



ASUN Operating Procedure – 2015

Operating Procedure Synopsis

Title: Institutional Review Board

Approval Date/Revision Date(s): 5/2021

Review Date(s):

Executive Cabinet Liaison: Vice Chancellor for Academic Affairs

Responsible Manager: Vice Chancellor for Academic Affairs

A. Purpose and Scope

This policy regarding the use of human subjects in grant-funded research activities recognizes the institution's responsibility to: comply with applicable Federal Regulations; protect the rights, well-being and personal privacy of individuals; assure a favorable climate for the conduct of academic-oriented inquiry; and protect the interests of ASUN. Individuals involved in fulfilling the requirements of this operating procedure include the Vice Chancellor for Academic Affairs, Academic Deans, Associate Deans, and Faculty.

B. Definitions

Institutional Review Board (IRB): The purpose of the IRB is to conduct initial and continuing reviews of projects that involve the use of human subjects in accordance with policy.

Principal Investigator: Under this policy, the following individuals are considered principal investigators:

- ASUN faculty members and staff
 - ASUN faculty members who are on leave, and who are conducting grant-funded research involving human subjects at ASUN, with grant funds administered by ASUN, or with ASUN students.
 - Researchers not affiliated with ASUN who are conducting primary research with human subjects on campus. These unaffiliated researchers include visitors to the campus and off-campus scholars engaged in human subject's research on campus. While at ASUN, these individuals may, through the courtesy of an on-campus liaison, conduct Board-approved research on human subjects. The liaison should provide the visitor with appropriate institutional forms including this operating procedure and assure that the forms are sent to the Board before the research is undertaken.
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C. Procedures

1. Any principal investigator related to ASUN who engages in scholarly research involving human subjects, either on-or off- campus, must apply to the Institutional Review Board (IRB) for approval of the research. Such approval must be obtained before undertaking the research. Individuals who meet the definition of a "principal investigator" must apply for approval from ASUN's IRB even if their research has been approved by another institutions or organizations IRB.

*All ASUN students, faculty, staff and administrators are expected to adhere to operating procedures.

2. No grant-funded research activity including human subjects shall be undertaken unless an IRB has reviewed and approved. This review shall determine whether the activity/research design will adequately protect the rights and welfare of such subjects.
3. Renewal petitions: Projects eligible for continued funding beyond the duration of the initial project award are subject to renewal application review. Projects for which scope of work or activities that involve human subjects change substantially during the project are also subject to renewal application review.
4. Minimum Risk Proposals-Expedited Review: Research activities which involve no more than minimal risk and in which the only involvement of human subjects as outlined below may be reviewed and approved through the expedited review procedure. Under this procedure, the IRB review may be carried out by the chairperson of the board, or, in the chairperson's absence, by a member of the board designated by the chairperson. In reviewing research under this procedure, the reviewer may not disapprove the research. A research activity can only be disapproved after review by the full Board. The following activities shall be eligible for expedited review:
 - a. Minor changes in previously authorized research during the period of which approval is authorized; and
 - b. Research involving survey or interview procedure where all of the following conditions occur:
 - i. Responses are recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects.
 - ii. The subject's responses, if they become known outside of the research, would not place the subject at risk of civil or criminal liability or be damaging to the subject's financial standing or employability.
 - iii. The research does not deal with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol, and is not likely to cause the subject undue stress, fatigue, or any other psychological reactions.
 - iv. The research proposal makes adequate provision for obtaining the informed and voluntary participation of subjects

All other cases require a full board review.

5. The Institutional Review Board will be composed of five members:
 - a. Vice-Chancellor for Academic Affairs (Chair)
 - b. Chair of the Faculty Association
 - c. Director for Institutional Research
 - d. A total of three faculty, one representing each Academic Division (Applied Sciences, Nursing and Health Professions, and General Education)
 - e. Registrar

In the event that a conflict of interest arises with a member of the IRB related to a project under review, the member will recuse himself or herself and not participate in the review for the process for that project. The review board will be guided by and operate in compliance with applicable sections of the Title 45, CFR, Part 46 Protection of Human Subjects, June 23, 2005. The IRB will accept petitions for review from principal investigators at any time and will return decisions within twenty (20) working days. Decisions will be in writing.

6. Petitions for Review will contain the following information:
 - a. Name of Principal Investigator with e-mail address and telephone number and signature and date
 - b. Name of Co-Principal Investigators with e-mail address and telephone numbers
 - c. Administering division or department of project

- d. Project duration
 - e. Project title
 - f. Funding Agency and Proposal ID number (if applicable)
 - g. Statement addressing real or potential conflict of interest
 - h. Summary of the extend involvement of human subjects in the project
 - i. Project summary
 - j. Copy of the grant proposal (if applicable)
7. Data gathered in the institutions normal operations are exempt, including data gathered for the purposes of:
- a. Fundraising
 - b. Market research for the purposes of admissions recruiting
 - c. Recruiting efforts for faculty or staff
 - d. Statistical data collected for the management of institutional affairs, including surveys of students, prospective students, and alumni
- Please note that a project that does not clearly fall into one of these categories should be brought to the IRB Chair for review. The determination as to whether a project is exempt from Board review cannot be made by the principal investigator(s) themselves.

D. Related Information

n/a