I. PURPOSE OF THE POLICY
This policy's purpose is to protect human subjects of original research conducted either at Kalamazoo College or by an employee or student of Kalamazoo College. It is intended to assure that subjects of research are aware of their rights and protections. Moreover, the College is required to assure the federal government that such safeguards are being provided and enforced. These safeguards are derived from ethical principles articulated in the Belmont Report issued by the national Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. Kalamazoo College follows the ethical principles articulated by the Belmont Report which are respect for persons, beneficence, and justice. Human subjects should enter into research voluntarily: and with adequate information. Possible risks to human subjects should be weighted against possible benefits and possible improvement of knowledge. Selection of human subjects should ensure that no group of participants is either consistently selected or deprived of the opportunity to participate. The IRB also recognizes that research with human subjects is a privilege - not a right, and that researchers must respect the dignity and integrity of study participants. The Institutional Review Board (IRB) is the body charged with reviewing, prior to its commencement, all research involving human subjects conducted under the auspices of Kalamazoo College. The procedures for review described below adhere to the regulations of the Department of Health and Human services (45 CFR 46, as amended and published in the Federal Register on June 18, 1991). The College has adopted sections from the policies of The College of Wooster, Middlebury College, and Bryn Mawr College.

II. WHO MUST COMPLETE AN APPLICATION FOR IRB REVIEW OF RESEARCH WITH HUMAN SUBJECTS?
Anyone who engages in scholarly research involving human subjects, either on- or off- campus. This includes:
- Kalamazoo College faculty and staff;
- Kalamazoo College students who conduct independent research and Senior Individualized Projects;
- Researchers not affiliated with Kalamazoo College conducting primary research with subjects on-campus; and
- Anyone analyzing unpublished data collected at Kalamazoo College.

Instructors assigning student research as part of a course need not submit a proposal, unless the instructor chooses to invite committee review. Nonetheless, each faculty member engaging in such an instructional activity is expected to maintain professional standards to protect any human subject in accordance with his or her field, and to ensure compliance with this policy. For Independent Study research, see Section VII.

*Visitors to the campus and off-campus scholars may engage in research involving human subjects on campus only with the permission of the Dean of Students Office. Once the Dean of Students Office has agreed to support the project, please file an application with the Kalamazoo College IRB. If you already have IRB approval from another institution for the project, in most cases, documentation of that approval will be sufficient to get Kalamazoo College IRB approval.
Human subject research is research involving data from or about living human beings. Any discipline may involve human subject research.

III. DEFINITIONS

area reviewer: member of IRB that reviews Applications for IRB Review of Research with Human Subjects forms for their Department or close academic area. The area reviewer will determine whether the application is “exempt” from review or requires IRB review. If the application requires IRB review, the application will be forwarded to the chair of IRB who will then assign a member of IRB to review the application.

data: facts, figures, and information. For the purpose of this policy, the term "data" is considered to be material from primary sources analyzed as part of scholarly efforts.

deception: intentionally misleading or providing untruthful information, any concealment, withholding information from participant, trickery, or deceit.

IRB: Institutional Review Board.

human subject: any specific living person, or information about a living person, who is the subject (participant) or object of study for the purpose of expanding our knowledge or understanding.

minimal risk: Federal guidelines state, "minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

original research: any activity conducted for the purpose of expanding knowledge or understanding, including the collection and analysis of data from questionnaires, observation, manipulation, sampling, experimentation, interview procedures, etc. Research using human subjects, even if it is simply verifying existing hypotheses, theses, theories, or ideas, is considered original research. This includes pilot projects and feasibility studies. Works dealing entirely with properly attributed secondary sources are not considered original research for the purposes of this policy. Activities where human subjects perform exclusively for instructional purposes* are not original research (i.e., are not subject to these reviews). Data gathering for the purposes of fundraising by the external affairs offices; market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; statistical data collected for the management of institutional affairs; and research with alumni, students, or parents regarding college activities and policies are excluded from the category of original research under the purview of this committee.

principal investigator: the primary person conducting the research. The principal investigator (P.I.) can be a professional or a student.

review: a process of oversight resulting in an acknowledgment of the status ("approved,"
"pending required amendments," or "denied") of a project under the guidelines of this policy.

**risk:** potential for physical, psychological, social, or financial harm.

**unreasonable harm:** any physical, psychological, social, or financial damage or injury, which might have been avoided without sacrificing the goals of the activity, as well as any damage or injury whatsoever whose extent can not be justified by the contribution of the research to the expansion of human understanding.

*Any publication issuing from the research precludes this exemption. All research with human subjects that is potentially publishable requires IRB review.*

**IV. WHO ARE THE MEMBERS OF THE IRB AT KALAMAZOO COLLEGE?**

The IRB consists of at least five faculty members appointed by the Provost; at least one member of the community unaffiliated with the College, also appointed by the Provost; and, serving ex officio, the Director of Faculty Grants and Institutional Research. Information about the current members of IRB can be found on the Kalamazoo College IRB webpage (reason.kzoo.edu/irb/).
V. GENERAL PRINCIPLES
All researchers conducting original research are responsible for protecting their subjects from the risk of unreasonable harm.

The principal investigator has initial responsibility for determining whether such a risk exists. A faculty member is responsible for supervising research undertaken by students in the context of courses or departmental or program curriculum.

If there is any doubt about risks, the principal investigator should contact the area reviewer for the IRB or the faculty grants associate.

The principal investigator should refer to and follow the guidelines of the relevant professional organizations and, where appropriate, those of governmental funding and regulatory agencies. Faculty members supervising student research have a responsibility for introducing the students to the Kalamazoo College guidelines (See Section VII).

At the minimum, research activities should conform to the following.

1. Subjects should be made fully aware of any risks.

2. The principal investigator shall explain to subjects, prior to their participation, the objectives of the research, the procedures to be followed, and the risks and potential benefits. In general this explanation should also be offered in writing. Investigators shall not use individuals as subjects unless satisfied that the subjects, or others legally responsible for the subject's well-being, freely consent to participation with a full understanding of the consequences. The IRB may waive these requirements only if all of the following three criteria are met.
   a) The committee is persuaded that the research cannot otherwise be done.
   b) The committee is convinced that the potential value of the research outweighs any potential risks to the subject.
   c) The research involves minimal risk. In general, subject consent is indicated in writing on an "informed consent" form.

3. Investigators shall respect the privacy of their subjects. Investigators shall protect confidential information given them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.

4. Subjects, including students who are participating in classroom experiments or faculty scholarship, shall not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participation in research, some other mechanism to "earn" that credit must also be made available to those students who choose not to participate as human subjects. Rewards for participation should be in line with the burden imposed by participation.

5. It shall be made clear to subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and without penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this shall be clearly stated as part of the informed consent statement.

6. Instructors who assign or supervise research conducted by students are responsible for ensuring that these students are qualified to safeguard adequately the well-being of the
7. Subjects of human research are generally provided the opportunity of access to the benefits of that research at its conclusion.

8. An investigator shall disclose to a subject, upon request, the source of support for the research.

VI. PROCEDURES

Faculty members, staff members, or students who are planning research projects involving human subjects are responsible for initiating the review process by submitting their research proposals to the IRB member who has been designated as the area reviewer for their department. A list of the area reviewers is given on the Kalamazoo College IRB webpage (reason.kzoo.edu/irb/). For guidelines specific to Senior Individualized Projects and other student-generated research, see Section VII. The area reviewer, a representative of the IRB, reviews the proposed research and then assigns the proposal to one of the following categories:

- exempt from IRB review
- expedited IRB review
- full IRB review

Many research projects will fall into the exempt category. Research in the exempt category (see Appendix A) requires no further review beyond the area level. Proposals determined by the area reviewer to require further review will be forwarded to the chair of the IRB. The chair of the IRB will document the submission and will either evaluate the proposal or designate a member of the IRB to conduct a review. If an expedited review, the chair may designate the same area reviewer or other member of the IRB to review the proposal. Proposals judged by the area reviewer or IRB chair to require full review will be reviewed by the IRB as a whole.

All research proposals are evaluated with regard to the degree of "risk," if any, to human subjects. The IRB will provide the area reviewer with training to aid in the determination of risk. If a research proposal is determined by the area reviewer to involve minimal or more than minimal risk, the area reviewer will send the proposal to the chair of the IRB for expedited or full review. Under an expedited review procedure, the chair or another member of the IRB, designated by the chair, will review the proposal; the proposed research must involve no more than minimal risk and the only involvement of human subjects must fall under one or more categories, specified under Expedited Review in Appendix A. Full committee review is required when the procedures of the research present more than minimal risk (Full Committee Review in Appendix A) to the subject and/or fall into one or more of the categories specified under Full Committee Review in Appendix A.

1. There are three possible outcomes to a Full Committee Review:
   a. Approved --no further action is required from the investigator prior to initiating the study;
   b. Pending required amendments --more extensive changes are required before the study may begin;
   c. Denied --the proposed research, because of the level of risk involved, cannot be initiated.
Research approved by the IRB that is continuing must be re-reviewed on an annual basis by the IRB. Researchers wishing to request a continuation of their research project should complete the Research Change or Continuation Form found on the IRB website. The IRB chair will determine whether a full or expedited review is required or whether the proposal is exempt from further review.

A letter describing the decision of the IRB will be sent to the investigator. Faculty members, staff members, or students who have submitted research proposals for review and have been asked to make revisions or have been denied approval may request the IRB to review its decision, and may write to or appear before the committee to discuss that decision.

The IRB will review a list of all projects approved via Full Committee Review that have been initiated or completed at the College or by College employees at least once a year. Review forms, copies of any source instruments (e.g., questionnaires, interview scripts, manipulation protocols, debriefing forms, etc.) and the consent form may be obtained from Chair of the IRB.

Approval of a human subject research proposal is good for one year, unless the project has acceptable but potential risk, in which case approval is given for a six-month period. If the project will continue beyond the approval period, Principal Investigators are required to submit a Research Change or Continuation Form and supporting documents for review prior to the expiration date of the initial approval. In the initial approval letter, principal investigators are asked to promptly report any unanticipated problems or adverse effects of the research to the IRB.

Appeals: In the event that an application is denied because the IRB feels the risks outweigh the benefits of the research, and the investigator disagrees with the committee's disapproval decision, the researcher may appeal the decision by re-submitting the same application form and: 1) a letter of appeal presenting the researcher's arguments for approval; and 2) any other pertinent information in support of the appeal. The letter should be directed to the IRB chair and mailed with enclosures to the IRB chair. Applications submitted for appeal will be considered by the full board at the next scheduled meeting date. The final decision of the IRB will be stated in writing to the investigator. If the proposal is not approved, the research cannot be conducted. There shall be no other appeals.

The researcher may at any point submit a revised proposal, which will be reviewed as a new application.

Nature of the Kalamazoo College Records: The College keeps records for five (5) years of original human subjects research that has undergone either a full or expedited review by the IRB, along with copies of any research documents (informed consent forms, questionnaires, interview scripts, stress protocols, behavioral manipulation protocols, drug protocols, non-FDA device protocols, debriefing forms, etc.), and a copy of any publication resulting from the research. These materials must be submitted with the Application For IRB Review of Research with Human Subjects and copies of any resulting publications should be submitted to the IRB for records as soon as available.

VII. PROCEDURES FOR SENIOR INDIVIDUALIZED PROJECTS AND OTHER
STUDENT GENERATED RESEARCH

1. All Students conducting research must have a faculty adviser. Faculty supervising these undergraduate projects are responsible for seeing that their advisees become familiar with the IRB Policies for Research with and Protection of Human Subjects at Kalamazoo College.
2. Faculty members are responsible for initial screening their advisees' research projects.
3. If it is determined that IRB review is necessary, the student must prepare an application for IRB Review of Research with Human Subjects Form and submit the application to the appropriate area reviewer (application form available at reason.kzoo.edu/irb/). All students must complete ethics training prior to submission of their IRB application.
4. If it is determined by the area reviewer that a project involves greater than minimal risk, the project must be submitted to the IRB for an expedited or full review and approval prior to initiating the research.
5. If there is any doubt as to whether the project should be reviewed by the IRB, the Chair of the IRB should be contacted.
6. If there is reasonable expectation on the part of the advisor and the student that the study will be externally funded and/or published, IRB approval must be obtained.

APPENDIX A

Categories of Review

All research, including that which the investigator believes falls into the exempt category, must be submitted to the area reviewer for confirmation of the relevant review category. The criteria used to determine the categories of review are described below.

FULL COMMITTEE REVIEW

If ANY of these apply:
1. The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
2. The research involves the collection or recording of behavior which, if known 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.
3. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of the research involve more than minimal risk to the subject (where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
5. Any research which does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

EXPEDITED REVIEW

Part A (all items must apply):
1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously
ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The procedures of this research present no more than minimal risk to the subject. ("Minimal risk" means that the probability and magnitude of harm or &scornfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

**Part B (at least ONE item should apply):**

1. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. [NB: These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio- or video-tapes, names will be recorded, even if they are not directly associated with the data).]

2. Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc); b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects.

3. Collection of data from voice, video, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

4. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows: a) Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; b) Involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family...
members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. [NB: Although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or videotapes, names will be recorded, even if they are not directly associated with the data).]

6. Research that involves deception. [NB: Deception must be scientifically justified and de-briefing procedures must be outlined in detail. All but minor or inconsequential cases of deception, as determined by the area reviewer, will be forwarded for full committee review.]

7. Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.

8. Research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where the research remains active only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; (d) where no subjects have been enrolled and no additional risks have been identified.

EXEMPT
Part A (all items must apply):
1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B). Category B 2 studies that include minors should be submitted for expedited review.

5. The research does not involve deception.

6. The procedures of this research are generally free of foreseeable risk to the subject.
Part B (at least ONE item should apply):

1. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). [NB: All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is exempt, whether or not data collection is anonymous.]

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

4. Research (including demonstration projects) conducted by or subject to the approval of federal department or agency heads, and designed to study, evaluate, or otherwise examine (i) public benefit or service programs (e.g., social security, welfare, etc.); (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.

5. Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives, or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the U.S. Department of Agriculture.
APPLICATION FOR IRB REVIEW OF RESEARCH WITH HUMAN SUBJECTS
Electronic Submission to Area Reviewer is Required*

Principal Investigator:

Title of Project:

Date application submitted:

Status of Applicant: Faculty Member Administrator/Staff Student

If Student Applicant provide:
Name of on-campus faculty advisor:

Has your advisor reviewed this application? Yes No
(a faculty advisor must review your application prior to submission for review)

Have you completed a research ethics training course or module? Yes No
If Yes, please indicate when, where, and with whom the ethics training was completed (this might be part of your departmental methods course or as an online module assigned by a faculty mentor/advisor. Examples that satisfy ethics training include completion of PSYC390 Experimental Methods, ANSO245 Qualitative Research Methods, or other courses that have deliberate and substantial ethics training components, or by completion of an online ethics training module such as “responsbileresearch.org” or “phrp.nihtraining.com”):

If No, stop the application process. You may not receive IRB review until you have completed ethics training.

Is this research part of your SIP? Yes No
Is this research in connection with a fellowship application? Yes No
If yes, state fellowship:
Anticipated graduation year and Major:
Please provide the following information relating to your application:

What is the purpose of the proposed study?

Describe the proposed subject sample including expected ages, genders, total number of subjects (including control subjects), and source of subjects. If subjects under the age of 18 will participate in your research, indicate the sample’s expected age range.

How will subjects be recruited and selected? (Please note if any of the following groups will be included as subjects: prisoners, pregnant women, the seriously ill, or mentally or cognitively compromised adults.)

Briefly describe all research procedures that will apply to human subjects. Be sure to indicate:

how will subjects be recruited?

approximately how much time each subject is expected to devote to the research.

how data will be collected and recorded (with or without identifiers? What instruments, materials, or equipment will be used? Will audio- or videotapes be used in data collection?). Attach copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact. Attach copies of all proposed tests, surveys, or questionnaires used in the research. If the written instrument is not ready at the time the application is submitted, a description of the topics or an approximate script should be submitted. In some cases, more specific details of questions to be used may be required.

methods for obtaining informed consent and assent in the case of minors. For minors, indicate how the consent of parents or legal guardians will also be obtained. Attach copies of all materials used to obtain informed consent or assent.

methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records at the conclusion of the research).

if deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. [If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.]

Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research. If subjects awarded extra credit in a course, students choosing to not participate in the study must be offered an alternative extra credit assignment.
comparable in time commitment/difficulty as the study.

Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher; employer/employee. If such a relationship exists, how will it affect the subject’s ability to participate voluntarily and how will the principal investigator handle it?

Indicate any grant support (internal or external) or commercial support for the project. Note: all externally funded projects must receive IRB review.