

**Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures**

SOP# 202.2	TITLE: Research Compliance Office Project Intake	Date Effective: 01/01/2022 Last Revision Date: 03/22/2023
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I. Purpose

This sets forth the procedures for processing IRB projects in InfoEd prior to assigning review.

II. Definitions

Each project submitted to InfoEd undergoes pre-review by the research compliance office to assess completeness of the package. The research compliance office communicates with the investigator(s) as needed. Once the submission is complete, the research compliance office makes a preliminary assessment of review type required.

III. Procedure

1. All projects submitted in InfoEd are first received by the research compliance office.
2. The research compliance office conducts an initial administrative review for the following items:
 - a. The Principal Investigator (PI) listed on the project is a full-time faculty or staff member at WCU;
 - b. All research personnel have completed the CITI human subjects training modules;
 - c. All research personnel have achieved the minimum score required in the human subjects training modules;
 - d. All required documents are included with the submission; AND
 - e. If research takes place off-site, an appropriate permission letter is included.
3. If any of the elements listed above are missing, the research compliance office reroutes the submission back to the investigator(s) requesting documentation or clarification.
4. The research compliance office conducts an initial review of the project and makes a preliminary assessment of type of review required.
5. The research compliance office screens the project to determine if HIPAA, FERPA, FDA, or other regulatory requirements apply based on the scope of the project. Once assigned, the Research compliance office notifies the application reviewer of any identified concerns in writing with suggestions for compliance.
6. The research compliance office screens the project to determine the funding source, if any, and to determine if any additional regulatory requirements apply based on the funding sponsor. Once assigned, the research compliance office notifies the application reviewer of any identified concerns in writing with suggestions for compliance.
7. The research compliance office screens the project to ensure compliance with other university review committees, including Conflict of Interest Committee, Export Control Review Committee, Institutional Animal Care and Use Committee, and Institutional Biosafety Committee.

8. Once the pre-review items are complete, the research compliance office assigns the project to a reviewer or to the full-board, as appropriate.

IV. Responsibilities

Research compliance office, IRB members, Investigators

V. References