MARICOPA COMMUNITY COLLEGES

IRB Tracking #:
Date Received:

MARICOPA COUNTY COMMUNITY COLLEGES DISTRICT
INSITUTIONAL REVIEW BOARD
ADVERSE INCIDENT REPORTING FORM

Directions to Researchers: This form must be completed any time a research subject experiences an adverse reaction to or unexpected event following an intervention by a researcher as part of an IRB reviewed protocol. Report any serious adverse event **POSSIBLY RELATED** to the study design or procedures that is unanticipated, meaning its occurrence was not cited in the protocol application reviewed by the IRB. An event is considered serious if it potentially affects the rights, welfare or safety of subjects in the study. This form must be submitted to the IRB chair and IRB Coordinator within 48 hours of becoming aware of the event.

Title of Research Proposal:
Investigator/Project Director:
College or Institutional Name:
Phone:
E-mail:

Adverse Event

Onset Date:

Date investigator/director learned of event:

Report Type: ☐ Initial ☐ Follow up

Event Status: ☐ Resolved ☐ On-Going

Please Describe the event, any treatment, and the outcome. Include pertinent subject history (provide additional pages if needed).

Do you recommend changes to the protocol? ☐ No ☐ Yes; if yes, attach proposal

Do you recommend changes to the consent form? ☐ No ☐ Yes; if yes, attach proposal

By signing this form, the Investigator/Project Director certifies that he/she has disclosed to the IRB all relevant information concerning this Unanticipated Adverse Event.

Investigator/Project Director Signature: _____ Date: _____

Email form to: irb_office@domail.maricopa.edu or fax to: (480) 731-8282