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I. PURPOSE OF THE INSTITUTIONAL REVIEW BOARD (IRB) at WEST LIBERTY UNIVERSITY (WLU)

The purpose of the WLU IRB is to protect the rights and welfare of human research participants. The IRB at WLU provides assistance to faculty, students, and staff to promote the protection of the participants of research, provide guidance to investigators in the proposal process, and review research for compliance with applicable federal law and local policies.

II. IRB AUTHORITY

A. The IRB has the authority and responsibility for reviewing all research projects involving human subjects to ensure that appropriate standards are met, and the research procedures do not infringe upon the safety, health, welfare, or life of those subjects.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

B. Per federal regulations, the IRB has the authority to (1) approve or disapprove a research proposal, or to require modifications to a proposal, (2) suspend or terminate a study, or impose restrictions or require modifications to a study as a condition for continuation, and (3) observe the consent process and research procedures.

C. The IRB will follow the guidelines for human subject research provided by the U.S. Department of Health and Human Services to the best of their ability.

III. IRB MEMBERSHIP

A. Requirements: The IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Federal Policy [46.107] provides that each IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

B. Membership Composition: Based on the federal policy guidelines, the WLU IRB will consist of at least five members of varied backgrounds to facilitate diversity in its composition. The IRB will include at least one member whose primary concerns are in a scientific area, and at least one member whose primary concerns are in a nonscientific area. The IRB will also include at least one person who is neither affiliated with the university nor an immediate family member of a person affiliated with the university. The composition of membership will include at least one member from each sex, and members from a variety of professions. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available in the IRB. These people are considered consultants and are not IRB members.

C. Membership selection:

1. **IRB Administrator:** The Provost will make a recommendation to the President, who will appoint an IRB administrator. The administrator will be a member of the IRB.

2. **IRB Chair:** The IRB administrator will appoint an IRB Chair. The IRB chair will be a member of the IRB.
3. **IRB WLU Members:** Before the end of the first month of the fall semester, the Deans of each College will recommend one faculty member and an alternate to serve on the IRB to the IRB chair. The IRB chair will make a recommendation to the IRB administrator, who will appoint the faculty IRB members and designate their alternates.
4. **Nonaffiliated member:** The IRB chair will make a recommendation to the IRB administrator, who will appoint a nonaffiliated WLU person as an IRB member and designate an alternate, if available.
5. **Other members:** The IRB chair may make additional recommendations to the IRB administrator in order to meet the membership composition guidelines or meet the needs of the University. The IRB administrator will appoint any additional IRB members as needed.

IV. IRB MEMBER RESPONSIBILITIES

A. **All IRB Members:** Members will serve on the IRB for one academic year. Members may serve for multiple terms. If an appointed member resigns from the IRB, their designated alternate, if available, will serve for the remainder of the term.

1. **Conflict of Interests:** Any IRB member (or consultant) that has a conflict of interest on a research proposal cannot participate in that review process associated with the conflict, except to provide information requested by the IRB. If necessary, the IRB chair will request a designated alternative to serve in the members stead in context of the conflict of interest.
2. **Training:** IRB members should have an understanding of the regulatory requirements, and IRB related policies and procedures. IRB members will complete the required training course(s).
3. **Research review**: IRB members will conduct reviews according to all applicable regulations.
4. **Reporting:** IRB members will report any known instance of serious or continuing noncompliance with federal regulation or determinations of the IRB to the IRB chair. Any allegations of research misconduct will follow the WLU Research Integrity (Policy 211).

B. IRB Administrator: The IRB administrator is responsible for promoting compliance with Federal and local regulations, including reporting as required.

1. **IRB Chair:** The administrator appoints the IRB Chair and the other IRB members based on recommendations from the IRB chair. The IRB administrator will serve as IRB chair or designate an alternative if the current chair resigns, has a conflict of interest, or is otherwise unavailable or unable to serve as an IRB chair.
2. **Training:** The IRB administrator has the responsibility to participate in applicable training and pursues ongoing educational activities to keep abreast of current events and regulations related to human subjects research. The IRB administrator will complete any of the training required of all IRB members in addition to any training specific to IRB administration. The IRB administrator will consult with the IRB Chair regarding human subjects training.
3. **Resources:** The IRB administrator may utilize University resources and staff for IRB related activities as appropriate.
4. **Records:** The IRB administrator will assist the IRB chair in maintaining IRB related documentation and ensuring compliance with Federal and local policies.

C. IRB Chair: The IRB chair is responsible for assisting the IRB administrator in promoting compliance with Federal and local regulations, including reporting as required.

1. **IRB members:** The IRB chair makes recommendations for IRB membership to the IRB administrator. The IRB chair may serve in the capacity of IRB administrator on an “as needed” basis with the President’s approval. The IRB Chair will lead IRB meetings, facilitate communication among IRB members and researchers, and promote compliance with University policies and procedures related to human subject research.

2. **Training:** The IRB chair will designate the required training for IRB members and Human Subject Researchers affiliate with WLU. The IRB chair will participate in applicable training and pursue ongoing educational activities to keep abreast of current events and regulations related to human subjects' research.
3. **IRB and researcher communications**: The IRB chair is the primary liaison between the researchers and the IRB. The IRB chair will receive the initial research proposal application and make the determination on what type of review is needed. The IRB chair informs the primary research investigator of the IRB decision regarding application submissions. The IRB chair may designate another IRB member to conduct initial or continuing review of research, and/or to conduct exempt reviews.
4. **Resources**: The IRB chair may utilize University resources and staff for IRB related activities as appropriate.
5. **Records:** The IRB chair will maintain IRB related records including but not limited to: list of IRB members, training certificates, IRB application materials and communications, IRB submission project decisions, and IRB reports. Records will be retained for a minimum of 3 years after completion of the research.

V. Responsibility of Human Subject Researchers

The IRB requires that all student research involving human subjects be sponsored by a WLU faculty member, both Undergraduate and Graduate students. Additional responsibilities not listed may be required per federal regulation or local policies or procedures.

A. All WLU human subject researcher responsibilities: This includes faculty sponsors and student researchers.

1. Protect the rights and welfare of human subjects that participate in research
2. Understand the ethical standards and regulatory requirements governing research activities with human subjects
3. Complete any required human subjects research training before submitting an IRB application
4. Follow WLU policies and procedures associated with human subject research
5. Ensure all research activities have IRB approval and are implemented as approved
6. Comply with IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others including adverse effect, safety reports, or data safety and monitoring summary reports

B. Principal Investigator (P.I.) responsibilities:

1. The P.I. personally conducts or supervises the research
2. Communicates appropriately with the IRB in a timely manner
3. Communicates relevant information, such as IRB decisions, to any others listed on the IRB application
4. Obtains IRB approval for any proposed changes to the research plan, including but not limited to, methodology or personnel changes, prior to its implementation
5. Make provisions for secured retention of complete research records and research materials as required
6. Ensure the confidentiality and security of all information obtained from and about human subjects
7. Ensure reporting compliance with IRB and, if applicable, federal and funding sponsor requirements.

C. Faculty-student research sponsor responsibilities:

1. Completion of the appropriate ethics training before sponsoring student research
2. Reviewing student project proposals before they are submitted for IRB review
3. Overseeing the conduct of the projects

4. Ensuring that students comply with appropriate ethical principles for the treatment of human subjects

5. Ensuring that students comply with WLU policies and procedures associated with human subjects research

6. Communicate appropriately, and in a timely manner, with student researchers and IRB. Prior to IRB submission, faculty sponsors should discuss with their student researchers who is the primary investigator for each project proposal (the faculty member, or the student, and any co PI's or co investigators). It is also suggested, but not required, that prior to IRB application submission, faculty members discuss and clearly indicate individual researcher responsibilities regarding the project. Additionally, faculty research sponsors should also consider discussing anything related to research dissemination, such as authorship order, with their research students.

D. Student Human Subjects Researcher responsibilities:

1. Obtain a faculty research sponsor

2. Communicate appropriately, and in a timely manner, with the faculty sponsor and IRB as needed

E. Cooperative research: For projects that involve more than one institution, each institution is responsible for protecting the rights and welfare of human subjects and for complying with any federal regulations or local laws.

VI. IRB Procedures for Research Review

The IRB is in session between September and May of each year. The meeting schedule and submission deadlines for all applications for the current year can be found on the IRB website. Application materials must be received electronically by the chair of the IRB at least 10 business days before a meeting to be considered at that meeting. The IRB chair disseminates the application to other committee members as needed for review and comment.

Regarding the review of research, the IRB considers several factors such as: (1) the risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk, (2) risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be reasonably expected to result, (3) selection of subjects is equitable, (4) informed consent will be sought from each prospective subject or their legal representative (5) informed consent will be appropriately documented, (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 subjects and maintain the confidentiality of data.

While the IRB does not assess the research design and methodology, if the study is sufficiently flawed in design or methodology such that greater than minimal risk is present for participants, the IRB may disapprove or require modifications to the research protocol.

A. Submission of Application: Application forms and information are accessible on the IRB website. Initial applications are completed online by the researcher which are forwarded to the IRB Chair. Applications can be submitted at any time however researchers should note the timeline for each of the different types of reviews. The IRB chair, or their designee, determines if the application has been appropriately completed and contacts the researcher regarding any necessary clarifications regarding the initial application. The IRB chair, or their designee, then determines the appropriate level of IRB review: no review required, exempt, expedited, or full review. All submissions, regardless of the type of review, will be accessible to all IRB members who may contact the Chair with any comments regarding the submission before the final notification of decision is sent to the researcher. Typically, IRB communications with the researcher is conducted via email, however, the IRB may request to talk to the researcher in person or over the phone.

B. Length of time for review: The length of IRB review from the submission of the initial application to the IRB decision depends on several factors: the type of review required, the timeliness of the researcher responding to IRB communications, amount of applications received and currently being processed by the IRB, and availability and responsiveness of IRB members. It is incumbent upon the researchers to allow for that necessary time of review, and to facilitate the review by being diligent in completing the application correctly and responding to feedback promptly.

C. Types of Reviews: Information regarding the types of reviews are guidelines. Special considerations such as the Health Insurance Portability and Accountability Act (HIPPA), Federal regulations, or other applicable law or local policies must be taken into consideration and included regarding IRB review. Items 1 - 4 refer to IRB applications for initial review.

1. IRB review not required. If the research application is determined to not meet the requirement of *human subjects research*, it is not required to be reviewed by the IRB. University policies and ethical guidelines regarding research are still applicable to the research project. The IRB chair, or their designee, will contact the researcher in writing with this decision. Typically, this determination will take 5-7 business days, however, it may take longer if clarification from the researcher is needed.

2. Exempt review: Submissions that meet the criteria for exempt review are reviewed at minimum by the IRB chair or their designee. Typically, turnaround time for IRB exempt review decisions is two weeks or less, however, it may take longer if clarification from the researcher is needed.
Exempt review criteria: An "exempt" IRB review is selected when the research falls into one of the six approved categories of exempt research (45 CFR 46.101 [b]) and is not applicable to research in a covered research category (e.g., FDA regulation - 21 CFR 50.20).

a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. If children are involved, procedures are limited to educational tests and observation of public behavior where the researcher(s) will NOT participate in the activities.

c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt in the above paragraph, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

e) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or

procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

f) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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 approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

3. **Expedited review:** Submissions that meet the criteria for expedited review are reviewed by the IRB chair or their designee, and at least one other IRB member. Typically, turnaround time for IRB decision is two weeks or less, however, it may take longer if clarification from the researcher is needed, or it is determined that a full review is warranted.
   Expedited review criteria: An "expedited" IRB review is selected when the research does not meet the criteria for exempt status but involves no more than minimal risk to subjects OR is being reviewed strictly for minor changes to previously approved protocols in the research project.
   Minimal risk means "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"
4. **Full review:** Submissions that meet the criteria for full review are typically reviewed by a quorum (aka majority) of IRB members which must include at least one member whose primary concern is in a nonscientific area.
   Full review criteria: A "full" IRB review is required when the research is defined as (a) a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (38 CFR 16.102d); (b) that involves human subjects (i.e., a living person about whom a researcher collects either identifiable private information OR data through an intervention or interaction); and (c) involves greater than minimal risk to those human subjects. A full review is required for any study that does not meet the requirements for an exempt or expedited review. In order to approve research, the IRB must determine that all of the requirements specified in 45 CFR 46.111 (and if applicable, 21 CFR 56.111) are satisfied.
5. **Amendments or Modification Review**: Changes that affect the subjects in any way cannot be made to approved studies, including informed consent documents, without prior IRB review and approval. An exception to this is any changes necessary to immediately protect subjects' safety as noted in 21 CFR 56.108(a)(4) and 56.115(a)(1). The amendment or modification review may fall under a "full" or "expedited" category, depending on the magnitude of the change and the effect of the change on the risks/benefits ratio.
   Amendment or Modification procedure: The Amendment or Modification form and information is accessible on the IRB website. This form is completed online by the P.I. and is forwarded to the IRB chair. The IRB chair, or their designee, determines if the form has been appropriately completed and contacts the researcher regarding any necessary clarifications regarding the submission. The IRB chair, or their designee, then determines the appropriate level of IRB review. See above for descriptions of expedited and full reviews.
6. **Continuing review:** The IRB must re-review studies at minimum of once every year. The IRB may require review more frequently depending on the IRB's assessment of the study's risk/benefit ratio and provisions provided by federal guidance (i.e. final rule HHS 2018). The frequency of review is indicated in the IRB notification of decision document. The continuing review may be a full or expedited review.

Continuing review procedure: The Continuing review form and information is accessible on the IRB website. This form is completed online by the P.I. and is forwarded to the IRB chair. The IRB chair, or their designee, determines if the form has been appropriately completed and contacts the researcher regarding any necessary clarifications regarding the submission. The IRB chair, or their designee, then determines the appropriate level of IRB review. See above for descriptions of expedited and full reviews.

D. IRB Notification of Decision: The IRB will notify the researcher in writing of its decision to not review, approve, modify, or disapprove the research. If modifications are needed, the researcher will communicate with the IRB chair, or their designee, regarding those modifications until a final decision is made in writing. Notifications of Decisions can be:

1. IRB review not required. Project does not meet the requirement of the policy definition of research with human subjects and therefore does not have to be reviewed by the IRB.

2. Approval of the proposal.

3. Approval with stipulations (for minor modifications to the proposal). Revisions must be sent to the chair, who will review and confirm the modifications. The proposal may be referred to the IRB if deemed necessary by the Chair.

4. Defer pending receipt of additional information (request substantive modifications or clarifications).

5. Disapproval of the proposal. Information on why the research is disapproved will be provided in writing.