



IRB Non-Compliance

Instances of non-compliance may include, but are not limited to:

- Proceeding with the protocol before obtaining final IRB approval.
- Failing to follow the established criteria or procedures that were approved by the IRB.
- Adding, removing or modifying a research instrument (or adding to an existing instrument) in a survey study without prior IRB approval unless the changes are within a range of anticipated potential changes specified as acceptable within the IRB approval.
- Personnel conducting research prior to their addition to an approved protocol.
- Implementing any change in the protocol without IRB approval.
- Exceeding the approved number of participants without IRB approval.

Reporting Consequences:

PVAMU's Federalwide Assurance (FWA) with OHRP is restricted to research funded by the federal DHHS. However, the same process for conducting investigations and taking actions by the IRB will apply to all research regardless of funding source. PVAMU reserves the right to voluntarily report any event that is not associated with federal funding to OHRP.