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

III. Procedure
WKU 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.

A Establishment and Structure of the Institutional Review Board (IRB)
1. The Institutional Review Board (IRB) shall be appointed by the Vice President for Research in a letter that specifies the appointment term (e.g., 2000-2003)
2. The membership of the IRB shall consist of a minimum of six members consisting of one faculty member from each academic college, a representative from the external community, and a Compliance Officer. The Chair 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 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. Decisions of the IRB are final as required by 45 CFR 46.109 and 112. No official in the institution may approve the research if it has not been approved by the IRB.

4. The Vice President for Research 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 an alternative date is designated by the Board. 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 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. 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 are encouraged to attend.

7. The IRB Chair, assisted by the Compliance Officer shall determine the appropriate review level for a given protocol.

8. The IRB chair must recognize the presence of anyone other than applicants and advisors.

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 Protection (OHRP) any instances of injuries to subjects and unanticipated problems involving risks to subjects or other involved;

4. Report to the Vice President for Research 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 this assurance.
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, 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.
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 Manager. 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. (Principal investigators are required to report significant changes in approved protocols as they occur).
11. Under no circumstances will approval be granted to applications submitted after data collection.
12. The IRB must require letters of cooperation and support from external research sites.

E IRB Procedures for Reviewing Proposals

1. 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 for the requests for exemption.
   c. Other research for which the IRB may use an expedite review procedure is that which involves 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 Research Compliance Website.
   d. Except for the condition in A.14 above, Expedited Review shall be conduct by the IRB Chair and the Compliance Manager. In cases, in which a conflict of interests exists with one of the reviewers, the Chair or Compliance Manager 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.
e. The recommendation of the reviewer(s) will be reported to the full committee and to the investigator by the Compliance Manager.

2. 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.
   d. The recommendation of the IRB will be reported to the investigator by the Compliance Manager.

IV Revisions

October 15, 1997
Revised November 21, 1997
Revised August 17, 1998
Revised November 20, 2000
Revised September 20, 2006
Revised November 22, 2010
Revised: September 23, 2011
Revised to conform to standard format 1/30/2012
Appendix A
Review of By-Laws/Pertinent Articles from 45 CFR 46

1. Section 46.109(a) IRB Review of Research
An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

2. Section 46.103 (b) Assurances
   a. Each institution engaged in research covered by these regulations shall provide written assurance that it will have a statement of principles governing the institutions in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding.
   b. Each institution will designate one or more IRBs established in accordance with the requirements of this subpart, and for which provisions are made for meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.
   c. A list of IRB members identified by name; earned degrees, representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.
   Changes in IRB membership shall be reported to the OHRP.
   d. Written procedures which the IRB will follow (i) for conducting initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; (iii) for insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (iv) for insuring prompt reporting to the IRB and to the OHRP of unanticipated problems involving risks to subjects or others.

3. Section 46.115 IRB Records
An institution shall prepare and maintain adequate documentation of IRB activities, including the following:
   a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by the investigators, and reports of injuries to subjects.
   b. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
   c. Records of continuing review activities.
   d. Copies of all correspondence between the IRB and the investigators

4. Other Requirements for Records
   a. A list of IRB members are required by 46.103(b)(4).
   b. Statements of significant new findings provided to subjects, as required by 46.116(b)(5)
   c. Written procedures for the IRB as required by 46.103 (b)(4). The records required by this regulation shall be retained for at least 3 years after completion of the research,
and the records shall be accessible for inspection and copying by authorized representatives of the OHRP at reasonable times and in a reasonable manner.

5. **Section 46.116 General Requirements for Informed Consent**

   Except as provided elsewhere in this and other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal right, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.

   a. The informed consent document must include a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
   
   b. A description of any reasonable foreseeable risks or discomforts to the subject;
   
   c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
   
   d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
   
   e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
   
   f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; and
   
   g. An explanation of whom to contact for answers to pertinent questions about the research subjects; rights, and whom to contact in the event of a research-related injury to the subject; and
   
   h. A statement that participation is voluntary, refusal to participate will involved no penalty or loss of benefits to which the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
   
   i. An IRB may approved a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, some or all of the elements of informed consent set forth above, or waive consent provided that the IRB finds and documents that:

   a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
      
      i. Programs under the Social Security Act, or other 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;
      
      iv. Possible changes in methods or levels of payment for benefits or services under those programs; and
b. The research could not practically be carried out without the waiver or alteration.

j. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practically be carried out without the waiver or alteration.

6. **Section 46.111 Criteria for IRB Approval of Research**

   a. In order to approve research the IRB shall determine that all of the following requirements are satisfied:
      i. Risk to subject are minimized:
         1. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
         2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
      ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
      iii. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.
      iv. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with and to the extent required by 46.117.
      v. Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.
      vi. Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.
      vii. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

   b. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severer physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.