ARROWHEAD REGIONAL MEDICAL CENTER

The Heart of a Healthy Community

How to fill out an IRB Application

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Office of Research and Grants
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ARROWHEAD REGIONAL MEDICAL CENTER
400 North Pepper Avenue
Colton, California 92324

INSTITUTIONAL REVIEW BOARD

Application for Initial Protocol Submission

INSTRUCTIONS: Your application includes this form and all documents as defined in ARMC-IRB Guidelines for Principal Investigator of which you have been provided a copy. Answer all questions in the application form. Do not answer questions with "see protocol." Failure to properly complete this application and provide the supporting documents will delay the review and approval of your protocol by the ARMC-IRB.	***FOR IRB OFFICE USE ONLY*** Type of Review: ☐Full Board ☐Expedite ☐Exempt IRB Protocol #: _____

PART A – TITLE/ INVESTIGATOR/ COORDINATOR INFORMATION

Title of Protocol:

Principal Investigator -	
Name:	**Hospital/Department:**
Phone Number:	**Mailing Address:**
E-mail Address:	

Sub-Investigator(s) -	
If more than one, attach separate sheet listing all	
Name:	**Hospital/Department:**
Phone Number:	**Mailing Address:**
E-Mail Address:	

Additional Sub-Investigators (see Attachment A)

PART B – LEVEL OF RISK

Level of Risk: ☐ **Minimal** ☐ **Moderate** ☐ **High**

- **Part A: Title/Investigator/Coordinator Information**
  - 1. List the title of the Protocol/Study you wish to conduct
  - 2. The Principal Investigator must be employed by, affiliated, or under contract with ARMC or the County of San Bernardino
  - 3. Sub-Investigator is anyone who wishes to participate in any part of your research who is affiliated with ARMC
  - 4. If you need additional space to add more sub-investigators, there is an Attachment A form that can be filled out and submitted with your application
- **Part B: Level of Risk**
  - The level of risk is dependent upon the type of study you wish to conduct. For example, Retrospective studies are typically minimal risk because they are mostly chart review studies, whereas Prospective studies have a higher risk due to the patients that may be participating in the study

PART C – SOURCE OF FUNDING/ SPONSOR

Indicate all applicable sources of funding and the sponsor

☐ Federal Sponsor	Name:
☐ Commercial Sponsor	Name:
☐ Foundation Sponsor	Name:
☐ Other (specify)	Name:
☐ No support	

PART D – CONFLICT OF INTEREST

Does the principal investigator or any sub-investigator (or any member of their immediate family) -

a. Own or control any equity interest in any drug, device or technology involved in this research study?
☐ Yes* ☐ No

b. Have a financial interest, direct or indirect, in any listed source of external support?
☐ Yes* ☐ No

c. Function as an advisor, employee, officer, director, or consultant for any listed commercial source of external support?
☐ Yes* ☐ No

**If yes, please attach detailed information to permit the IRB to determine if such involvement should be disclosed to potential subjects.*

PART E – RECRUITMENT INFORMATION

Subject Matter - *Check all that apply*

☐ Investigational New Drug	IND #
☐ Investigational New Device	IDE #
☐ Marketed Drug, New Indication	
☐ Marketed Drug, Approved Indication	
☐ Non-drug Study	

Duration of study: # ☐ Months ☐ Years

Will you be advertising? ☐ Yes* ☐ No

**If yes, please attach a sample of the advertisement.*

Subjects Involved - *Check all that apply*

Subjects	Number	Age Range
☐ Healthy (normal) Subjects		
☐ Patients		

Classification - *Check all that apply*

☐ Adults	☐ Physically Handicapped	☐ Cognitively Impaired
☐ Minors (< 18yrs)	☐ Pregnant Women	☐ Comatose
☐ Male	☐ Non-English Speaking:	☐ Prisoners *
☐ Female	Specify-	*Record Review Only

Degree of involvement of subjects - *Check all that apply*

☐ Experimentation	☐ Medical Record
☐ Observation	☐ Other (specify):

- **Part C: Source of Funding/Sponsor**
  - Check the box appropriately associated with your study
- **Part D: Conflict of Interest**
  - Check the appropriate box associated with your study. If you are unsure if there may be a conflict of interest, please email ARMC-IRB@armc.sbcounty.gov for any questions
- **Part E: Recruitment Information**
  - Under Subject Matter-if you are conducting a study that includes an IND/IDE you must include the number provided by the FDA
  - Under Subjects Involved-Check all that apply. Also, you **must** check the Non-English Speaking box, unless you can justify your reasoning for **only** using English speaking participants.
  - Under Degree of involvement of Subjects: these boxes are also dependent on the type of protocol (Prospective vs. Retrospective). Check all that apply.

Source of subjects - *Check all that apply*

- ☐ ARMC In-Patient transfers
- ☐ ARMC Out-Patients
- ☐ Other (specify):
- ☐ ARMC Emergency Dept
- ☐ County/State Public Health

PART F – CHECKLIST FOR APPLICATION - *protocol submission contains the following:*

- ☐ Study Objectives
- ☐ Background
- Study Design
- ☐ Degree of Human Subject Involvement
- ☐ Informed Consent (as applicable)
- Confidentiality statement

PART G – APPROVALS: CLINICAL

"I have read ARMC-IRB Investigator Guidelines and signed the Principal Investigator's Statement of Assurance"

_____ _____

Principal Investigator **Date**

"This protocol has been reviewed for scientific merit and has the academic endorsement of this department."

_____ _____

Department Chair **Date**

PART H – APPROVALS: RESOURCE UTILIZATION

NURSING CARE: Will nurses be asked to provide study-associated care beyond the usual given for the patient's condition? (e.g., extra vital signs, administration of additional medications, more frequent monitoring, additional education)?

Yes ☐ No ☐

If yes, please describe below, then provide appropriate signature:

Chief Nursing Officer Approval_____

Date:_____

LABORATORY: Does the study require additional tests that would not be part of usual care for the patient's condition? Yes ☐ No ☐

If yes, please describe below, then provide appropriate signature:

- Under Source of Subjects: Check all that apply

- **Part F: Checklist for Application**
  - Again, this is dependent on your type of study

- **Part G: Approvals Clinical:**
  - Requires the Principal Investigator's signature & date
  - Requires the Department Chair's signature & date

- **Part H: Approvals: Resource Utilization:**
  - If any boxes are checked yes, they require a signature & date from the department
  - Part H: continued onto next slide

MEDICAL IMAGING: Does the study require additional imaging procedures that would not be part of usual care for the patient's condition? Yes ☐ No ☐

If yes, please describe below, then provide appropriate signature:

Medical Imaging ManagerApproval_____
Date:_____

OTHER DEPARTMENT(S):_____:
Does the study require additional hospital resources beyond that which is customarily provided? Yes☐ No ☐

If yes, please describe below, then provide appropriate signature:

AdministrativeApproval:_____ Date:_____

CHIEF FINANCIAL OFFICER APPROVAL:

Have appropriate reimbursement arrangements been made? Yes ☐ No ☐
Comments:

Assistant Administrator Fiscal Services:_____Date_____

Chief Financial Officer Approval: _____Date:_____

- **Part H Continued:**
  - Please refer to slide 4 for details on how to fill this page in

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Principal Investigator Statement of Assurance

By signing below I agree/certify that:

- I have reviewed this protocol submission and agree to accept responsibility for the scientific conduct of this project.
- I will conduct this research in strict compliance with all Federal and/or State Regulations and ARMC-IRB standard operating procedures.
- **I will ensure that all sub-investigators and other study personnel assisting in this research are fully educated as to the entire protocol and consent process as well as data and record keeping requirements.**
- I will not enroll any individual into this research study until I have received final approval in writing from the ARMC-IRB or at any period of time where renewal approval has expired or enrollment has been suspended by either the ARMC-IRB or the study sponsor.
- I will submit any additions, corrections or modifications to the full protocol or the informed consent document to the ARMC-IRB for approval before implementing them.
- I will promptly report to the IRB, any serious adverse reactions, events, complications, or protocol deviations which may occur as a result of this study.
- I will respond promptly to all requests for information or materials from the ARMC-IRB or the IRB Office and will submit annual progress reports in a timely manner for ARMC-IRB renewal approval. It is understood *Exempt* approval expires one year from the date of approval.
- I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, that of his/her authorized representative.

Principal Investigator Name:

_____ _____

Signature **Date**

- **Principal Investigator Statement of Assurance:**
  - This page ensures that all investigators and sub-investigators that are participating in this study are fully educated and are up to date with the processes of the IRB and the requirements that must be followed