roll was called and the following members voted “aye”: Mr. Armbrust, Dr. Frisbie, Mr. Fulkerson, Mr. House, Mr. Sloan, Ms. Johnson, Mr. Turner, and Mr. Abney. The motion passed. A copy of approved RTP personnel is included with the Official Minutes of the Board of Regents.

Report from the Council on Academic Affairs

Dr. Vice presented to the Board the following agenda items which have appropriate department, Faculty Senate and Council on Academic Affairs endorsement for the Board approval. Agenda items 3a-qq, program revisions, was recommended to the Board for approval. Mr. Sloan made a motion to approve; Ms. Johnson seconded. The motion was approved by voice vote.

Dr. Vice presented to the Board agenda items 3rr, 3ss and 3tt, programs lowering hours. Mr. Sloan made a motion to approve; Mr. Abney seconded. The motion was approved by voice vote.

Dr. Vice presented items 3uu, 3vv and 3ww for Board approval. Mr. House made a motion to approve; Dr. Frisbie seconded. The motion carried.

Dr. Vice presented item 3xx, program suspension. Mr. Abney made a motion to approve; Mr. House seconded. The motion was approved by voice vote.

Regulation 4.1.12R, Course Registration, Revision (Information Item)

For informational purposes, Dr. Janna Vice presented Regulation 4.1.12R, Course Registration to the Board. Regulation 4.1.12R addresses facilitation of timely progress toward degree completions for students. The revision to 4.1.12R adds Veterans to the list of student populations eligible for early class registration. No Board action was required for this item. A copy of the 4.1.12R is included with the Official Minutes of the Board of Regents.

Proposed Revision, Policy 4.4.12P, Protecting Human Subjects in Research & Proposed Revision, Policy 4.4.13P, Humane Care and Use of Animals in Research and Teaching Activities

Dr. Vice presented revisions to Policy 4.4.12P, Protecting Human Subjects in Research and Policy 4.4.13P, Humane Care and Use of Animals in research and Teaching Activities to the Board for approval. Dr. Frisbie made a motion to approve, Mr. House seconded. The motion was approved by voice vote. Copies of the approved policies are included with the Official Minutes of the Board of Regents.

Protocol for Approval of Certificate Programs (Information Item)

Dr. Janna Vice presented an information item pertaining to Protocol for Approval of Certificate Programs for the Board’s consideration. The revisions address definitions and clarifications regarding Certificates and the approval process for Certification Programs. A copy of this item is included with the Official Minutes of the Board of Regents.
TO:    Dr. Doug Whitlock  
       President 
 
FROM:  Sherry Robinson  
       Sherry Robinson, Executive Assistant to the Provost for Policy and Process 
 
DATE:  December 13, 2010  
 
RE:    Protecting Human Subjects in Research  
 
Executive Summary  

Policy 4.4.12P (Protecting Human Subjects in Research) is submitted for your consideration. The current policy was last approved by the Board of Regents in 1999. The revision of this policy was extensive enough to make the usual deletion/addition impossible. The current policy can be found on the policy website. The revised policy has now been vetted by the Faculty Senate and the Provost Council, both of whom have recommended support. Some recommendations for minor changes were made by University Council and during the 30-day comment period; those recommended changes are reflected in the attached draft policy. 

Please let me know if you have any questions or need any additional information. 

Presidential Action:  
☐ Recommend approval and submission to the Board of Regents for adoption  
☐ Approve (no Board of Regents approval is required)  
☐ Submit to President’s Cabinet for advisement  
☐ Submit to __________________________ for further review, drafting, or stakeholder feedback  
☐ Not approved/ not recommended for submission to the Board of Regents  
☐ Other action recommended  

[Signature]  
12/13/10  

Date  

Eastern Kentucky University is an Equal Opportunity/Affirmative Action Employer and Educational Institution.
Summary of Updates to
Policy 4.4.12: Protecting Human Subjects in Research

Policy 4.4.12 was updated in 2009 to more effectively convey the University’s responsibility for compliance with 45 CFR, Part 46, Protection of Human Subjects. Changes reflected in the new policy will not impact the current operation of the IRB, as it is currently operating in accordance with the federal regulations.

The following is a summary of changes from the previous policy:

- The new policy more clearly outlines the responsibility of the Institutional Review Board (IRB) and defines its membership and appointment terms.

- The most significant changes were made to the “Responsibilities” section of the policy to outline responsibilities of various offices, which did not exist in the previous policy.

- The revised policy more clearly documents the process for seeking IRB approval in each of the three levels of review (exempt, expedited, and full reviews), and to better define types of research that may be reviewed in each category.

- The new policy includes reporting requirements (i.e., including continuing reviews and final reports) that are outlined in the federal regulations and are now a formal part of the IRB process.

- The required elements of informed consent were updated to be in compliance with federal regulations and to facilitate investigator understanding of the consent process.

- Review considerations were added to the policy to define the types of issues that are evaluated by the IRB during the review process.
Policy Comments

Each policy gets 30 days for comments.

Search
Enter some text and press enter!

About EKU Blogs-List of Blogs

Human Subjects

Posted October 19th, 2010 by sherry

The comment period on the Protecting Human Subjects in Research policy has ended.

Filed under: academic

One Response to “Human Subjects”

* Matthew Pianalto Says: November 8th, 2010 at 1:22 pm

I think that the policy should say something about WHO is in charge of selecting members of the IRB, and in what ways that person or group will be accountable for appointing appropriate members. There should be a maximum amount of transparency in the selection process and the current policy draft leaves this important business a bit of a mystery.

Recent Posts

* On Call Duty
* Course Registration
* Human Subjects
* Animal Welfare
* Interim Sponsored Dependent

October 2010

S M T W T F S
1  2
3  4  5  6  7  8  9
10 11 12 13 14 15 16
17 18 19 20 21 22 23
24 25 26 27 28 29 30
31
» Sep  Nov »

© 2010 EKU :: FOIA Statement :: Web Feedback :: RSS
Bill 1 legislation. The partnership would represent the first collaboration of this kind in Kentucky between a local school district and a 4-year university.

Implementing a Middle College on the EKU campus would create a new Madison County high school and be the district’s first pilot program. EKU would provide classrooms, office space, service, and support while the Madison County Schools would fund the necessary costs for staffing and equipping the high school. The proposed collaboration would be detailed in a memorandum of agreement for 60 juniors participating the first year and thereafter, 60 juniors and 60 seniors per year with students completing a minimum of 18 college credit hours.

Feedback and questions can be sent to Dr. Gabbard. The proposal will be returned to the Provost Council for support at a later meeting.

3. **Alcohol Education Initiatives** – New initiatives are being considered by Student Affairs for alcohol education and prevention to address alcohol related risks and impact on education. Currently, alcohol abuse education is presented in some first-year Academic Orientation Courses by guest speakers upon request. The *AlcoholEdu for College* prevention program is being proposed for implementation at EKU. In this program, students respond to an initial survey to create a personalized user experience that encourages them to consider alcohol behaviors and set personal goals. Input and questions can be sent to Dr. Jim Conneely and Ms. Adrienne Bauer.

IV. **Action Items**

1. **Council on Academic Affairs Report:**
   a. **Regulation 4.1.12R, Course Registration, Revision** – A motion was proposed to approve the Regulation 4.1.12R, Course Registration, Revision.

   The motion carried by unanimous vote.

2. **Policy 4.4.12P, Protecting Human Subjects in Research** - A motion was proposed to approve Policy 4.4.12P, Protecting Human Subjects in Research.

   The motion carried by unanimous vote.

3. **Policy 4.4.13P, Humane Care and Use of Animals in Research and Teaching Activities** - A motion was proposed to approve Policy 4.4.13P, Humane Care and Use of Animals in Research and Teaching Activities.

   The motion carried by unanimous vote.

V. **Good of the Order/Announcements**

1. EKU will host the Council on Postsecondary Education (CPE) meeting, Friday, November 5, at 10:00 a.m. in the Library, Grand Reading Room.

2. The Financial Planning Committee meets this afternoon. Meeting materials will be forwarded to the Provost’s Council.
A renovation project will begin soon to update the landscaping in front of the Keen Johnson building. The project is being financed by the Donovan Trust Fund, which is a fund specifically established for campus beautification.

**NEW BUSINESS:**

**Report on Encompass.** Deans Carrie Cooper and Jerry Pogatshnik reported on Encompass, a new digital storage system that will house electronic submissions of theses, dissertations, and other research. For fall 2010, theses and dissertations may be submitted electronically and in hard copy format. However by Spring 2011, all submissions will be handled electronically.

**Posthumous Degree for Robert Hundley-Doria.** Senator Poffenberger moved approval, seconded by Senator Wade. Motion carried.

**Protecting Human Subjects in Research Policy.** Senator Vice moved approval, seconded by Senator Matthews. Motion carried.

**Animal Care and Use Policy.** Senator Vice moved approval, seconded by Senator Schmelzer. Motion carried.

**Report from Council on Academic Affairs.** - Senator Vice

**New Option**
1. Safety, Security and Emergency Management Ergonomics Option

**New Certificate**

**New Concentrations**
3. Anthropology Concentration within the Associate of General Studies program (A.G.S.)
4. Sociology Concentration within the Associate of General Studies program (A.G.S.)
5. Political Science Concentration within the Associate of General Studies Program (A.G.S.)
6. History Concentration within the Associate of General Studies Program (A.G.S.)
7. Mathematical Sciences Concentration with the Associate of General Studies Program (A.G.S.)

**Program Suspension**
8. Correctional and Juvenile Justice Studies Minor

**Program Revisions**
9. Journalism B.A. – *add JOU 305W as an option for JOU 305*
10. Public Relations B.A. - *Add JOU 305W as an option for JOU 305*
11. Journalism Minor -*add JOU 305W as an option for JOU 305*
12. Sociology Minor in Deviance/Criminology – revise program requirements
13. Biology M.S. – *replace BIO 710 (dropped course) with BIO 810 from each program 26 and option*
14. Master of Fine Arts in Creative Writing – *To alter the existing catalog description of the MFA 28 program’s curriculum and exit requirements to reflect significant changes agreed upon by the current faculty members teaching in the program. These include: 1) Revised dates for the Summer and Winter Residencies; 2) A formal creative thesis (previously not required); 3) A written exit examination (previously not required).*
15. History Teaching B.A. – *reflect the dropped courses (HIS 415 and 450) and the course changes (HIS 290 and 450W)*
16. Master of Music in Theory/Composition – *revise required courses*
Protecting Human Subjects in Research

Policy Statement

Whenever a Principal investigator/Project Director (PI/PD) affiliated with Eastern Kentucky University engages in a project that involves human subjects, EKU must ensure compliance with federal policies safeguarding human subjects. This applies to all university projects involving human subjects whether funded from internal or external sources.

Eastern Kentucky University and the federal government require that the proposed project be reviewed and approved by the Institutional Review Board (IRB) and remain subject to continuing review by the IRB. In particular, funds administered by a department or agency may not be expended for projects involving human subjects until reviewed and approved by the IRB.

To be in compliance, EKU must establish the IRB to review proposed and ongoing research and provide the following:

1. A statement of principles governing EKU in the discharge of its responsibilities for protecting the rights and welfare of human subjects in projects conducted at or sponsored by the institution.
2. A list if IRB members identified by name, earned degrees, and representative capacity.
3. Written procedures which the IRB will follow:
   a. For conducting initial and continuing reviews of project activities.
   b. For reporting its findings and actions to the PI/PD and appropriate university officials.
   c. For ensuring prompt reporting to the IRB of proposed changes in project activity, and for ensuring that these changes not be initiated without IRB review and approval.
   d. For ensuring prompt reporting to the IRB, university officials, and the appropriate funding source of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB or any suspension or termination of IRB approval.

Entities Affected by the Policy

- Students, faculty, and staff in departments, colleges, or units conducting activities involving humans as research subjects
- Subrecipients participating in activities involving human research subjects
- IRB members
- Sponsored Programs staff

Page 1 of 8

This policy has not yet been reviewed under Policy 1.1.1. For purposes of cataloging, it has been placed in an abbreviated form of the policy template. It remains an official university policy and will eventually be reviewed under Policy 1.1.1.
Policy Procedures

Membership of the Institutional Review Board (IRB)

Federal Requirements Regarding Membership. The composition of the IRB is detailed in 45 CFR Part 46 as follows:

1. The IRB shall have at least five members, with varying backgrounds, to promote an adequate review of the project activities.
2. The IRB shall be sufficiently qualified through the experience, expertise, and diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
3. If the IRB regularly reviews projects that involve a vulnerable category of subjects, such as children, prisoners, pregnant women, handicapped, cognitively impaired persons, terminally ill patients, minorities, elderly persons, or economically or educationally disadvantaged persons, and even normal (i.e., healthy) volunteers such as students and employees or international subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
4. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
5. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family if a person who is affiliated with the institution.
6. A simple majority of the members if the IRB shall constitute a quorum with the stipulation that at least one member whose primary concerns are nonscientific areas must be present for the IRB to review proposed projects. For the project to be approved, it must receive the approval of the majority of those members present at the meeting.
7. No IRB may have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
8. The IRB may, in its discretion, invite individuals with expertise in special areas to assist in the review of issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

University Requirements Regarding Membership. In addition to the federal requirements for IRB membership, there are several university requirements as follows:

1. In accordance with the university committee structure, the IRB reports to and advises the Associate Vice President for Research and Dean of the Graduate School on issues related to human subjects in research.
2. All members of the IRB are appointed by the President or his/her designee, as are two alternates.
3. The Chair shall be the Director of Sponsored Programs and shall be a non-voting member.
4. The Legal Counsel shall be the University Counsel and shall be a non-voting member.
5. Members’ terms are three years, staggered, so that the majority of the members are retained each year; members may serve no more than two terms in sequence.
6. Support services are provided by the Office of Sponsored Programs with all records being maintained in that office.
7. Minutes are copied to the Dean of the Graduate School, the appropriate PI/PD, and to the IRB.

Duties and Responsibilities of the IRB

1. The IRB must review proposed projects involving human subjects prior to initiation of the research. If such activity is undertaken without the intention of involving human subjects, but the PI/PD later proposes to involve human subjects, the revised project must be reviewed and approved by the IRB before it proceeds.
2. The IRB has the authority to approve, require modification of, or disapprove research or project activities.
3. The IRB shall require the PI/PD to provide documentation of informed consent.

Page 2 of 8

This policy has not yet been reviewed under Policy 1.1.1. For purposes of cataloging, it has been placed in an abbreviated form of the policy template. It remains an official university policy and will eventually be reviewed under Policy 1.1.1.
4. The IRB shall notify the PI/PD and the appropriate institution official(s), in writing, of its approval or disapproval of a proposed project, or of modifications required to secure IRB approval. If the IRB disapproves a project, it shall include in its written notification a statement of the reasons for its decision and give the PI/PD an opportunity to respond. Even in disapproval, the IRB will always work with the PI/PD to revise the project to allow for approval.

5. The IRB shall conduct continuing review of continuing projects covered by this policy at intervals appropriate to the degree of risk, but not less than once a year. In addition, the IRB shall have authority to observe or have a third party observe the consent process and the project activity.

6. The IRB has authority to suspend or terminate approval of a project that is not being conducted in accordance with the requirements of the IRB, or that has been associated with unexpected serious harm to subjects, researchers, or a PI/PD. Any suspension or termination shall include a statement of the reasons for the action of the IRB and shall be reported promptly to the PI/PD, university officials, and the appropriate funding sources.

7. When appropriate, the IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
   a. Copies of all proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by the PI/PD and reports of injuries to subjects.
   b. Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on the actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or for disapproval of project activity; and a written summary of the discussion of controverted issues and their resolution.
   c. Records of continuing review activities.
   d. Copies if all correspondence between the IRB and the PI/PD.
   e. 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 anticipated contributions to IRB deliberations.
   f. Changes in IRB membership, as necessary.

Type of Review

The IRB will require that the PI/PD of any project involving human subject submit to the IRB an appropriate request for review. If the project is submitted to the funding agency prior to submission to the IRB, the IRB staff will indicate on the appropriate page that the proposal is pending and/or furnish to the PI/PD a statement if the IRB status of the proposed project.

Projects involving human subjects will be in one of three categories for IRB review: exemption from review, expedited review, or full review.

Exempt from Review

For a project to be exempted from review, the PI/PD must file a Review Application and Protocol as well as an Exemption Request with the IRB.

1. Exemption from review will be granted by the Chair of the IRB, or the Chair designee, to projects falling within the categories described in 45 CFR Part 46.110 and for amendments to the list, if any. The Chair or the Chair designee may require additional information to determine exemption eligibility. Exemption from review will not be granted for projects using vulnerable populations such as those described in this policy.

2. When the above review procedure is used, the IRB members shall be informed of protocols which have been approved under the procedure. Upon the request of the IRB, additional information will be made available.

3. Records of all exemption requests will be kept on file in the Office of Sponsored Programs for a minimum of three years.

Expedited Review

Page 3 of 8

This policy has not yet been reviewed under Policy 1.1.1. For purposes of cataloging, it has been placed in an abbreviated form of the policy template. It remains an official university policy and will eventually be reviewed under Policy 1.1.1.
At the request of the PI/PD. The IRB will review, through an expedited procedure, projects involving no more than minimal risk to subjects. The IRB may also use the expedited review procedure to review minor changes in previously reviewed projects during the period for which the approval is authorized.

1. Expedited review will be conducted for projects having minimal risk and classification in one of the expedited review categories described in 45 CFR Part 46.110.

2. Expedited review is not allowed for projects where children are the subjects. Some funding agencies may have stipulations regarding the age of children and the PI/PD must be in compliance with those stipulations. Eastern Kentucky University will comply with the requirements set forth in 45 CFR 46 Subpart D, which provides additional protection for children involved in projects.

3. One copy of the Expedited Review Application and Protocol will be submitted to the IRB for review. The review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among the voting members of the IRB.

4. Approval will be given if the IRB member(s) and/or the Chair agree that the project meets the criteria for expedited review and for IRB approval.

5. The IRB member(s) conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the project. The reviewer(s) shall refer any protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other protocols to the full committee whenever full committee review is warranted.

6. When the expedited review procedure is used, the IRB Chair or member(s) conducting the review shall inform IRB members if protocols which have been approved under the procedure.

Full IRB Review

When not eligible for exemption or expedited review, each proposal will follow an approved format known as a human subjects protocol. This protocol includes the following sections: purpose, background, study methodology, risks and precautions, procedures to maintain confidentiality, consent form, number and type of subjects and controls, any necessary special approvals, location of the study, source of funds, and the names of those responsible for supervision (if appropriate).

Risk

The PI/PD bears the responsibility of assessing possible risks to human subjects involved in the project and of taking appropriate steps to minimize those risks wherever possible. Before it may approve projects, the IRB must determine that the following criteria are satisfied:

1. **Risks to subjects are minimized.** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the project 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. Risk is minimized by using procedures which:
   a. are consistent with sound research design;
   b. do not unnecessarily expose subjects to risk; and
   c. whenever appropriate, utilize procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable in relation to anticipated benefits.** If any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the project (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the project).

Selection of Subjects

Federal regulations require that the IRB give special consideration to protecting the rights and welfare of particularly vulnerable subjects, such as children (anyone under age 18), prisoners, pregnant women, handicapped, cognitively impaired persons, terminally ill patients, minorities, elderly persons, economically or educationally disadvantaged persons, and normal volunteers such as students and employees or international subjects. Investigators need to take additional special precautions when involving such special cases of subjects.

1. **Equitable selection of subjects.** In making this assessment the IRB will take into account the purposes of the project and the setting in which it will be conducted. Of particular importance is the
recognition of special problems of projects involving vulnerable populations such as those listed above. The primary issue surrounding the participation of such specialized populations in projects is whether the subjects have real choice regarding their participation in the project, or whether their situation prohibits the exercise of free choice. A similar issue relates to the exclusion of specialized populations. Unless there is an overriding reason for exclusion, children should not be arbitrarily excluded from such research.

2. Pregnant Women. Any project in which women of childbearing potential are possible subjects may inadvertently include pregnant women. For information about additional protections of fetuses or pregnant women, consult Subpart B - Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in vitro Fertilization, of 46 CFR Part 45.

3. Prisoners. Because of their incarceration prisoners may be under constraints which could affect their ability to make truly voluntary and uncoerced decisions regarding participation in a project. For information concerning additional protections of prisoners, consult Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, of 46 CFR Part 45.

4. Children or Minors. The special vulnerability of children makes consideration of involving them as subjects in projects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are - addressed in Subpart D - Additional Protections for Children Involved as Subjects of Research, of 46 CFR Part 45.

5. Students, Employees and Normal Persons as Subjects in Projects. Federal regulations do not provide explicit protections for students, employees, and normal (i.e., healthy) volunteers as subjects in projects. There are some special considerations for involving these groups in a project. Volunteers for whom no therapeutic benefit can result from participation in a project should be exposed to risks that are minimized to the greatest extent possible. Normal volunteers, including students and employees, should generally be recruited through announcements or advertisements rather than through individual solicitations. Personal solicitations increase the likelihood that participation will be the result of undue influence. Pls/PDs should also consider that students may be under age, in which case they would fall into two special classes as normal (i.e., healthy) and underage subjects.

6. Students as Conductors of Projects. Students are often required to conduct projects as part of the course work for a class. When that project involves human subjects, the project may require IRB review. The concern here is not for the students in the class but for the subjects of the project, who may or may not themselves be students. If the faculty member teaching the course and supervising those students conducting the project intends to, or may possibly make use of the student findings in his/her own work, then the student project should be submitted for IRB review and approval. If, however, these activities are intended solely for the practice and experience of the student investigators, IRB approval will not be necessary. Faculty are cautioned to have student investigators follow good research practices in obtaining informed consent from subjects in the project and maintaining confidentiality. The University is potentially liable for any project conducted under its auspices.

7. International Subjects in Projects. Human subjects projects conducted in foreign countries by American PIs/PDs require compliance with federal regulations for protection of human subjects in all material respects, just as they would if the project were conducted wholly within the United States. Further information about the above classes of subjects and other specialized populations may be found in Protecting Human Research Subjects: Institutional Review Board Guidebook, by the Office of Protection from Research Risks (OPRR).

Informed Consent

The IRB is responsible for safeguarding the consent process in addition to the entire project relationship to ensure open and free communication between the PI/PD and the prospective subject. The IRB, therefore, expects the PI/PD to follow the process of informed consent, that is, to explain to human subjects involved in a project: 1) the nature and aim of the project; 2) the subject's role in the project; and 3) the possible risks to the subject's physical, psychological, or emotional well-being. This explanation is necessary as individuals invited to participate in the project must have sufficient understanding of what is being asked of them before they can fairly assess the cost to themselves. No informed consent, whether oral or written, may include any exculpatory language through which the subject waives or appears to waive any legal rights, or releases or appears to release the PI/PD, the sponsor, the institution or its agents from liability for negligence.

Page 5 of 8

This policy has not yet been reviewed under Policy 1.1.1. For purposes of cataloging, it has been placed in an abbreviated form of the policy template. It remains an official university policy and will eventually be reviewed under Policy 1.1.1.
1. **General Requirements for Informed Consent.** Prospective human subjects shall be given the following information in language understandable to the subject:
   a. 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 reasonably foreseeable risks or discomforts to the subject.
   c. a description of any benefits to the subject, if any, which may reasonably be expected from the research.
   d. a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject.
   e. a statement describing the extent to which confidentiality of records identifying the subject will be maintained.
   f. a statement describing the extent of confidentiality of subject records.
   g. an explanation of possible compensation and medical treatment in the event of injury from research involving more than minimal risk.
   h. an explanation of contact persons regarding the research, subjects’ rights, and potential research-related injury.
   i. a statement that participation is voluntary and the subject may discontinue participation at any time, and that refusal to participate or withdraw from the project will involve no penalty or loss of benefits to which the subject is otherwise entitled.

2. **The Consent Form.** The PI/PI may use the consent form provided by the IRB or may devise a consent form that contains the same basic elements. If the PI/PI devises a different consent form, it must be written in language easily understandable to the subjects. The possibility of illiteracy should be considered as should the need for communication in a foreign language. The subject must be given adequate opportunity to read the form before signing it.

   The written consent form shall state that the subject has agreed to participate in the project. The written consent form may either provide the subject with the basic information required by the federal government as outlined above, or it may simply state that this information has been presented orally. If this information is all presented orally, the investigator must have a witness to the oral presentation.

   When children or minors are involved in projects, regulations require the assent of the child or minor along with the permission of the parent or guardian. PIs/PDs should be aware that many college students are under age, and therefore need to obtain, in addition to the subject’s consent, the permission of a parent or guardian to the subject’s participation in the project. The subject’s parent or guardian must be given adequate opportunity to read the form before signing it.

3. **Waiving of Informed Consent.** The IRB may approve a consent procedure which does not include or which alters some or all of the elements of informed consent set forth in this section provided the PIs finds and documents that:
   a. the research involves no more than minimal risk to the subjects;
   b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
   c. the research could not practically be carried out without the waiver or alteration.
   d. when appropriate, the subjects will be provided with additional pertinent information after participation.

   The IRB may also waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   a. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject will be asked whether he or she wants documentation linking him or her with the research, and the subject’s wishes will prevail.
   b. that the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research content.

   For other exceptional circumstances under which the IRB may waive or alter the requirement to obtain an informed consent, see Sections 46.116 and 46.117 of 45 CFR Part 46.

**Privacy**

The IRB must ensure that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. This is required regardless of the population from which the subjects for the project are selected.
Definitions

Assent
A child's affirmative agreement to participate in research. Mere failure to object to should not, absent affirmative agreement, be construed as assent.

Beneficence
Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm.

Children
Persons who have not attained the legal age for consent, which in Kentucky, is anyone under the age of 18.

Human Subject
A living individual about whom an investigator (whether professional or student) conducting research obtains data (a) through intervention or interaction with the individual or (b) identifiable private information.

Institution
Eastern Kentucky University

Institutional Review Board (IRB)
The EKU body charged with ensuring the University's compliance with federal regulations governing the protection of human research participants.

Interaction
Communication or interpersonal contact between investigator and subject

Intervention
Both physical procedures by which data are gathered and manipulations of the subject or subject's environment that are performed for research purposes

Justice
Fairness in distribution of research benefits

Private information
Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Research
An activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalized knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective (Belmont Report). As defined by 45 CFR Part 46, research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Respect of Persons
Recognition of the personal dignity and autonomy of individuals with special protection of those persons with diminished autonomy.

University
Eastern Kentucky University

Violations of the Policy

Failure to comply with this policy could result in the termination or suspension of the applicable project.

Interpreting Authority

Associate Vice President for Research

Page 7 of 8

This policy has not yet been reviewed under Policy 1.1.1. For purposes of cataloging, it has been placed in an abbreviated form of the policy template. It remains an official university policy and will eventually be reviewed under Policy 1.1.1.
Statutory or Regulatory References

Code of Federal Regulations for Protecting Human Research Subjects

Policy Adoption Review and Approval

<table>
<thead>
<tr>
<th>Date</th>
<th>Entity</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 22, 1999</td>
<td>Council on Academic Affairs</td>
<td>Recommended Support</td>
</tr>
<tr>
<td>May 3, 1999</td>
<td>Faculty Senate</td>
<td>Recommended Support</td>
</tr>
<tr>
<td>July 29, 1999</td>
<td>Board of Regents</td>
<td>Adopted</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Entity</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 21, 1973</td>
<td>Board of Regents</td>
<td>Adopted</td>
</tr>
</tbody>
</table>
PROTECTING HUMAN SUBJECTS IN RESEARCH

RESPECT FOR PERSONS

JUSTICE

BENEFICENCE

POLICY AND PROCEDURE GUIDELINES

Institutional Review Board
Division of Grants and Contracts
Eastern Kentucky University
1998 - 1999
Changes from Part I of Abstract Eastern Kentucky Institutional Review Board Policy:

University Requirements Regarding Membership

- Members and alternates are appointed by the President for three year, staggered terms.
- Voting membership in the IRB shall consist of one faculty member from each college in the University. If possible, these faculty will chair the college/department IRB/Human Subjects Review Committee.
- The Director of the Division of Grants and Contracts shall chair the IRB, convene the initial meeting of the newly constituted committee for election of the chair from among its members, but shall be a nonvoting member.
- The University Attorney shall be the Legal Counsel but shall be a nonvoting member.

Duties and Responsibilities of the IRB

- The IRB must review proposed projects involving human subjects that will be submitted to Federal agencies for funding.
- The IRB has authority to approve, require modification of, or disapprove research or project activities.
- The IRB shall require documentation of informed consent for projects.
- The IRB shall conduct continuing review of continuing projects at intervals appropriate to the degree of risk to human subjects.
- The IRB has authority to suspend or terminate approval of a project that is not being conducted in accordance with the human subjects requirements.
- The IRB shall prepare and maintain adequate documentation of IRB activities.
Academic Affairs and Research, the appropriate PIF/PIF and to the IRB.

9. Any issues are reported to the President of the Graduate School. The Academic Vice President. For the chair, the office.

8. Support services are provided by the Division of Grants and Contracts with all records

7. Members serve three years, subject to the majority of the members are

6. The Legal Counsel shall be the University Attorney and shall be a non-voting member.

For election of the chair, the members from among the members.

5. The chair shall be the Director of the Division of Grants and Contracts and shall be a

4. All members of the IRB are appointed by the President, subject to the designation, as are two

3. Each college will also have one alternate, who will function in the absence of the

2. Young members in the IRB will consist of one faculty member from each college.

1. In accordance with the university by-laws, the IRB reports to the President.

University Requirements

Membership Requirements. In addition to the federal

Changes on Page 2 of Easton University Institutional Review Board Policy.
Changes on Page 4 of Eastern Kentucky University Institutional Review Board Policy:

Policy on Type of Review

The IRB must review projects involving human subjects with the exception of those that can be reviewed at the department/college level. If a project is approved at the department/college level, that project does not need to be reviewed by the University IRB. The University IRB must be notified by the department/college IRB/Human Subjects Review Board of the results of the review process.

All federally-funded projects involving human subjects will be reviewed by the University IRB. The University IRB will require that the PI/PD of any project involving human subjects submit to the IRB an appropriate request for review. If the project is submitted to the funding agency prior to submission to the IRB, the IRB staff will indicate on the appropriate page that the proposal is pending and/or furnish to the PI/PD a statement of the IRB status of the proposed project.

Federally-funded projects involving human subjects will be in one of three categories for IRB review: exemption from review, expedited review, or full review.
ABSTRACT

The Guidelines are developed as an aid to Eastern Kentucky University faculty, staff, or students who wish to pursue projects involving human subjects that may obligate them to satisfy federal and possibly state requirements regarding such research. The policies and procedures described in these Guidelines are based on Title 45 Code of Federal Regulations Part 46 - Protection of Human Subjects. The policies and procedures are administered by the Institutional Review Board (IRB) at Eastern Kentucky University.

The IRB exists primarily to protect the rights and welfare of human subjects in projects. But it is also the aim of the IRB to foster research and project activity and to assist faculty and staff engaged in either.

The Policy and Procedure Guidelines are divided into four parts, each briefly described below:

Part I. The Function and Membership of the Institutional Review Board

Federal Requirements Regarding Membership
- The IRB shall have at least five members.
- The members shall be sufficiently qualified through experience, expertise, and diversity to promote respect for their advice and counsel in safeguarding human subjects.
- One member shall represent scientific areas, one member shall represent nonscientific areas, and one member shall represent the community.
- Individuals with expertise in special areas may be invited to assist in review but may not vote with the IRB.
- No member may participate in initial or continuing review of any project with which the member has conflicting interest except to provide information requested by the IRB.

University Requirements Regarding Membership
- Members are appointed by the President for three year, staggered terms
- The Director of the Division of Grants and Contracts shall chair the IRB but shall be a nonvoting member.
- The University Attorney shall be the Legal Counsel but shall be a nonvoting member.

Duties and Responsibilities of the IRB
- The IRB must review proposed projects involving human subjects.
• The IRB has authority to approve, require modification of, or disapprove research or project activities.
• The IRB shall require documentation of informed consent for projects.
• The IRB shall conduct continuing review of continuing projects at intervals appropriate to the degree of risk to human subjects.
• The IRB has authority to suspend or terminate approval of a project that is not being conducted in accordance with the human subjects requirements.
• The IRB shall prepare and maintain adequate documentation of IRB activities.

Part II. Policies and Criteria By Which Protocols Will Be Evaluated

• Projects involving human subjects will be in one of three categories of IRB review: 1) exempted from review, 2) expedited review, and 3) full review.
• Projects related to educational practices, the use of educational tests, the study of existing data, or taste and food quality evaluation may generally be exempted from review.
• Projects involving: 1) no more than minimal risk to subjects, and 2) inclusion in one or more of the categories defined in Federal regulations, may be subject to expedited review by the IRB chair or designated IRB member(s).
• Full IRB review is required for those projects that do not meet the criteria for expedited review or exemption from review.
• The IRB must determine that risks to subjects in proposed projects are minimized and are reasonable in relation to anticipated benefits.
• The IRB must ensure that proposed projects have equitable selection of subjects and give special consideration protecting the rights and welfare of vulnerable subjects.
• The IRB must ensure that projects provide for informed consent, i.e., the explanation of the nature and aim of the project, the subject’s role in the project, and the possible risks to the subject in order for prospective subjects to consider whether or not to participate.
• The IRB must ensure that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Part III. Preparing and Submitting a Protocol

• Protocols must have the following: abstract of the project; purpose or objectives of the project; background which led to the formulation of the project; project methodology; potential risks and precautions; procedures to maintain confidentiality; characteristics of subjects and controls; process of obtaining informed consent; steps taken to maintain confidentiality and privacy; special approvals, if required.
Other items to be submitted with the protocol include copies of all instruments to be used in the project; the informed consent form; IRB application for protocol review; required approvals for use of preexisting specimens; signatures of advisors or other individuals who must provide approval for the proposed project.

Part IV. Appendices

Appendix A

- Checklist For Protocol Review
- Application For Project Protocol Review, Form DGC.PR1.1998
- Human Subjects Protocol, Form DGC.PR2.1998
- Application For Exemption From Review, Form DGC.PR3.1998
- Application For Expedited Review, Form DGC.PR4.1998
- Informed Consent Form Sample
- Assent/Parental Consent, Form DGC.PR5.1998

Appendix B

- Title 45 Code of Federal Regulations Part 46 - Protection of Human Subjects
- Federal Register, November 9, 1998

The IRB takes seriously the responsibility of monitoring research or projects involving human subjects. In addition to protecting human subjects, the IRB can function to prevent problems that could result in the loss of funding or lawsuits that could damage the researcher, project director, and/or Eastern Kentucky University.

Should a project be disapproved, the IRB will work with the faculty or staff member to develop revisions that will ensure compliance and protect all individuals involved.
PREFACE

These materials are published as an aid to Eastern Kentucky University faculty, staff, or students who wish to pursue projects involving human subjects and may therefore be obligated to satisfy federal and possibly state requirements regarding such research. Two documents, *The Belmont Report*, and *45 CFR Part 46 - Protection of Human Subjects*, provide definitions of basic terminology relevant to the protection of human subjects in research. Some of the terms would also be applicable to faculty or staff engaged in projects. The terms and their definitions are:

1. **Research**: an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective (*Belmont Report*).

   Research is defined by *45 CFR Part 46* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. It is possible that demonstration or service projects funded by contracts may include research activities.

2. **Human Subject**: a living individual about whom an investigator (whether professional or student) conducting research obtains data (a) through intervention or interaction with the individual or (b) identifiable private information.

   *Intervention* includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

   *Interaction* includes communication or interpersonal contact between investigator and subject.

   *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record) (*45 CFR Part 46*).

3. **Respect for Persons**: recognition of the personal dignity and autonomy of individuals with special protection of those persons with diminished autonomy (*Belmont Report*).

4. **Beneficence**: obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm (*Belmont Report*).

5. **Justice**: fairness in the distribution of research benefits (*Belmont Report*).

   The Institutional Review Board (IRB) exists primarily to protect the rights and welfare of human subjects in projects. But it is also the aim of the IRB to foster research and project activity and to assist faculty, staff, or students engaged in either. Approval from the IRB provides you with the assurance that your project *as outlined* is in compliance with applicable regulations.
TABLE OF CONTENTS

Part I. The Function and Membership of the Institutional Review Board (IRB)
   Federal Regulations Requiring the Establishment of the IRB 1
   Membership of the IRB 1
      Federal Requirements 1
      University Requirements 2
   Duties and Responsibilities of the IRB 3
Part II Policies and Criteria By Which Protocols Will Be Evaluated
   Policy on Type of Review 4
   Policy on Risk 5
   Policy on Selection of Subjects 5
   Policy on Informed Consent 7
   Policy on Privacy 8
Part III Submitting a Project Protocol
   Timing of Protocol Submission 10
   Elements of a Protocol 10
   Protocol Review Process 11
   Follow-Up Reports Required by the IRB 11

Appendix A: Checklists and Forms
   Checklist for Project Protocol Review
   Form DGC.PR.1.1998, Application for Project Protocol Review
   Form DGC.PR.2.1998, Human Subjects Protocol
   Form DGC.PR.3.1998, Application for Exemption from Review
   Form DGC.PR.4.1998, Application for Expedited Review
   Informed Consent Form Sample
   Form DGC.PR.5.1998, Assent/Parental Consent Form

Appendix B: 45 CFR Part 46 - Protection of Human Subjects
   Federal Register, November 9, 1998
PART I. The Function and Membership of the Institutional Review Board (IRB)

FEDERAL REGULATIONS REQUIRING ESTABLISHMENT OF THE IRB.

Whenever a Principal Investigator/Project Director (PI/PD) affiliated with Eastern Kentucky University engages in a project that involves human subjects, EKU must ensure compliance with federal policies safeguarding human subjects. This applies to all university projects involving human subjects whether funded from internal or external sources.

Eastern Kentucky University and the federal government require that the proposed project be reviewed and approved by the IRB and remain subject to continuing review by the IRB. In particular, funds administered by a department or agency may not be expended for projects involving human subjects until reviewed and approved by the IRB. Moreover, failure to comply with this policy could result in the termination or suspension of the applicable project.

To be in compliance, EKU must establish the IRB to review proposed and ongoing research and provide the following:

1. A statement of principles governing EKU in the discharge of its responsibilities for protecting the rights and welfare of human subjects in projects conducted at or sponsored by the institution.
2. A list of IRB members identified by name, earned degrees, and representative capacity.
3. Written procedures which the IRB will follow:
   a. for conducting initial and continuing reviews of project activities.
   b. for reporting its findings and actions to the PI/PD and appropriate university officials.
   c. for ensuring prompt reporting to the IRB of proposed changes in project activity, and for ensuring that these changes not be initiated without IRB review and approval.
   d. for ensuring prompt reporting to the IRB, university officials, and the appropriate funding source of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB or any suspension or termination of IRB approval.

MEMBERSHIP OF THE IRB.

Federal Requirements Regarding Membership. The composition of the IRB is detailed in 45 CFR Part 46 as follows:

1. The IRB shall have at least five members, with varying backgrounds, to promote an adequate review of project activities.
2. The IRB shall be sufficiently qualified through the experience, expertise, and
diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
3. If the IRB regularly reviews projects that involve a vulnerable category of subjects, such as children, prisoners, pregnant women, handicapped, cognitively impaired persons, terminally ill patients, minorities, elderly persons, or economically or educationally disadvantaged persons, and even normal (i.e., healthy) volunteers such as students and employees or international subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
4. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
5. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
6. A simple majority of the members of the IRB shall constitute a quorum with the stipulation that at least one member whose primary concerns are in nonscientific areas must be present for the IRB to review proposed projects. For the project to be approved, it must receive the approval of a majority of those members present at the meeting.
7. No IRB may have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
8. The IRB may, in its discretion, invite individuals with expertise in special areas to assist in the review of issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

University Requirements Regarding Membership. In addition to the federal requirements for IRB membership, there are several university requirements as follows:
1. In accordance with the university committee structure, the IRB reports to and advises the Vice President for Academic Affairs and Research and to the Dean of the Graduate School on issues related to human subjects in research.
2. All members of the IRB are appointed by the President or his/her designee, as are two alternates.
3. The Chair shall be the Director of the Division of Grants and Contracts and shall be a non-voting member.
4. The Legal Counsel shall be the University Attorney and shall be a non-voting member.
5. Members’ terms are three years, staggered, so that the majority of the members are retained each year; members may serve no more than two terms in sequence.
6. Support services are provided by the Division of Grants and Contracts with all records being maintained in that office.
7. Minutes are copied to the Dean of the Graduate School, the appropriate PI/PD, and to the IRB.
DUTIES AND RESPONSIBILITIES OF THE IRB.

1. The IRB must review proposed projects involving human subjects prior to initiation of the research. If such activity is undertaken without the intention of involving human subjects, but the PI/PD later proposes to involve human subjects, the revised project must be reviewed and approved by the IRB before it proceeds.

2. The IRB has authority to approve, require modification of, or disapprove research or project activities.

3. The IRB shall require the PI/PD to provide documentation of informed consent (see Part II).

4. The IRB shall notify the PI/PD and the appropriate institution official(s), in writing, of its approval or disapproval of a proposed project, or of modifications required to secure IRB approval. If the IRB disapproves a project, it shall include in its written notification a statement of the reasons for its decision and give the PI/PD an opportunity to respond. Even in disapproval, the IRB will always work with the PI/PD to revise the project to allow for approval.

5. The IRB shall conduct continuing review of continuing projects covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. In addition, the IRB shall have authority to observe or have a third party observe the consent process and the project activity.

6. The IRB has authority to suspend or terminate approval of a project that is not being conducted in accordance with the requirements of the IRB, or that has been associated with unexpected serious harm to subjects, researchers, or a PI/PD. Any suspension or termination shall include a statement of the reasons for the action of the IRB and shall be reported promptly to the PI/PD, university officials, and the appropriate funding sources.

7. When appropriate, the IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
   a. Copies of all proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by the PI/PD and reports of injuries to subjects.
   b. Minutes of IRB meetings 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 project activity; and a written summary of the discussion of controverted issues and their resolution.
   c. Records of continuing review activities.
   d. Copies of all correspondence between the IRB and the PI/PD.
   e. 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 anticipated contributions to IRB deliberations.

Changes in IRB membership shall be reported as necessary.
PART II. Policies and Criteria
By Which Protocols Will Be Evaluated

POLICY ON TYPE OF REVIEW

The IRB will require that the PI/PD of any project involving human subjects submit to the IRB an appropriate request for review. If the project is submitted to the funding agency prior to submission to the IRB, the IRB staff will indicate on the appropriate page that the proposal is pending and/or furnish to the PI/PD a statement of the IRB status of the proposed project.

Projects involving human subjects will be in one of three categories for IRB review: exemption from review, expedited review, or full review.

Exemption from Review. For a project to be exempted from review, the PI/PD must file a Review Application and Protocol as well as an Exemption Request with the IRB.

1. Exemption from review will be granted by the Chair of the IRB, or the Chair designee, to projects falling within the categories described in 45 CFR Part 46.110 (see Appendix B) and/or amendments to the list, if any. The Chair or the Chair designee may require additional information to determine exemption eligibility. Exemption from review will not be granted for projects using vulnerable populations such as those described in the Policy on Selection of Subjects in Part II.

2. When the above review procedure is used, the IRB Board members shall be informed of protocols which have been approved under the procedure. Upon the request of the IRB, additional information will be made available.

3. Records of all exemption requests will be kept on file in the Division of Grants and Contracts for a minimum of three years.

Expedited Review. At the request of the PI/PD, the IRB will review, through an expedited procedure, projects involving no more than minimal risk to subjects. The IRB may also use the expedited review procedure to review minor changes in previously approved projects during the period for which the approval is authorized.

1. Expedited review will be conducted for projects having minimal risk and classification in one of the expedited review categories described in 45 CFR Part 46.110 (see Appendix B).

2. Expedited review is not allowed for projects where children are the subjects. Children are persons who have not attained the legal age of consent, which in Kentucky, is anyone under the age of 18. Some funding agencies may have stipulations regarding the age of children and the PI/PD must be in compliance with those stipulations. Eastern Kentucky University will comply with the requirements set forth in 45 CFR 46 Subpart D, which provides additional protection for children involved in projects.

3. One copy of the Expedited Review Application and Protocol will be submitted to the
IRB for review. The review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among the voting members of the IRB.

4. Approval will be given if the IRB member(s) and/or the Chair agree that the project meets the criteria for expedited review and for IRB approval.

5. The IRB member(s) conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the project. The reviewer(s) shall refer any protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other protocols to the full committee whenever full committee review is warranted.

6. When the expedited review procedure is used, the IRB Chair or member(s) conducting the review shall inform IRB members of protocols which have been approved under the procedure.

**Full IRB Review.** When not eligible for exemption or expedited review, each proposal will follow an approved format known as a human subjects protocol. This protocol includes the following sections: purpose, background, study methodology, risks and precautions, procedures to maintain confidentiality, consent form (see Part II), number and type of subjects and controls, any necessary special approvals, location of the study, source of funds, and the names of those responsible for supervision (if appropriate).

**POLICY ON RISK**

The PUPD bears the responsibility of assessing possible risks to human subjects involved in the project and of taking appropriate steps to minimize those risks wherever possible. Before it may approve projects, the IRB must determine that the following criteria are satisfied:

1. **Risks to subjects are minimized.** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the project 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. Risk is minimized by using procedures which: a) are consistent with sound research design; b) do not unnecessarily expose subjects to risk; and c) whenever appropriate, utilize procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable in relation to anticipated benefits,** if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the project (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the project).

**POLICY ON SELECTION OF SUBJECTS**

Federal regulations require that the IRB give special consideration to protecting the rights and welfare of particularly vulnerable subjects, such as children (anyone under age 18), prisoners, pregnant women, handicapped, cognitively impaired persons, terminally ill patients, minorities, elderly persons, economically or educationally disadvantaged persons, and normal volunteers such as students and employees or international subjects. Investigators need to take
additional special precautions when involving such special cases of subjects.

1. Equitable selection of subjects. In making this assessment the IRB will take into account the purposes of the project and the setting in which it will be conducted. Of particular importance is the recognition of special problems of projects involving vulnerable populations such as those listed above. The primary issue surrounding the participation of such specialized populations in projects is whether the subjects have real choice regarding their participation in the project, or whether their situation prohibits the exercise of free choice. A similar issue relates to the exclusion of specialized populations. Unless there is an overriding reason for exclusion, children should not be arbitrarily excluded from such research.

2. Pregnant Women. Any project in which women of childbearing potential are possible subjects may inadvertently include pregnant women. For information about additional protections of fetuses or pregnant women, consult Subpart B - Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in vitro Fertilization, cf 46 CFR Part 45 in Appendix B.

3. Prisoners. Because of their incarceration prisoners may be under constraints which could affect their ability to make truly voluntary and uncoerced decisions regarding participation in a project. For information concerning additional protections of prisoners, consult Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, of 46 CFR Part 45 in Appendix B.

4. Children or Minors. The special vulnerability of children makes consideration of involving them as subjects in projects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are addressed in Subpart D - Additional Protections for Children Involved as Subjects of Research, of 46 CFR Part 45 in Appendix B.

5. Students, Employees and Normal Persons as Subjects in Projects. Federal regulations do not provide explicit protections for students, employees, and normal (i.e., healthy) volunteers as subjects in projects. There are some special considerations for involving these groups in a project. Volunteers for whom no therapeutic benefit can result from participation in a project should be exposed to risks that are minimized to the greatest extent possible. Normal volunteers, including students and employees, should generally be recruited through announcements or advertisements rather than through individual solicitations. Personal solicitations increase the likelihood that participation will be the result of undue influence. PIs/PDs should also consider that students may be under age in which case they would fall into two special classes as normal (i.e., healthy) and underage subjects.

6. Students as Conductors of Projects. Students are often required to conduct projects as part of the course work for a class. When that project involves human subjects, the project may require IRB review. The concern here is not for the students in the class but for the subjects of the project, who may or may not themselves be students.

    If the faculty member teaching the course and supervising those students conducting the project intends to, or may possibly make use of the student findings in her/his own work, then the student project should be submitted for IRB review and
approval. *If, however, these activities are intended solely for the practice and experience of the student investigators, IRB approval will not be necessary.* Faculty are cautioned to have student investigators follow good research practices in obtaining informed consent from subjects in the project and maintaining confidentiality. The University is potentially liable for any project conducted under its auspices.

7. International Subjects in Projects. Human subjects projects conducted in foreign countries by American PIs/PDs require compliance with federal regulations for protection of human subjects in all material respects, just as they would if the project were conducted wholly within the United States.

Further information about the above classes of subjects and other specialized populations may be found in *Protecting Human Research Subjects: Institutional Review Board Guidebook*, by the Office of Protection From Research Risks (OPRR). This publication is available through the Division of Grants and Contracts.

**POLICY ON INFORMED CONSENT**

The IRB is responsible for safeguarding the consent process in addition to the entire project relationship to ensure open and free communication between the PI/PD and the prospective subject. The IRB therefore expects the PI/PD to follow the process of *informed consent*, that is, to explain to human subjects involved in a project: 1) the nature and aim of the project; 2) the subject’s role in the project; and 3) the possible risks to the subject’s physical, psychological, or emotional well-being. This explanation is necessary as individuals invited to participate in the project must have sufficient understanding of what is being asked of them before they can fairly assess the cost to themselves. No informed consent, whether oral or written, may include any exculpatory language through which the subject waives or appears to waive any legal rights, or releases or appears to release the PI/PD, the sponsor, the institution or its agents from liability for negligence.

1. **General Requirements for Informed Consent.** Prospective human subjects shall be given the following information in language understandable to the subject:
   a. 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 reasonably foreseeable risks or discomforts to the subject.
   c. a description of any benefits to the subject, if any, which may reasonably be expected from the research.
   d. a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject.
   e. a statement describing the extent to which confidentiality of records identifying the subject will be maintained.
   f. a statement describing the extent of confidentiality of subject records.
   g. an explanation of possible compensation and medical treatment in the event of injury from research involving more than minimal risk.
   h. an explanation of contact persons regarding the research, subjects’ rights, and potential research-related injury.
   i. a statement that participation is voluntary and the subject may discontinue
participation at any time, and that refusal to participate or withdraw from the project will involve no penalty or loss of benefits to which the subject is otherwise entitled.

2. The Consent Form. The PI/PD may use the consent form provided by the IRB (see Appendix A) or may devise a consent form that contains the same basic elements. If the PI/PD devises a different consent form, it must be written in language easily understandable to the subjects. The possibility of illiteracy should be considered as should the need for communication in a foreign language. The subject must be given adequate opportunity to read the form before signing it.

The written consent form shall state that the subject has agreed to participate in the project. The written consent form may either provide the subject with the basic information required by the federal government as outlined above, or it may simply state that this information has been presented orally. If this information is all presented orally, the investigator must have a witness to the oral presentation. (See the standard IRB consent form in Appendix A.)

When children or minors are involved in projects, regulations require the assent of the child or minor along with the permission of the parent or guardian (see Appendix C). PIs/PDs should be aware that many college students are under age, and therefore need to obtain, in addition to the subject's consent, the permission of a parent or guardian to the subject’s participation in the project. The subject’s parent or guardian must be given adequate opportunity to read the form before signing it.

3. Waiving of Informed Consent. The IRB may approve a consent procedure which does not include or which alters some or all of the elements of informed consent set forth in this section provided the IRB finds and documents that:
   a. the research involves no more than minimal risk to the subjects;
   b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
   c. the research could not practically be carried out without the waiver or alteration.
   d. when appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may also waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   a. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case each subject will be asked whether he or she wants documentation linking him or her with the research, and the subject's wishes will prevail.
   b. that the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context.

For other exceptional circumstances under which the IRB may waive or alter the requirement to obtain and document informed consent, see Sections 46.116 and 46.117 of 45 CFR Part 46.

POLICY ON PRIVACY

The IRB must ensure that when appropriate, there are adequate provisions to protect
the privacy of subjects and to maintain the confidentiality of data. This is required regardless of the population from which the subjects for the project are selected.
PART III: Preparing and Submitting A Proposal

TIMING OF PROTOCOL SUBMISSION

Projects involving human subjects (as defined in Part II), must be approved by the IRB whether funding is requested from internal university-funded grants or from external sources. Because timing of protocol submissions varies somewhat depending on the source of funding, PIs/PDs must indicate whether a protocol is for internal or external funding. Generally, PIs/PDs can expect a review response within one to three weeks from the date of a protocol submission except for protocols submitted during finals week or during summer when the IRB does not meet.

Some federal departments or agencies require IRB approval prior to submission of grant proposals while others do not. It is the responsibility of the PI/PD to follow proposal guidelines carefully or to contact the Chair of the IRB who is also the Director of the Division of Grants and Contracts for clarification of timing of IRB approval.

ELEMENTS OF THE PROTOCOL

The protocol is the formal design or plan of an experiment or project; specifically it is the plan submitted to the IRB for review and to an agency for funding. The following information must be provided in the protocol before the IRB will begin the review process (NOTE: Incomplete protocols will not be reviewed by the IRB and will be returned to the researcher with a memo requesting additional information):

1. **Completed forms** required for initial submission (see Appendix A) with all necessary signatures.

2. A copy of the letter to be given or read to potential participants that explains the purpose of the project, the participant’s role in the project, the expected duration of the project, and any potential adverse effects that the participant might experience.

3. A copy of the informed consent form to be signed by participants. PIs/PDs may use the informed consent form in Appendix A or may devise their own form. The form must conform in all respects to the general requirements of informed consent described in these guidelines.

4. A copy of all instruments (i.e., surveys or questionnaires) to be administered to participants. This includes both widely accepted copyrighted instruments as well as original instruments developed by the protocol author. If the project is in its formative stage, the protocol should include a working draft of each instrument. Final versions of all instruments must be submitted to the IRB as soon as possible.

5. Projects involving vulnerable subjects, previously defined as children, prisoners, pregnant women, handicapped, cognitively impaired persons, terminally ill patients, minorities, elderly persons, economically or educationally disadvantaged persons and normal volunteers such as students,
employees, or international subjects may require additional information and procedures. (See Subparts B, C, and D of 45 CFR Part 46 in Appendix B.) Protocols involving these subjects must be initiated well in advance of proposal deadlines, especially if IRB approval must accompany the proposal.

PROTOCOL REVIEW PROCESS
Each complete protocol will be reviewed within the previously identified time frame as follows:

1. Complete protocols will be mailed to individual IRB members after they are received by the chair of the IRB.
2. The IRB will meet to discuss protocols. The chair of the IRB will notify the PI/PD in writing of the IRB vote on the protocol. If the protocol cannot be approved in its present form, the PI/PD will be advised of the specific changes required to secure approval of the protocol.
3. Revisions of any kind, whether recommended by the IRB or initiated by the PI/PD, must be reviewed by the IRB. Once the revised protocol is received by the chair of the IRB, the protocol will be returned to the IRB members for review. Final approval will be granted if a majority of IRB members approve the revised protocol.

FOLLOW-UP REPORTS REQUIRED BY THE IRB
The IRB is required to conduct continuing review of continuing projects covered by the policy in these guidelines. PIs/PDs of projects with durations of more than one year should submit a completed Form C (Appendix A) to the IRB annually. If any revisions are made to a project or if any unforeseen risks arise during an investigation, the PI/PD must submit Form C to the IRB, fully explaining all changes or unexpected risks. Upon completion or termination of a project, the PI/PD must also submit Form C.

Failure of the IRB to enforce submission of follow-up reports could seriously compromise future attempts by EKU faculty to secure external funding. Therefore, any researcher who fails to submit follow-up reports may not submit new protocols for review until all follow-up reports for previous grants are completed.
APPENDIX A
Eastern Kentucky University
Institutional Review Board
Checklist For Project Protocol Review

1. Projects Exempt From Review

Projects defined in 45 CFR Part 46.101 are exempt from review. A full description of these categories can be found in Appendix B. General categories of projects exempt from review include:

- normal educational practices such as educational instructional strategies, instructional techniques, curricula, or classroom management techniques.
- educational tests, survey procedures, interview procedures or observation of public behavior.
- collection or study of existing data.
- demonstration projects.
- taste and food quality evaluation.

Projects which include subjects from vulnerable populations as previously described are not eligible for exemption from review.

The following items need to be submitted for exemption from the review process:

____ Application For Project Protocol Review (DGC.PR1.1998)
____ Human Subjects Protocol (DGC.PR2.1998)
____ Application For Exemption From Review (DGC.PR3.1998)
____ Survey Instrument
____ Project Explanation For Subject (if necessary)
____ Informed Consent Form
____ Approval For Preexisting Specimen Release (if necessary)
____ Advisor/Course Instructor Signature (on DGC.PR1.1998, if required)

2. Expedited Project Review

Expedited review is allowed on projects which involve no more than minimal risk to human subjects and which involve only procedures listed in the categories defined in 45 CFR Part 46.110. Expedited review may not be appropriate for vulnerable populations. A full description of the newly revised categories published in the Federal Register, November 9, 1998, can be found in Appendix B. The general categories of expedited review include
- some clinical studies of drugs and medical devices
- collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- prospective collection of biological specimens by noninvasive means
- collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice
- collection of data, documents, records, or specimens solely for nonresearch purposes
- collection of data from voice, video, digital, or image recordings
- collection of data on individual or group characteristics or behavior
- continuing review of previously approved research
- continuing review of research not conducted under an investigational new drug or device application

The following items need to be submitted for an expedited review process:

- Application For Project Protocol Review (DGC.PR1.1998)
- Application For Expedited Review (DGC.PR4.1998)
- Survey Instrument (if necessary)
- Project Explanation For Subject
- Informed Consent Form
- Assent/Parental Consent Form (DGC.PR5.1998, if necessary)
- Approval For Preexisting Specimen Release (if necessary)
- Advisor/Course Instructor Signature (on DGC.PR1.1998, if required)

3. Projects Requiring Full Review

Full HSRC review is required for projects that are not eligible for exemption from review or expedited review. It is also required for projects which use vulnerable populations and children under age 18.

The following items need to be submitted for the full review process:

- Application For Project Protocol Review (DGC.PR1.1998)
- Survey Instrument (if necessary)
- Project Explanation For Subject
4. Projects Involving Children: Assent and Parental Consent

Projects using children as subjects must have an assent form in addition to the appropriate forms listed under Projects Requiring Full Review. Assent means the potential subjects' affirmative agreement to participate in the project. Mere failure to object should not, in the absence of affirmative agreement, be construed as assent. The following list indicates how assent of children should be handled.

- Children under 7 years of age are assumed to be incapable of giving assent.
- Children from 7 to 18 years of age are assumed capable of giving assent. However, assent of the child may be waived if the child is limited by maturity or psychological state.
- The State of Kentucky considers age 18 as the legal age for entering into a contract. Subjects who are 18 may sign the Informed Consent Form as an adult. Some Federal agencies consider children to be anyone under the age of 21, so the PI/PD must be certain to meet specific agency requirements.

The following list indicates the situations requiring parental consent:

- Projects that involve no more than minimal risk or that may be of direct benefit to the child require the consent of only one parent.
- Projects that involve greater than minimal risk without direct individual benefits require the consent of both parents unless there is only one reasonably available parent. Guardian consent should be substituted under appropriate legal constraints.
- Parental or guardian consent may be waived if the project protocol does not require such consent to protect the subjects (i.e., neglected or abused children), provided an appropriate protection mechanism is substituted.
- Special provisions must be made for children who are wards of the state or any other agency, institution, or entity to be included in projects involving greater than minimal risk without direct individual benefit.
Eastern Kentucky University
Institutional Review Board
Application for Project Protocol Review

Please type or clearly print the information requested. Date

1. PI/PD Name Office Phone
2. Department or Administrative Unit
3. Position and/or Academic Rank
4. Funding Source (check appropriate blank) External Internal
5. Name of Funding Source
6. Grant Period (indicate month and year) Beginning Ending

7. Review Requested (check one) Full Expedited Exemption from Review
   If you have requested expedited review, please also complete the Request for Expedited Review (DGC.PR.2). If you have requested exemption from review, please also complete the Request for Exemption from Review (DGC.PR.3).

8. Describe the human subjects in this project: Age Range Gender
   Social, Economic, or Educational Group
   Number of Subjects in this Study

9. What is the source of the subjects?

10. Location where project will be conducted

11. Name of administrator from project site granting permission for the project:

12. How will data be recorded to ensure anonymity and confidentiality of the subjects?
Review Application Check List: The following items have been included in my application:

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Narrative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consent Form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site Approval</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey Instrument</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Abstract. Please attach an abstract (250 words maximum) that summarizes 1) the purpose of the project, 2) all procedures to be implemented, 3) the effects these procedures may have on participants, and 4) expected results.

Use additional pages, if necessary, to complete the items below.

1. Purpose. List the objectives of your project.

2. Background. Describe past or other research findings that lead to the formulation of the project.

3. Project Methodology. Describe the research procedures that will be used in this project.

4. Risks and Precautions. Describe any potential risks, i.e., physical, psychological, social, or legal, and assess their likelihood or seriousness. Where appropriate, describe alternate treatments or procedures that might be substituted.

5. Procedures to Maintain Confidentiality. Describe the steps that will be taken to maintain the confidentiality of the project subjects and any identifiable private information that may be collected.
6. **Subjects and Controls.** Describe the characteristics of the subject population such as their anticipated number, age range, gender, ethnic background and health status. Describe the use of control and experimental groups and whether the subjects will be randomly selected. If any vulnerable populations are involved in the project, include a statement indicating the reasons for using these groups.

7. **Informed Consent.** Indicate the steps that will be taken to maintain the general requirements for informed consent, and how this information will be presented to the subjects.

8. **Privacy.** Indicate the steps that will be taken to maintain confidentiality and privacy of the subjects.

9. **Special Approvals.** Indicate whether special approvals are required from administrators at the project location and how those have been obtained.
Eastern Kentucky University
Institutional Review Board
Application for Exemption from Review

Project Name__________________________________________________________

PI(s) / PD(s)_________________________________ Soc. Sec. Number________

Department_________________________________ Phone________________

PI(s) / PD(s) Signature________________________________________________

Faculty Advisor / Instructor For Student Research________________________

Faculty Advisor / Instructor Signature____________________________________

Location of Project____________________________________________________

Source of Funds________________________________________________________

Mark the category or categories below which describe your research.

1. Projects 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.

2. Projects 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.
   Attach questionnaire(s).

3. Project involving the use of educational tests (cognitive, diagnostic, aptitude,
   achievement), survey procedures, interview procedures, or observation of public
   behavior that is not exempt under category (2), 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. Attach a copy of any questionnaire to be used.

4. Project 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. Attach specimens release form if applicable. (Specimens must be preexisting.)

5. 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.

6. 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 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.
Mark the category or categories below which describe your research.

1. Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (i.e., x-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus, provided
the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects or subject's responses to questioning.

7. Moderate exercise by health volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to the subjects. Research involving sensitive matters such as sexual or political behavior may require full review. Expedited review is not appropriate if the subjects' responses, if known outside the research, could place them at risk of civil or criminal liability or damage their financial standing or employability.

10. Research on drugs or devices for which an investigational new drug exemption or investigational devise exemption is not required. (Note: Drugs or devices must be commercially available and the protocol may not include randomization of participants. The Board may request full review if, in their opinion, the participant will be at greater than minimal risk.)

This space for reviewer comments:

Reviewer Signature

Date
NOTE: The following sample is provided as an outline from which a consent form can be developed. It may be used as shown, but because many projects will not require answers to all questions, PI(s)/PD(s) may develop an alternate form to obtain the informed consent of project subjects. If a new form is developed, remember to use terminology the intended subject can easily comprehend.

You are invited to participate in a research project entitled (state project name). We hope to learn (state what the project is designed to discover or establish). You were selected as a possible participant because (state why selected).

If you decide to participate, we (state names of investigators) will be (describe procedures to be followed). The purpose of these procedures is to (describe purposes, how long the procedures will take, and their frequency). The procedures may (describe any discomfort and inconveniences which might reasonably be expected and identify any procedures which might be considered experimental). The benefit to you (describe parts of the project that might be considered beneficial to the subject or others). Any information that is obtained in connection with this project which can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. If you give us your permission by signing this form, we plan to disclose (state the persons or agencies to whom the information will be furnished and the nature of the information to be furnished).

If the subject will receive compensation (describe the amount or nature). If there is a possibility of additional costs to the subject because of participating, (describe the amount or nature). If physical injury is a possibility from physical activity or other stimuli, (describe and include a statement where medical treatment might be available if needed).
Your decision whether or not to participate will not prejudice you future relations with Eastern Kentucky University. If you decide now to participate and later change your mind, you are free to discontinue participation without prejudice or penalty.

If you have questions at any time (give the name of an individual, a phone number and an address where that individual can be contacted).

You are making a decision whether or not to voluntarily participate in this project. Your signature indicates that you have read and understood the information provided above and that you have decided to participate.

__________________________  ____________________________
Date                                                                     Signature

__________________________  ____________________________
Pl/PD Signature             Relationship to the Subject
(This line should not appear on forms that will be given to subjects consenting for themselves.)
Eastern Kentucky University
Institutional Review Board
Assent/Parental Consent Form

You are making a decision whether or not to have your child participate in this study. Your signature indicates that you have decided to allow your child to participate, that you have read (or been read) the information provided above and that you have received a copy of this consent form.

Signature of Parent or Person Responsible

Date

Signature of PI/PD

Date

Signature of Witness

Date

Assent of Child

(Name of Child) has agreed to participate in research (Title of Project)

Signature of Parent or Person Responsible

Date

Signature of Child

Date

Waiver of Assent

The assent of (Name of Child) was waived because of (check those that apply) Maturity. Psychological state of the child.

Signature of Parent or Person Responsible

Date
University 1998-1999 budget. While the committee failed to meet with President Kustra, it did meet with Mr. James Clark, Vice President for Governmental Relations and Planning, to discuss the budget process among various levels at the institution. At the request of the Senate Chair the committee examined what the steps are for formulating the annual budget at Eastern and how the faculty can provide added input into the budget process. A preliminary report was submitted to the Senate Chair stating that it was difficult to see any clear path for the flow of information into the budget process by faculty through a chain of command.

Committee on Faculty Rights and Responsibilities: Senator Rink

Senator Rink reported that the committee considered a number of issues during the year which included sexual orientation, equal benefits for domestic partners, creation of a faculty workload model, tuition waivers and/or reduction of tuition at EKU for family members, and appeals procedures at Eastern. He offered several motions.

Motion 1

Senator Rink moved "that the Chair of the Faculty Senate appoint an ad hoc committee of five members to study, as well as make recommendations on, the issue of equal benefits for all domestic partnerships for faculty and staff at Eastern Kentucky University, and that this ad hoc committee return with a report to the Faculty Senate by late Fall of 1999." Senator Dunston seconded the motion. Senator Murray moved to postpone discussion of the motion until the Senate addresses the earlier issue (motion by Senator Flanagan) which was postponed until the September Senate meeting. Senator Banks seconded the motion, which was approved.

Motion 2

Senator Rink moved "that the Chair of the Faculty Senate appoint an ad hoc committee of five members to study as well as make recommendations on the issue of tuition waivers and/or reduction of tuition for dependents of faculty at Eastern Kentucky University, and that this ad hoc committee return with a report to the Faculty Senate by late Fall of 1999." Senator Steinbach seconded the motion. Senator Haycock wondered what the definition of dependent was. Senator Rink responded that the committee will define terms. Senator raised a question as to how this motion will impact the recently approved Board of Regents dependent tuition policy. Senator Goodwin moved to postpone the motion. Senator Merita Thompson seconded the motion, which was defeated by a standing vote of 21 to 22. Senator Taylor called the question and the original motion was approved.

Reports from Ad Hoc Committees

Ad Hoc Committee on Teaching by Contract Staff and Classified Personnel: Senator Harley

Senator Harley moved the following motion:

- "That the University change/amend its policy on teaching by contract staff and classified personnel as listed on page 104 of the Faculty/Staff Handbook (1998-2000)
- From: 2. Receive approval of their immediate supervisor and the appropriate department chair, college dean, and vice president.
- To: 2. Receive approval of their immediate supervisor (if teaching is done during official University work hours) and the appropriate department chair, college dean, and vice president.
- Delete all of number 3.
- From: 4. Teach only during those time periods that do not conflict with their normal work schedules or assigned duties if receiving supplemental pay. For example, those persons whose normal work schedule is from 8:00 a.m. to 4:30 p.m. could not teach and receive supplemental pay until after 4:30 p.m. In cases where no supplemental pay is given, the immediate supervisor may approve teaching during normal working hours.
- Delete all of number 4.
- To: 3. Teach no more than one class (3 hrs.) during the normal working hours during each semester (fall, spring, intercession, summer).

Senator Flanagan seconded the motion, which was approved.

Report from the Council on Academic Affairs: Senator Davis

Senator Davis moved approval of proposals from the Council on Academic Affairs. The Senate approved the following proposals:

- New degree program from the Department of Medical Services Technology: Bachelor of
Science in Medical Practice Management;
- New options (Insurance and Financial Planning) in the Bachelor of Science in Insurance and Risk Management degree program;
- New degree program from the Department of Mathematics, Statistics, and Computer Sciences: Master of Science in Applied Computing (Business Computing, Industrial Computing, and Software Engineering);
- From the Division of Grants and Contracts: revisions to the Policy and Procedure Guidelines for Protecting Human Subjects in Research.

Adjournment

Senator Davis moved that the Senate adjourn. It adjourned at 4:22 p.m.

ORGANIZATIONAL MEETING OF THE 1999-2000 FACULTY SENATE
May 3, 1999

After a ten-minute recess to allow the new senators to be seated, Senate Chair Janssen called to order the organizational meeting of the 1999-2000 Faculty Senate. The new members of the Senate are: Julie Brown, Medical Services Technology; Gary Corder, Law Enforcement; A. G. Dunston, History; Virginia Falkenberg, Psychology; Ordelie Hill, English; Milton Hodge, Military Science; Dawn Jackson, Health Information; Alice Jones, Geography and Planning; Nancy Mckenney, Libraries; Phyllis Murray, Health Education; Jane Rainey, Government; Pam Schloemann, Baccalaureate Nursing; Guenter Schuster, Biological Sciences; Karen Spears, Art; Jessica Stephens, English; John Taylor, Mass Communications; and Margaret Willingham, Libraries.

The following members of the Senate were absent:

<table>
<thead>
<tr>
<th>M. LeVan</th>
<th>D. Smith</th>
<th>C. Lewis</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. Stephens</td>
<td>N. MacKinnon*</td>
<td>R. Thompson</td>
</tr>
<tr>
<td>M. Patrick*</td>
<td>L. Tyson</td>
<td>T. Powers*</td>
</tr>
</tbody>
</table>

*Indicates prior notification to the Senate Secretary

Remarks from the President: Senator Kustra

President Kustra welcomed the new Senators. He told them that they would be involved in many important activities over the next year and that he appreciated their time and dedication to the institution.

Remarks from the Executive Committee: Senator Janssen

Senator Janssen welcomed the new members and called their attention to the dates for the 1999-2000 Senate meetings to be held in the South Room of the Keen Johnson Building.

New Business

Election of the Senate Chair

Three person were nominated for the position of Faculty Senate Chair at the April meeting of the Senate. Those nominated were: Senators Harley, Miller, and Murray. The results of the first ballot were: Senator Murray 19 votes, Senator Miller 18 votes, and Senator Harley 15 votes. In the next ballot the results were: Senator Murray 28 votes and Senator Miller 23 votes. Thus, Senator Murray was elected Faculty Senate Chair for the 1999-2000 academic year.

Election of the Senate Secretary

Chair Janssen announced that Mr. Charles Hay will be relinquishing his position as Secretary to the Faculty Senate. Senator Flanagan nominated Charles Hay to serve as Faculty Senate Secretary for the 2000 calendar year. Senator Johnson seconded the motion. Mr. Hay was elected with the stipulation that his successor will be selected as soon as possible and assume the position as Secretary to the Faculty Senate on January 1, 2000.

Election of Members to Standing Committees

Executive Committee (1 opening)