

Reportable Event Form

Any unanticipated problems or changes to the study protocol that involve risks to subjects or others MUST be reported to the Director of Institutional Research (tinleyjj@roanestate.edu) within 10 days.

Unanticipated problems and/or changes include:

- Unanticipated problems involving risk of harm (physical, psychological, economic, or social) to participants or others
- Risks or consequences of participating in the study that occur with a greater frequency, duration, or severity than what is documented in the protocol, informed consent, or other study documents
- Other changes that might affect the risk-benefit ratio for participants, including but not limited to any changes to the protocol taken without prior IRB approval in order to eliminate apparent immediate hazards to participants
- Protocol deviations in which there have been a *substantive* deviation from the IRB-approved protocol AND the deviation adversely affects
 - the rights, welfare or safety of subjects;
 - the integrity of the research data; or
 - the subjects' willingness to continue participation.
- Non-compliance with RSCC's IRB Policy, for any reason
- Death or injury that is *possibly, probably, or definitely related* to the study procedures

Research Study Title: _____

Research End Date: _____ IRB Approval Number: _____

Principal Investigator: _____

Institution, Organization, or Department: _____

Mailing Address: _____

Phone Number: _____ Email Address: _____

Name(s) of Co-Investigator(s): _____

Please describe the reportable event in detail.

How have you, or will you, resolve the problem?