Guidance on the Reporting of Protocol Deviations/Violations

What constitutes a protocol deviation or violation?

- A ***Protocol Deviation*** is an inadvertent act (from the perspective of the PI and study staff) in which the protocol is not followed. Examples that are reportable to the IRB include the accident loss of consent forms, or study materials with participant information, or an accidental misread of a laboratory value as being within the reference range when it actually is sufficiently abnormal to preclude study participation by the subject.
- A ***Protocol Violation*** is an intentional act (from the perspective of the PI and study staff) in which the protocol is not followed. Examples that are reportable to the IRB include the PI prescribing or administering the wrong drug on the study, or the study subject being scheduled to return for follow-up intervention outside the protocol-dictated window as a convenience to the PI or the study staff.

When must protocol deviations/violations be reported to the IRB?

- A protocol deviation or violation is reportable to the IRB if the event is likely to adversely affect:
    - The rights and welfare of the research subject;
    - The safety of the research subject;
    - The integrity of the research data; and/or
    - The subject's willingness to continue study participation

    - Such events should be reported to the WCU IRB within <u>10 business days</u> of the time the PI becomes award of the event; **however, an unanticipated study-related death must be reported to the WCU IRB within 24 hours of the occurrence of the event.**

- A compliant from a research subject that cannot be resolved by the study staff or an audit finding, internal or external, that is directly related to activities described in the protocol and requires corrective action by the study staff must be reported to the WCU IRB. The complaint and audit finding are considered either a protocol deviation or violation, depending on the perspective of the PI and study staff

- Absence of consent or alteration of the consent process without prior written WCU IRB approval is considered a protocol violation and must always be reported to the IRB. **A lapse in IRB approval for a study must always be reported to the IRB as a protocol violation.** Likewise, the suspension or disqualification of an investigator is considered a violation that must always be reported to the WCU IRB.

- If a deviation or a violation occurs that is unlikely to affect the rights, welfare or safety of the research subject or the integrity of the research data, the IRB need not be notified. An example is a delay in a subject's return for follow-up because of a death in the subject's family, but with no interference in the eventual completion of the study.

How should the protocol deviation/violation be reported to the IRB?

The **Notification of Protocol Deviation/Violation Form** must be used for reporting protocol deviations/violations to the WCU IRB. If the problem or event is both unanticipated and indicates that

the research places subjects or others at a greater risk of hard (including physical, psychological, economic, or social harm) than was previously known or recognized, the form called **Notification of an Adverse Event** should be used in addition to the Protocol Deviation/Violation report form.

Submit form(s) via email to Dr. Leonardo Bobadilla, Chair of the IRB (lbobadilla@wcu.edu) and to Andrea Moshier, Research Compliance Officer (amoshier@wcu.edu)