

ANNUAL REPORT

Institutional Review Board

**University of North Alabama
Florence, Alabama**

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Date submitted

Submitted to: Dr. Kristy Oden
Chair, Shared Governance Executive Committee

UNIVERSITY OF NORTH ALABAMA

ANNUAL REPORT

2022-2023

I. Executive Summary

As of the end of July 2023, the Institutional Review Board (IRB) received 119 proposals and 22 modifications submitted to the committee during the 2022-23 period. The IRB approved 113 protocols and 22 modifications. Three proposals remained pending and an investigator withdrew a protocol. Among the three protocols pending, we had only one research proposal requiring full review, but the research still needed to submit a required document (gatekeeper letter). The IRB rejected two proposals submitted by investigators from other institutions—the two proposals failed to meet ethical, regulatory, or methodological standards. So, the IRB had no proposal requiring full review during this period.

II. The Committee's Charge

1. To review compliance with and administer the University of North Alabama policy on the Use of Human Research Participants
2. To examine the University of North Alabama policy on the Use of Human Research Participants annually and assess university practices in light of the information obtained
3. To propose changes in university practices relating to the use of human research participants
4. To handle any proposals the committee may make affecting university policy according to section C.2 "Shared Governance Procedure for Policy Change Recommendations"
5. To submit a final written report electronically by the first day of the fall semester to the Vice President for Academic Affairs and Provost with a copy sent to the Chair of the SGEC.

III. Committee Members/Leadership Meeting

1. *November 10, 2022*
 - a. Elected Dr. Jill Simpson as IRB vice chair
 - b. Decided to remove the Covid-19 restrictions of collection including physical presence or contact
2. *November 14, 2022*
 - a. Discussion of procedures for reviewing a substantial number of research proposals from a research method class in a graduate program.
 - b. Based on the definition of research, "a systematic investigation (including development, testing, and evaluation) designed to develop or contribute to generalizable knowledge," most studies in the class are not considered

research. However, since most research subjects in the class are students under 18, the IRB had to review the protocols.

- c. However, considering the extensive number of proposals ($N \approx 60$) from a class, it appears necessary to implement detailed guidelines for the course.
- d. Dr. Cornelius and Dr. James created a set of guidelines (effective in spring 2023) for the research projects in the class.

3. *January 19, 2023*

- a. A zoom meeting with a staff (Mr. Sam Kim) of Key Solutions
- b. To gather information about the IRB proposal submission system and explore benefits/advantages and potential applications of utilizing the system.
- c. Given the annual number of submitted proposals ($N \approx 100$) and the favorable utility of IRB submission through Canvas, an external system charging an unrealistic cost (about \$30,000/Annual) and requiring too much training time to familiarize the system seems unnecessary and inappropriate.

4. *June 27, 2023*

- a. Met to examine a proposal titled “Exploring the impact of event registration policy on student engagement” from other institution.
- b. After reviewing the research proposal and materials with careful consideration, we have decided not to move forward with the research due to several concerns outlined below:
 - i. *The risks to the participants involved in the study are not adequately justified.*
 - ii. *The IRB has concerns about the appropriateness of conducting a single-site interview regarding the confidentiality and privacy of participants in the study.*
 - iii. *We have identified significant discrepancies between the protocol and other submitted materials (e.g., recruiting materials, interview questions).*
 - iv. *The IRB disapproved the proposal and did not advise them to resubmit similar research protocols to collect any data at UNA since ensuring the safety and welfare of the participants is of utmost importance to us.*

IV. Committee’s Actions and Accomplishments

What were the Committee’s actions and accomplishments this year relative to each of the items of the charge?

- a. As of the end of July 2023, the Institutional Review Board (IRB) received 119 proposals and 22 modifications submitted to the committee during the 2022-23 period. The IRB approved 113 protocols and 22 modifications. Three proposals remained pending. Among the three protocols pending, we had only one research proposal requiring full review, but the research still needed to submit a required document (gatekeeper letter). The IRB rejected two proposals submitted by investigators from other institutions—the two proposals failed to meet ethical, regulatory, or methodological standards. So, the IRB had no proposal requiring full review during this period.
- b. All members completed the IRB Member Basic Course through CITI training

- c. Implemented and improved IRB submission systems utilizing Canvas.
 - i. Provided specific guidelines indicating requirements, steps, and procedures for research proposal, modification, and renewal submission.
 - ii. Set up IRB committee members' roles and permissions in the system to secure documents stored on Canvas.
 - iii. Utilized the system to communicate with researchers when revisions are needed and keep researchers informed about the status of their submissions, modifications, and renewals.
- d. Listed a prisoner representative member with appropriate background and experience to serve in that capacity.
- e. Dr. Alexander approved IRB chair compensation (salary supplement), ensuring the position recruitment of a diverse pool of candidates from tenured faculty and considering the time-consuming role requiring a significant level of expertise.
- f. Developed an IRB reviewer's checklist (internal review only).
- g. Promptly assessed protocols within the designated timeframe.
- h. Thanks to Dr. Williams's efforts, the IRB joined the SMART IRB.

V. Identified Weaknesses/Formal Recommendations from the Former Committee

- a. Whenever the chair position changes hands, the IRB chair must be highly versed in ethical procedures and standards necessary to review IRB proposals.
 - i. *The IRB chair successfully finished the mandatory training program and consistently engaged in self-directed learning to enhance their professional development in the role.*
- b. The IRB chair position changes annually, which results in loss of experience, knowledge, consistency in procedures for submitting a protocol, and retaining IRB documentation and protocols.
 - i. *The vice chair reviewed a substantial number of protocols during this period (2022-2023) while developing comprehensive skills and knowledge as a leader on the committee. In addition, Dr. Laura Williams helped us to ensure a smooth transition of knowledge and expertise when the position changes hands.*
- c. The workload associated with the IRB chair makes it challenging to find tenured faculty members to volunteer to act as committee chair; as a result, this workload falls on junior/untentured faculty members. This can place junior faculty in precarious positions with individuals across campus, considering that junior faculty acting as chair must take positions to ensure subjects are appropriately protected against senior faculty across the campus and within their department.
 - i. *Regarding the concern, given the recommendation and suggestion from Dr. Williams and the former IRB Chair, Dr. Joseph, Dr.*

Alexander granted approval for compensating the IRB chair. The decision aims to enhance the recruitment of a diverse pool of candidates, mainly including tenured faculty members, after considering the time-consuming role requiring significant expertise.

- ii. *Successfully recruited tenured faculty members acting as chair and vice chair.*
- d. Lack of central location for important documents and files to be retained.
 - i. *While not flawless, resolved and addressed the issues when utilizing Campus as a submission system during this term.*
- e. The current IRB protocol submission process is unnecessarily tedious, requiring multiple documents to be sent via email and managed solely by the IRB chair.
 - i. *While not flawless, resolved and addressed the issues when utilizing Campus as a submission system during this term.*
 - ii. *Continually implemented and improved IRB submission systems using Canvas.*

VI. What does the Committee plan to accomplish?

- a. The new chair, vice chair, and current committee members plan to accomplish short- and long-term goals and objectives.

VII. What are the Committee's weaknesses?

- a. During the term (2022-23), the committee made tremendous endeavors to resolve the identified issues and concerns in the roles and responsibilities of the committee. However, there are some common areas for improvement (e.g., the substantial workload of initially reviewing research proposals assigned to the IRB chair and vice-chair and certain limitations of Canvas when utilizing it as a submission system of the IRB).

VIII. Comments

It is my great honor and privilege to collaborate with dedicated colleagues, mainly thanks to Dr. Williams, Dr. Simpson, IRB members, and researchers at UNA.