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FHU FLORIDA HEBREW UNIVERSITY

Institutional Review Board (IRB) Policies and Guidelines for Torah-Based Research

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INTRODUCTION

In adherence to the timeless wisdom of the Torah, "You shall surely pursue justice" (*Devarim* 16:20), Florida Hebrew University (FHU) establishes this Institutional Review Board (IRB) Policy. This document outlines the framework and principles guiding the ethical review of research involving human subjects, ensuring the protection of their rights and welfare in alignment with Federal regulations, the Common Rule, and Halakhic values.

PURPOSE

The purpose of the FHU IRB is to:

1.Review research proposals to ensure ethical standards are met, safeguarding the dignity, rights, and safety of participants.

2.Foster an environment where scholarly inquiry proceeds with integrity, respect, and in congruence with both secular and Jewish ethical principles.

SCOPE

This policy applies to all research activities involving human beings conducted under the auspices of FHU, regardless of the location of the research or the source of funding.

LANGUAGE AND APPROACH

For the purpose of avoiding treating human souls as objects, IRB commission institutes the following terminology:

- A person who agrees to participate in a study is to be described as "participant." Under no circumstances, an individual shall be called "human subject," "subject," "human participant,"
- Torah prohibits use to conduct census of indivuals by pointing to them. Instead, an object representing the individual must be submitted and then counted. Instead of using terminology, "50% of participants," researchers are to use "50% of the surveys submitted," "out of 124 surveys submitted, 25 tells us the following results."

2. IRB COMPOSITION AND AUTHORITY

2.1 IRB COMPOSITION AND MEMBERSHIP GUIDELINES

IRB Composition

1. The IRB will consist of a diverse group of minimum of five (5) individuals with expertise in relevant scientific areas, ethics, Halakhic law, and community sensibilities.
2. Membership will include at least one member whose primary expertise is in scientific areas, one member whose primary expertise is in non-scientific areas, one community member unaffiliated with FHU to provide an external perspective, and one member who possesses halakhic expertise.

Member Roles

Chairperson: the Chairperson leads the IRB and ensures that the Board carries out its responsibilities according to federal regulations and institutional policies. The Chairperson sets the agenda, facilitates meetings, and may represent the IRB in external relations.

Vice Chairperson: the responsibilities of the Vice Chairperson are to assist the Chair and to assume the Chair's duties in his/her absence.

Board Members: the duties of the board members are to review research submissions, participate in discussions, attend meetings, contribute to the decision-making process, assist in educational efforts, and monitor ongoing research as required.

Community Member: the role of the community member who is particularly sensitive to issues like privacy and community impact, is to provide perspective from the general population.

Member Qualifications

IRB Chair

The qualifications of the IRB Chair shall include experience in Research, Knowledge of Regulations, including local laws and guidelines such as the Belmont Report, the Common Rule, and FDA regulations in the United States, leadership and communication skills, ethical sensitivity, and commitment to education.

All Other Members

- Expertise: Members must possess expertise in pertinent areas to critically evaluate research protocols. This includes representatives with scientific, ethical, and non-scientific backgrounds to provide comprehensive assessments.
- Diversity: The IRB will reflect diversity in its membership composition, considering factors such as professional background, gender, race, cultural background, and sensitivity to community attitudes, to ensure respect for its advice and counsel in safeguarding the rights and welfare of human participants.
- Training: Prospective members should have training or experience in ethical research practices and regulatory knowledge pertaining to the conduct of studies involving human participants.

Election and Invitation Procedures

- Selection Process: New IRB members are to be invited by the existing IRB Board, the University President, or nominated by other IRB members. Candidates are vetted to ensure they meet the IRB's standards for expertise, diversity, and commitment to ethical research practices.
- Invitations to Potential Members: Initial interest and suitability are assessed through a preliminary talk with potential candidates over the phone. Following this, an official invitation letter detailing the role, responsibilities, and training requirements of an IRB member is sent by mail.
- Letter of Acceptance: Upon agreeing to join the IRB, candidates are required to submit a Letter of Acceptance, affirming their agreement to

serve. This letter may be returned via mail or email and is kept on file as part of the official IRB records.

Term of Service

- **Length of Term**: Members serve a term of three years. This duration is chosen to ensure continuity of expertise and institutional memory within the IRB while allowing for periodic infusion of new perspectives.
- **Renewal**: At the end of a term, membership may be renewed following a review of the member's contribution and agreement to continue serving.
- **Staggered Terms**: Terms are staggered to prevent the simultaneous turnover of the entire board, thereby maintaining continuity in IRB operations and mentorship for new members.

Responsibilities of Members

- **Attendance and Participation**: Members are expected to attend IRB meetings regularly and contribute to the review and discussion of research protocols.
- **Preparation**: Prior to meetings, members should thoroughly review all meeting materials and be prepared to discuss and vote on research protocols.
- **Conflict of Interest**: Members must disclose any potential conflicts of interest with research proposals under review and recuse themselves from the decision-making process when necessary.

Orientation and Training

- **Initial Orientation**: New members receive an orientation to familiarize them with IRB processes, policies, and expectations.
- **Ongoing Education**: Members are encouraged to engage in ongoing education to stay informed about evolving ethical standards, regulations, and best practices in human participant research.

Performance Review and Continuation Criteria for IRB Members

Overview

Maintaining high standards of participation, ethics, and responsibility among IRB members is crucial for the effective functioning of the board. This section outlines the process for reviewing member performance and criteria for continuation or termination in a manner that promotes professionalism, respect, and the shared goal of protecting human participants in research.

Performance Review

- **Regular Assessments**: IRB members will undergo regular performance assessments to ensure active participation, adherence to IRB guidelines, and contributions to discussions and decision-making.
- **Feedback and Support**: Members identified as needing improvement will receive constructive feedback and support to address specific areas of concern, emphasizing professional development and effective participation on the board.

Continuation Criteria

- **Engagement and Attendance**: Continuous service as an IRB member requires consistent engagement with IRB activities and regular attendance at meetings.
- **Compliance with Guidelines**: Members must adhere to IRB guidelines and ethical standards in their review of research protocols and conduct as board members.
- **Contribution to IRB Goals**: Members should actively contribute to the IRB's mission of ensuring the protection and welfare of human participants in research.

Process for Non-Performance

- **Mutual Review Meetings**: Should a member consistently fail to meet the outlined criteria, a meeting will be convened with IRB leadership to discuss concerns and potential paths forward.

- Decision-making: Decisions regarding a member's continuation on the board will be made considering their overall contributions, the ability to address identified issues, and the needs of the IRB.
- Respectful Transition: In cases where it is mutually agreed that continuation is not feasible, the member will be afforded a respectful transition off the board, acknowledging their service and contributions.

By implementing these policies, FHU ensures its IRB is composed of dedicated, qualified individuals who can effectively oversee the ethical conduct of studies involving human participants, thereby upholding the university's commitment to research integrity and participant protection.

2.2 IRB AUTHORITY

1. **Definition:** Authority is the power or right to make decisions, to govern, or to direct actions within a specified area or on particular matters. It encompasses the IRB's legal and institutional power to review, approve, modify, or disapprove research proposals within its jurisdiction.
2. **Scope of Oversight**: The types of research and activities subject to IRB oversight include:
   a. **Research Involving Human Participants**: Any activity intended to contribute to generalizable knowledge and which involves data collection from or about living individuals. This includes, but is not limited to, surveys, interviews, tests, interventions, or observations of public behavior.
   b. **Social, Behavioral, and Educational Research**: Studies involving human participants aimed at understanding or improving the human condition in areas such as psychology, sociology, education, and criminal justice. This could involve studying cognition, societal norms, educational interventions, and behavioral phenomena.
   c. **International Research**: Research activities involving human participants that are conducted outside the United States. Such research must adhere to U.S. regulations and may be subject to additional local laws and customs.
   d. **Exempt and Expedited Review Categories**: Certain categories of research that involve minimal risk to participants may qualify for an exemption or may be eligible for an expedited review process. However, only the IRB has the authority to determine the level of review required.
   e. **FHU Non**-Faculty Research: Projects conducted by the certified FHU Non-Faculty researchers for the purpose of contributing to the Torah-based research within the Torah-observant communities and society at large.
   f. **Student Research**: Projects conducted by students (undergraduate, graduate, or postgraduate) for the purpose of fulfilling a degree requirement, including theses and dissertations, that involve human participants.

g. Pilot Studies and Preliminary Research: Small-scale preliminary studies designed to inform the design of a future study. Even if they are exploratory, they must be reviewed if they involve human participants.
h. Secondary Data Analysis: Research involving the analysis of existing data, documents, records, or specimens, if the data is identifiable or if it involves sensitive information where the context might pose additional risks.
i. Collaborative Research: Research that is conducted jointly with other institutions. Each institution engaged in the research is responsible for safeguarding the rights and welfare of human participants and is subject to IRB review.
j. Internet-Based Research: Studies involving interactions with participants through the Internet, including surveys, observational studies, and any form of online data collection that involves individuals' personal information.

3. Mandate for Review and Approval: no human participants research can commence without IRB review and approval. IRB has the authority to review all aspects of the research to ensure the protection of the rights and welfare of the human subjects.
4. Power to Suspend or Terminate Approval: the IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.
5. Requirement for Modifications: IRB has the authority to require modifications to research proposals as a condition of approval to ensure compliance with ethical standards and federal regulations.
6. Monitoring and Compliance: the IRB's role is to conduct ongoing monitoring of approved research, including the authority to observe consent processes and the conduct of the research.
7. Reporting: the IRB has responsibility to report to appropriate institutional officials, the Office for Human Research Protections (OHRP), and other federal agencies any unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with IRB requirements, and suspension or termination of IRB approval.
8. Independent Authority: the IRB operates independently of other institutional authorities and has the power to make autonomous decisions about the ethical and regulatory appropriateness of human subject

research. No entity or individual within the institution may approve research that has not been approved by the IRB.

9. Educational Role: Besides regulatory oversight, the IRB plays a role in educating researchers about ethical considerations and regulatory requirements for research studies of human participants.

2.3 Jurisdiction, Applicability, and Responsibilities

Jurisdiction

1. Definition: Jurisdiction is the specific range or scope within which an organization, like an IRB, has the power to operate or enforce its rules. It delineates the boundaries of the IRB's oversight, specifying what types of research activities, locations, and subjects come under its review.
2. Scope: The Institutional Review Board (IRB) at Florida Hebrew University (FHU) has the jurisdiction to oversee all research activities involving studies of human participants that are conducted under the auspices of FHU. This oversight applies to research regardless of its location or source of funding and includes, but is not limited to, the following:

A. Research Conducted by FHU Affiliates: Any research involving human subjects conducted by FHU faculty, students, or staff, whether on FHU property or at external locations.
B. Collaborative Research: Research projects in collaboration with other institutions, organizations, or individuals that involve FHU affiliates or use FHU resources.
C. Externally Funded Research: Research funded by external grants, contracts, or cooperative agreements that involve studies of human participants and include FHU participation or use of its facilities.
D. Internally Funded Research: Research not externally funded but utilizing FHU resources or involving human subjects and FHU personnel.
E. Non-Funded Research: Research activities that do not receive external or internal funding, but involve studies of human participants and are conducted under the auspices of FHU.
F. International Research: Research involving studies of human participants that is conducted outside the United States by FHU faculty, students, or staff.

G. **Exempt Research**: Research that may qualify for exemption as per federal regulations, yet still requires IRB oversight to confirm exempt status.
H. **Minimal Risk Research**: Research activities that involve minimal risk to participants and may be eligible for expedited review procedures.

Applicability

All research activities involving studies of human participants require IRB review and approval before initiation.

This applies to research that:

1. **Involves FHU Affiliates**: Engages faculty, students, or staff of FHU in the design, conduct, or reporting of research.
2. **Utilizes FHU Property or Non-Public Information**: Uses FHU's property, non-public information, or resources for research activities.
3. **Engages with the FHU Community**: Interacts with or recruits participants from the FHU community, including alumni, and other associated individuals.

Exempt Research

Certain categories of research may be exempt from IRB review. However, a determination of exempt status must be made by the IRB or an authorized IRB official.

Research may be deemed exempt if it involves:

1. **Educational Practices**: Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. **Anonymous Surveys and Interviews**: Surveys, interviews, or educational tests if the information is recorded anonymously and cannot be linked back to the subjects.
3. **Public Behavior Observation**: Observation of public behavior, including visual or auditory recording, where there is no interaction with the persons being studied, and no identification of the subjects is made.
4. **Analysis of Existing Data**: Research involving the collection or study of existing data, documents, records, or specimens if these sources are

publicly available or if the information is recorded by the investigator in such a way that subjects cannot be identified.

Expedited Review Process

An expedited review process is available for research that involves no more than minimal risk to human participants and falls into one or more of the federally defined expedited review categories.

These categories typically include:

1. Minor Changes: Minor changes in previously approved research during the period for which approval is authorized.
2. Collection of Samples and Data: Collection of biological samples by noninvasive means or collection of data through noninvasive procedures routinely employed in clinical practice.
3. Research on Individual or Group Behavior: Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The IRB or a designated reviewer from the IRB committee has the authority to conduct an expedited review. Research eligible for expedited review must still comply with all applicable IRB requirements, including informed consent and privacy protections.

Non-Exempt Research Requiring Full Review

Research that does not qualify for exemption or expedited review must undergo a full IRB review. This includes research with more than minimal risk or involving vulnerable populations, such as children, prisoners, pregnant women, or individuals with impaired decision-making capacity.
All research, regardless of review type, must adhere to ethical and halakhic principles, provide adequate protection for human subjects, and comply with all federal, state, local, and institutional regulations and policies concerning research studies of human participants. It is the responsibility of the researcher to seek IRB review and approval, and to maintain compliance throughout the research project.

Responsibilities

By clearly defining the jurisdiction and detailing the responsibilities of the IRB, this section ensures that all parties involved in research are aware of the IRB's authority, the breadth of its oversight, and its commitment to safeguarding the rights and welfare of research participants. This framework supports a transparent, ethical research environment at Florida Hebrew University.

1. Review and Approval: Emphasize the IRB's responsibility to review and approve, require modifications in, or disapprove all research activities within its jurisdiction to ensure the protection of human subjects.
2. Monitoring and Compliance: Outline the IRB's duty to monitor approved research for compliance with approved protocols and to conduct periodic reviews as required.
3. Education and Training: Highlight the IRB's role in providing education and training for the research community on ethical considerations and regulatory requirements for conducting research with human subjects.
4. Reporting and Documentation: Specify the IRB's responsibility for maintaining comprehensive records of its activities and for reporting significant findings or compliance issues to institutional officials and federal agencies as applicable.
5. Responding to Concerns: Describe the processes for responding to concerns or complaints from research subjects or others about ethical or procedural issues in research.

2.4 BOARD OPERATIONS AND MEETING PROTOCOLS

This section aims to ensure the efficient operation of the IRB and maintain the highest ethical standards for the protection of human research participants at Florida Hebrew University.

Frequency of Meetings

1. Regular Meetings: The IRB will hold regular meetings at intervals adequate to ensure the timely review of research protocols. The standard schedule will be determined annually and adjusted as needed.
2. Special Meetings: Special meetings may be called by the Chairperson or at the request of any board member if an urgent review is necessary.

Meeting Procedures

1. Agendas: Agendas for each meeting will be set by the Chairperson and distributed to members at least one week in advance of the meeting.
2. Quorum: A quorum shall consist of a majority of the voting members, including at least one (1) member whose primary concern is in a nonscientific area. The IRB may not conduct reviews without a quorum present.
3. Voting Procedures: Decisions will be made by a majority vote of the members present. In the case of a tied vote, the Chairperson will have the authority to cast the deciding vote.
4. Documentation: Minutes will be kept for each meeting to document the attendance, activities, and decisions of the Board. These will include a summary of the deliberations, the vote on these actions, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution.

Protocol Review Process

1. Submission Due Dates: Researchers must submit protocols by the specified due date to be considered for review at the next scheduled IRB meeting.
2. Pre-Meeting Distribution: Submitted protocols will be distributed to all members well in advance of the meeting, allowing adequate time for review.

3. Primary Reviewer System: One or more primary reviewers will be assigned to each protocol to conduct an in-depth review and present their findings to the Board.

Conduct of Review

1. Opening Procedures: Each meeting will begin with a confirmation of a quorum, an introduction of new members, and a request for the declaration of conflicts of interest.
2. Protocol Discussions: Each protocol will be discussed in detail, focusing on the risk-benefit ratio, informed consent, and participant protections. Investigators may be invited to clarify points and answer questions.
3. Closed Sessions: The IRB may enter into a closed session to discuss sensitive aspects of a protocol when necessary. The reasons for closing a session will be documented in the minutes.

Record Keeping

Minutes: Detailed minutes will be maintained for each meeting, documenting attendance, discussions, and decisions. These records will be retained as required by federal regulations and institutional policy.
Storage and Access: Records will be stored securely, with access limited to authorized personnel, to ensure confidentiality and compliance with regulatory requirements.

Post-Meeting Actions

Communicating Decisions: The IRB's decisions will be communicated to the researcher in writing within one week of the meeting with the exception of the holidays. Required modifications or reasons for disapproval will be clearly stated.
Follow-Up Actions: Follow-up actions, such as monitoring the consent process, will be outlined and communicated to the researcher as necessary.

Suspension or Termination of IRB Approval

Criteria and Procedures: The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the board's decisions, conditions of approval, or regulatory requirements.

Amendments and Continuing Review

Procedure for Amendments: Researchers must submit amendments to the IRB for review and approval prior to implementation, except where necessary to eliminate apparent immediate hazards to subjects.

Continuing Review Frequency: Ongoing research will be subject to continuing review at intervals appropriate to the degree of risk, but not less than once per year.

3.RESEARCHER CATEGORIES

Each category of researcher has distinct roles and responsibilities, but all must adhere to FHU's policies regarding ethical conduct, human participant protection, and any other specific requirements laid out by the IRB. Collaboration across categories is encouraged where it enhances the quality and scope of research, provided that all collaborative efforts are in line with FHU's values and IRB regulations.

Researcher Categories

3.1 Faculty Researchers

- Definition: Faculty members employed by FHU who engage in research as part of their academic duties.
- Expectations: They are expected to lead research projects, mentor stu-dent researchers, and adhere to the highest standards of research integri-ty and ethical conduct.

3.2.1 FHU Non-Faculty Researchers

- Community Member Researcher:
  - Definition: Individuals from the local or broader community who engage in research relevant to their interests or fields of expertise without holding a formal position at FHU.
  - Support: FHU provides access to resources and guidance, and researchers are expected to contribute positively to FHU's research portfolio while maintaining ethical standards.
  - Certification and Training: All Non-Faculty researchers must complete a Torah-based Qualitative Research certification course as well as IRB training.
  - Collaborative Torah-Observant Researcher from Other Institutions:
  - Definition: Researchers affiliated with other academic or research institutions who share FHU's commitment to Torah observance and wish to collaborate on research projects.
  - Collaboration: Such researchers engage in joint projects that benefit from shared expertise and resources, with all involved parties adhering to the ethical guidelines and oversight provided by the FHU IRB.
  - Certification: Certification and Training: All Non-Faculty researchers must complete a Torah-based Qualitative Research certification course as well as IRB training.

3.2.2. FHU Non-Faculty Researcher Qualifications and Guidelines

Overview
Florida Hebrew University (FHU) encourages scholarly contributions from individuals outside our faculty through the FHU Non-Faculty Research program. This initiative enables researchers who are not current faculty members to undertake research projects that uphold and contribute to FHU's academic and Torah-based values.

Eligibility, Qualifications, and Affiliation

The FHU Non-Faculty Research program is open to scholars, community members, and professionals who meet the following qualifications:

1. Language Proficiency and Communication Excellence: Candidates must possess a high level of English and Lashon Kodesh (when applicable) proficiency, showcasing superior writing abilities that ensure clear and impactful communication of research findings.
2. Torah Observance:
    - For Women: Adherence to tzniut (modesty), taharat mishpachah (family purity laws), observance of full kashrut, Shabbat observance, and hair covering for married women.
    - For Men: Demonstrated good moral character, observance of full kashrut and Shabbat, commitment to regular Torah study, engagement in conscientious speech, and preference for Torah values over prevailing pop culture.
3. Training and Certification: Participants are required to undergo 8-10 hours of FHU Torah-based qualitative research training as well as 4 hours of IRB compliance training. Successful completion awards a Certificate of FHU Non-Faculty Research.
4. Educational Background: While a B.A./M.A. or M.S./Ph.D. enhances the application, it is the adherence to Torah values and the potential impact of the research that are of paramount consideration.

Conflict of Interest and Funding

- All research conducted is considered part of FHU's scholarly output. Therefore, it must be free from external influences or conflicts of interest that could compromise its integrity.
- Researchers are responsible for securing their funding in alignment with IRB guidelines. FHU commits to reasonable efforts in assisting researchers in this pursuit. Regardless of external funding status, a stipend of $400.00 will be provided as a gesture of support for the research effort.
- Funding sources must not introduce any conflicts of interest, ensuring the research remains aligned with FHU's mission and ethical standards.

Access, Compliance, and Intellectual Property

- Researchers may be granted access to specific FHU resources, with such access determined on a case-by-case basis to facilitate the research process.
- Compliance with FHU's IRB guidelines is mandatory, ensuring all research activities meet the highest standards of ethical conduct and respect for Torah mitzvot.
- Intellectual property generated from FHU Non-Faculty Research is subject to FHU policies, safeguarding the interests of both the researchers and the institution while promoting the dissemination of Torah-aligned scholarship.

3.3 Student Researchers

- Undergraduate and Graduate Students:
    - Definition: Students at FHU who participate in research as part of their educational program.
    - Mentorship: They work under the close supervision of faculty researchers and are expected to learn and practice responsible research conduct, including the ethical treatment of human participants.

4. RESEARCH SUBMISSION AND REVIEW PROCESS

4.1 Initial Submission Requirements

All research involving studies of human participants must be submitted to the IRB for review prior to the initiation of the project.

The initial submission should include:

- **Research Proposal**: A detailed description of the research objectives, methodology, data collection strategies, and potential impacts.
- **Participant Documentation**: Copies of informed consent forms, recruitment materials, and any surveys or questionnaires to be used.
- **Risk Assessment**: An analysis of potential risks to participants and steps taken to mitigate those risks.
- **Data Management Plan**: A plan for how data will be collected, stored, and protected during and after the research process.

4.2 Review Procedures and Timelines

Upon receipt of the initial submission, the IRB will conduct a preliminary assessment to determine the level of review required:

- **Exempt Review**: Research that involves minimal risk and fits into one of the federally defined exempt categories may qualify for an exempt review, typically completed within 1-2 weeks.
- **Expedited Review**: Studies that involve minimal risk, but do not qualify for exemption may be eligible for expedited review, generally completed within 2-4 weeks.
- **Full Board Review**: Research that presents more than minimal risk will be reviewed by the full IRB committee. Full board reviews are scheduled according to the IRB's regular meeting cycle, usually within 4-6 weeks.

Researchers will be notified of the review outcome or if additional information is required to proceed.

4.3 Criteria for Approval

The IRB will approve research based on the following criteria:

- **Risks to Participants**: The risks to participants must be minimized and reasonable in relation to the anticipated benefits.

- Informed Consent: The research must include a process for obtaining informed consent from participants that is clear, comprehensive, and documented.
- Privacy and Confidentiality: There must be adequate provisions to protect the privacy of participants and maintain the confidentiality of data.
- Safeguards for Vulnerable Populations: Additional safeguards must be included for research involving vulnerable populations to ensure ethical treatment.
- Compliance with Applicable Laws and Regulations: The research must comply with all applicable laws, regulations, and institutional policies.

The IRB reserves the right to request modifications, to disapprove research that does not meet these criteria, or to require additional safeguards for participants. Researchers are obligated to report any changes to the research protocol or unforeseen issues that arise during the course of the study.
By adhering to these processes and criteria, the IRB ensures that all research involving human participants is conducted ethically and in compliance with the highest standards of research integrity.

4.4 Appeals Process for Non-Approval

In the event that a research proposal is not approved, the researcher has the right to appeal the IRB's decision. The appeal must be based on new or additional information that might affect the IRB's review of the project.

The Appeals process is as follows:

- Submission of Appeal: The researcher must submit a written request for an appeal within 30 days of receiving the non-approval notification. This request should include the reasons for the appeal and any new information or modifications to the research proposal.
- Review of Appeal: The appeal will be reviewed by an Appeals Commit-tee, which may be composed of IRB members who did not participate in the original decision, as well as potentially an outside expert if deemed necessary.
- Meeting and Deliberation: The Appeals Committee will convene a meeting to discuss the appeal. The researcher may be invited to present their case in person or via a written statement.
- Final Decision: After careful consideration, the Appeals Committee will make a final decision, which may uphold the original decision, reverse it, or

suggest modifications to the proposal. The final decision will be communicated to the researcher in writing.

The decision made by the Appeals Committee is final and binding, and it concludes the appeals process within the IRB's structure. Researchers are encouraged to consider the feedback from both the initial review and the appeal deliberations to refine their research proposals for future submissions if necessary.

5. RESEARCHER RESPONSIBILITIES

5.1 Ethical Conduct

Researchers at Florida Hebrew University are expected to uphold the highest standards of ethical conduct in their work. This includes maintaining integrity in data collection and analysis, ensuring accuracy in research findings, and respecting the dignity and rights of all human participants. Researchers must avoid any form of misconduct, including plagiarism, fabrication of data, or misrepresentation of research outcomes.

5.2 Compliance with Legal Requirements and Halakhic Principles

Research conducted under the auspices of FHU must comply with all applicable legal requirements as well as Halakhic (Jewish law) principles. This dual compliance ensures that research practices not only meet secular regulatory standards but also align with Torah values and ethics. Researchers must consult with appropriate legal and Halakhic authorities when designing and conducting their studies to ensure full compliance.

5.3 Ongoing Reporting and Post-Approval Monitoring

After receiving IRB approval, researchers are responsible for providing ongoing reports of their study's progress at intervals specified by the IRB. They must also promptly report any adverse events or unanticipated problems involving risks to participants or others. Post-approval monitoring includes submitting any proposed changes to the research protocol for IRB review before implementtation. Researchers are required to maintain records and data in accordance with IRB requirements, which may be subject to audit by the IRB at any time.
Through adherence to these responsibilities, researchers affirm their commit-ment to the ethical and principled conduct of research, reinforcing the trust placed in them by the university, the research community, and the society at large.

6. TORAH-BASED RESEARCH CONSIDERATIONS

6.1 Ensuring Alignment with Torah Values

Research at Florida Hebrew University must not only comply with ethical standards common to all scholarly inquiry, but also adhere to the values and principles derived from Torah teachings. Investigators are required to design and conduct research in a way that respects and reflects Torah law and ethics. This includes seeking guidance from knowledgeable Halakhic authorities when questions arise regarding the intersection of Torah law and research practices.

6.2 Handling Sensitive Topics

When research involves topics that are considered sensitive within Torah law, such as matters of personal or family privacy, modesty, or other areas with specific Halakhic implications, it is imperative that these subjects are approached with the utmost sensitivity and respect. Researchers must employ methods that protect participants' dignity and privacy while ensuring that the collection and analysis of data comply with both ethical and Halakhic standards.

6.3 Participant Engagement and Consent

The process of engaging participants and obtaining consent for research must be clear, transparent, and conducted in accordance with Halakhic principles. Consent forms and processes should be designed to ensure that participants are fully informed in a manner consistent with Torah teachings. This includes providing participants with all necessary information regarding the research, ensuring that their participation is voluntary, and respecting their right to withdraw from the study at any time without repercussion.

7. DATA MANAGEMENT AND PRIVACY

7.1 Data Collection and Storage

- Data Collection: Researchers must collect data in a manner that is consistent with the approved protocol and only collect information that is essential for the study's objectives. All data collection methods must be transparent to the participants.
- Data Storage: All collected data must be stored securely and in compliance with both FHU's data protection policies and relevant privacy laws. Data should be stored in a way that limits access to authorized personnel only, using encrypted databases where necessary.

7.2 Privacy Protections

- Anonymization and Pseudonymization: Where possible, researchers should anonymize or pseudonymize data to protect the identity of participants. Identifiers should be removed or altered to prevent the tracing of data back to individual participants.
- Access Control: Implement strict access controls to ensure that only the research team members who need to work with the data have access to it, and they must comply with confidentiality agreements.
- Legal Compliance: All data management practices must comply with applicable federal, state, and local privacy laws, as well as FHU's policies on privacy.

7.3 Sharing and Publishing Data

- Data Sharing: Any sharing of research data with third parties must be performed in accordance with the consent provided by the participants and must protect their privacy and confidentiality.
- Publishing Data: When publishing results, researchers must ensure that no individual participant can be identified from the published data, unless explicit consent has been obtained for such identification.

7.4 Data Retention and Destruction

- Retention Period: FHU requires that data be retained for at least three years after the final project closeout, aligning with the period during which it may be audited or requested by regulatory agencies or sponsors.
- Destruction of Data: After the retention period, data should be destroyed in a secure manner that prevents its reconstruction. Electronic data should be deleted using methods that prevent future retrieval, and physical data should be shredded or incinerated.

- Handling of Materials Containing Hebrew Letters: Any data recorded on paper that contains Hebrew letters must be disposed of according to Halakhic standards, typically by placing it in a *genizah* until it can be buried.

Researchers must document the retention period and destruction of data, keeping a record of what data was destroyed, when, and how. This ensures that FHU can demonstrate compliance with data protection policies and other regulatory requirements.

8. SPECIAL POPULATIONS AND VULNERABLE GROUPS

8.1 Identifying Vulnerable Populations

Vulnerable populations are those susceptible to coercion or undue influence due to their age, socioeconomic status, health, or ability to give consent, among other factors. FHU researchers are responsible for identifying if their research involves such populations, which requires special attention and procedures to ensure ethical conduct.

8.2 Additional Protections

For vulnerable populations, additional layers of protection must be incorporated into the research design. This includes but is not limited to obtaining consent through legally authorized representatives, considering the power dynamics within the research relationship, and ensuring the absence of coercion.

8.3 Inclusion and Equity in Research

Inclusion in research ensures that all individuals, regardless of their background, are adequately represented and have equal access to participate in research. Equity means that the research design and conduct consider the differing needs and circumstances of participants, providing equal opportunities for benefits and minimizing any potential burdens.

9. COMPLIANCE AND REPORTING OF NON-COMPLIANCE

9.1 Investigating Reports of Non-Compliance

- Initial Assessment: Upon receiving a report of potential non-compliance, a preliminary assessment will be conducted to determine the validity of the claim.
- Formal Investigation: If the initial assessment warrants further inquiry, a formal investigation will be initiated. This will be led by a designated compliance officer or a committee, ensuring that the process is unbiased and thorough.
- Confidentiality: The investigation will be conducted confidentially to protect all involved parties, maintaining integrity and fairness throughout the process.

9.2 Consequences of Non-Compliance

- Range of Consequences: Consequences for confirmed non-compliance can range from a warning or mandated retraining to more severe penalties such as suspension of research activities, withdrawal of IRB approval, or reporting to external bodies where required by law or policy.
- Proportionate Response: The response to non-compliance will be proportionate to the severity and frequency of the infraction, as well as the level of risk posed to research participants.

9.3 Procedures for Addressing Concerns

- Communication: Researchers will be informed of any non-compliance findings and will have the opportunity to respond to the concerns raised.
- Corrective Actions: When non-compliance is confirmed, the IRB will outline required corrective actions, which may include modifications to the research protocol, additional oversight, or other remedial steps.
- Documentation: All findings and corrective actions will be documented in the IRB records. Researchers must provide evidence of corrective action completion within a specified timeframe.

10. CONFLICT OF INTEREST

a. **Definition of Conflict of Interest**: A conflict of interest in research occurs when a researcher has financial, professional, or personal interests that could compromise or appear to compromise their judgment, objectivity, or loyalty to the university and the principles of academic and research integrity. This may include situations where a researcher, or their close family members, stand to gain financially from the research results, hold a significant financial interest in a company that could be affected by the research findings, or have relationships that may influence their research decisions. Detailed conflict of interest scenarios are contained in a separate Conflict of Interests Documentation.

10.2 Attestation of No Conflicts

- **No Conflict of Interest Form**: All researchers are required to sign a No Conflict of Interest Form attesting that they have no financial, professional, or personal conflicts that would bias their research. The signed form must be submitted to the IRB as part of the initial documentation.
- **Proactive Resolution**: If a potential conflict of interest is identified after submitting the form, researchers must proactively resolve the conflict and inform the IRB immediately.

10.3 Reporting and Transparency

- **Clear Expectations**: FHU expects researchers to maintain a high standard of ethics by avoiding any and all conflicts of interest throughout the research process.
- **Documentation and Record-Keeping**: The IRB will keep all No Conflict of Interest Forms on file as part of the researchers' records, ensuring transparency and accountability in the research conduct at FHU.

FHU's firm policy on conflicts of interest ensures that all research is conducted impartially and with the utmost integrity, free from any influence that could compromise the research's objectivity or credibility.

11. TRAINING AND EDUCATION

11.1 IRB Member Training

- Initial Training: New IRB members must complete an introductory training program that covers the ethical and legal principles of human participant protection, as well as the specific policies, procedures, and expectations of the FHU IRB.
- Continuing Education: All IRB members are required to engage in ongoing education to stay current with evolving regulations, ethical standards, and best practices in research oversight.

11.2 Researcher Training Programs

- Mandatory Training: Researchers engaged in studies involving human participants must complete mandatory training prior to beginning their research. This training includes topics such as research ethics, consent processes, data confidentiality, and reporting requirements.
- Specialized Training: Depending on the nature of their research, additional specialized training may be required, particularly for research involving vulnerable populations, complex ethical issues, or sensitive topics.

11.3 Ongoing Educational Resources

- Access to Materials: FHU will provide access to a library of resources, including manuals, webinars, and guidelines on research ethics and compliance.
- Workshops and Seminars: Regularly scheduled workshops and seminars will be conducted to provide researchers and IRB members with opportunities to discuss ethical issues and learn from real-world case studies.

12. RECORD KEEPING AND DOCUMENTATION

12.1 IRB Records Retention Policy

- Duration: FHU's IRB will retain all records relating to research protocols, including applications, approved consent documents, progress reports, and correspondence, for a minimum of three years after the completion of the research. This period may be extended to comply with federal regulations.
- Comprehensive Records: Records will include documentation of all IRB proceedings, such as meeting minutes, deliberations, actions taken, votes, and the basis for requiring changes in or disapproving research.

12.2 Access to IRB Documents

- Researcher Access: Researchers will have access to their own IRB records upon request, in accordance with FHU's policies and procedures.
- Regulatory Oversight: Regulatory agencies may also access relevant IRB documents as required by law or policy.

12.3 Document Disposal Policy

- Secure Disposal: After the retention period, IRB documents containing sensitive or confidential information must be disposed of in a manner that protects participant privacy and data confidentiality. This will include practices such as shredding paper documents and securely erasing electronic files.
- Halakhic Compliance: Any documents containing Hebrew letters or words will be disposed of in accordance with Halakhic standards, respecting religious traditions and practices.

13. RESEARCH FUNDING

Principles of Funding Acceptance

- Alignment with Mission: All research funding must align with the mission and values of Florida Hebrew University, including adherence to Torah principles and academic independence.
- Donor Agreements: Donor agreements must explicitly state that the donors have no control over the research methodology, findings, conclusions, or publication.

Review of Funding Sources

- IRB Oversight: The IRB will review the sources of funding for potential conflicts of interest to ensure that they do not compromise the ethical conduct of research.
- Transparency and Disclosure: Full disclosure of funding sources will be part of the research protocol submission, and any changes in funding must be reported to the IRB.

Use of Funds

- Appropriate Use: Funds must be used as stipulated by the approved research protocol, and any deviation from this must receive prior approval from the IRB.

14. COMMUNITY RELATIONS AND PUBLIC AFFAIRS

14.1 Community Relations

- Engagement and Dialogue: FHU is committed to maintaining a strong, mutually beneficial relationship with the Torah-observant community, Jewish communities, and society-at-large. This involves open dialogue, community engagement events, and consideration of community needs and values in research endeavors.
- Community Feedback: Regular feedback mechanisms will be established to gauge community sentiment and respond to any concerns related to ongoing research.

14.2 Collaborations with Other Institutions

- Joint Ventures: Collaborative ventures with other research institutions will be pursued to enhance the scope and impact of research. These partnerships will be based on shared values and objectives, particularly those that advance Torah-based scholarship.
- Ethical Alignment: All collaborations must be vetted to ensure ethical alignment with FHU's principles and IRB requirements.

14.3 Public Relations

- Communication Strategy: A clear communication strategy will be developed to accurately represent and publicize research activities and findings to the broader public, while maintaining the confidentiality and dignity of research participants.
- Media Interactions: Interactions with media will be managed to ensure consistent, accurate, and positive representation of FHU and its research activities.

14.4 Research Publication Policies and Procedures

- Integrity in Reporting: Research findings will be reported with integrity, transparency, and accuracy. Researchers are required to adhere to the highest standards of publication ethics.
- Credit and Authorship: Proper credit and authorship will be assigned in all research publications, reflecting actual contributions in accordance with recognized scholarly standards.
- Public Access: Whenever possible, research findings will be made accessible to the public, subject to considerations of confidentiality and propriety.

15. AMENDMENTS, CONTINUING REVIEW, AND CLOSURE

15.1 Process for Amendments

- Submission of Amendments: Researchers must submit any proposed changes to an ongoing study to the IRB for review before implementation. This includes modifications to the study design, consent forms, or recruitment strategies.
- Review and Approval: Amendments will be reviewed promptly, and researchers will be notified of the IRB's decision. Minor amendments that do not affect the risk level to participants may be eligible for expedited review, while significant changes may require a full board review.

15.2 Continuing Review Requirements

- Scheduled Reviews: As part of the continuing review process, researchers must submit progress reports at intervals specified by the IRB, which is typically on an annual basis.
- Assessment of Progress: The IRB will assess the progress of the study, ensuring ongoing compliance with ethical standards, and determine whether any modifications are necessary or if the study can continue as approved.

15.3 Study Closure Procedures

- Completion of Research: When a study is completed, researchers must submit a closure report to the IRB, outlining the outcomes and confirming that all data collection has ceased.
- Data Retention: Upon study closure, researchers must maintain all research-related records for a period of three years, unless a longer retention period is required by law or regulation.
- Final Reporting: Final reports should summarize the study's findings and any implications or contributions to the field. The IRB may also request a copy of the final published research or any presentations given on the study's findings.

16. IRB POLICY REVIEW AND REVISION

Overview

To ensure the Institutional Review Board (IRB) policies remain effective, relevant, and compliant with federal regulations and ethical standards, Florida Hebrew University (FHU) is committed to a process of regular review and, if necessary, revision of its policies.

Periodic Review

- Regular Assessment: The IRB policies shall be reviewed on a biennial basis or more frequently as required by changes in regulations or institutional priorities.
- Stakeholder Engagement: The review process will involve key stake-holders, including IRB members, researchers, administrators, and where appropriate, external experts.

Updating and Amending Policies

- Authority for Amendments: The FHU President and the IRB Board hold the authority to approve amendments to the policies.
- Documentation of Changes: All updates and amendments will be documented, with a clear record of the rationale for changes and the effective date of the new policy.

Communication of Changes

- Notification: The IRB office will notify all affected parties of policy changes, including researchers and administrative staff, in a timely manner.
- Training: Following significant policy updates, additional training or informational sessions may be offered to ensure understanding and compliance.

17. APPENDICES

17.1 Sample Forms and Templates are available for download from FHU IRB Researcher Portal Page: https://www.floridahebrewuniversity.org/irb-forms-and-templates

1. Initial Application Form
2. Protocol Template
3. Informed Consent Form
4. Assent Form (for studies involving minors)
5. Recruitment Materials Form
6. Data Management Plan Form
7. Amendment Form
8. Continuing Review Form
9. Closure Report Form

17.2 GLOSSARY OF TORAH-BASED RESEARCH TERMS

PURPOSE

The Glossary in an IRB policy book serves multiple purposes and audiences. Even within a Torah-observant community, there can be varying levels of familiarity with specific terms, especially when they relate to technical or legal aspects of research.
Additionally, a glossary can aid:

1. Non-Torah-Observant Researchers: Researchers from outside the community who may not be familiar with the terms but are involved in Torah-based research at the institution.
2. Students and Trainees: Students who are learning about research methodologies and ethical considerations as part of their education.
3. External Reviewers or Collaborators: People from other institutions, funding agencies, or regulatory bodies who may interact with the IRB documentation.
4. Administrative Staff: Staff members who may need to understand the terminology to effectively administer and oversee research projects.

GLOSSARY

Achat Esre (Eleven): The Hebrew number eleven.
Aravit: The evening prayer service in Jewish tradition.
Arba (Four): The Hebrew number four.
Basari (Fleischig): Pertaining to meat; describes food, dishes, or utensils used for meat in observance of kosher laws.
Chalavi (Milchik): Pertaining to dairy; describes food, dishes, or utensils used for dairy under kosher practices.
Chamish (Five): The Hebrew number five.
Chag/Chaghim: Festivals or holidays in the Jewish calendar.
Chumash: The Five Books of Moses, often in printed form, which includes the Torah and traditional commentaries.
Daven: A Yiddish term for praying.
Derech Eretz: Ethical conduct and good manners prescribed by Jewish tradition.

Dinim: Judges; often refers to judicial matters within the context of Halakha.

Echad (One): The Hebrew number one.
Gemilut Chasadim: Acts of loving-kindness.
Halakha: Jewish law and jurisprudence based on the Torah and rabbinic literature.
Hilonit: A secular Jewish person, often associated with a secular lifestyle and perspective within Israeli society.
Hilul Hashem: Desecration of God's name; actions by Jews that bring disrespect to God or Judaism in the eyes of others.
Kashrut: The body of Jewish law dealing with what foods can and cannot be eaten and how those foods must be prepared and eaten.
Kosher Certification: A verification that food products comply with kashrut, often represented by a symbol or seal from a certifying agency.
Maariv: The evening prayer service on Shabbat and Jewish Torah-based holidays.
Melakha: The 39 categories of work prohibited on Shabbat.
Mikveh: A ritual bath used for purification according to Jewish law.
Mincha: The afternoon prayer service in Jewish tradition.
Mishpatim: Laws, specifically referring to the commandments and legal statutes within the Torah.
Muktzeh: Items that are prohibited to be moved on Shabbat, with certain exceptions.
Navi'im: The Prophets; the second section of the Tanakh (Hebrew Bible), containing the books of the prophets.
Niddah: The period during and following a woman's ovulation cycle when physical contact with her spouse is prohibited until after immersion in a mikveh.
Pasul: Invalid or disqualified from use for a specific religious purpose.
Pikuach Nefesh: The principle that preserving human life overrides almost all other religious prohibitions.
Shabbat: The Jewish Sabbath, a day of rest observed from Friday evening to Saturday evening.
Shacharit: The morning prayer service in Jewish tradition.
Shechita: The ritual slaughtering of animals for food.
Shemonah (Eight): The Hebrew number eight.
Shesh (Six): The Hebrew number six.
Sheva (Seven): The Hebrew number seven.
Shlishi (Tuesday): The third day of the week in the Hebrew calendar.
Shomer Negiyah: The practice of avoiding casual physical contact with members of the opposite gender.

Shomer Shabbat: An observant Jew who adheres to the laws and customs of Shabbat, refraining from all forms of prohibited work from sunset on Friday until nightfall on Saturday.
Shtayim (Two): The Hebrew number two.
Shtem Esre (Twelve): The Hebrew number twelve.
Taharat HaMishpacha (Family Purity): Jewish laws concerning marital relations, the female ovulation cycle, and the immersion in a mikveh. These laws are observed by many in the Jewish community and can impact participant availability and behavior in research settings, especially regarding topics related to health, psychology, and social studies.
Tanakh: An acronym for Torah (Law), Nevi'im (Prophets), and Ketuvim (Writings); the Hebrew Bible.
Tehillim: The Book of Psalms, part of the Ketuvim section of the Tanakh.
Tevilat Keilim (Toivel): The immersion of utensils in a mikveh to render them kosher.
Tishah (Nine): The Hebrew number nine.
Treif: Literally "torn"; refers to food that is not kosher, either because of the source of the food or the way it was processed.
Tzedakah: Charity, considered a religious obligation.
Tzniut: Modesty in behavior, dress, and speech.
Yichud: The prohibition of seclusion in a private area with an individual of the opposite gender who is not a family member.
Yom Chamishi (Thursday): The fifth day of the week in the Hebrew calendar.
Yom Rishon (Sunday): The first day of the week in the Hebrew calendar.
Yom Shabbat (Saturday): The Sabbath, the seventh day of the week in the Hebrew calendar.
Yom Sheni (Monday): The second day of the week in the Hebrew calendar.
Yom Shishi (Friday): The sixth day of the week in the Hebrew calendar.

17.3 CONTACT INFORMATION FOR IRB:

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