



Non-Compliance Determinations for Research

When possible non-compliance is reported, IRB members, of the IRB committee of record, may receive the report at the next convened IRB meeting for their review. The IRB of record makes the final determination on whether the evidence supports a finding of non-compliance, serious non-compliance or continuing non-compliance and prescribes any corrective action plan(s) that may be required. A finding of combined serious and continuing non-compliance is also possible. This guidance describes the differences among the available determinations before the IRB.

IRB Determinations for Non-Compliance

Non-Compliance – The failure to comply with all federal regulations, including Veteran’s Administration regulations and guidance, state and local requirements, WSU Policy and determinations of the IRB.

Serious Non-Compliance – The failure to comply with all federal regulations, including Veteran’s Administration regulations and guidance, state, and local requirements, WSU Policy and determinations of the IRB that involve one or more of the following:

- Harm to research participants;
- Exposing research participants to a significant risk of substantive harm;
- Compromising the privacy and confidentiality of research participants;
- Damage caused to scientific integrity of the research data that has been collected;
- Willful or knowing non-compliance on the part of the investigator;
- Adversely impacting ethical principles

Continuing Non-Compliance – A repeated pattern of non-compliance with all federal regulations, including veteran’s regulations and guidance, by an individual investigator or research staff member either on a single protocol or multiple protocols. Examples of non-compliant activities include:

- Conducting research without IRB approval
- Non-use or misuse of consent forms (i.e., consent/assent not obtained, wrong consent document used, missing signatures, failure to document consent process);
- Failure to follow approved protocol;
- Modifying or changing protocol without prior IRB approval;
- Failure to report unexpected problems, unanticipated events or adverse reactions or not reporting in a timely fashion;
- Failure to maintain adequate records;
- Inadequate training of investigators or research staff;
- Other failure to follow University policies and federal regulations;
- Failure to comply with an IRB request