POLICY & PROCEDURE DOCUMENT

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I. Purpose and Scope

A. General

1. This Policy applies to all research, research training, experimentation, biological testing, and related activities, involving human subjects at Western Kentucky University (WKU).

2. The policies and procedures herein apply to all parts of WKU including satellite facilities, branch campuses, properties, facilities run by affiliated and related foundations and so forth.

II Policy

A. General Principles

Western Kentucky University hereby gives assurance that it will comply with all federal, state, and local laws and regulations related to research involving human subjects.

B. Definition of Research

Office for Human Research Protections (OHRP) 45CFR46.102(l): *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

III. Procedure

This institution has established an Institutional Review Board (IRB) in order to regulate research involving human subjects at WKU in line with all applicable federal, state and local regulations. The WKU IRB reviews all research protocols involving human subjects; reviews and addresses concerns involving the use of human subjects in research; advises faculty, staff and students on the ethical conduct of research involving people; conducts appropriate reviews of the University's program, and develops guidelines to ensure compliance with federal and state regulations.

A. Establishment and Structure of the Institutional Review Board (IRB)

1. The IRB shall be appointed by the Associate Provost for Research and Graduate Education in a letter that specifies the appointment term (e.g., 2000-2003)

2. The membership of the IRB shall consist of one faculty member from each academic college, a representative from the external community, and a Compliance Officer. Co-Chairs shall be elected by a majority of the IRB and, if a faculty member, receive one course release time per semester or alternate form of commensurate compensation. The Compliance Officer of the Office of Research Integrity shall coordinate the activities of the IRB.

3. Members of the IRB shall serve three-year terms, with the exception of the Compliance Officer who shall serve continuously. Members may serve up to two full consecutive terms.

4. The Associate Provost for Research and Graduate Education will respect the impartial and independent nature of the IRB and will not interfere in its actions or deliberations.

B. Meetings of the IRB

1. The IRB shall meet on the fourth Friday of each month throughout the year unless the Board designates an alternative date. Times and locations of meetings will be coordinated by the Compliance Officer and transmitted by email to the members. Meetings will be held in person except in exceptional situations where electronic means acceptable to OHRP can be used to convene a full board quorum.

2. The Compliance Officer (or designee) shall be responsible for taking minutes at each meeting and emailing the minutes to the members before the next scheduled meeting.

3. All minutes shall be approved electronically by the members at the conclusion of the meeting by majority vote. In exceptional cases minutes may be approved at the next full board meeting.

4. A majority of the membership is required to be present for all votes. The results of all votes shall be recorded in the minutes.

5. To be reviewed by the full board, applications must be submitted by the first of each month. Applications shall be submitted to the Compliance Officer.

6. Principal investigators whose applications require full board review shall be present at the full board meeting. Faculty advisors of students submitting a proposal for full board review should also be present at that meeting. The IRB Chair, assisted by the Compliance Officer shall determine the appropriate review level for a given protocol.

7. The IRB Chair must recognize the presence of anyone in attendance at the IRB meeting other than applicants and advisors, and their presence will be recorded in the minutes.

C. Responsibilities of the Compliance Officer

The Compliance Officer shall be responsible for reporting information, as appropriate to the University administration, federal agencies, and investigators on a variety of issues.

Specifically, the Compliance Officer shall:

1. Have the responsibility of initial administrative review of all applications to determine completeness;

2. Keep investigators aware of decisions and administrative processing affecting their respective protocols;

3. Report to the Office of Human Research Protections (OHRP) or other relevant regulatory authority any instances of injuries to subjects and unanticipated problems involving risks to subjects or others involved in funded research when warranted;

4. Report to the Associate Provost for Research and Graduate Education information received concerning noncompliance by investigators, injuries to subjects, and unanticipated problems involving risks;

5. Maintain information concerning the IRB's reasons for the termination or suspension of IRB approval;

6. Report any changes in the IRB's membership to the OHRP;

7. Provide certification of review in cases of supplements to funded protocols and

8. Prepare and maintain adequate documentation of the IRB's activities and membership in accordance with 45 CFR 46.103, 46.115 and 46.116 (b) (5).

D. Institutional Review Board Responsibilities

1. The IRB shall have the responsibility to review and the authority to approve, require modification in, or disapprove all activities or proposed changes in previously approved activities covered by the federal regulation 45 CFR 46. (also see Research Misconduct and Non-Compliance Policy).

2. The IRB shall approve research based on the criteria specified in 45 CFR 46.117.

3. The IRB shall require documentation of informed consent in accordance with 45 CFR 46.117.

4. The IRB shall have the authority to waive or alter some or all of the elements of informed consent provided that it finds that the requirements set forth in 45 CFR 46.116 (c. 1, 2) (d. 1, 2, 3, 4) have been met.

5. The IRB shall have the authority to determine which projects need verification from sources other than the research investigators and that no material changes have occurred since previous IRB review.

6. The IRB shall have the authority to conduct periodic review of the investigator's study records.

7. The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements or that has been associated with unexpected serious harm to the subjects. Any suspension or termination of approval shall include a written statement of the reasons for the IRB's action, and shall be reported promptly to the investigator. The suspension or termination of an approval will also be reported to the Associate Provost for Research and Graduate Education, the Provost and Vice President for Academic Affairs (Institutional Officer), the dean and department head/chair/director (or equivalent), and to any federal funding agency as required by federal regulations.

8. The IRB shall have the authority to suspend or terminate approval of a protocol if the investigator fails to submit a continuing review report within the due date given by the Compliance Officer. The IRB shall have the authority and the responsibility for promptly reporting information to the Compliance Officer, the OHRP, or both on a variety of issues. In conjunction with this requirement, the IRB must be prepared to receive and act on information received from a variety of sources, such as human subjects, research investigators, the Compliance Officer, or other institutional staff.

9. The IRB shall have the authority to observe or have a third party observe the consent process and the research.

10. The IRB shall review all approved protocols annually, as a minimum.

11. Principal investigators are required to report significant changes in approved protocols as they occur. The IRB shall review changes to approved protocols before the investigator may carry out a study in the modified manner.

12. Under no circumstances will approval be granted to applications submitted after data collection.

13. The IRB must require letters of cooperation and support from external research sites.

E. IRB Procedures for Reviewing Proposals

1. Exempt from Review

   a. The IRB Chair, assisted by the Compliance Officer, will determine if proposals are exempt from review. Principal investigators have the responsibility to bring all studies to the attention of the Compliance Officer and may not self-determine exempt status.

   b. Principal investigators may make an appeal to any member of the IRB if the initial reviewing member of the IRB does not grant “exempt from full board review” status.

   c. The IRB may use expedited review procedures for studies granted “exempt from full board review” status.

2. Expedited Review

   a. The IRB may use an expedited review procedure to review minor changes previously approved research during the period for which approval is authorized.

   b. The IRB may use an expedited review procedure for studies that involve no more than minimal risk to subjects and in which the only involvement of human subjects will be in one or more of the categories specified in 45 CFR 46, as specified on the WKU, Office of Research Integrity website.

   c. The IRB Chair and the Compliance Officer shall conduct expedited Review. In cases, in which a conflict of interests exists with one of the reviewers, the Chair or Compliance Officer may designate another board member to conduct the review. The IRB member(s) conducting the expedited review may exercise the full authority of the IRB except that the reviewer(s) will refer a proposal to the full committee for review whenever they believe that full committee review is warranted.

   d. The recommendation of the reviewer(s) will be reported to the full committee and to the principal investigator by the Compliance Officer.

3. Full IRB Board Review

   a. The IRB will function in accordance with 45 CFR 46.108

   b. Members of the IRB are excluded from review of projects or activities in which they have an active role or conflicts of interest, except to provide information requested by the IRB.

   c. The principal investigator, or, if applicable, the co-investigator, is required to appear in person before the respective IRB during the initial review to present the application and to answer questions concerning the protocol unless this requirement is waived by the IRB. Where students are acting as a principal investigator and presenting to the full IRB, their faculty mentor should also be present.

   d. The recommendation of the IRB will be reported to the principal investigator by the Compliance Officer.

F. IRB Procedures for Noncompliance

1. Definitions

a. Noncompliance

Failure to comply with applicable federal regulations, state or local laws, the requirements or determinations of the IRB, or university policy regarding research involving human subjects. Noncompliance may be minor (non-serious), serious, and may also be continuing.

b. Minor or non-serious noncompliance

Noncompliance that does not increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data.

c. Serious noncompliance

Noncompliance that increases risk to research participants, compromises participants' rights or welfare, or affects the integrity of the research/data.

d. Continuing noncompliance

Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a researcher's lack of understanding of IRB requirements.

2. Procedures for Handling Allegations of Noncompliance

a. Allegations of noncompliance should be reported to the IRB Chair, the Compliance Officer, the Associate Provost for Research and Graduate Education, or the Institutional Official without delay.

b. All allegations will remain confidential to the furthest extent possible.

c. The Compliance Officer and the IRB Chair will evaluate the severity of the allegations and will determine whether the criteria for an inquiry are met. If an inquiry is warranted, the Institutional Official will be notified, and in consultation with the Institutional Official, the IRB Chair will send written notice of the allegation to the investigator and will request a written response. The IRB Chair will also evaluate the severity of the allegation to determine if immediate actions are necessary to ensure the ongoing protection of research participants.

d. The IRB Chair, or IRB may suspend or terminate approval of an investigator's research and/or secure critical documents at any time during or following an inquiry or investigation if necessary to assure the protection of research participants.

3. Inquiry

a. The IRB Chair (or designee) will review the allegation of noncompliance, the response of the researcher(s), and any other information necessary to determine whether a full

investigation is necessary. At the conclusion of the inquiry, the IRB Chair (or designee), will report findings to the IRB, the Compliance Officer, the Institutional Official, dean, and department head/ chair/director (or equivalent).

b. In consultation with the Institutional Official, the IRB Chair will notify the researcher(s) in writing of the inquiry outcome, including a statement of the reasons for the decision.

c. Possible outcomes of the inquiry include:

1. Dismissal of the allegation (i.e., unsubstantiated)
2. Referral to other university processes (e.g. research misconduct)
3. No further action required (i.e. for minor violations)
4. Corrective actions (i.e. for minor violations)
5. Review of convened IRB required (i.e. noncompliance may be serious and/or continuing but further investigation is not needed)
6. Referral to IRB investigative subcommittee for further investigation (when results of the inquiry indicate that additional fact finding is required to assess the alleged noncompliance)

4. Investigation

a. An investigation will be initiated when the results of the inquiry indicate that additional information is required to assess the alleged noncompliance.

b. The IRB Chair may request that a subcommittee of the IRB be formed to further investigate allegations of noncompliance. The subcommittee will be facilitated by the Office of Research Integrity staff and advised by University Counsel as necessary. At least one member of the subcommittee should possess expertise appropriate for review of the potential noncompliance; additional IRB members or external consultants may also be included as determined necessary by the subcommittee Chair.

c. Researchers will be informed in writing of the further investigation. The institutional official, dean, and department head/chair/director (or equivalent) will also be notified that an IRB investigation will take place. A written response from the researcher will be requested, depending upon the nature of the alleged noncompliance, to facilitate the review and conclusion of the investigation. The researcher, research staff, or others may be interviewed and/or an audit may be conducted during the investigation, as deemed necessary.

d. Possible outcomes of the investigation include:

1. Dismissal of the allegation (i.e. unsubstantiated)
2. Referral to other appropriate university processes (e.g. research misconduct review)
3. No further action required (i.e. for minor violations)
4. Corrective action(s) required (i.e. for minor violations)
5. Review by convened IRB required (i.e. noncompliance is considered to be serious and/or continuing)

e. When the IRB subcommittee determines that serious and/or continuing noncompliance has occurred, the subcommittee’s summary report will be forwarded to the researcher.

The researcher will be given an opportunity to respond to the subcommittee's findings in writing. The researcher may also respond in person to the IRB at the convened meeting during which the noncompliance review will take place, to be scheduled following the receipt of the researcher's response.

f. If review by the convened IRB is not warranted, the researcher will be informed in writing of the results of the investigation and required corrective actions, as applicable. The Associate Provost for Research and Graduate Education, Institutional Official, dean and department head/chair/director (or equivalent) will also be informed. Suspended IRB approval may be reinstated, as appropriate, based on the determinations of the IRB subcommittee and the response of the researcher. Reinstatement of IRB approval(s) will be reported by the Compliance Officer to those previously informed of the suspension.

5. Convened Full Board IRB Review

a. At a convened meeting, the IRB will review allegations or findings of noncompliance following inquiry or further investigation. The IRB will consider the information from the initial inquiry, further investigation, summary report from the IRB Subcommittee (if applicable), the researcher's response (if applicable), and any other relevant materials to assess the seriousness of the potential noncompliance and to consider possible corrective actions. The IRB will make final determinations in closed session by majority vote of a quorum of the members at the convened meeting.

b. The researcher will be notified in writing of the final decision of the IRB. If not previously reported, any suspension or termination of IRB approval or noncompliance determined to be serious and/or continuing will be reported by the Compliance Officer.

6. Corrective Actions

a. Corrective actions will be based on the nature of the noncompliance, degree to which research participants were placed at risk, occurrence of previous noncompliance, etc. The range of possible corrective actions includes, but is not limited to the following:

    1. Modification(s) in the research protocol or research procedures
    2. Modification(s) in the consent process or on the consent form
    3. Providing additional information to current research participants (required when such information may relate to their willingness to continue the research)
    4. Providing additional information to past research participants
    5. Reconfirming consent of current research participants
    6. Requiring additional follow-up/monitoring for current and/or past research participants
    7. Monitoring of the research (including audits) or consent process
    8. Education or mentoring for the investigator and/or research staff
    9. Additional reporting, including modifications of the continuing review schedule
    10. Placing limitations on the investigator's research activities or use of research data
    11. Suspension of IRB approval for one or more of the investigator's studies
    12. Termination of IRB approval for one or more of the investigator's studies

b. The Chair of the IRB (or designee), the investigative Subcommittee, or the convened IRB may review the investigator(s)' response to corrective actions. If the researcher

does not comply with the required corrective action(s) within the time specified in the corrective action plan, additional action may be required, including suspension or termination of IRB approval(s) for ongoing human subjects research activities. The researcher(s) will be notified of resolution of corrective actions or the need for additional action(s). If not previously reported, any suspension or termination of IRB approval will be reported by the Compliance Officer.

7. Researcher Appeal

   Regulations require that the decision of the IRB with respect to research involving human subjects is final. However, the convened IRB may review a researcher's request for reconsideration or appeal to a determination regarding noncompliance and/or corrective actions as warranted by the presentation of new information or unusual circumstances. All appeals must be made within 30 days of his/her notification of the IRB's findings. The IRB will review a researcher's request or appeal within 30 days, and the researcher will be notified in writing of the IRB's decision within 14 days of the review. The IRB's decision will be final.

8. Reporting

   Noncompliance determined to be serious and/or continuing or any suspension or termination of IRB approval will be promptly reported by the Compliance Officer to the researcher, the IRB, the Associate Provost for Research and Graduate Education, the Institutional Official, the researcher(s)' dean and department head/chair/director (or equivalent), the Office of Sponsored Programs, research collaborators, and any sponsoring federal department or agency.

9. Record Retention

   Records relating to review and investigation of noncompliance will be retained by the Office of Research Integrity for a minimum of three years.

IV. Applicable Regulations and Guidelines Used to Develop This Policy

45 CFR 46: Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Research Subjects

V. Revisions

January 2012
To conform to standard format.

January 2014
To explicate exemption.

May 2016
Policy revised to reflect name change of the Office of Research and Creative Activity and new organizational structure.

August 2017
Policy revised to describe IRB procedures for responding to allegations of non-compliance.

June 2021

Non-substantive changes resulting from fifth year review in accordance with Policy 0.000V.