

APPENDIX M

RESEARCH

Oklahoma Baptist University recognizes that in higher education both teaching and research are essential to a vigorous institution and a sound curriculum. However, since Oklahoma Baptist University is primarily a teaching institution, research is encouraged but not formally required of any faculty member. Research involving human subjects or vertebrate animals which is proposed by University faculty, students, administrators, or staff and which will involve OBU students, will be completed as part of an OBU contractual agreement, or will be conducted in the name of or under the auspices of Oklahoma Baptist University shall be approved by OBU's Institutional Research Board before research activities are commenced. On-campus projects, which involve little or no risk to human subjects, as defined below, are exempt from this procedure. All projects conducted under the auspices of OBU, which require participation of off-campus subjects must be approved. Any project, whether exempt from the procedure or approved by the committee, shall be conducted according to the ethical standards established by the profession of such research.

I. Institutional Review Board

- A. Description: Oklahoma Baptist University's Institutional Review Board (IRB) is an administrative body established to provide for the rights and welfare of human research subjects recruited to participate in research activities conducted by all OBU faculty, staff, and students as well as outside researchers who are interested in conducting research involving OBU populations.
- B. Purpose
 1. Minimize the risk to human and vertebrate animal research subjects and researchers.
 2. Ensure that appropriate informed consent procedures are followed including disclosing any possible risks to participants (physical, emotional, psychological, employability, etc.) and disclosing how the data will be used and disseminated.
 3. Ensure that research is ethically conducted.
 4. Promote equity in human subject research.
 5. Protect OBU's mission.
- C. Objectives
 1. Provide oversight for any human subject and vertebrate animal research involving OBU employees, students or others directly involved in the OBU community who are either conducting the research or are serving as research subjects.
 2. Review research submissions that involve human and vertebrate animal subjects.
 3. Assess that proposed research projects adequately meet the criteria for approval set forth by any applicable federal and state regulations and OBU policies, procedures, and mission.
 4. Assist investigators to develop and implement practical strategies and solutions that uphold the protection of research subjects' rights and the welfare of researchers.
 5. Identify and provide training opportunities for researchers.
 6. Provide periodic review of ongoing research projects.

D. Authority

1. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.
2. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. Those officials, however, may not approve research if that research has been previously disapproved by the IRB.
3. Except in very rare and limited circumstances, the IRB cannot review research that has already been conducted.
4. The IRB has the right to discontinue a research project that is not being conducted in accordance with the approved proposal or in cases of significant harm to participants. IRB notification of such to the researcher(s) will include rationale.

E. Composition

1. The IRB will be composed of four faculty members and the Chief Academic Officer.
2. The IRB will consist of qualified individuals with various backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
3. Once elected, members will serve on the IRB for a minimum of three consecutive years.
4. Members of the IRB must provide documentation of a completed IRB education module.
5. The IRB, in its discretion, may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

II. Definitions: IRB terms as defined by the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services

- A. Harm: An event or undesirable and unintended, although not necessarily unexpected, effect of the research occurring in human subjects as a result of (a) the interventions and interactions used in the research; or (b) the collection of identifiable private information under the research; or (c) the undesired changes in thought processes and emotion.
- B. Human subject: A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.
- C. Informed consent: Documents that address autonomy and consent issues.
- D. Minimal risk:
 1. The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
 2. See the U.S. Department of Health and Human Services website for a description of research methodologies involving minimal risk:
<http://www.hhs.gov/ohrp/policy/expedited98.html>.
- E. Vulnerable populations: Individuals who lack the capacity to provide informed consent or whose willingness to participate in research may be unduly influenced by others. Populations that are potentially vulnerable include: children, pregnant women, human fetuses, prisoners, mentally disabled persons, economically or educationally disadvantaged individuals, and geriatric populations.

III. Human Research Project Activities Requiring IRB Approval

- A. Intervention
- B. Interview
- C. Observation

D. Survey

E. Institutional data with personal identifiers

IV. Categories of Research Proposals and Reviews

A. Research Projects Exempt from IRB Review: Research projects involving little or no risk which fit the following criteria are exempt from IRB review.

1. Research conducted by OBU employees to collect and analyze institutional data such as satisfaction surveys, course evaluations, interest surveys, etc. to improve or evaluate standard practices.
2. Research which involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) if the researcher records the information so obtained in such a manner that the test subjects remain anonymous.
3. Research involving the collection or study of existing data, if either the data are publicly available, or the researcher records the data in such a manner that the subjects to remain anonymous.
4. Feasibility and market analysis surveys.

B. Full IRB Review Research Proposal

1. Research projects that involve more than minimal risk to participants and/or that involve vulnerable populations or vertebrate animals require full Board review.
2. Researcher training is required prior to submission to IRB. (See Researcher Training).

C. Expedited IRB Review Research Proposal

1. Research project that involve no more than minimal risk to participants and do not involve vulnerable populations but are presented beyond the realm of the actual classroom, including thesis publication, are eligible for expedited review which involves review by the IRB Chair and one additional IRB member.
2. Research training is required prior to submission to IRB.

D. Classroom Research Proposal

1. Research projects are considered classroom research if they meet the following criteria.
 - a. Involve human participants for instructional purposes only
 - b. Involve no more than minimal risk to participants
 - c. Do not involve vulnerable populations or vertebrate animals
2. Completion of researcher training is up to the discretion of the course instructor.
3. This type of research requires the instructor to approve the projects and submit a Faculty Assurance Form for Classroom Projects to the IRB, which serves as the IRB proposal for all projects in the class, making the projects exempt from full Board review.
4. If a student's project does not meet the definition of classroom research or if the student plans to publish or present research findings outside the realm of the actual classroom (including thesis publication), then the student should submit a separate IRB proposal after completing research training.

V. Does My Project Require IRB Review and Approval?

A. Question 1: Is this research on human subjects or vertebrate animals?

1. If NO, then do not submit an IRB research proposal.
2. If YES, then proceed to Question 2.

B. Question 2: Does the research project involve vulnerable human populations, greater than minimal risk to human participants or vertebrate animals?

1. If YES, then complete NIH researcher training and research submission protocol.
2. If NO, then proceed to Question 3.

C. Question 3: Will this research be presented or published outside the classroom, including thesis publication?

1. If YES, then complete NIH researcher training and research submission protocol for expedited IRB review.
2. If NO, then this qualifies as a classroom research project. The instructor should complete and submit the Faculty Assurance Form for Classroom Projects to the IRB.

VI. Researcher Requirements

- A. When required, researchers must complete researcher training (see Researcher Training) before submission of the research proposal to the IRB.
- B. Informed consent will be sought by the researcher from each prospective research participant or the prospective research participant's legally authorized representative (see Informed Consent).
- C. Researcher will protect participants from unnecessary physical and emotional harm, psychological distress and undue influence related to the research project.
- D. The IRB review must be conducted before human participants are involved in the research, including study advertisement and subject recruitment, and before vertebrate animals are involved in research.
- E. IRB approval must be completed before the research study can begin.
- F. Once the researchers' research proposal has been approved, researchers must immediately notify the IRB of any subsequent changes in the research protocol.
- G. Research proposals are only granted approval for a one year period. If research extends beyond a period of one year, and the research procedures have not changed, then the researcher shall request an extension by emailing the IRB Chair. If research extends beyond a period of one year, and the research procedures have changed, then the researcher must submit a new proposal to the IRB Chair.
- H. If the researcher's research project does not have the required OBU IRB approval, the project cannot be recognized by OBU and OBU faculty, staff and students cannot be involved as research subjects or in the collection of data. If a research project lacking the required IRB approval is performed by an OBU student, the project may not be accepted to fulfill any academic requirements.
- I. Complaints about research conducted by or with OBU community members will be directed to the IRB for response.
- J. Researchers must inform the IRB Chair immediately if any harm or adverse event occurs to research participants, either human or vertebrate animal. The IRB will review reports of harm to participants on a case-by-case basis.

VII. Researcher Training

- A. For human subject research projects requiring researcher training (see Categories of Research Proposals and Reviews), all research team members must complete the National Institutes of Health (NIH) tutorial: Protection of Human Research Participants located at: <https://phrp.nihtraining.com/users/login.php>
 1. OBU faculty and staff as well as external researchers may complete the NIH tutorial or provide evidence of successful completion of a comparable human subjects' protection tutorial within the previous two years.
 2. Once successfully completed, the researcher should print a copy of the certificate for successful completion and email a copy to the IRB Chair.
 3. Once a certificate of successful completion is obtained by the IRB, it will remain valid for a period of two years from the date of completion.
- B. For vertebrate animal research projects, all research team members must read and abide by the Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training located at <https://grants.nih.gov/grants/olaw/tutorial/relevant.htm>

- VIII. Informed Consent: Informed consent is provided to participants in writing and includes the following.
- A. Explanation of purposes, procedures and timetable of the research.
 - B. Description of potential risks if present and means of treating these if harm could occur (i.e., list of available counseling services with contact information).
 - C. Description of any expected benefits.
 - D. Description of provision for anonymity and/or confidentiality.
 - E. Description of voluntary nature of participation and ability to discontinue participation if desired.
 - F. Names of individuals to contact for answers to questions.
 - G. If applicable, separate statement and signature line for permission to audio or video tape participants.
 - H. If informed consent is not to be obtained, the risk must be minimal and reasons must be justifiable (e.g., the inability to conduct the research if participants are informed of its purpose).
- IX. Researcher Submissions to IRB
- A. Researchers submit their research proposals to the IRB using the online submission process located on the OBU IRB website.
 - B. OBU Student Submission Protocol
 1. Review your research proposal with your faculty advisor.
 2. Obtain faculty advisor's approval using the Faculty Approval of Student Research Form.
 3. Scan the completed Faculty Approval of Student Research Form and save an electronic copy.
 4. Submit the following online to the IRB Chair
 - a. Human Subject or Vertebrate Animal Research Proposal
 - b. Faculty Approval of Student Research Form
 - c. Researcher training
 - i. For human subject research - NIH researcher training certificate of successful completion
 - ii. For vertebrate animal research - Researcher's signature on Vertebrate Animal Research Proposal indicating they have read and will abide by the Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training located at: <https://grants.nih.gov/grants/olaw/tutorial/relevant.htm>
 - d. Informed Consent documentation (for human subject research)
 - e. Any researcher-created instruments i.e. Surveys
 - C. OBU Faculty Classroom Research Proposal Submission Protocol
 1. Prepare a list of projects to be completed by the students in your class.
 2. Complete the Faculty Assurance Form for Classroom Projects.
 3. Send both documents as email attachments to the IRB Chair.
 - D. OBU Employee Submission Protocol
 1. Human Subject or Vertebrate Animal Research Proposal
 2. Researcher training
 - a. For human subject research - NIH researcher training certificate of successful completion
 - b. For vertebrate animal research - Researcher's signature on Vertebrate Animal Research Proposal indicating they have read and will abide by the Principles for the

Utilization and Care of Vertebrate Animals Used in Testing, Research and Training
located at: <https://grants.nih.gov/grants/olaw/tutorial/relevant.htm>

3. Informed Consent documentation (for human subject research)
 4. Any researcher-created instruments i.e. Surveys, etc.
- E. External Researchers' Submission Protocol
1. Human Subject Research Proposal
 2. NIH researcher training certificate of successful completion or evidence of completion of a comparable human subject protection tutorial within the past two years.
 3. Informed Consent documentation
 4. Any researcher-created instruments
- X. IRB Research Proposal Review Protocol
- A. Research proposal and required accompanying documentation will be submitted electronically to the IRB Chair.
- B. IRB Chair will review research proposal and accompanying documentation and determine whether the proposal entails the following.
1. Full IRB review
 2. Expedited IRB review
 3. Classroom Research Proposal IRB review
 4. Exemption
- C. Full IRB review protocol
1. IRB Chair will assign the research proposal to all IRB faculty members for review.
 2. IRB faculty members will review research proposal and submit findings to IRB Chair within a one week time frame.
 3. IRB Chair will compile IRB faculty research proposal findings and perform one of the following based on IRB faculty recommendations.
 - a. The IRB Chair will notify the researcher(s) that the research proposal is rejected and will return the research proposal to the researcher(s) with IRB comments for required revisions prior to resubmission. If the research proposal with requested revision is resubmitted by the researcher(s), beginning with step 10.C.1. the protocol sequence will be repeated.
 - b. A research proposal that is determined to be acceptable by the IRB faculty will be sent to the Provost for review along with IRB faculty members' recommendations for approval and associated comments.
 4. Provost will review research proposal and IRB recommendations and submit response to IRB Chair.
 - a. If the Provost approves the research proposal, the IRB Chair will notify the researcher(s) with one of the following responses.
 - i. Research proposal approved.
 - ii. Research proposal approved with identified stipulations which must be met.
 - b. If the Provost rejects the research proposal, the IRB Chair will notify the researcher(s) that the research proposal is rejected and will return the research proposal to the researcher(s) with IRB comments for required revisions prior to resubmission. If the research proposal with requested revision is resubmitted by the researcher(s), beginning with step 10.C.1. the protocol sequence will be repeated.
- D. Expedited IRB review protocol
1. Following IRB Chair review, the IRB Chair will assign the research proposal to one IRB member for review.

2. IRB member will review proposal and submit findings to IRB Chair within a three-day time frame.
 3. Beginning with step 10.c.iii, the process sequence will be repeated with the exception that if the research proposal is rejected, the IRB Chair will assign the review of the proposal to only one IRB member as opposed to full IRB review.
- E. Classroom Research Proposal IRB review protocol
1. This type of research requires the instructor to approve the projects and submit a Faculty Assurance Form for Classroom Projects to the IRB Chair, which serves as the IRB proposal for all projects in the class, making the projects exempt from full IRB review.
 2. The IRB Chair will review the projects in order to determine if each meets the criteria for a classroom research project.
 3. The IRB Chair will contact the instructor of record indicating whether or not the identified classroom research projects each meets the criteria set forth for such projects.
 4. If one or more projects do not meet the criteria set forth for such classroom projects, the instructor and researcher(s) will be contacted and asked to either revise the project so that it does meet the classroom project criteria or follow the protocol for either the Full or Expedited IRB Review Research Proposals.

XI. IRB Appeal Protocol

- A. An appeal protocol is only in effect if the researcher wishes to retain research protocol that the IRB has previously identified as unacceptable and subsequently rejected.
- B. The IRB appeal protocol requires a one-time resubmission of the original proposal along with the researcher's detailed explanation as to why the research proposal should be approved by the IRB in its present form.
- C. The research proposal will be reviewed by all members of the IRB who will submit their findings to the IRB Chair. The appeal process requires both the IRB faculty and Provost to concur, with neither party being able to override the other.
- D. The IRB Chair will submit to the researcher a summary of the IRB findings related to the appeal.
- E. If during the appeal process, the IRB again rejects the researcher's proposal, the researcher may not appeal a second time but does have the option of revising the research proposal based on IRB recommendations and resubmitting the proposal to the IRB.