a sponsored study, contact [ARMC-IRB@armc.sbcounty.gov](mailto:ARMC-IRB@armc.sbcounty.gov) in advance.

- **Case Studies-** Are a single case or case series (not to exceed 3 cases) which you intend to present or publish. These do not require an IRB application. However, the IRB does require a statement of intent via a memo or email. An exempt approval letter will be issued outlining the Principal Investigator’s responsibility for protecting the patient’s PHI. Some journals may now require signed consent for case studies. We have a template available by request.

***The IRB Office will not process your application until complete. The required documents should be submitted as described in these guidelines. Any omissions will result in a delay in approval of your project.***

## INITIAL PROTOCOL SUBMISSION

### **Application Submission:**

Each application should include the following in the order listed below:

- IRB Application including Principal Investigator Statement of Assurance
- NIH Certificate for each investigator listed
- Protocol Summary
- English Informed Consent (Prospective and Sponsored, Spanish will be translated after approval)
- California Experimental Subject’s Bill of Rights (Prospective and Sponsored)
- Copy of questionnaire, survey, brochure, scripts, or any material provided to participant

### **Application for Initial Protocol Submission**

Applicant must complete sections A-G. Application must include signature from Principal Investigator (which must be an Attending or permanent ARMC staff with privileges) and the Department Chair.

### **Principal Investigator Statement of Assurance:**

Principal Investigators must sign the Principal Investigator Statement of Assurance which provides the ARMC-IRB confirmation that the Investigator has read and understands the responsibilities of conducting research at the Medical Center.

## NIH Certificates

All investigators listing on the application or Attachment A, must provide an NIH Certificate within 3 years. <http://phrp.nihtraining.com/users/login.php>

## Protocol Summary:

- 1) Principal Investigators are required to prepare a summary of the protocol to include the following:
- 2) Full title of the protocol, Investigators
- 3) Introduction/Literature Review- summarize relevant literature that led you to research problem and approach.
- 4) Objectives: research question, purpose of the study, hypothesis
- 5) Study type: Retrospective or Prospective
- 6) Methods: location, start and stop dates, type of research (Biomedical, Drug, Biologic, Device, Tissue/Blood specimen, other), inclusion and exclusion criteria (should be justified in the background information/literature review), subject recruitment and screening (number of subjects, age, gender, English speaking, subject materials, promotional advertising (promotional advertisements used for recruiting subjects must be submitted to the ARMC-IRB for review and approval), etc.
  - a) Consent Process: Specific description of informed consent process to include—but not limited to: who, how, training, when, where, considerations, privacy and time for decision-making/discussion, consent capacity determination (who and how); Method of subject identification and randomization: coding system, subject randomization/group selection process; Privacy of Medical and Research Records information/medical records, Medical Release forms, HIPAA compliance/authorization form
  - b) 'Identifiers of our single patient are strictly limited to medical record number, ethnicity, age and sex, along with associated clinical data. All published poster presentations, abstracts and papers will be de-identified, with all names, medical record numbers and any other identifying material removed. Patient's age, sex and race will be used in publication for educational purposes. Only the principal investigator, co-investigator and research coordinator will have access to the data that is obtained. Medical records and presentation documents will be kept within an encrypted password protected file on a password protected computer that is accessible only to the investigators involved in the study'
- 7) Study Design and Analysis: Description of interventional procedures and data collection procedures: to include lab evals, tests, specimen amounts and schedules, clinical assessments/schedule/follow up procedures, case report forms, data collection forms (with description of subject codes), study instruments, rating scales, interview guides, plans for statistical analysis of data when appropriate. Please include any additional information that will assist the ARMC-IRB in the review of your protocol.
  - a) If an Investigational New Drug (IND) is involved, provide the following information: (1) name of drug, (2) source of drug, (3) dosage and schedule of administration, (4) status with Food and Drug Administration and IND#, (5) review of animal studies and previous human studies, (6) reported side effects.
  - b) For an approved drug used in an experiment, provide similar information: (1) name, (2) source, (3) dosage, (4) how administered, (5) side effects.

- c) If an Investigational Device (ID) is involved, provide the following information: (1) name of device, (2) manufacturer, (3) status with Food and Drug Administration and ID#, (4) review of animal studies and previous human studies, (5) reported adverse effects.
- 8) Risks/Benefits: assess potential risks to subjects, benefits either direct or indirect by adding to body of knowledge.
  - a) Less than minimal risk: research in which there is no known physical, emotional, psychological, or economical risk. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.).
  - b) Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - c) Greater than minimal risk: research procedures that may include risk beyond that ordinarily encountered by subjects (e.g. maximal exercise testing, experimental drugs, biologics or medical devices, stressful psychological testing, use of special populations). This research requires some benefit analysis comparable to the risk and full review by the IRB.
- 9) Funding Source: Any funding source should be indicated in the protocol and the application. Note if subjects will be compensated, if so, how much.
- 10) References in the following format:
  - a) Doe, John. Article Title. Journal of Medicine. Date etc.

#### **Informed Consent (Prospective and Sponsored Studies):**

The Informed Consent document is a separate document prepared in the second person, using non-technical language (approximately the sixth grade reading level). It should be easily understood by all research subjects including the assent of children when appropriate in pediatric studies. Keeping this in mind, enter text concerning your study into the ARMC template provided. If you include non-English speaking subjects in your research study, the Informed Consent must be in the language of the subject being consented. The ARMC IRB has a contracted translator service for this purpose.

#### **Experimental Subject's Bill of Rights (Prospective and Sponsored Studies):**

Please use the form included in the research section of the California Healthcare Association Consent Manual. A copy is included at the back of these guidelines. It is available in English and Spanish.

#### **IRB APPROVAL**

- **Exempt Approval**-This is granted by the IRB Chair for retrospective and case studies. Only complete applications with signed applications, NIH certificates, and protocol summaries will be reviewed.
- **Full Board Approval**-Prospective and sponsored studies must go before the board for approval. This involves having two IRB member conduct a review of the protocol summary and informed consent. Their critiques will be reviewed at the next scheduled IRB meeting (2<sup>nd</sup> Monday of each month). The board will then vote to approve the study. Following the meeting the IRB will issue a signed Letter of Approval and your research may begin.
- **Conditional Approval**-A conditional approval is given when the board members feel that corrections are need to either: the study design, informed consent, or material given to participants. Following the meeting the IRB Coordinator will provide a list of requirements from

the board. Once these requirements are fulfilled, the IRB Coordinator will issue a signed Letter of Approval and your research may begin.

### **AFTER APPROVAL**

As a research investigator, you are responsible for the following reporting requirements:

1. **Annual Reviews** – You are responsible for reporting research progress to the IRB at one year intervals. Annually, you will be sent a questionnaire that is to be completed and returned to the IRB Office in a timely manner. The IRB then reviews the progress and approves the study's continuation, unless advised otherwise.
2. **Addition of new staff** – You are responsible for ensuring new research staff is qualified to assist in your research study and submit a memo to the IRB along with NIH Certificate for any added investigators during the length of the study.
3. **Adverse Events** – If an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention has occurred at any site of the study, you are responsible to immediately report to the IRB Office any such event.
4. **Revisions to the Study's Protocol and/or Consent(s)** - You are responsible to immediately report to the IRB Office any changes made to the protocol and/or consent(s). Included in the initial packet is a form "Request to Revise an Approved Protocol." Submit to the IRB Office this form filled out in its entirety, to include the following:
  - a. Attach page(s) showing corrections made.
    - Delineate all items that are to be removed from the document.
    - Italicize all items that are being added to the document.
  - b. Attach a complete "clean" copy of the protocol and/or consent(s).All modifications made to either the protocol and/or consent(s) must be approved by the IRB prior to the implementation of any of these documents. Minor revisions may be reviewed by expedited review, and major revisions may be reviewed via full board review.
5. **Completion/ Withdrawal/ Termination of a Study** – You are responsible for immediately notifying in writing the IRB Office when any study has been completed, withdrawn, or terminated.