# The American University of Kurdistan
# Policy of Institutional Review Board on the Use of Human Subjects in Research

Policy Number: AS034
Effective Date: May 28, 2023

## CONTENT



## I. INTRODUCTION

a. **Authority**: The Board of Trustees (herein referred to as "Board") at The American University of Kurdistan (herein referred to as "AUK" or "University") is authorized to establish rules and regulations to govern and operate the University and its programs.

b. **Purpose**: This policy aims at overseeing research involving human subjects at AUK.

c. **Scope**: This policy applies to all faculty and students as well as associate researchers who are conducting research at AUK using living individuals or pre-existing data that contain private information about living people.

## II. ROLES AND RESPONSIBILITIES

a. **Responsible Executive**: Provost

b. **Responsible Administrator**: Provost

c. **Responsible Office**: Provost & Legal Office

d. **Policy Contact:** Provost

## III. DEFINTION

**Human Subjects**: A living individual about whom a researcher (whether professional or student) conducts research that: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**Intervention:** Includes both physical procedures by which information or biospecimens are gathered (e.g. collection of specimens from subjects) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction**: Includes communication or interpersonal contact between investigator and subject.

**Private Information:** Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

**Identifiable Private Information:** Is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**An Identifiable Biospecimen:** Is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**Institutional Official (IO**): Is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms this policy. The responsible executive is the Provost.

**Institutional Review Board (IRB):** The IRB is established in accordance with and for the purposes expressed in this policy.

**Legally Authorized Representative (LAR):** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research. If there is no applicable law addressing this issue, the LAR is an individual recognized by institutional policy as acceptable for providing consent in the nonresearched context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. AUK's Legal Counsel is the LAR.

**Minimal risk**: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Research Integrity:** The Office of the Provost provides the administrative oversight for human subjects research. This involves serving as a resource for education and information, facilitating and maintaining communication mechanisms such as the website, providing guidance and feedback to investigators, providing administrative support to the IRB, ensuring all requirement of this policy are met.

**Principal Investigator (PI):** The individual with the responsibility for conducting the research or other activity described in a proposal for an award. The terms "principal

investigator" or "project director" may be used interchangeably in accordance to the agency's program language.

**Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. The following activities are deemed not to come under the purview of this IRB policy:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Internal studies by the institution of its own practices, aimed at improving those practices but not at contributing to generalizable knowledge, are not considered research for the purposes of this policy. However, the Office of the Provost should be contacted to verify that no IRB review is required.

## IV. POLICY STATEMENT

This policy aims at overseeing research involving human subjects at AUK. It covers all faculty and students as well as associate researchers who are conducting research at AUK using living individuals or pre-existing data that contain private information about living people. The policy applies to both funded or unfunded research. The IRB protects human subjects and upholds the standard operating procedures of privacy protection. The IRB guides the researcher and protects against malpractice in research involving human objects. The IRB assures that the risks of research conducted at AUK are compatible with the expected benefits, and are guided by the ethical principles such as those described in the Belmont Report of the U.S. Department of Health and Human Services (DHHS):

> https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

which provides the foundation and framework for standard operating procedures. No human research shall be conducted or authorized by AUK unless the IRB has reviewed and approved the proposed human research project.

**APPLICABILITY**

This policy applies to all research involving human subjects, including research by any person who is a faculty or staff member or student at the university, regardless of where the actual research takes place. It also applies to research conducted by individuals who are not faculty members or students at AUK, if the human subjects are members of AUK community.

## VI. POLICY PROCEDURES

1. The IRB consists of a minimum of five members representing a variety of professional disciplines, including at least one member of the student body and one person who is not affiliated with AUK, to analyze and complete an adequate review of research activities commonly conducted by the institution. The members are appointed by the President upon recommendation by the Provost.
2. The IRB provides for initial and continuing review of protocols involving human subjects. It assures that the rights of determination, privacy and confidentiality are maintained through its procedures, and it strives to protect subjects from undue harm by upholding the minimum risk requirement. The IRB follows appropriate ethical principles such as those described in the Belmont Report referenced under **IV. Policy Statement.**
3. A researcher must submit a protocol to the IRB prior to initiation of the research project. The researcher can only start the research after gaining approval from the IRB.
4. The IRB reviews the protocol to determine the measures are in accordance with the cited mentioned ethical principles. If a study presents a potential conflict of interest, additional information must be provided to the IRB. Before the IRB can approve the research protocol, the PI, all co-investigators and all personnel named on the protocol who will have human subjects' interaction or access to identifiable data must successfully complete the IRB online training addressing the ethical aspects and appropriate conduct of research involving human participants. The PI, all co-investigators, and all personnel named on the protocol who will have human subjects' interaction or access to identifiable data must fill in and sign the "Data Confidentiality Agreement for Research" and submit it to the IRB (Appendix 1).
5. The IRB approves qualifying research protocols only if it meets the following requirements:
    - Risks to subjects are minimized
    - Risks are reasonable in relation to anticipated benefits
    - Selection of subjects is equitable
    - Informed consent is obtained or appropriately waived from all prospective subjects
    - Subjects' privacy is protected and the confidentiality of data is maintained
    - Appropriate safeguards are incorporated for vulnerable subjects
6. Informed consent must be sought from each participant or his/her legally authorized representative and appropriately documented.
7. The research subject has the right to lodge a concern (e.g., allegation), complaint or question. A designated spokesperson for the research subject (past, current, or prospective), family member, or anyone with a concern about a human research study

may raise concerns, complaints, or questions about a research project by telephone, in writing, or in person to the Office of Grants Management or the IRB Chair.

8. The IRB Chair and the Director of the Office of Grants Management are responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff. These issues are handled in a timely manner in order to assure the protection of human subjects, and the IRB holds any violators accountable to the applicable regulation.
9. The IRB provides additional protections pertaining to research, development and related activities involving fetuses, pregnant women and in vitro fertilization of human ova, as well as for prisoners involved in research and additional safeguards in research when that research involves children, individuals institutionalized as mentally disabled and other potentially vulnerable groups in accordance with federal regulations.

## SANCTIONS

Failure of researchers to comply with the requirements of this policy may result in administrative actions including removal from a human subjects research protocol, removal as PI from a research grant/contract, or termination from employment at AUK. Disciplinary action will be taken commensurate with the severity and/or frequency of the offense in accordance with relevant University policies. For further information, see policy HR003 – Employee Code of Conduct.

## VII. POLICY HISTORY

a. **Approved by**: Board of Trustees

b. **Adopted**: May 28, 2023

**Appendix 1**

# INTERNAL REVIEW BOARD

# DATA CONFIDENTIALITY AGREEMENT FORM FOR RESEARCH

XXXXXXXXX (hereinafter known as "Researcher"), has requested to conduct a survey for research purposes at the American University of Kurdistan (AUK). Researcher has submitted the survey that has been approved by Internal Review Board (IRB) and has requested to share the survey questions with XXXX. Accordingly, AUK has agreed to Research's request, provided that Researcher agrees to comply with the terms and conditions set forth herein:

## I. Research Objective/s

Researcher shall explain the aims of conducting his/her research. For example, what do you hope to achieve and what will you use the survey for?

_____
_____
_____
_____

## II. Confidentiality

1. Researcher hereby agrees that he/she will use the data derived from the survey solely for the purpose of conducting the proposed research. Researcher agrees that he/she will maintain the confidentiality of personally identifiable respondents' data contained in the survey questions in a secure location. Researcher shall restrict access to personally identifiable respondents' data to those who are participating or assisting in the performance of the research. If Researcher breaches this Confidentiality Agreement, AUK shall then be entitled to injunctive relief against such violation. AUK shall also be entitled to pursue any other legally permissible remedy available because of such breach.
2. For purposes of this Confidentiality Agreement, the term "personally identifiable respondents' data" includes, but is not limited to: (a) the respondent's name and contact information; (b) the name of the respondent's parent or other family member; (c) the address of the respondent or the respondent's family; (d) Respondent's marital status, date of birth, and gender; (e) a list of personal characteristics that would make the respondent's identity easily traceable; and (f) other information that would make the respondent's identity easily traceable.
3. Researcher may publicly release reports per research proposal, derived from information contained in the survey, provided that such reports reflect the original research proposal and do not contain any personally identifiable respondent's data. In addition, Researcher agrees to provide a copy of the final research report(s) to the Provost Office of AUK.

Researcher agrees that he/she will not release or disclose any of the survey data in any manner except as expressly described in this Confidentiality Agreement, unless Researcher has received prior written authorization from AUK.

4. Researcher agrees that he/she will promptly return the encrypted data obtained in the survey upon written request by AUK. Researcher further agrees that he/she will destroy the survey data when it is no longer needed for the purposes described in this Confidentiality Agreement.

## III. Data Protection

Researcher shall explain the means and methods ensuring the encryption of data
_____
_____
_____
_____

By signing below, Researcher accepts and agrees to the terms and conditions set forth in this Confidentiality Agreement.

Name and Title of Researcher: _____

Signature of Researcher: _____ Date: _____