

HUMAN SUBJECTS REVIEW BOARD

STATEMENT OF PURPOSE

St. Edward's University has created the Human Subjects Review Board (HSRB), whose primary purpose is to verify that the use and treatment of human subjects participating in research at this University is ethical and in compliance with established standards.

Although researchers are ultimately responsible for the ethical treatment of their human subjects, it is the policy of St. Edward's University that all Full-Time, Visiting, and Part-Time Faculty conducting research at this University involving humans must present their research plans by completing the necessary forms provided by the HSRB and obtain approval from the HSRB before commencing their projects or beginning data collection. This policy also applies to student researchers who are collecting data under the supervision of a faculty member. Students engaged in projects for Honors Theses, independent research courses, or faculty-student collaborations which utilize participation by human subjects should seek approval through their faculty sponsor.

Principal investigators or co-principal investigators who are formally affiliated with SEU and conduct research associated with other institutions are also required to seek approval from the HSRB, unless they have received approval from an approved Institutional Review Board (IRB) at their host institution. In this case, a copy of the approval form must be sent to the Human Subjects Review Board at St. Edward's University.

The task of the HSRB is not to evaluate the soundness of the research, the merits of the research design, nor the contributions of the research to the larger scientific literature. Rather, the Human Subjects Review Board is charged with evaluating a project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, use of deception, and potential risk to participants. (These standards are addressed in forms available from the HSRB.)

"Research" is defined as "work which contributes to generalized knowledge about a subject." Work undertaken as part of a course for the purpose of illustrating a particular technique or methodology is not considered research and therefore does not require approval by the Human Subjects Review Board. Similarly, research using laboratory animals, online databases, or other forms of archival research (i.e., research pursuits that do not require eliciting responses from, taking measurements of, or otherwise studying human participants) are not reviewed by the HSRB. (An exception to this general principle occurs when archival research presents the possibility of lack of confidentiality, risk to human subjects, or lack of informed consent. For example, if medical or insurance records of identifiable patients are examined for research purposes there would be some question about the protection of the human subjects who provided those records.) It should be noted that several categories of research are exempt from the review process, including questionnaire or survey research with adults which does not involve sensitive topics.

Researchers should generally expect up to two weeks of processing time, although projects which meet all the necessary criteria may be processed within a few days. Faculty who have specific deadlines for courses involving research (e.g., research practica or theses) or for grant proposal submissions should inform the Chair of the HSRB of these deadlines at the beginning of the relevant semester, preferably within the first two weeks. Every effort will be made to accommodate these needs. Should research involving human subjects be undertaken without the HSRB's prior approval, the University may terminate, suspend, or postpone the research project.

Human Subjects Review Board, Spring 2008

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STATEMENT OF ETHICAL PRINCIPLES

St. Edward's University is committed to the pursuit of excellence in teaching, research and public service. Concomitantly, the University seeks to protect the welfare of every person who may be involved in research and training projects. Members of the University community, while upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers: for competence, for objectivity, for consideration of the best interests of the University and society, and for the welfare of every participant in a project. The University gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended). Additionally, this institution will comply with the requirements set forth in 45 CFR 46 Subpart D which provides additional protections for children involved in research. Thus, the following principles are affirmed and should be interpreted in the broad context provided by the code of medical and general ethics promulgated by the World Medical Association as the Declaration of Helsinki and by the Ethical Principles in the Conduct of Research with Human Participants of the American Psychological Association.

1. Since the participation of humans in research and training projects may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on-campus or off-campus.
2. All activities involving humans as subjects must provide for the safety, health and welfare of every individual. Rights, including the right of privacy, must not be infringed.
3. The direct or potential benefits to the subject, or the importance of the knowledge to be gained, must outweigh the inherent risks to the individual.
4. Participation in projects must be voluntary and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the Human Subjects Review Board (HSRB) as provided in 45 CFR 46.116(c). Methods that are in accordance with the requirements of 45 CFR 46.116 and 45 CFR 46.117 and adequate and appropriate to the risks of the project must be used to obtain the subject's informed consent.
5. Consent should be obtained whenever possible from the participants themselves. If a subject is not legally or physically capable of giving informed consent, a legally authorized representative may do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Parents, for example, may not expose their child to risk except for the child's benefit.
6. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or can refuse to participate; in either case, without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information and to be free from undue embarrassment, discomfort, anxiety, and harassment.
7. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. When the investigator is a student, responsibility for the conduct of the research and the supervision of human subjects lies with the faculty sponsor. Such information shall not be communicated to others unless the following conditions are met:
 - a. Explicit permission for the release of identifying data is given by the individual.
 - b. Information about individuals may be discussed only for professional purposes and only with persons clearly concerned with the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy.

c. Provisions must also be made for the maintenance of confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the HSRB and carried out by the principal investigator until the records are destroyed. Records which contain personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project.

8. Projects will be given initial and continuing review by the HSRB as set forth in (Section IV, Paragraph 4). All members of the University community involved in investigation and training are responsible for continual monitoring to assure compliance of their research with these principles.

9. No individual involved in the conduct and/or supervision of a specific project shall participate in HSRB review, except to provide information.

10. A second review may be required if: (a) a long interval has elapsed between HSRB review and project initiation; (b) if the proposed effort is in a rapidly changing scientific area; or (c) if the principal investigator wishes to change procedures after the proposed project has been reviewed by the HSRB. In no case will work take place without at least an annual review.

11. In all cases, the investigator should show practical regard for the St. Edward's University community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles (for example, concerning confidentiality, informed consent, debriefing, and regard for the health, safety and welfare of all human subjects) could impugn the investigator's own name and the reputation of the University. The investigator does not abdicate ethical and legal responsibility merely by complying with this protocol. It is always the responsibility of the investigator to obtain clearance from the HSRB prior to the initiation of any research activity involving the use of human subjects. Failure to do so may result in personal restrictions on the research activities of such individuals, as well as potentially endanger all federal funding to the University.

Ethical Principles of Psychologists

effective date: December 1, 1992

www.apa.org/ethics/code.html#6.06

Sections on Research

6.06 Planning Research.

(a) Psychologists design, conduct, and report research in accordance with recognized standards of scientific competence and ethical research.

(b) Psychologists plan their research so as to minimize the possibility that results will be misleading.

(c) In planning research, psychologists consider its ethical acceptability under the Ethics Code. If an ethical issue is unclear, psychologists seek to resolve the issue through consultation with institutional review boards, animal care and use committees, peer consultations, or other proper mechanisms.

(d) Psychologists take reasonable steps to implement appropriate protections for the rights and welfare of human participants, other persons affected by the research, and the welfare of animal subjects.

6.07 Responsibility.

(a) Psychologists conduct research competently and with due concern for the dignity and welfare of the participants.

(b) Psychologists are responsible for the ethical conduct of research conducted by them or by others under their supervision or control.

(c) Researchers and assistants are permitted to perform only those tasks for which they are appropriately trained and prepared.

(d) As part of the process of development and implementation of research projects, psychologists consult those with expertise concerning any special population under investigation or most likely to be affected.

6.08 Compliance With Law and Standards.

Psychologists plan and conduct research in a manner consistent with federal and state law and regulations, as well as professional standards governing the conduct of research, and particularly those standards governing research with human participants and animal subjects.

6.09 Institutional Approval.

Psychologists obtain from host institutions or organizations appropriate approval prior to conducting research, and they provide accurate information about their research proposals. They conduct the research in accordance with the approved research protocol.

6.10 Research Responsibilities.

Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), psychologists enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party.

6.11 Informed Consent to Research.

(a) Psychologists use language that is reasonably understandable to research participants in obtaining their appropriate informed consent (except as provided in Standard 6.12, Dispensing with Informed Consent). Such informed consent is appropriately documented.

(b) Using language that is reasonably understandable to participants, psychologists inform participants of the nature of the research; they inform participants that they are free to participate or to decline to participate or to withdraw from the research; they explain the foreseeable consequences of declining or withdrawing; they inform participants of significant factors that may be expected to influence their willingness to participate (such as risks, discomfort, adverse effects, or limitations on confidentiality, except as provided in Standard 6.15, Deception in Research); and they explain other aspects about which the prospective participants inquire.

(c) When psychologists conduct research with individuals such as students or subordinates, psychologists take special care to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

(d) When research participation is a course requirement or opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

(e) For persons who are legally incapable of giving informed consent, psychologists nevertheless (1) provide an appropriate explanation, (2) obtain the participant's assent, and (3) obtain appropriate permission from a legally authorized person, if such substitute consent is permitted by law.

6.12 Dispensing With Informed Consent.

Before determining that planned research (such as research involving only anonymous questionnaires, naturalistic observations, or certain kinds of archival research) does not require the informed consent of research participants, psychologists consider applicable regulations and institutional review board requirements, and they consult with colleagues as appropriate.

6.13 Informed Consent in Research Filming or Recording.

Psychologists obtain informed consent from research participants prior to filming or recording them in any form, unless the research involves simply naturalistic observations in public places and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm.

6.14 Offering Inducements for Research Participants.

(a) In offering professional services as an inducement to obtain research participants, psychologists make clear the nature of the services, as well as the risks, obligations, and limitations. (See also Standard 1.18, Barter [With Patients or Clients].)

(b) Psychologists do not offer excessive or inappropriate financial or other inducements to obtain research participants, particularly when it might tend to coerce participation.

6.15 Deception in Research.

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible.

(b) Psychologists never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences.

(c) Any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research. (See also Standard 6.18, Providing Participants With Information About the Study.)

6.16 Sharing and Utilizing Data.

Psychologists inform research participants of their anticipated sharing or further use of personally identifiable research data and of the possibility of unanticipated future uses.

6.17 Minimizing Invasiveness.

In conducting research, psychologists interfere with the participants or milieu from which data are collected only in a manner that is warranted by an appropriate research design and that is consistent with psychologists' roles as scientific investigators.

6.18 Providing Participants With Information About the Study.

(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and psychologists attempt to correct any misconceptions that participants may have.

(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.

6.19 Honoring Commitments.

Psychologists take reasonable measures to honor all commitments they have made to research participants.

6.20 Care and Use of Animals in Research.

(a) Psychologists who conduct research involving animals treat them humanely.

(b) Psychologists acquire, care for, use, and dispose of animals in compliance with current federal, state, and local laws and regulations, and with professional standards.

(c) Psychologists trained in research methods and experienced in the care of laboratory animals supervise all procedures involving animals and are responsible for ensuring appropriate consideration of their comfort, health, and humane treatment.

(d) Psychologists ensure that all individuals using animals under their supervision have received instruction in research methods and in the care, maintenance, and handling of the species being used, to the extent appropriate to their role.

(e) Responsibilities and activities of individuals assisting in a research project are consistent with their respective competencies.

(f) Psychologists make reasonable efforts to minimize the discomfort, infection, illness, and pain of animal subjects.

(g) A procedure subjecting animals to pain, stress, or privation is used only when an alternative procedure is unavailable and the goal is justified by its prospective scientific, educational, or applied value.

(h) Surgical procedures are performed under appropriate anesthesia; techniques to avoid infection and minimize pain are followed during and after surgery.

(i) When it is appropriate that the animal's life be terminated, it is done rapidly, with an effort to minimize pain, and in accordance with accepted procedures.

6.21 Reporting of Results.

(a) Psychologists do not fabricate data or falsify results in their publications.

(b) If psychologists discover significant errors in their published data, they take reasonable steps to correct such errors in a correction, retraction, erratum, or other appropriate publication means.

6.22 Plagiarism.

Psychologists do not present substantial portions or elements of another's work or data as their own, even if the other work or data source is cited occasionally.

6.23 Publication Credit.

(a) Psychologists take responsibility and credit, including authorship credit, only for work they have actually performed or to which they have contributed.

(b) Principal authorship and other publication credits accurately reflect the relative scientific or professional contributions of the individuals involved, regardless of their relative status. Mere possession of an institutional position, such as Department Chair, does not justify authorship credit. Minor contributions to the research or to the writing for publications are appropriately acknowledged, such as in footnotes or in an introductory statement.

(c) A student is usually listed as principal author on any multiple-authored article that is substantially based on the student's dissertation or thesis.

6.24 Duplicate Publication of Data.

Psychologists do not publish, as original data, data that have been previously published. This does not preclude republishing data when they are accompanied by proper acknowledgment.

6.25 Sharing Data.

After research results are published, psychologists do not withhold the data on which their conclusions are based from other competent professionals who seek to verify the substantive claims through reanalysis and who intend to use such data only for that purpose, provided that the confidentiality of the participants can be protected and unless legal rights concerning proprietary data preclude their release.

6.26 Professional Reviewers.

Psychologists who review material submitted for publication, grant, or other research proposal review respect the confidentiality of and the proprietary rights in such information of those who submitted it.