



*The Heart of a  
Healthy Community*

# Modifications and Renewals

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Office of Research and Grants  
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# Modifications

- All modifications or changes to on-going research must go through the IRB
- An inter office memo (see below) will need to be submitted to the IRB for review signed and acknowledged by the PI
- Most minor modifications such as adding or removing sub-investigators will be approved quickly. However, other modifications may require a more in depth evaluation.

**DATE:**

**PHONE:** 909-580-1000

**FROM: PRIMARY INVESTIGATOR  
DEPARTMENT**

**TO: INSTITUTIONAL REVIEW BOARD**

<b>SUBJECT</b>	<b>PROTOCOL AMENDMENT/ADD SUB-INVESTIGATOR(S)</b>
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**Protocol #:** [Click here to enter text.](#)

**Protocol Title:**

Please insert text on what you wish to amend here.

Kind Regards,

Principle Investigator (Signature)



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# Renewals

- Any on-going research (Prospective/Retrospective) must be renewed on an annual basis with the IRB
- The IRB Coordinator will contact the PI and other researchers 60 days prior to the renewal date so our records may be updated
- If a study is on-going the attached form must be completed and sent back promptly
- If a study has been completed or closed, the form must be filled out completely and sent to the IRB so the study may be closed

# Prospective Renewal Form

- There are 2 types of annual renewal forms
- All information must be included with the most up to date status of your study
- Once this is filled out, signed by the PI and sent back to the IRB Coordinator, an approval letter will be sent to either extend the study for another year or close the study

ARMC Institutional Review Board  
ANNUAL REVIEW FORM

Protocol #:

Renewal Due:

Protocol:

Please indicate the current status of this project:

- COMPLETED. Please List Completion Date:
- TERMINATED. Please list Termination Date: and state reason:
- ONGOING

**PLEASE COMPLETE THE FOLLOWING INFORMATION RELATIVE TO THE MOST RECENT PROTOCOL APPROVAL YEAR:**

Number of subjects enrolled this past protocol approval year \*:

Number of subjects enrolled since initial protocol approval date:

Number of subjects withdrawn since initial protocol approval date:

Have any adverse events occurred?

- YES. Please specify:
- NO

Has any new information come to light since the last review of this protocol?

- YES. Please specify:
- NO

Have there been any modifications to the protocol or consent that have not yet been reported to the IRB?

- YES. Please attach copy of the modified consent form
- NO

\_\_\_\_\_  
*Principal Investigator (Print & Sign)*

\_\_\_\_\_  
*Date*

\*If protocol is relative to a device, please note the pt MR# and date used.

# Retrospective Annual Renewal Form

- The Retrospective form here on the left must be completely filled out before submitted
- Once it has been reviewed by the IRB an approval letter to extend the study will be sent

DATE: Date PHONE: (909) 580-0000  
FROM: PRINCIPAL INVESTIGATOR  
TO: INSTITUTIONAL REVIEW BOARD

ECT REQUEST FOR ANNUAL REVIEW OF APPROVED PROTOCOL

Protocol #: [Click here to enter text.](#)

Protocol Title: [Click here to enter text.](#)

To comply with regulations, the Institutional Review Board annually reviews previously approved research.

**Check one:**

Study was completed -Date \_\_\_\_\_

**\* Please provide copy of study findings/manuscript to IRB**

Study is on-Going. Please approve for the upcoming year.

**\*If study is on-going please provide status of project in the space below. Include total number of records reviewed**

\_\_\_\_\_  
\_\_\_\_\_

Additional Comments \_\_\_\_\_

Signature of Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

APPROVED Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Michael M. Neeki, DO, MS, FACEP; IRB Chair



# No response to Annual renewal

- If the IRB does not receive a response after 3 attempts to contact the PI, or other researchers the study will automatically be closed. You must re-apply with the IRB if you wish to continue the study once it has already been closed.