**Frequently Asked Questions**

**What is the Kentucky Wesleyan College IRB?**

The Institutional Review Board (IRB) is a Kentucky Wesleyan College (KWC) committee tasked with the supervision of all research that involves human subjects.  The IRB requires that all research involving human subjects conducted by faculty, students or staff affiliated with KWC be reviewed and approved by the IRB prior to data collection.

The main emphasis of the IRB is to determine whether the risk to the participants is minimized and is reasonable when weighed against the benefits of the project for its participants. In addition, the IRB evaluates whether the selection of participants is equitable and particularly vulnerable populations are safeguarded with respect to their rights and safety.

Investigators must be familiar with and behave according to the spirit and letter of federal and professional guidelines pertaining to human research as summarized in Title 45, Part 46, of the Code of Federal Regulations (<http://ohsr.od.nih.gov/guidelines/45cfr46.html>) and in the Belmont Report (<http://ohsr.od.nih.gov/guidelines/belmont.html>).

**Why does KWC have an IRB Review Process?**Federal regulations that stipulate “each institution or agency which conducts or which proposes to conduct or authorize human research shall establish a human research review committee…No human research shall be conducted or authorized by such institution or agency unless…such committee has reviewed and approved the proposed human research project…”  KWC faculty, students, and staff are subject to these regulations.

**What is the definition of research?**The Office of Human Subjects Research (OHRP) defines research as "… a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge". (<http://ohsr.od.nih.gov/guidelines/45cfr46.html#l46102>). If the intent does not fall within the above classification, IRB review and approval is not required.

**What is the definition of a Human Subject?**OHRP defies a human subject as "… any living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information." Even mundane research conducted with paper-and-pencil questionnaires qualifies as human experimentation.

**What are the expectations of the IRB when I submit my proposal?**
The main expectation is that the proposal be presented in a thorough and professional manner. Reviewers focus on the areas of purpose, methodology, risks/benefits, handling of informed consent, so as to ensure that your research plan provides adequate protection for the rights and welfare of the human subjects involved.

For student researchers, faculty must sign off that the study was carefully reviewed and meets the faculty member's standards. The researchers must address all questions in the appropriate form. All potential subject protections must be anticipated and described.

Few proposals are approved on the first submission. It is more likely for a proposal to be approved with modifications. The most common reason for non-approval is lack of appropriate human subjects' protections: not enough is being done to protect subject identity or to protect the subject from physical or psychological harm.

**How can I best maintain confidentiality for study participants?**
Anonymity, or the inability to determine the identity of a subject participant, is always a best practice in protecting the confidentiality of participants. In some studies, however, anonymity is not possible. This is particularly noted in studies where the researcher wants to follow-up with a participant at a later time or connects two sources of data to the same participant.  In this case, the IRB recommends maintaining a separate and secured code list of participant names and code numbers. Once the data have been entered into a database, the code lists are shredded.

**Research Using Web-Based Surveys**
Web-based surveys require careful scrutiny in order to protect the anonymity or confidentiality of subjects.  These surveys need to have a provision for excluding research subjects who are under the age of 18.  The researcher must provide specific, detailed information about the type of information that is collected AND the underlying technology being used to collect the data.  For example, does the program/software/survey technology collect any electronic identifying information?  Does the survey involve collecting any information that is regarded as private or could be harmful to the participant if revealed?  How does the program/software/survey technology provide a means for preventing multiple survey completions by subjects?  How does the program/software/survey technology prevent "hacking" into the data base?

**How is my proposal reviewed?**
In the policies and procedures, you will see a detailed check list that indicates the levels of review for proposals. There are three basic levels: full review, expedited review, and exempt from review. Full review is required for studies of vulnerable populations or those that exhibit greater than minimal risk. Expedited review is required for minimal risk studies. Exempt from review is a category basically of anonymous surveys and program reviews. The level of review is determined by the researcher and affirmed by the IRB committee.

**In the past, the research projects I assigned to my students did not require IRB review.  Is that still the case?**Students’ research projects may be approved as “exempt” from IRB review, but they are no longer excused from participating in the review process.  The chair of the IRB, or his/her designee, can determine if the project is qualifies for exemption.  In order to make this determination, the student must submit a Human Research Review Request Form along with a brief summary of the research.

**Why isn’t student research automatically exempt?**Whether the researcher is a student, faculty or staff member, their research may be exempt if it falls into one of the proper exemption categories (<http://ohsr.od.nih.gov/guidelines/45cfr46.html#l46110>).  These are usually research projects conducted solely within the confines of the classroom and overseen by a faculty member.  When a student’s project cannot be exempted by the IRB chair, this is usually because it involves studies of a potentially sensitive nature or includes human subjects from a protected population, such as prisoners or parolees, minors, those who are socioeconomically, educationally or linguistically impaired, the elderly, pregnant women, among others.  These types of projects cannot be automatically exempted simply because they are student projects.  Since they are being done as an assignment by a KWC employee, the College is ultimately responsible for the proper conduct of the research.

**How do I know if the research I am conducting in a class does not need to be reviewed?**
As indicated in the IRB policies and procedures, research conducted as part of a class does not require IRB review if it is a normal part of the students course work, has a primary goal of developing research skills, is closely supervised by the faculty member, and is not anticipated to result in public dissemination. Please contact the IRB chair if you are not sure if your study fits in this category.

**How does IRB approval benefit me?**Having your research protocol approved by the IRB tells your research participants that you have taken the appropriate steps to assure their protection.  In the event this is called into question, you will have the College’s protection because you have followed the appropriate institutional procedures.  IRB approval also makes it possible for the results of your research to be published in professional journals, many of which have set standards for treatment of human research subjects in accordance with federal guidelines.

The review process also offers our students with an excellent educational opportunity.  Students should not perceive the process to be an institutional obstacle in their education, but rather be brought to understand that it is part of the normal and expected process.

**How much time does the approval process take?**The average review process takes between 2-3 weeks, although it will vary depending on when the proposal is submitted.  High volume times such as the beginning and end of the semester may result in slightly longer review periods.  In addition, the faculty review will take additional time if your protocol is submitted during a holiday break or the summer semesters.  If the IRB requests modifications, there will be a subsequent reevaluation of the protocol, which can take additional time.  In submitting your protocol, you should plan to allow for sufficient lead time before the actual research must begin.

In a course where all students are expected to conduct different research projects, the instructor is encouraged to batch mail his/her students’ proposals.  This will expedite the process and ensure that all students conform to the timelines set by the instructor.

What can I (or my student) do to get a protocol approved quickly?

1. Tailor your protocol to address only those issues of concern to the IRB
2. Do not include a full literature review
3. Make sure to include the appropriate attachments
4. Cover in detail all issues relating to participant confidentiality and informed consent.
5. If the protocol includes a letter of consent, make sure the contact information for the IRB Chair is included.  The following phrase should be used on all consent letters or, when no letter used, either the cover letter or survey (for anonymous survey):

**What do I need to consider if I am going to compensate the study participants with money or gifts?**
The researchers must be aware that incentives are taxable and must be reported to the KWC business office.  This process will require that participants fill out a specific form (1099) so the business office can process the payment and withhold the appropriate tax.  Researchers must present in the research proposal a provision for protecting the identity of subjects by separating all business office forms, payments and budget numbers from the subject data.  It is critical to ensure that the subjects' identity and research findings are not identifiable through the study budget or business office forms.

*For questions about your rights as a research subject, you may contact the Chair of the Kentucky Wesleyan College IRB, Roger Gardner at (270) 852-3223*