

IRB Confidentiality Policy

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Policy Statement

During the process of initial, continuing review, or amendment of an activity, material provided to the IRB and Office of Research and Sponsored Projects Operations shall be considered privileged information. The IRB assures the confidentiality of the concepts, methodology, and data contained within materials submitted to the IRB for any type of review. It is the responsibility of the UIW IRB Members to maintain confidentiality regarding communications between the Board and any member of the UIW faculty, staff, and student body. All IRB Members and staff annually confirm their adherence to confidentiality of the privileged information contained within communications to the Board.

The following represent a limited set of circumstances under which protocol content or investigator information may be extended to the additional parties listed therein.

Description and Procedures

A. Consulting with External Subject Matter Experts

At times, the IRB may invite individuals with competence or necessary expertise to determine the scientific soundness of a research protocol or make an accurate determination of the risk to subjects. When required, the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may request the assistance of an external subject matter expert to perform an in-depth review of the study.

External subject matter experts are not considered to be members of the IRB, are utilized only for expert review, have no voting rights, must disclose any conflict of interest with the protocol, and must sign a confidentiality agreement spanning the contents of the reviewed protocol(s).

External subject matter experts will be given a copy of all protocol materials and requested to submit a risk assessment of the protocol activities. The risk assessment and any recommendations will be disseminated to the IRB members reviewing the protocol.

B. Communicating Student Research Concerns

Should an IRB representative become concerned with the quality or content of a student's IRB protocol, the faculty supervisor will be contacted in an attempt to assist the student. If an issue persists, the IRB representative will notify the IRB Chair. The IRB Chair may consult other IRB

Members to assist in developing human subjects protection education. If the issue regards academic integrity, UIW policy for academic integrity will prevail. If the issue remains unresolved, additional assistance may be sought.

C. Resolving Disputes between a Faculty Investigator and an IRB Representative

If a conflict arises between an IRB representative and a faculty investigator, the IRB representative will notify the IRB Chair, and the dispute will be arbitrated by the IRB Chair and Associate Provost for Research and Graduate Education. If the conflict remains unresolved, additional arbitration may be sought.

D. Reporting Non-Compliance

As a regulatory body operating under federal guidelines, the IRB is required to report non-compliance on the part of any researcher to: the supervising faculty (in the case of student non-compliance); university officials, to include academic dean or provost; federal regulatory bodies; any associated funding agencies; and any sites where research is conducted.

[Effective Date](#)

August 24, 2020

[Revision History](#)