Keiser University
Institutional Review Board

IRB Handbook for Keiser University

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Keiser University
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THE KEISER UNIVERSITY INSTITUTIONAL REVIEW BOARD

The Keiser University Institutional Review Board (IRB) approves research conducted at or in affiliation with Keiser University.
The following information describes the mission, guiding principles, and procedures for the IRB.
The Keiser University Institutional Review Board is not subject to supervision outside of Keiser University.
The Keiser University Institutional Review Board is registered with the Office for Human Research Protections, OHRP# IRB00012102*.

*The Keiser University IRB does not have an FWA and may not review for Federally funded research or programs.

SECTION 1: MISSION & GUIDING PRINCIPLES

1:1 Mission

The mission of the Keiser University IRB is to ensure the ethical treatment of human participants in the conduct of any and all research by any individual affiliated with or conducting research within Keiser University in accordance with the guidelines set forth in the Code of Federal Regulations (Title 45).

Each investigator proposing a research project must submit an IRB application form. This policy applies regardless of source of funding and location of study to all research studies or pilot studies conducted by or on faculty, staff, students, or employees of Keiser University, or by or on Keiser University as an institution. These guidelines apply to all human subjects research.

1:2 Guiding Principles

The IRB review will determine whether participants will be placed at risk and, if risk is involved, that the following standards are maintained:

1. Risks to participants are minimized. (This principle is an essential condition for approval);

2. Participants in the study (or their guardians) are fully aware of the risks and that individuals may withdraw from the study at any time without any form of penalty;

3. Risks to the participant are so outweighed by the sum of the benefits to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept these risks;

4. Rights and welfare of any such participants will be adequately protected;

5. Legally effective, informed consent will be obtained, by adequate and appropriate methods in accordance with the provisions of this guide and unless legally waived;

6. Conduct of the activity will be reviewed at intervals determined by the IRB, but not less than annually unless determined exempt from continued review.

The determination of when an individual is at risk is a matter of the application of common sense and sound professional judgment as it relates to the circumstances of the research activity in question. It is important to note all possible risks and address how these will be minimized.

1. The IRB will carefully weigh the relative risks and benefits of the research procedures to be applied to the subject. It is rare for a study involving participants to have no risks. Thus, investigators should be careful to indicate any type of possible risks in the application that might include emotional as well as physical risks, especially for participants who are members of vulnerable populations.

2. Research activities designed to yield fruitful results for the benefit of individual participants or overall society may incur risks to the participants provided such risks are outweighed by the benefit to be derived from activities.

3. The degree of risk involved in any activity should never exceed the humanitarian importance of the problems to be solved by that activity. Likewise, compensation to volunteers should never be such as to constitute an undue inducement to the subject.

4. There is a wide range of medical, social, and behavioral research projects and activities in which no immediate physical risk to the subject are involved, e.g., those utilizing personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, or stored data. However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, all of which may constitute a risk.

5. Some studies depend upon stored data or information that is often obtained for quite different purposes. In these cases, the IRB will determine whether the use of these materials is within the scope of the original consent or whether consent should be obtained or waived.

1:3 Ethical Principles

Keiser University IRB adopts, as part of its guiding principles, the Ethical Principles in guidelines for the protection of participants of human research as published by the national commission (Belmont Report).

1:4 Code of Federal Regulations

Keiser University IRB adopts, as part of its guiding principles, the Code of Federal Regulations. These regulations are adopted in their most current version. When disagreements arise between the Keiser University IRB policies and procedures and the above Parts of Title 45 of the Code of Federal Regulations, the latter shall be given priority.

1:5 Caution

The Keiser University IRB will err on the side of caution in ensuring the protection of study participants. Keiser University's IRB will consider Exempt, Expedited, and Full Review studies.

SECTION 2: MEMBERSHIP & GOVERNANCE OF THE IRB

2.1 Membership

The IRB shall have at least five members, with varying backgrounds, to completely and adequately review research activities commonly conducted by the institution. At least one member will be a working scientist, at least one member will be a non-scientist, and at least one member must be someone who is not affiliated with the university. Where the research involves vulnerable populations (see 45 CFR part 46, subparts B, C, and /or D), the membership of the IRB shall be modified to address the review requirements. The IRB shall be sufficiently qualified through the experience and expertise, as well as the sex, cultural and ethnic diversity of the members to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants in research. Alternates to the IRB members will also be appointed so that, in case of absence, IRB meetings and deliberations can proceed without undue delay.

Each IRB member shall be appointed for a term of three years with the possibility of succeeding terms. Terms of members are staggered so that not all terms expire in the same academic year.

The Vice-Chancellor of Academic Affairs will designate the Institutional Director of Research (IDC) at Keiser University, who will serve as both the IRB Analyst and Chairperson. The IDC will select the IRB members and alternates from a pool of volunteer candidates. The IRB Chairperson will report to the Vice-Chancellor of Academic Affairs in their IRB role. If the Chairperson position is separated from the IDC, the IRB Chairperson's term will typically be three years, with the possibility of renewal. However, this is a voluntary position and serves at the discretion of the Vice-Chancellor of Academic Affairs. As IRB Analyst, the Chairperson will act as the primary reviewer for exempt and expedited applications and oversee the assignment and approval of application reviews. Additionally, the Chairperson must stay informed on IRB best practices and federal regulations, ensuring that documentation is updated at least every two years.

The IRB Chairperson may designate another IRB member ("designee") with sufficient experience and expertise to serve in the capacity of the chair to review applications for

research that may be exempt, may be reviewed under expedited procedures, or for research that may be exempt with limited review of certain conditions for privacy and confidentiality. IRB members are required to maintain related CITI certification, review assigned applications in a timely manner and attend board meetings.

The IRB may, from time to time, appoint expert consultants to advise it on research projects for which the IRB determines that it may not have sufficient expertise. These consultants may attend meetings in person or may submit written materials as requested by the IRB Chairperson, but they do not constitute IRB membership for purposes of establishing a quorum, and they may not vote.

2:2 Rules of Order

The IRB will conduct all procedures and meetings in compliance with federal regulations, including the Common Rule (45 CFR 46) and FDA regulations (21 CFR 56). IRB meetings will be structured to ensure a thorough and ethical review process while maintaining flexibility for discussion and consensus-building.

The IRB will maintain a quorum, requiring more than half of the voting members to be present, including at least one member whose primary concerns are non-scientific. All IRB decisions and research determinations must comply with federal regulations and institutional policies. To ensure transparency and accountability, the IRB will follow established written procedures for reviewing research protocols and documenting its deliberations.

Meeting minutes will be recorded for every session and will include details such as attendance, studies reviewed, determinations made, required modifications to research protocols, risk assessments, and justifications for decisions. If any issues arise that require extensive discussion, the minutes will reflect key arguments, concerns, and resolutions. These records will be maintained in accordance with institutional and regulatory guidelines.

Rather than following a formal parliamentary procedure, the IRB will use a structured yet adaptable approach to facilitate discussions and ensure ethical decision-making. Meetings will be conducted in a manner that allows all members to contribute meaningfully to the review process, ensuring compliance with federal guidelines while maintaining an efficient workflow.

2:3 IRB Meeting Schedule

The IRB will schedule one meeting each term or as needed to meet the demands of research at Keiser University. The IRB Chairperson or the chairperson’s designee on a continuous basis may review and make determinations on research eligible for exemption from IRB review, for research eligible for expedited review, or for research that could be exempt but requires limited review of certain conditions for privacy and confidentiality (may use expedited review procedure). Applications may be reviewed by the IRB Chairperson or the chairperson’s designee but will subsequently be reported by

the reviewer to the full IRB at the next scheduled meeting. Full Reviews require review by the full board and the approval of a majority of the IRB committee members.

2:4 Time Required for Approvals

In general, and where applications are complete, the IRB approval process for exempt students is seven (7) days. Research reviewed under expedited procedures will generally require 14 days for approval. Full Reviews (provided the application is complete) may require 30 days for approval. In all cases, the IRB will work to minimize the turnaround time for all approvals. Investigators should ensure that their applications are complete and that all required documentation is submitted with the application.

2:5 IRB Meetings and Approvals

A quorum of members (50% +1) is required at all convened meetings. Lack of a quorum prohibits convening a meeting and if a quorum is lost during the meeting, the meeting must be suspended until a quorum is restored. If the non-scientist IRB member is not present, even in the presence of a quorum of other members, the meeting cannot be convened or continued.

Upon review, a protocol may result in the following actions:

1. "Approved" – The application is approved as written with no conditions. These protocols do not have an expiration date; however, the IRB should be notified upon completion.

2. "Approved- Continued Review Needed" – The application is approved as written with no conditions, These protocols must be completed or renewed by the specified expiration date, typically one year.

3. "Conditionally Approved" – Approved with stipulations identified by the IRB and communicated in writing to the principal investigator (PI). Requesting conditional approval is appropriate when an application may only be complete once the IRB has reviewed and approved the protocol(s). This approval process may occur when a research site will not grant permission to conduct the protocol before IRB approval, or in rare cases when a live link for a survey will only be available after approval. All missing documentation must be submitted to the IRB and the protocol must be granted full approval prior to contacting participants or beginning data collection.

4. "Disapproved" – Application is not approved because the risks outweigh the potential benefits or the protocol has significant deficiencies (e.g., missing documentation with no explanation; insufficient discussion of risks/risk mitigation; insufficient documentation of informed consent).

SECTION 3: PREPARATION & CRITERIA OF RESEARCH PROTOCOLS

3:1 Criteria for IRB Approval of Research

In order to approve research, the IRB will determine that all of the following requirements are satisfied:

1. Risks to participants are minimized:
   (a) by using procedures which are consistent with sound research design and that do not unnecessarily expose participants to risk, and
   (b) by using procedures already being performed on the participants for diagnostic or treatment purposes, whenever possible.

2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of participants is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

4. Informed consent is sought from each prospective participant, or the participant's legally authorized representative, in accordance with, and to the extent required by 45CFR46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45CFR46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

8. Research conducted at the place of employment is carefully reviewed because of the risk of a dual relationship that the investigator may have with the research participants; that is, there may be perceived bias or perceived coercion to participate by subjects in these studies. In writing their proposals, principal investigators must clearly address in writing any conflict of interest that such studies can present in a formal statement.

9. Research conducted using data from within Keiser University must include the KU Internal Studies Request to Access Data Form. After receiving IRB approval, this form will be sent to the Vice-Chancellor of the Graduate School or the Vice-Chancellor of Academic Affairs at KU for final approval.

10. Research conducted in another institution (e.g., a hospital or school) must include a signed permission letter from a supervisor/administrator who is authorized to grant permission to conduct the research at that site. The letter must either be on institutional letterhead and must have an original or secured electronic signature, or if permission is given by electronic mail (e-mail), it must be sent directly to the research mentor (dissertation chair or research advisor), verified by the research mentor and included in the IRB application. If the institution requires KU IRB approval prior to giving its consent, the “Conditional Approval” box should be checked under Application Status and the PI should indicate that the site permission is missing in the application. If the other institution also has an Institutional Review Board, in accordance with the 2019 Federal Guidelines, the KU IRB will accept that institution's IRB determination and will not review the protocol for adherence to ethical guidelines. However, documentation of IRB approval, as well as the application that was approved, must be submitted to the KU IRB and certified by the KU IRB before beginning the research protocol in affiliation with KU. Regardless of where the IRB approval is from, if the protocol includes data collection within KU, an Internal Studies Request to Access Data form must be submitted and approved before

    10a. Research recruitment in social media groups requires documented permission to post or collect data within the group.

    10b. Research recruitment using email lists from private groups or memberships that the researcher has access to requires explicit permission to use the email list for that purpose.

    10c. Using directory information to recruit participants requires a letter of approval from the organization, even if the directory is publicly accessible.

11. Research conducted outside the United States must include a letter of assurance stating that the researcher will comply with the laws and regulations of the governing bodies overseeing the research location. These laws must be clearly identified, and the protocols for adherence must be documented. This documentation should include either a link to an official site detailing the regulations or a letter from a research institution or similar authority outlining the applicable regulations.

12. Research funded by an outside source or conducted at the researcher’s place of employment must include a conflict of interest summary. The summary should disclose the investigator's connection to the funding source, as well as any potential monetary, personal, or professional benefits that may result from the study. This includes, but is not limited to, direct financial gain, stock ownership, consulting fees, professional advancement, or any other personal or institutional advantage that could influence the research.

3:2 Studies Requiring Review

To ensure the protection and ethical treatment of human subjects, and to comply with federal and state law, Keiser University requires that prior to their initiation all research projects including human subjects be reviewed and a determination of conformance with applicable laws and regulations be made by Keiser University.

3:3 Student Applications: Faculty Research Advisor, Mentor, or Dissertation Chair

Prior to submission to the IRB, all student research protocols must be reviewed by the student's dissertation chair or faculty research advisor. The advisor must be from the student's institution and must hold a graduate degree in a relevant field of study. The faculty research advisor/dissertation chair will sign the IRB application as confirmation that the project has scientific merit and the protocol conforms to IRB submission guidelines and includes all required documentation. Student applications will not be accepted without this signature. Responsibility and accountability for the research is a shared one between the student and their faculty research advisor/dissertation chair.

See additional information under General IRB Procedures: Student Principal Investigators.

SECTION 4: DEFINING RESEARCH

4:1 What is Research?

45 CFR Section 46.102(l): "Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

4:2 Definition of Human Subjects

45 CFR Section 46.102 (e)(1): "Human subject means a living individual about whom an investigator (whether professional or student) conducting research" (1) obtains data 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".

Scholarly work that does not fall under these definitions of research or human subjects does not need IRB approval. However, if an investigator is unsure about whether their proposed research project requires IRB action, they should contact the IRB Chairperson for clarification.

4:3 Education Versus Research

Often classroom exercises intended to teach research methodology, skills, and the like may involve the need for students to collect data or practice assessments in some manner. When the exercise is solely for educational purposes (learning or professional development within that specific course only) and will not be shared outside of the classroom, there is no need for IRB approval as this is not research (see the definition above). Instructors should use caution in overseeing the assignments to ensure the learning experience will not place anyone at risk in any way and they are responsible for educating students in proper conduct of such assessments and for the privacy of the

participating individuals. For example, if students are learning about interviewing procedures, they may practice on each other or people they know who may be willing to volunteer. This is not considered research and, as such, may not ever be used towards data for a research report of any kind shared beyond that particular classroom. Collecting data from participants for research without first obtaining IRB approval is a serious violation of University policy (see IRB Protocols and Deviations under General IRB Procedures).

SECTION 5: GENERAL IRB PROCEDURES

5:1 Principal Investigators

Principal Investigators (PIs) are the primary individuals responsible for the content of the IRB application and adherence to Keiser University IRB Protocols.

The PI listed on the research protocol is responsible for ensuring all investigators on the project adhere to the IRB certified protocol.

5:2 Student Principal Investigators

Only graduate students in good standing are permitted to be student principal investigators. Undergraduate students are encouraged to engage in research with faculty members, but their research experience is, by design, closely mentored, and they are not permitted to be principal investigators for research involving human subjects.

The student PI submits the appropriate IRB Application and all required documentation to his or her faculty research supervisor/dissertation chair, at the time appropriate to the student's specific program of study.

If the student’s project is not a degree requirement, they must find a faculty research advisor to oversee the work and submit the application to the IRB.

The faculty research advisor/dissertation chair reviews the application and accompanying documents for accuracy and completeness, signs, dates and submits the application to the IRB Chair or designee. Incomplete applications will be returned without review.

Keiser University student investigators may not communicate directly with IRB members. All communication (reviews, comments, requests for information) will be in writing to the faculty research advisor/dissertation chair whose responsibility it is to communicate with the student.

5:3 Co-Investigators and Additional Investigators (including Student Investigators)

All investigators involved in data collection or analysis must submit a Bio/Role Form (see Application Forms) and a valid Collaborative Institutional Training Initiative (CITI) certificate before beginning work on the project.

CITI certification may be waived for research assistants/experimenters—individuals who are solely responsible for administering the protocol and/or collecting data without any further involvement in the research—by completing a PROXY form. However, all Principal Investigators (PIs), Co-Investigators, and faculty advisors must complete CITI training before IRB approval.

The Principal Investigator (PI) is responsible for ensuring that all members of the research team are properly trained in ethical research practices, particularly in areas such as voluntary participation, as outlined in the research protocol.

5:3a Collaborative Institutional Training Initiative (CITI) Module Requirements

CITI training for Keiser University consists of various courses, each containing a series of related modules. Every investigator must complete all required modules within their assigned course, achieving a score of at least 80% on each module.

Additional modules or courses may be required depending on the research area. For example, an investigator conducting research in a clinical hospital setting must complete both the general research ethics course and the relevant Health Information courses.

All researchers must submit their CITI course completion certificate, including a list of completed modules and corresponding scores, along with their IRB application.

The following courses are options for researchers:

> Social & Behavioral Investigators - Minimal Risk Only:
> Investigators engaging in Exempt or Expedited research including an adult population excluding research included in the categories below. Complete all Required Modules and any relevant Optional Modules.
>
> Social & Behavioral Investigators - Including Children:
> Investigators engaging in research including minors. Complete all Required Modules and any relevant Optional Modules.
>
> Social & Behavioral Investigators - Including Prisoners:
> Investigators engaging in research including prisoners. Complete all Required Modules and any relevant Optional Modules.
>
> Social & Behavioral Investigators - Elementary/Secondary School based Research:
> Investigators engaging in research taking place in an elementary or

secondary school. Complete all Required Modules and any relevant Optional Modules.

Clinical Practice or Clinical Research Investigators:
Investigators engaging in research including clinical treatment, trials or other clinical related research. Complete all Required Modules and any relevant Optional Modules.

Nursing Investigators:
Investigators engaging in research that concerns health related or nursing practice. Complete all Required Modules and any relevant Optional Modules.

Research Mentors:
Faculty or professionals who are serving as a mentor to a student (or other) research. This includes all dissertation committee members. Complete all Required Modules and any relevant Optional Modules. Submit your completed report along with each application submitted.

IRB Members:
Keiser University IRB members must complete all Required Modules and any relevant Optional Modules. Submit your completed report directly to the IRB Chair.

5:4 Submission Process

IRB applications should be submitted as complete documents in the electronic IRB portal located at https://keiseruniversity-t.uat.cayuse.com. If the researcher does not have the ability to create an account, they should contact the IRB Chair at irb@keiseruniversity.edu.

5:4a Student Submissions

Keiser University students may not submit applications for IRB review directly. All student applications must be submitted with a faculty sponsor, such as a faculty advisor, research mentor, or dissertation chair. The faculty sponsor listed on the application must actively oversee and work with the student throughout the research project. Faculty sponsors must ensure compliance with IRB policies throughout the study, not just at the submission stage.

If the student's status changes during the protocol—such as no longer being overseen by the faculty sponsor or experiencing a change in university affiliation—data collection must cease immediately, and the IRB must be notified.

Students affiliated with Keiser University, but not enrolled as Keiser University students, who wish to conduct research within the Keiser University system may submit applications to the KU IRB. However, they must also list a faculty sponsor on their application.

5:4b Submission of Research Protocols

Applications should be submitted in the Keiser University IRB portal. Submission from individuals outside of Keiser University should submit completed applications directly to the IRB at irb@keiseruniversity.edu.

5:4c Submission Review Process

Completed applications are received by the IRB Analyst, assigned a protocol number, determined for type of review, either reviewed as Exempt or assigned to an IRB member reviewer(s) familiar with the subject matter. Review progress may be seen in the submission area. Incomplete applications will be returned and need to be resubmitted.

5:5 Notification of IRB Decisions

Approval[1] must be obtained prior to any research being initiated by the investigator. Failure to follow this guidance is a violation of Federal Law and University Policies. It may result in the investigator's research being discontinued and may result in other disciplinary consequences up to and including dismissal from the university.

Investigators are notified of IRB decisions in writing (email and/or written correspondence) upon completion of the IRB review, regardless of the type of review. Correspondence will include the following:

1. Study title
2. IRB determination
3. Date of determination
4. Date of approval decision and the date the study can begin
5. Basis for the determination and a statement that the investigator is welcome to resubmit the protocol, if disapproved.

If approved, the research study must adhere to the following:

1. Research must be conducted according to the protocol that was approved by the IRB.

2. Any changes to the protocol, such as procedures, consent forms, addition of participants, materials or study design must be reported and an Application for

[1] Note. Whenever the word "conformance" or "approval" appears in these policies and procedures, it usually refers to an IRB approval. The term “approval” in this context does not imply that the IRB has assured the scientific merit of the research – that is the Dissertation Chair’s, Faculty Research Advisor’s or Principal Investigator’s responsibility. The IRB’s role is to determine whether or not a research protocol conforms to requirements for the protection of human subjects.

Revisions must be submitted to and approved by the IRB prior to implementation. Please note that if any enrolled adult study participants enter a category of "vulnerable populations" (45CFR part 46 subparts B, and/or C) (e.g., a female participant becomes pregnant, a participant is incarcerated), a modification and re-review by the IRB will be necessary.

3. Any adverse events or reactions must result in (temporary) cessation of the study and must be reported to the IRB immediately.

4. All participants should be given a copy of the informed consent document approved by the IRB for use in the study.

5. Exempt doctoral-level and faculty research protocols approved after July 2019 do not have an expiration date unless specified by the IRB, in accordance with the revised Common Rule.
Research projects undergoing expedited or full review by the convened IRB are approved for one year and require annual review. Depending on the project and approval conditions, the IRB may request annual updates for studies determined to be exempt, exempt with limited review, or requiring internal approval. If an update is required, this will be noted in the IRB approval notification.
Renewals and continued reviews must be submitted at least one month before the approval period ends. Failure to submit the required renewals or continuing reviews on time will result in the need for a new application

6. When the study is complete, all PIs must file a Notification of Completion of Protocol to the IRB. This must be done prior to graduation for student investigators.

7. Correspondence to the IRB (including email) regarding any approved project should include the IRB protocol number assigned to the project, the study title, and the PI's last name.

5:6 Continued Review

Any research activity that required an expedited or full review by the convened IRB that has received approval by the IRB is subject to continuing review and annual reapproval. Research protocols determined to be exempt (with or without limited review) are not subject to continuing review and reapproval unless noted by the IRB.

5:7 IRB Protocol Deviations and Violations

In accordance with 45 CFR 46.113, the IRB may suspend or terminate any Keiser University-affiliated research found to be in violation of IRB requirements.
Suspected deviations or violations should be reported using the Protocol Deviation/Violation Report Form or emailed directly to the IRB Chair at irb@keiseruniversity.edu. The identity of the reporter will be kept confidential unless otherwise agreed upon.

Investigators suspected of non-compliance with IRB protocols, as mandated by federal guidelines or the Keiser University IRB, will be required to suspend their research until the IRB Chair determines whether the issue constitutes a minor deviation or a more serious violation. The IRB Chair will:

1. Review the suspected deviation or violation,
2. Notify the Principal Investigator (PI) of the allegations,
3. Discuss the matter with the investigator, and
4. Request a written response from the investigator.

Based on this response, the IRB Chair will determine whether the incident qualifies as a protocol deviation or violation and will proceed with the appropriate review process.

5:7a Deviations

Minor deviations may include, but are not limited to, failure to report protocol changes (such as changes in the status of enrolled participants to include vulnerable populations), improper use of consent forms, or failure to renew IRB approval.

Suspected deviations will be reviewed by the IRB Chair.
The chair will review the investigator's written response to the allegation. If additional information is needed, the chair will meet with the PI to gather further details before making a final determination on whether a deviation has occurred. The chair may discuss the case with the board should there be questions on the determination of the deviation.

If the chair determines that the issue is not a minor deviation but a possible protocol violation, the case will be escalated to the full IRB committee for further review. The full committee will then:

1. Determine whether a protocol deviation or violation has occurred,

2. Prepare a written report with their decision and recommended actions, and

3. Submit the report to the Vice-Chancellor of the Graduate School and/or Academic Affairs for confirmation or modification of the recommended actions.

The IRB Chair will then communicate the final decision and any required corrective actions to the PI and/or the individual under investigation.

5:7b Violations

If the IRB Chair or the initial committee determines that a suspected transgression may constitute a more serious violation, a hearing with the full IRB will be required. The full IRB will assess the case and determine appropriate actions regarding the research and the investigator, based on the severity of the violation—if any is found.

A protocol violation occurs when there is a significant deviation from the approved research protocol, which may include, but is not limited to:

- Changes in participant details, investigators, or research venue without prior IRB approval,

- Potential or actual harm to participants that was not previously disclosed and approved in the application, or

- Other investigator misconduct that compromises the integrity of the study.

All alleged or admitted violations will be reviewed by the full IRB committee. A majority of members must be present, and if a conflict of interest exists, alternate members will be engaged. The IRB will determine the appropriate course of action and submit recommendations to the Vice-Chancellor of the Graduate School and/or Academic Affairs.

Investigators accused of an IRB protocol deviation or violation are required to attend the IRB hearing. If an investigator refuses to attend, their research will remain suspended, and the following actions will be taken:

- Student investigators will face suspension from course participation and enrollment until a hearing is held.

- Faculty and staff investigators will be reported to their superior, who will follow university protocols for non-compliance.

Decisions made by the majority of the IRB committee will be presented to the Vice-Chancellor of the Graduate School and/or Academic Affairs for final approval before being communicated to the investigator.
All alleged or confirmed IRB deviations or violations will be reported in confidence at the next scheduled IRB meeting.

5:7c Appeals

Any individual found in violation of IRB protocol has the right to appeal the decision of the IRB to the Vice-Chancellor of the Graduate School and/or Academic Affairs. The appeal must be filed within two weeks from the date of the notified decision of the IRB. The appeal must be in writing and must state the grounds for the appeal. A report of the outcome of each appeal shall be presented by the Vice-Chancellor of the Graduate School and/or Academic Affairs. Final appeals may be heard by following the University grievance procedure, as found in the Keiser University Catalog.

5:8 Internet Based Surveys or Data Collection

Investigators may collect data via social media or list-serves and may also post surveys online.

Permission to contact members of a list-serve or post in a social media group must be included in the application.

Specific social media sites and list-serves must be named along with any regulations or permissions concerning research.

The survey -as it appears online- must be printed or saved, and included in the application. The working link to the online survey must be included in the application and the online survey must be identical to the material submitted in the application.

Completion of items on a survey must not be required. If items are set to a forced response, an option stating "prefer not to answer" or "no response" must be included. This is required to ensure participation is voluntary.

Informed consent must be included at the start of all online surveys. Information on this requirement for Survey Monkey, for example, can be found at : http://help.surveymonkey.com/articles/en_US/kb/How-does-SurveyMonkey-adhere-to-IRB-guidelines. See the application materials for the required informed consent for online studies. Response to informed consent is permitted to be set to required.

If the participant does not agree to the informed consent, there should be a redirect option so that the participant may change the response.

The final item or submission link on an online survey must provide an option for participants to opt-out of the survey and not have their responses included in the study.

Confirmation that the server does not collect IP addresses must be included in the IRB submission unless this is disclosed in the Informed Consent.
In addition to the survey itself, all materials used for recruitment purposes and/or ALL correspondence or advertisements seen or read by potential participants must also be included in your application and certified. When using a service to recruit participants (MTurk, Survey Monkey etc.), all qualifiers and incentives must be included in the application.

SECTION 6: TYPES OF APPLICATIONS/ REVIEW

6:1 Categories of Approval

There are three categories of approval that are accepted by the Keiser University IRB: EXEMPT (Level 1), EXPEDITED (Level 2), and FULL REVIEW (Level 3). The investigator must assess the level of risk, or exposure to sensitive or harmful experiences, due to participation in the study and assign a category status to the application.

6:2 Studies Qualifying for Exempt Review (Level 1)

In accordance with Federal regulations (see 45CFR46.104, Common Rule), studies are exempt from review when they meet one of the categories of minimal risk research. Exempt studies must still submit to the IRB to verify the exempt status.

An exempt review procedure includes the review of research involving human participants by the IRB Analyst or chairperson or by one or more CITI certified reviewers

designated by the chairperson from among members of the IRB should the chairperson have a conflict of interest or if the chairperson deems it necessary to do so.

Decisions on the status of the proposal are typically made quickly: in less than two weeks

Exempt proposals require electronic copies of the IRB Exempt Review Application, all research instruments, recruitment materials, bios/roles, CITI reports and relevant documents as noted in the application. Materials should be submitted in a single submission and in the exact form it will be distributed to participants. If the study is web-based, the presentation should be as close as possible to what participants will see. A web-link to the study should be included or will need to be updated and included when available. All incomplete applications will be returned and should expect a delay in the review time. Expected review time begins once a complete application is submitted for review.

For exempt research, minor changes may be made to an approved study without submitting the revisions to the IRB; however, significant changes still must be submitted for review. Examples of minor changes include slight change in sample size, spelling or wording on recruitment documents. Examples of significant changes include location change, large sample change, or the addition of new assessment materials. Investigators who are unsure should contact the IRB at irb@keiseruniversity.edu.

The following categories may apply for an exempt review for Keiser University:

1. Normal Educational Practices
   "Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."[§46.104(d)(1)]

2. Surveys, Interviews, Educational Tests, Observations of Public Behavior
   Research including surveys, interviews, educational tests, and observations of public behavior qualifies as exempt if the information collected is recorded in a way participants cannot be identified (directly or indirectly) and should the information disclosed be shared beyond the research, it does not put the participant at risk* (criminal, civil, financial, employability, educational advancement or reputation) and it does not include sensitive inquiries on the subject's behaviors including the subject's mental health, use of alcohol, drugs or other addictions, or sexual attitudes, preferences or practices. This type of research is limited to interactions. Interventions do not qualify under this exemption. Surveys that are anonymous that include the use of clinical mental health assessment tools, include self-harm or suicide-related

questions, even if no identifiable information is collected, do not qualify as exempt.

Research that is identifiable, even if sensitive, and provided that there is a limited IRB review of the appropriateness of the privacy and confidentiality protections, may also be exempt under this section (Revised Common Rule, section 104(2)).

3. Benign Behavioral Intervention (New - Revised Common Rule 2019)

Benign behavioral interventions are defined as “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else” (45CFR46.104 (d)(3)).

Benign behavioral interventions apply to interventions including verbal, written and/or audiovisual (with specific consent) responses from an adult participant only and at least one of the following are true: Information is recorded in a way that protects the participant’s identity from being known (directly or indirectly) and/or should the information disclosed be shared beyond the research, it does not put the participant at risk (criminal, civil, financial, employability, educational advancement or reputation). Deception of the nature or purpose of the study is only permitted if the participants explicitly agree to “circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research” and the information is revealed at the end of the study.

Research of this type that yields data that are identifiable, even if sensitive, and provided that there is a limited IRB review of the appropriateness of the privacy and confidentiality protections may also be exempt under this section (Revised Common Rule, Section 104(3)).

4. Secondary Research

Secondary research qualifies as exempt and does not require participant consent if the identifiable information is publicly available; data (biospecimens or other data) is deidentified and not able to be linked to the subjects and the investigator will not re-identify the subjects; identifiable private information is maintained in accordance with HIPPA regulations. The use of continuously updated records is permitted as long as the investigator is not collecting the

data (it remains secondary data) and privacy is maintained in accordance with the regulations (see 45CFR46. 104 (4)).

5. Federal Research
   Research that is conducted or supported by Federal Research and is designed to study, evaluate, improve or otherwise examine public benefit or support programs. Keiser University does not support this research at this time. See 45CFR46. 104 (5) for more information.

6. Consumer Taste Tests and Food
   Taste and food quality evaluation and consumer acceptance research: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or Certified by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. For more information see 45CFR46. 104 (6).

7. Storage and Maintenance of Secondary Research
   Category 7 exemption concerns the storage and maintenance of identifiable material and biospecimens for which broad consent is required. Given the burdensome tracking requirements applying to this exemption, reliance on Broad Consent will not be accepted at Keiser University. For more information see 45CFR46. 104 (7).

8. Use of Identifiable Data or Specimens
   Category 8 exemption concerns the use of identifiable data or biospecimens for which broad consent is required. Due to the extremely burdensome tracking, restriction and reliance on Broad Consent for Category 8 exemption, reliance on Broad Consent will not be accepted at Keiser University. For more information see 45CFR46. 104 (8).

Exemptions do not apply to research involving children, except for research involving observation of public behavior of children when the investigator(s) does not participate in or instruct the alteration of the activities being observed or as noted under exemption category 1. Exemptions typically do not apply to research involving pregnant women, fetuses, or prisoners. Children may be included in exempt research only for educational testing as noted above or observation of public behavior only where the investigator does not participate (see Subpart D of the HHS regulations (45 CFR 46). In order to collect anonymous survey data via the Internet, all identifiers must be excluded. For example see : http://help.surveymonkey.com/articles/en_US/kb/How-do-I-make-surveys-anonymous.

6:3 Studies Qualifying for Expedited Review (Level 2)

According to federal regulations, certain categories of research, involving no more than minimal risk to human participants, can be reviewed by an expedited review process (see 45 CFR 46.110 and 21 CFR 56.110). Expedited research involves no greater than minimal risk unless the research includes a vulnerable population, deception or clinical trials. Two weeks may be required for processing and approval. While two IRB member's (the designated IRB Chairperson [2] and/or their designee) signatures are required for an approval, the full board must approve a rejection; thus, a rejection may take up to one month to review. In addition, all applications are available for IRB members to review and ask questions. The IRB may upon review consult medical or other experts as needed or determine if the research requires a full review if there is a concern the research is more than minimal risk.

If a protocol has been determined to be minimal risk, it may be considered for expedited review if it falls under at least one of the following categories:

1. Approved drug or device. Research including approved drug or devices must use the drug or device only in the way that is intended according to its labeling.

2. Blood Sampling[3]

3. Noninvasive Specimen Collection[5]

4. Noninvasive Routine Clinical Procedures. Noninvasive routing clinical procedures include MRIs, EKGs, exercise, strength testing, weight and other noninvasive procedures in the form for which they are intended. These do not include x-rays or any sedation or anesthesia.
5. Use of Data Collected for Non- Research. Category 5 includes materials that were collected with permission but for non-research purposes (charts, records, specimens) that may be used for research when de-identified and if the investigator's role is only to analyze the data or material (for example, chart reviews).

6. Collection of Data from Recordings. Category 6 includes the analysis of video, audio or other recordings that do not put the participant at risk (criminal, civil, financial, employability, educational advancement or reputation).

[2] Should there be a conflict of interest for the IRB chairperson, a second IRB member will serve as a reviewer.

[3] At this time, protocols falling under Categories 2 (Blood Sampling) and 3 (Noninvasive Specimen Collection, are not eligible for review under the Keiser University IRB. For more information please contact the IRB at irb@keiseruniversity.edu.

7. Low-Risk Behavioral Research. Low-risk behavioral research includes research on individual and group behavior and characteristics (cognition, beliefs or practices, language, motivation, emotional intelligence, social behavior) or research that includes surveys*, interviews, focus groups, program evaluation and other human factors evaluations and do not put the participant at risk (criminal, civil, financial, employability, educational advancement or reputation). Minimal risk behavioral research qualifies for an Exempt review under the Revised Common Rule (refer to the exempt review information). Research including children as subjects may be reviewed using Expedited procedures providing the research is no greater than minimal risk in accordance with 45 CFR 46.404. Minimal risk is defined as the probability and magnitude of harm not exceeding those ordinarily encountered in daily life or routine examinations (45 CFR 46.102(j)).

   *Even if the surveys are anonymous, when using clinical mental health assessment tools, an expedited review is required. Surveys including self-harm or suicide-related questions require a full board review.

In addition to meeting the general eligibility criteria described above, the research must also meet the approval criteria as follows:

- The proposed procedures must be consistent with sound research design, and when possible, procedures already being performed on participants should be used.

- The risks of the research must be minimal.

- Subject selection must be equitable. In addition, research involving subjects that may be vulnerable to coercion (children, individuals with special needs or economically or educationally disadvantaged) must be properly addressed for equitable selection and participation.

- Informed consent must be signed and documented prior to the initiation of the study unless a waiver of consent and/or documentation of consent has met the waiver criteria at 45 CFR 46 and 21 CFR 50 have been reviewed.

- Where appropriate, there is a plan to collect and monitor data to ensure public safety.

- The privacy of participants and maintenance of confidentiality of data is protected.

- Where necessary, additional safeguards have been included to protect vulnerable participants. If the research includes minors in a school setting, applications must directly address whether or not the institution is inclusive and the protection of those with special needs. Extensive detail describing

procedures designed to protect vulnerable participants is required. Vulnerable populations include children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons. All research conducted in an educational setting must include a statement concerning the protection of any special needs population in the institution. In addition, any letter of approval to conduct research including a special needs population, must also include specific approval to include those with educational or behavioral plans. For studies involving vulnerable populations, additional safeguards must be in place per 45 CFR 46 Subparts B, C, and D.

6:4 Studies Qualifying for Full Review

Research projects that involve sensitive material (except as noted above), do not fit in the exempt or expedited review categories, or are greater than minimal risk, require a full review by the convened IRB. Extensive detail describing procedures designed to protect participants is required. Full Review applications must adhere to the following:

1. The proposed procedures must be consistent with sound research design, and, when possible, procedures already being performed on participants should be used.

2. The risks of the research must be reasonable in relation to the anticipated benefits, if any, to the participants and the importance of the knowledge that may be gained.

3. Subject selection must be equitable.

4. Informed consent will be signed and documented prior to the initiation of the study.

5. Where appropriate, there is a plan to collect and monitor data to ensure public safety.

6. The privacy of participants and maintenance of confidentiality of data is protected.

7. Where necessary, additional safeguards have been included to protect vulnerable participants.

Examples of studies requiring a full committee review are randomized treatment studies, survey development testing the effects of a drug, behavioral interventions that may not be benign, novel interventions or illegal behavior, studies including behavioral symptoms among pregnant minors or the impact on children’s health of exposure to poor environmental conditions.

A majority (75%) of IRB members must approve the proposal and sign the approval for the protocol. Thirty days may be required for processing after receipt of a complete application.

SECTION 7: INFORMED CONSENT

7:1 Consent Process

Ethical practice and law require that participants' consent be intelligent, knowing, and voluntary. It is essential that consent to participate be obtained under circumstances where participants have (1) reasonable time to listen to investigators' explanations and (2) participants' physical, mental, or psychological state does not impede comprehension of information or the ability to make rational and non-coerced choices. See 45 CFR 46.116 for details.

7:2 Elements of Informed Consent

Except as described below in the Waiver of Informed Consent, investigators may not enroll human participants in research unless they have obtained the legally effective, written, informed consent of the subject or the subject's legally authorized representative, prior to enrollment of the subject in the research. Investigators are responsible for ensuring that participants, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence. Information provided to potential participants or their representatives must be in language that is understandable to the subject or representative. No process of obtaining consent may include exculpatory language through which the participant waives any of their legal rights or releases or appears to release the investigator, sponsor, or institution or its agents from liability for negligence.

The IRB, at its discretion to comply with changing requirements, has the authority to alter these requirements and/or waive the informed consent process.
Verbal consent must be documented and witnessed by another party who can speak the native language unless it is exempt research where verbal consent is the only option (telephone interactions, for example).

Research conducted in an environment with populations including non-English speakers, must include plans for accommodating these individuals or otherwise noted in the inclusion/exclusion criteria.

The Revised Common Rule states the following must be included at the start of every consent and must be written in a way that a layperson can understand. We recommend the language in the consent not exceed an 8th-grade writing level. Consent must conform to the following:

- Begin with a "concise and focused presentation of key information".
- Include a clear statement that participation is voluntary Include a clear summary of the research procedures, including the anticipated participation commitment and the purpose of the research.

- Include a clear statement of any reasonably foreseeable risks or discomforts.

- Include a clear statement of any expected benefits Include a statement on alternative treatments or procedures (if this is relevant to the study).

Consent must also include how identifiable information will be handled and explicitly state if the data will be de-identified or not and whether or not the data may be used in future research. Consent must also state if clinically relevant research results will be given to individual participants. Research involving biospecimens must include whether or not these specimens will be used to generate a commercial profit.

7:3 Consent Form

The documented consent form is a statement that gives potential participants enough information about the study, and sufficient opportunity to read and review the consent form, to allow meaningful decisions about participation. Contact information for the principal investigator and the IRB Chairperson must be included in the consent. Make sure to complete the form completely. Instructions appear in bracketed areas [ ] and should be deleted for the final version.

- IRB Consent Form for Level 1 (paper consent), Level 2 and 3 Research Protocols. Consent may be reformatted for online distribution but must present all information clearly in the same format as the Keiser University Informed Consent.

Informed Consent must be included at the start of all online surveys.

7:4 Assent

In studies involving participants who are legally incapable of consent but who are able to understand information on the study, an Assent form – in addition to the consent form- should be included. The documented Assent Form is a statement that gives potential participants who are minors or legally incapable of consent but who are able to understand information on the study a chance to make an informed decision concerning participation in the research study. A prerequisite for an Assent Form is the Consent Form signed by a legal guardian.

Minors over the age of 7 but not yet 18 years of age must give their assent (even if parental consent is obtained). Verbal assent should be acquired from minors under the age of 7 whenever possible (i.e., A 6-year-old can agree to participate, whereas an infant cannot). The exception to this is when the study involves a teacher conducting activities that are associated with normal classroom protocol.

This form should be written in language directed to the targeted participant’s physical or cognitive age as appropriate. Investigators must obtain and document the Informed

Assent of minors and legally incompetent persons to participate in the research project. Parental or guardian permission does not negate the individual's right to choose to not participate. For those unable to understand the language in the Consent form, a revised Assent form with more straightforward language should be used.

7:5 Audio/Visual Consent

If the participants will be recorded by audio or video, an additional consent must be signed. Add the appropriate information to the consent form for the participant.

7:6 Waiver of Informed Consent

The IRB may waive the requirements for obtaining informed consent [see 45 CFR 46.116 (d)], or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed above, provided that:

1. The research involves no more than minimal risk to the participants.

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

3. The research could not practicably be carried out without the waiver or alteration; and, whenever appropriate, the participants will be provided with additional pertinent information after participation.

4. When appropriate the subjects will be provided with information after participation in the study.

5. If the study includes elements of deception to obtain natural responses or there is a manipulation whose outcomes cannot be shared without possibly interfering with the response, pertinent information must be disclosed at the end of the subject's participation in the study.

All waivers of informed consent must be formally requested by investigators and include justification for the request of the waiver. Note- that a waiver of consent does not excuse sharing the required elements of the study (study description, risks, voluntary nature, confidentiality and contact information), however, the information may be shared in other ways, such as in a recruitment letter.