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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 review proposed corrective actions, and/or prescribes any additional 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 as resulting actions or corrective actions.

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

Corrective Action

If the review of the initial report and the supporting data meets the definition of serious and/or continuing non-compliance, the report will be presented at the next convened meeting of the appropriate IRB. The

appropriate IRB makes the final determination on whether the evidence supports a finding of serious or continuing non-compliance and prescribes any corrective action plan(s) that may be required.

IRB action(s) and/or corrective actions are to be based on the nature of the non-compliance, degree to which research participants were placed at risk, occurrence of previous non-compliance etc.

The range of possible actions that the Chair, Vice-Chair or convened IRB may take include but are not limited to:

• Suspension of enrollment of new participants	• Note the occurrence of the Unanticipated Problem, but take no action
• Suspension of research procedures in currently enrolled participants	• Accept report as submitted pending amendment with consent form changes
• Suspension of the research	• Require a change in the continuing review period
• Termination of the research	• Require additional monitoring by the IRB
• Notification of participants when such information may relate to current participants' willingness to continue to take part in the research or there is a risk to the health or safety of the past or current participants	• Request a for-cause audit of the protocol, if not already done, and/or a follow-up audit
• Request additional information or clarification from the PI and/or data safety monitoring committee	• Request further inquiry into other protocols utilizing the experimental drug/device/intervention or procedure in question
• Require changes in the protocol, consent form or other protocol documents	• Determine if a detailed plan for safe withdrawal of participants form the research must be developed to protect their rights and welfare of participants • Require that this plan be submitted to the IRB for review and approval
• Require current participants to be re-consented to protocol with the changes in the informed consent	• Require that appropriate federal regulatory agencies, sponsors, and institutional officials be notified of any Unanticipated adverse reactions or Unanticipated events involving risks to participants or others according to WSU IRB policy 13-2: IRB Institutional Reporting of Unanticipated Problems, Suspensions and Terminations, Serious & Continuing Non-Compliance
• Request modifications to the corrective action plan	• No other action required
• Require IRB Education	• Additional information needed from PI
• Require the submission of a Follow Up Unanticipated Problem Report	• Other action

Effective Corrective Action and Prevention Plan (CAPA)

An effective corrective action plan:

- A process that addresses the event, solves the problems, identifies causes, takes corrective action and prevents reoccurrence of the root causes.
- This can include education, process improvements to eliminate causes of non-compliance or deviation from approved procedures and eliminating reoccurring non-compliance, resulting in continuing non-compliance.

Ask the following questions:

1. Was the issue acknowledged and addressed?
2. Are there steps to prevent reoccurrence?
3. Is there a plan to deter reoccurrence?
4. If reoccurrence, what differs from the process (plan) already in place?
5. How will the plan be assessed to monitor adherence?