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:	

Research Coordinator -	
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 C – SOURCE OF FUNDING/ SPONSOR

Indicate all applicable sources of funding and the sponsor	
☐ Federal Sponsor (FDA, NIH, etc.)	Name:
☐ Commercial Sponsor (Pharmaceutical, Device, etc.)	Name:
☐ Foundation Sponsor	Name:
☐ Other (specify)	Name:
☐ No support / Internal ARMC project	

PART D – CONFLICT OF INTEREST

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

a. Function as an employee, advisor, officer, director, consultant, or other paid position for any listed sponsor? ☐ **Yes** ☐ **No** **(if yes, see Attachment B)**

b. Receive income (monies paid for services rendered) or non-financial support (drugs, equipment, travel expenses, administrative support, etc.)?

☐ **Yes** ☐ **No** **(if yes, see Attachment B)**

c. Hold equity interest (stocks) in any listed commercial sponsor?

☐ **Yes** ☐ **No** **(if yes, see Attachment B)**

d. Have a loan arrangement with any listed sponsor?

☐ **Yes** ☐ **No** **(if yes, see Attachment B)**

e. Have intellectual property (patents, copyrights, and/or royalties) relevant to the study?

☐ **Yes** ☐ **No** **(if yes, see Attachment B)**

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

Source of subjects - *Check all that apply*

- ☐ ARMC In-Patient
- ☐ ARMC Out-Patients
- ☐ Other (specify): transfers
- ☐ 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**

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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**