Charter for Baker University INSTITUTIONAL REVIEW BOARD for the Ethical Treatment of Human Participants in Research

TITLE

This body shall be known as the Baker University Institutional Review Board.

PURPOSE

The purpose of the Baker University IRB is to insure the ethical conduct in research involving human participants.

SPECIFIC RESPONSIBILITIES

1. To assure the University that human participants used in research or educational programs are not at undue risk and that the participants are informed of any risks.

2. To advise the Office of the Chief Academic Officer of the University's compliance with federal guidelines and inform the University policy and procedures regarding the protection of human participants, and to certify to the Office of the Academic Affairs that any research project or activity involving human participants has been reviewed and approved by the IRB.

SCOPE

This Board is to review all research involving human participants, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

1. The research is sponsored by this institution, or
2. The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

The term "research" herein denotes a systematic investigation or testing and evaluation designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be conducted as a component of another program not usually considered research.

Certain kinds of activities that might be called "human subjects research" do not require review for the protection of human subjects. The following kinds of activities do not require such review:

- accepted and established service relationships between professionals and clients where the activity is designed solely to meet the needs of the client;
- research using only historical documents; and
- research using only archaeological materials or other historical or pre-historical artifacts.

Pilot studies, pre-tests, and other "preliminary" investigations are considered research, and must be reviewed unless they fall into one of the excluded categories listed above.

Classroom activities may include instructing students in human research methodologies and techniques. If the sole purpose of the activity is to teach students research techniques or methodology and not to develop or contribute to generalizable knowledge, it is not considered to be research. However, if students will practice research methodologies on human beings, they should be instructed in the ethical conduct of such activities and should be advised to obtain informed consent from their practice subjects.

Quality improvement and quality assurance activities conducted solely for the intent of maintaining or improving quality of services provided by an institution, likewise, are not considered research activities. However, if the data collected are generalizable and are to be shared outside of the institution through discussion, presentation, or publication, the activity qualifies as research. Sometimes, data from a quality improvement or quality assurance activity become of interest to the external community after they have been analyzed. In these cases, the research use of the data collected for another purpose must be reviewed.

PROCEDURES

Proposals requiring the use of human participants will be submitted to the Chairperson of the Baker University Institutional Review Board. Proposals must be submitted by the Principal Investigator. The Chairperson, representing the Board, will determine the review category which is most appropriate for the proposed research, and will advise Institutional Research of that determination. The Chair will consider the degree of risk the proposed research places upon human participant(s), and whether or not proper safeguards are planned and/or operational. All proposed research involving human participants, unless found by the IRB Chair to be Exempt, shall be reviewed either by the Expedited Review process or Convened Board Review. For Expedited Review, the Chair and two members of the committee would comprise the Board. For Convened Review, the entire membership must participate.

MEMERSHIP

The IRB shall have at least five voting members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

Consideration should be given to including at least one member of the Board who has experience in ethical decision-making. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

Aside from requirements stipulated in the next section (Expertise), at-large membership will be drawn from the faculties of concerned programs of the University.

Expertise

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

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.

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.

Conflict of Interest

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Ad Hoc Membership

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

These individuals may not vote with the IRB. A representative from the Office of the Academic Affairs will serve as non-voting *ex-officio*.

Membership Procedures

Committee members will be appointed by the Chief Academic Officer of the University in accordance with any applicable regulations governing committee participation.

The incoming Chairperson is elected annually by the voting members before the end of the

academic year to assume duties at the beginning of the next academic year. The outgoing Chairperson is responsible for coordinating election of a new Chairperson.

The incoming Chairperson is responsible for calling the initial meeting of the Board and relaying all necessary information relating to specific responsibilities and time lines.

Any member who misses more than two regularly scheduled consecutive meetings without cause will be asked to resign.

Terms of Appointment

Three-year staggered terms.

MEETING SCHEDULING AND AGENDAS

The Board will meet a **minimum** of once each Fall and once each Spring semester. The Faculty Senate Chairperson will be included in the distribution list for all meeting scheduling and agendas.

RECORDS AND RECORD KEEPING

The IRB must prepare and maintain adequate documentation of IRB activities. In addition to the written IRB procedures and membership lists required by the Assurance process, such documentation must include copies of all research proposals reviews, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to participants.

Minutes of meetings must carry sufficient detail to include attendance, actions taken by the IRB, the vote on all actions taken, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution. IRB records are to be maintained for three years; records pertaining to completed research must be maintained for three years after its completion. All records must be accessible (at reasonable times and days) for inspection and copying by authorized representatives of the department or agency supporting or conducting the research.

Committee Charter will be reviewed annually, at the first meeting of the academic year. Changes to the Charter are to be made by the Chief Academic Officer of the University.

APPEALS

Appeals of IRB decisions and recommendations will be made to the Chief Academic Officer.

Criteria for Approval of research Protocols Involving Human Participants

In order to approve research, the IRB will have determined that

- Risks to participants are minimized
    1. by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
    2. whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result.
- Selection of participants will not be coercive. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly aware of the special problems of research involving vulnerable populations.
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative.
- Informed consent will be appropriately documented.
- When appropriate, the research plan will make adequate provision for monitoring the data collected to insure the safety of participants.
- When appropriate, there will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of the data.

Research by Investigators from Other Institutions

In the case that a researcher from another university or organization requests access to students, faculty or staff of Baker University, approval will be granted if the principal investigator supplies the Chair of the Baker IRB a copy of the IRB approval from his or her home institution, and only in the case that the approval clearly indicates that the research falls under either **Exempt** or **Expedited** class of review. If the research required **Convened** board review at the home institution and thus presents more than minimal risk to Baker students or employees, then it must be reviewed under Convened board review by the Baker IRB.

CLASSES OF REVIEW

Exempt

This category is for research in which no identifying information is collected with the data. Typical cases of this class are observational research in which participants are observed in public places, or survey data collected via mail or electronic instruments. Additionally, the information collected from the participants in Exempt research may not be of a sensitive nature, whether or not the behavior is exhibited in public or voluntarily and anonymously submitted.

The Exempt status applies to research (including Institutional Research) conducted for educational testing and survey procedures relevant to educational and institutional goals, under

the following conditions:

1. if no identifying information will be recorded that can link participants to the data;
2. if disclosure of the data could not reasonably place the participants at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation; or
3. the research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.

Expedited Review

Expedited Review would involve research that is considered to put participants "at minimal risk." There are chiefly three types of research that fall into the "minimal risk" category: In the first case, there are no obvious characteristics of the research design that risk harm to the participants, but the participants are placed into the research setting by the researchers, who thereby assume responsibility for their care during the course of data collection. A participant entering a research lab becomes the responsibility of the investigator, and is automatically considered at minimal risk. A second case would be research that would ordinarily be classified as Exempt, but includes the collection or discussion of information that may be reasonably deemed "sensitive," and/or the data are collected along with identifying information.

Expedited review is also appropriate for research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, focus group, human factors evaluation, or quality assurance methodologies.

Convened Board Review

This class of review is for research in which participants are placed "at some risk," wherein it may be reasonably presumed that some (even few) participants might react to the research participation adversely. This may arise from an experimental manipulation, from research employing deception, or from research into sensitive (or potentially sensitive) areas of behavior. Additionally, this class of review is required for research involving participants who are potentially vulnerable to coercion or undue influence, or belong to traditionally-protect populations such as the mentally or physically disabled, children under the age of 18, older adults, pregnant women, and criminal offenders (i.e., inmates, parolees, or probationers). The board may convene via e-mail due to time and geographical constraints.

Guidelines for Obtaining Informed Consent

The ethical principle of respect for persons requires that human research participants be given the opportunity to choose what shall and shall not happen to them. Valid informed consent requires:

1. disclosure of study procedures and potential risks to prospective research participants;
2. their comprehension of the information; and
3. their voluntary agreement, freed from coercion and undue influence, to participation.

The informed consent document must be complete and clearly written in order that the participants may make an informed decision.

Requirements for Informed Consent

Unless otherwise waived by an IRB-approved protocol, research investigators must obtain valid informed consent from all participants (or their legally-authorized representatives) engaged as participants in any research conducted under the aegis of Baker University. Generally (and with only limited exceptions for cause), after the researcher has explained the study to the participant, the informed consent of the participant is documented by signing the protocol's written consent document. The participant receives a copy of the document, and the signed copy is stored in such a manner as to preserve the confidentiality of the participant.

Basic Elements of Written Informed Consent Documents

Unless otherwise authorized by the IRB, participants must be offered at least the following, in writing, prior to their participation:

- A statement that the study involves research;
- an explanation of the purpose of the research and the expected duration of the participation;
- a description of the procedures to be followed, and identification of any procedures that are experimental;
- a description of any foreseeable risks or discomforts to the participant, an estimate of their likelihood, and a description of the steps that will be taken to minimize or prevent them;
- a description of the benefits of the research, either to the participant him- or herself, or to the more general scientific endeavor;
- a disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant;
- a statement describing to what extent records will be kept confidential, including a description of who may have access to the records;
- for research involving more than "minimal risk," an explanation and description of any compensation and any medical treatments that are available if research participants are injured, where further information may be obtained, and whom to contact in the event of a research-related injury;
- an explanation of whom to contact for answers to pertinent questions about the research participant's rights;
- a statement that participation is voluntary, and refusal to participate or continue participation (once begun) will involve no penalty or loss of benefits to which the participant is otherwise entitled.