WCU Non-compliance of Internal Review Board (IRB) Protocol Policy

Accommodations for individuals with disabilities in accessing these policies are available upon request by emailing accessiblepolicy@wcupa.edu

Purpose and Scope

This policy applies to all research that requires approval by WCU Internal Review Board (IRB) pursuant to the research sponsor or federal/state regulations.

Policy Statement

Non-compliance with IRB guidelines is a violation of university policy on the use of human subjects and, in some circumstances, of federal regulations for the protection of human participants. Any incident of non-compliance with IRB policies and procedures must be reported to the Associate Provost for Research and Creative Activity and the Chair(s) of the IRB immediately. Non-compliance is defined as a failure by an investigator to abide by federal or state regulations or university policy governing the protection of human participants in research, including the requirements or determinations of the IRB (see additional information below in Definitions). Incidents of non-compliance must be reported to ensure the protection of the rights of human participants and to uphold WCU's assurance to the federal government.

Policy Procedures

Procedures for Monitoring and Addressing Non-compliance

All faculty, staff, students, and administrators are responsible for supporting the ethical conduct of research involving human participants at WCU. This includes reporting possible non-compliance promptly to the IRB Chair(s) and the Associate Provost for Research and Creative Activity (APRCA) so

it can be addressed, with educational and other corrective actions taken, if needed. **If a situation of non-compliance is reported or identified, the following steps will take place:**

- Once an individual is made aware of non-compliance it must be reported to the IRB Chair(s) and the Associate Provost for Research and Creative Activity (APRCA)within 48 hours.
- Once reported, the APRCA and IRB Chair(s) will connect to discuss the potential non-compliance concern. In the case of serious or continuing non-compliance, the APRCA can elevate directly to the Dean, Provost, and/or Director of Labor Relations.
- A meeting with the IRB Chair(s) and the individual identifying the non-compliance situation will occur within 5 business days of the reported incident.
- An electronic letter describing the non-compliance concern is prepared by the IRB Chair and/or APRCA offering the Principal Investigator(s) (PI) and other potential researchers involved an opportunity to respond, in writing, specifying a time within which the response must be provided.
- If the PI offers a timely and satisfactory explanation for the concern, the non-compliance concern will be concluded, and the researcher will be notified in writing.
- If the PI offers an explanation that fails to satisfy the complaint, or if the PI fails to respond within the specified time period, the IRB Chair(s), in consultation with the APRCA, will make a determination of whether the action appears to have involved deliberate disregard (Serious) or lack of knowledge/awareness (Non-Serious).
    - Consideration will be given to the length of time the individual has been engaged in research, the extent and nature of

previous involvement with the IRB, and any previous communications with the IRB.

- If it is determined that the action is not serious, the IRB Chair(s) and the APRCA will follow up with the PI and provide education/awareness around the topic.
- If it is determined that the action has been deemed serious or continuing non-compliance, an ad-hoc committee (see Appendix A for ad-hoc committee charge) may be convened to process the Non-compliance incident and determine next steps.

All reports of Non-compliance will be kept confidential, except when reporting to the Provost, Labor Relations, the Office of Human Research Protections (OHRP), and/or to funding agencies as necessary.

Possible Actions by the University

Federal regulations require that instances of serious or continuing non-compliance in research that is funded be reported to the OHRP, unless projects are deemed Exempt; however, the University may choose to report to OHRP regardless of funding or Exempt status, depending on the given circumstances. Sponsors, administrators, and others (e.g., Labor Relations, Department Chairpersons, Deans) may also be notified. Initial reports to OHRP will be made as soon as possible and at a maximum within 4 weeks of the IRB/APRCA making a determination as to the nature of the concern.

Non-compliance involving minimal or no risk to participants or first occurrences that are believed to be the result of ignorance or misinterpretation of IRB policy will not result in a report to OHRP, although records will be kept in the Office of Research and Sponsored Programs and other sanctions or requirements for education may be applied.

Federal regulations (**45 CFR 46.113**) provide the IRB with the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements. Depending upon the nature and seriousness of the non-compliant activity, the IRB may take the following actions:

1. Send a formal letter and require a response from the investigator with a plan for corrective actions
2. Require the investigator to complete additional human participants protection training
3. Require that research participants previously enrolled in the study be contacted and provided with additional information and/or re-consented
4. Suspend or terminate the study
5. Freeze sponsored research grants
6. Determine that data collected during non-compliance cannot be used for publication
7. Require that data collected during non-compliance be destroyed
8. Disqualify the investigator from conducting research involving human participants at the university

Serious or continuing non-compliance with federal regulations or the requirements or determinations of the IRB may lead to suspension or termination of research. PIs who receive written notification to suspend or terminate a research study involving human participants must cease immediately all research activities for that project, including interactions with human participants, recruitment, analysis of data, publications, and presentations. In the case of serious or continuing non-compliance, the IRB and university administration will address the question of the

investigator's qualifications to conduct human participants research in the future.

The University will also take remedial action, as necessary, regarding the welfare of the participants and the research data gathered in non-compliance. Further, the IRB may refer instances of serious or continuing non-compliance to Labor Relations, the Provost and/or the appropriate Dean, who may decide whether to impose disciplinary sanctions. The distinction between remedial action taken by the IRB and disciplinary action taken by a university administrator is: Remedial action is action that the IRB takes or may require on behalf of present or future human participants in research. Disciplinary action, in this context, is a penalty imposed by administrators on an investigator for non-compliance with human subjects or related research regulations.

Definitions

Non-compliance is defined as a failure by an investigator to abide by federal or state regulations or university policy governing the protection of human participants in research, including the requirements or determinations of the IRB.

- Examples typically involve no or minimal risk to participants or first occurrences that are believed to be the result of lack of knowledge or misinterpretation of IRB policy

Serious non-compliance is defined as an action that potentially places participants at more than minimal risk and involves deliberate disregard for the regulations or the determinations of the IRB. Examples include, but are not limited to:

- Beginning or continuing more than minimal risk research without IRB approval

- Serious misuse or non-use of consent forms
- Failure to secure IRB approval before introducing changes in an on-going protocol, when those changes potentially constitute more than minimal risk to the participants
- Unknowingly not reporting adverse events or unanticipated problems consistent with WCU policy
- Failure to secure IRB approval before beginning research that may result in potential harm or risk to the participant
- Initiating protocol changes without IRB approval that may result in potential harm or risk to the participant

Continuing non-compliance: If an investigator engages in multiple occurrences of any level of non-compliance (serious or otherwise) and the IRB believes that the non-compliance involves deliberate disregard of IRB policy, that constitutes continuing non-compliance.

Appendix A

WCU Non-compliance Ad-hoc Committee: Purpose and Charge

The WCU IRB non-compliance ad-hoc committee is charged with providing oversight of IRB compliance components to assure that the University is compliant with federal, state, and local regulations, as well as university policies related to human-subjects research.

The APRCA and the IRB Chair(s) will serve as standing committee members, with additional ad-hoc committee members consisting of faculty, staff, or managers from across colleges/schools with no perceived conflict of interest, to be selected who will also serve on this subcommittee. Those serving on the ad-hoc

committee will also be expected to maintain confidentiality, privacy, and discretion of all matters discussed in the committee meetings.

References (if needed)

Office for Human Research Protections

45 CFR 46

WCU Use of Human Subjects in Research Policy.

Reviewed by: Associate Provost for Research and Creative Activities; Office of Research and Sponsored Programs

Office of Labor Relations Review: Name and title

Policy Owner: Associate Provost for Research and Creative Activities; Office of Research and Sponsored Programs

Approved by:

Jeffery L. Osgood, Jr., Ph.D.
Executive Vice President and Provost (interim)

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