

A message from the Washington State University Human Research Protection Program (HRPP) and Institutional Review Board (IRB).

WSU Researchers,

The purpose of this message is to address expectations of the WSU HRPP and IRB with regard to protection of participants (and researchers) during the conduct of human subject research.

The IRB expects that Investigators and their research staff will act to protect the rights and welfare of participants involved in WSU research involving human subjects. The HRPP also expects that necessary precautions will be taken to protect research staff.

At times, it may become apparent to the researcher that acting in the best interest of a research participant will cause a deviation from an IRB approved protocol. The cause may be emergent (e.g. like present concerns involving potential spread of a disease) or non-emergent (a chance occurrence). Potential issues that may be encountered in emergent situations include but are not limited to: insufficient staff to safely/effectively conduct research or the research location becomes unsafe for the participants.

Regardless of the cause, the IRB expectation is the same: always act (using your best judgement) to avoid unnecessary harms to research participants and staff. In the event that doing so causes (or will cause) a deviation from your approved protocol, the following actions are recommended:

1. If you reasonably expect that deviation from a protocol will become necessary and have time to submit an amendment to the IRB to address the anticipated deviation, please do so. The IRB office will expedite review of amendments intended to minimize (or decrease) risks to subjects.
2. If you anticipate a deviation from your protocol but do not have time to submit an amendment, consider at least informing the IRB (phone or e-mail) that you anticipate you will need to deviate from your protocol. The IRB can provide guidance and document that notification was made in advance of the deviation and a reporting form can be submitted later (as soon as practicable).
3. If a deviation is required to avoid harming a participant and there is insufficient time to either submit an amendment or inform the IRB via other means, the expectation of the IRB is that you will report the deviation as soon as is practicable.
4. If you reasonably expect that the deviation is likely to repeat, the IRB office will work with you to determine the best approach (including potentially amending your protocol) to address these potential exceptions.
5. Deviations from a protocol that are made, in good faith, solely for the purpose of protecting research participants or others will rarely be considered non-compliance (e.g. only if the above guidance is not followed), these deviations will be classified as exceptions and the IRB office will work with you to determine any future actions required to address the exception/deviation.

To simplify this process, the IRB/HRPP has implemented a new consolidated **IRB reporting form** that can be used to report **ANY** protocol related event including deviations, exceptions, adverse events and UPIRSOs (unanticipated problems involving risks to subjects and others). This form can be used to report any type of event, even if you are unsure how to classify the event, simply describe the event and IRB staff will assist you in classifying and handling of the event. The policy and procedure manual is being updated to reflect this change. To access the reporting form, please go to: <http://irb.wsu.edu/forms.asp> and select "IRB Reporting Form".