

Reporting Unanticipated Problems, New Risks Identified, and Instances of Noncompliance

Investigators are never to conceal problems that arise, whether they are major or minor. The SUNY Cortland IRB requires that investigators report all problems to the IRB immediately. The SUNY Cortland IRB needs to be aware of any kind of problems, even when they seem to be manageable or very minor at the time. This allows the IRB to address the participant's needs more quickly and in an appropriate manner. Furthermore, early reporting of all problems provides an opportunity for the IRB and/or institution to assist the investigator with necessary modifications and it will help us to avoid similar issues in future research.

If a problem arises during the conduct of your research study, please contact the IRB. Call the IRB if the matter is urgent (607) 753-2511 and email information about less urgent matters to irb@cortland.edu. The IRB will provide you with further instructions. If the problem is minor, a protocol modification may be all that is required. Major problems may require external reporting. If your research is externally funded, copy (cc) the email to the Interim Director of RSPO: [Elizabeth Speziale](mailto:Elizabeth.Speziale@Cortland.edu) **Do not contact a research sponsor directly, wait for instructions from RSPO.** RSPO will review the appropriate procedures for reporting for your funding agency.

SUNY Cortland IRB Reporting Requirements

Some problems, of course, are more serious than others. OHRP provides guidance to investigators, IRBs, and institutions about reporting problems. SUNY Cortland has adopted the OHRP recommendations for reporting unanticipated adverse events on all research (funded or not funded). See OHRP Guidance Document, "*Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events*" ([click here](#)). When required by OHRP regulations, the Institutional Official reports all incidents to OHRP.

Adverse Events

Defined by ORRP as, *any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.* All types of adverse events are to be reported to the IRB immediately (within five days). Email detailed information to irb@cortland.edu.

Protocol Violations

Details and relevant background information for all incidents fitting the description of a *Protocol Violation* are to be submitted by email to the IRB (irb@cortland.edu) immediately (within 10-days). The IRB will notify all other parties who may be affected. Protocol modifications are to be submitted, using the normal [Protocol Modification Request](#) procedures, when appropriate or when requested by the IRB.

Protocol Deviations

Details and relevant background information for all incidents fitting the description of a *Protocol Deviation* are to be submitted by email to the IRB (irb@cortland.edu) *under any one of the following three circumstances:*

1. When the participant becomes aware of the protocol deviation;
2. When the participant is affected, in any way, by the protocol deviation;
or
3. If the protocol deviation becomes systematic (occurs to more than one participant; represents a trend; represents a recurring problem).

Details and relevant background information for all incidents fitting the description and requirements of a reportable *Protocol Deviation* are to be submitted by email to the IRB (irb@cortland.edu) immediately (within 10-days). The IRB will notify all other parties who may be affected. Protocol modifications are to be submitted, using the normal [Protocol Modification Request](#) procedures, when appropriate or when requested by the IRB.

If you have any questions about our reporting requirements, contact irb@cortland.edu for guidance and for more information.