

**WOR-WIC COMMUNITY COLLEGE
INSITUTIONAL REVIEW BOARD
NEGATIVE INCIDENT REPORT 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).

[Empty box for event description]

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@worwic.edu