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RESEARCH INVESTIGATOR'S MANUAL
A GUIDE TO THE INSTITUTIONAL REVIEW BOARD
(IRB) PROCESS

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A. Introduction

The Saint Augustine's University Institutional Review Board (IRB) for the Protection of Human Subjects was established to ensure that the University complies with all federal regulations which govern research involving human subject protection. Saint Augustine's University's policy is to protect the rights and welfare of all human volunteers who participate in research activities conducted under the auspices of the University.

B. Definitions

The IRB has adopted the definitions used by the U.S. Department of Health and Human Services, Office for Human Research Protections (OHRP) and the 45 CFR 46:

- 45 CFR 46 – Code of Federal Regulations: Title 45 Public Welfare, Part 46 Protection of Human Subjects is a federal policy that guides the conduct of research involving human subjects.
- Federalwide Assurance (FWA) – The FWA is documentation of an institutional commitment to comply with Federal regulations and maintain adequate programs and procedures for the protection of human subjects. It is the principal mechanism for compliance oversight by OHRP.
- Human subject – A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - Data through intervention or interaction with the individual, or
 - Identifiable private information.
- Institutional Review Board (IRB) – A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.
- Minimal risk – 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.
- Research – Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

C. Institutional Responsibilities

1. Federalwide Assurance (FWA)

The FWA is required for all Department of Health and Human Services (DHHS) funded research involving the use of human subjects. It is a formal commitment made by an institution to provide for the protection of human subjects. Any institution with a FWA agrees to and is responsible for protecting human subjects. The FWA is not required for research that has not received federal funding but an institution may make the decision to hold all research involving human subjects to the standards listed in the FWA. ***Saint Augustine's University has agreed to hold all research to the federal standards.***

The FWA includes the following important components:

- Saint Augustine’s University assures that all research involving human subjects, regardless of funding source, will be guided by the ethical principles in *The Belmont Report*, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, lays out the basic ethical principles and guidelines to consider when conducting research involving human subjects. The three ethical principles, as defined in the Belmont Report include:
 - *Respect for Persons* - Individuals should be treated as autonomous agents or human beings. Persons with diminished autonomy are entitled to protection.
 - *Beneficence* – Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. (do not harm; and maximize possible benefits and minimize possible harms)
 - *Justice* - The ethical principle requiring that the burden and benefits of research shall be distributed equitably.

The University will be guided by these ethical principles and use them as a foundation for all research conducted with human subjects.

- Saint Augustine’s University assures that it will apply *Title 45 Code of Federal Regulations Part 46 and all of its subparts (A, B – addition protections for pregnant women, human fetuses and neonates, C – additional protections for prisoners, and D – additional protections for children)* to all human subject research. Whereas the Belmont Report discusses ethical principles, 45CFR46 discuss the federal rules for conducting research involving human subjects.
- The University’s IRB Registration number is – IRB00012464.

2. Institutional Oversight

Two additional sections of the FWA describe institutional oversight of the human protections program at Saint Augustine’s University and list the individuals responsible for such oversight.

- The *Signatory Official*, according to Office of Institutional Research and Planning (OIRP), is responsible for “setting the tone for an institutional culture of respect for human subjects”. The designated Signatory Official is Dr. Linda Gunn-Jones, Director of Title III Funding/Office of Sponsored Programs.
- The *Human Protections Administrator* is the primary contact for DHHS OHRP and has administrative responsibility for SAU Human Protections Administration that includes ensuring that human subjects involved in research are adequately protected and that SAU remains in compliance with regulations. The Human Protections Administrator shall be the Director of the Office of Research and Sponsored Programs, Dr. Linda Gunn-Jones, or their designee. The human protections program is guided through the SAU OFFICE OF RESEARCH AND SPONSORED PROGRAMS, also directed by Dr. Linda Gunn-Jones.

D. Does Your Study Require IRB Review?

All research involving human subjects must be submitted to the IRB for review prior to initiation. In order to determine if your proposed work must be submitted for review consider the following:

1. Are you conducting research?

The federal definition of research is “a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” If you are not conducting research, your work does not have to be reviewed by the IRB, **HOWEVER**, if you have any doubt about your study, contact the OFFICE OF RESEARCH AND SPONSORED PROGRAMS.

2. What is a systematic investigation?

A systematic investigation usually attempts to answer a question or attempts to prove or disprove a hypothesis.

3. What is “contributing to generalizable knowledge”?

The statement applies to sharing the information/data/results that you obtain in your investigation with others in the classroom setting, at a poster presentation, in a publication, or at a conference. If you are unsure about your plans to share your results at a time in the future you should submit an IRB application for review.

4. What is a human subject?

A human subject is a 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.

E. Education Requirements

All personnel who will work on research projects are required to complete training in the responsible conduct of research involving human subjects. Personnel must be retrained every two years.

The OFFICE OF RESEARCH AND SPONSORED PROGRAMS requires all research personnel to successfully complete one of the following before submitting a new IRB application for review:

- U.S. National Institutes of Health, National Cancer Institute, Human Participant Protections Education for Research Teams online training module.
- Collaborative IRB Training Initiative (CITI). SAU does not have a license for this course but some researchers have completed the course through their collaborations with other institutions.
- Attendance at a seminar where the main purpose is to discuss the responsible conduct of research involving human subjects.
- A CERTIFICATE OF COMPLETION FOR ANY OF THE ABOVE SHOULD BE SUBMITTED WITH YOUR IRB APPLICATION.

F. Research Investigator Responsibilities

All research investigators and their key personnel must comply with the following guidelines:

1. Responsibilities Before IRB Approval

- All investigators must obtain IRB approval for each research protocol involving human subjects prior to initiating the study.

- The principal investigator is required to prepare the “*New Protocol Application Form*” and provide the research proposal, informed consent form(s), study instruments, recruitment materials, focus group questions and any other relevant documentation to the IRB.
- The principal investigator and/or faculty advisor may request or may be asked to attend a full board meeting when his or her protocol is under review.
- The principal investigator and all key personnel working on the research project must complete the required human subjects’ protections educational training prior to beginning the research. Proof of training in the form of a certificate must be supplied to the IRB with the application. IRB applications from investigators who have not completed the required education will be returned without review.
 - Faculty advisors of student investigators must also complete the training.
- Research activities involving institutions and agencies outside of Saint Augustine’s University must receive written approval from the appropriate official within the agency. The written approval must be submitted with the IRB application.

2. Responsibilities After IRB Approval

- Investigators must provide a copy of the IRB-approved and stamped informed consent form to each participant at the time of consent. All documentation must be stored as outlined in the IRB application in a secure location for a minimum of three years after the completion of the study.
- Principal investigators must promptly report proposed modifications to approved studies to the IRB using the “*Modification to a Previously Approved Protocol Form*”. No changes to the study should be initiated without prior IRB review and approval. Some modifications may require full IRB review.
- Principal investigators must inform their co-investigators from cooperating institutions that any change in a previously approved protocol must be submitted to the appropriate IRB and approved before implementing the change.
- If findings are developed during the course of the research that may have an effect on participant’s willingness to continue in the study, Principal Investigators must report the findings to both the IRB and study participants.
- Principal investigators must report all adverse events and unanticipated problems that involve risks to study participants immediately to the IRB using the “*Adverse Event Reporting Form*”.
- The IRB will send a letter to the principal investigator 2 months before the expiration of a study as a reminder that the study will expire soon. Principal investigators are required to submit the “*Continuation or Termination of an Approved Protocol Form*” indicating if they will continue the study or terminate the study. In general, the IRB grants approvals for no more than one year. Some studies may be approved for a shorter time depending on the nature of the research. If an IRB approval has expired research activities must cease.

G. Criteria for IRB Approval of Research

(45 CFR 46.111) (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and 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 research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. 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 cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

H. Levels of Review

1. Exempt from Review

The following research activities are considered exempt from federal regulations as stated in 45 CFR 46.101(b):

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- Research 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.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:**
 - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifies linked to the subjects; and

- 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.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 - The human subjects are elected or appointed public officials or candidates for public office; or
 - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic formation is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research and demonstration 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 level of payment for benefits or services under those programs.
- 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 found 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 US Department of Agriculture. (45 CFR 46.101(b))

2. Expedited Review

Expedited review categories of research shall comply with "Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure". 63 FR 60364-60367, November 9, 1998.

- Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
- Prospective collection of biological specimens for research purposes by noninvasive means.
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for

marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- 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, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Continuing review of 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 no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Full Board Review

All proposed research deemed by the IRB chair to fit neither the exempt or expedited review must be reviewed by the full IRB. In addition, the IRB may require full review of any research submitted or approved under expedited review and any research not approved by expedited review.

The primary criteria for full board review are the risk to participants during the procedures and interactions between participants and researchers.

Examples of research activities that must be reviewed by the full IRB include:

- Research in which potential participants may not be given sufficient information to make decisions about whether to participate and accept potential risks. This may include research in which outright deception or incomplete disclosure of the purpose of the study might reasonably affect a person's decision to participate in the study.
- Research involving more than minimal risk, where defined as "the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests".
- Non-curricular, interactive research in primary and secondary schools.
- Research in which participation per se in the study constitutes a risk (e.g., identification as a participant in a drug-use survey). This would include research in which researchers have applied for a waiver of documentation of consent, which can be used as a method of reducing risks to participants who may be placed at risk simply by being involved in the study.

- Research on special populations, e.g., minors, prisoners, pregnant women and mentally incompetent persons.
- Research involving potential risks to participant's right to privacy and/or threats to confidentiality.

4. Continuing Review

The IRB is required to re-evaluate research projects at appropriate intervals not less than once a year. For research involving no more than minimal risk, the approval period is generally one year from the date of the convened meeting at which the protocol was reviewed and approved. For research involving greater than minimal risk, the IRB will determine the appropriate approval period.

Investigators are required to submit the *Continuation or Termination of an Approved Protocol* form to the IRB before the expiration date of the study.

An original protocol may have received an expedited review but the continuing review may go to the full IRB, as deemed necessary by the IRB Chair or a designee.

Continuing review is required for continued analysis of identifiable information but is not required if the data have been de-identified.

- For new analysis of previously collected identifiable data, a new IRB protocol is required.
- For a new analysis of previously collected de-identified data, no IRB review is required.

I. Forms Used to Provide Information to the IRB

The following forms are used to communicate with the SAU IRB. These forms are updated periodically, and may include:

1. New Protocol Application Form
2. New Class Project Application Form
3. Consent to Participate in a Research Study
4. Modification to a Previously Approved Protocol Form
5. Continuation or Termination of an Approved Protocol Form
6. Adverse Event Reporting Form

J. Contact Information

Saint Augustine's
University IRB
Boyer Building
Room 002
Raleigh, NC 27610

Telephone: 919-516-4500
Fax: 919-516-4002
Email: lgunn-jones@st-aug.edu

K. Glossary of Terms

Authorized Institutional Official - An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

Belmont Report - Under the auspices of the former United States Department of Health, Education, and Welfare (later renamed the Department of Health and Human Services), the Belmont Report was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and was entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The report was created on April 18, 1979 and gets its name from the Belmont Conference Center where the document was drafted. The conference center, once a part of the Smithsonian Institution, is in Elkridge, Maryland, 10 miles south of Baltimore, and is now operated by Howard Community College. The Commission was initiated in response to public outrage over revelations about the Tuskegee Syphilis Study (1932–1972).

Beneficence - An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

Children - Persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. In Texas, a child is anyone under 18 years of age. See also Vulnerable Subjects.

Cohort - A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

Common Rule - In 1991, 14 other Federal departments and agencies joined the U.S. Department of Health and Human Services in adopting a uniform set of rules for the protection of human subjects of research, identical to subpart A of 45 CFR 46. This uniform set of regulations is the Federal Policy for the Protection of Human Subjects, informally known as the "Common Rule."

Compensation - Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research. (*Compare: Remuneration.*)

Competence - Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (*See also: Incompetence, Incapacity.*)

Confidentiality - Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Declaration of Helsinki - The Declaration of Helsinki, developed by the World Medical Association, is a set of ethical principles for the medical community regarding human experimentation. It was originally adopted in June 1964 and has since been amended multiple times.

DHHS - A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

Ethics Advisory Board - An interdisciplinary group that advises the Secretary, HHS, on general policy matters and on research proposals (or classes of proposals) that pose ethical problems.

Exempt - Whether or not a research activity is exempt is determined by the IRB, NOT the researcher. In general, the types of research activities that will be considered exempt are:

Research conducted in established or commonly accepted educational settings, involving normal educational practices;

Research involving the use of educational tests, survey procedures, etc., unless the information is identifiable and disclosure would place the subject at risk (Important Note: Survey and interview research with children are NOT EXEMPT!);

Research involving educational tests, surveys, interviews or observation of public behavior if the subjects are elected or appointed public officials or federal statutes require confidentiality without exception.

Research involving the collection or study of existing data if the sources are publicly available or the information is recorded in a manner in which the subjects cannot be identified

Research and demonstration programs designed to study, evaluate, or examine federal public benefit or service programs.

Expedited Review - Certain kinds of research can be reviewed more quickly by one or more experienced IRB members either because the research is found by the reviewer(s) to involve no more than minimal risk, or it involves minor changes in previously approved research during the period (one year or less) for which approval was authorized. Whether or not review of a research activity is expedited is determined by the IRB, NOT the researcher.

45 CFR 46 - Refers to the Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects. 45 CFR 46 is the the U.S. Government policy for ensuring that the human subjects of behavioral and biomedical research receive the protections to which they are entitled and to minimize risks to them.

Federal Policy (The) - The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy. (Also known as the "Common Rule.")

Full Review - Research that potentially poses more than minimal risk to human research subjects must be reviewed by the entire IRB.

Grant - Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (*Compare: Contract.*)

Human Subject - A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information; i.e., information about behavior in a context in which an individual can reasonably expect that no observation or recording is taking place or information provided for specific purposes that the individual can reasonably expect will not be made public.

Human Subject Research - Any research or clinical investigation that involves human subjects.

Informed Consent - Informed consent is a legal condition whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of any actions. The individual needs to be in possession of all of her/his faculties, such as not being mentally retarded or mentally ill and without an impairment of judgment at the time of consenting. Impairments include illness, intoxication, drunkenness, using drugs, insufficient sleep, and other health problems.

Some acts cannot legally take place without informed consent. In other cases, consent of someone on behalf of a person not considered able to give informed consent is valid. Examples of this include the parents or legal guardians of a child or caregivers for the mentally ill.

Informed consent is important in social/behavioral and biomedical research. For example in survey

research, people need to give informed consent before they participate in the survey. In medical research the Nuremberg Code has set a base standard since 1947, and most research proposals are reviewed by ethics committees (IRBs).

Institutional Assurances - Formal documentary assurance submitted by an institution to the U.S. Office for Human Research Protections attesting to the institution's compliance with the requirements set forth in 45 CFR 46. Institutions engaged in research which is covered by 45 CFR 46 and which is conducted or supported by a federal department or agency must provide written assurance satisfactory to the department or agency head that it will comply the policy.

Institutional Review Board - An independent administrative body established to protect the rights and welfare of human research subjects. It consists of at least five members from varied disciplinary backgrounds who are qualified to review research. Membership should be diverse, with at least one member having a scientific background and at least one having a nonscientific background. Members should not participate in decisions in which they have conflicts of interest. People with specialized expertise may be invited to advise on specific reviews where the body lacks expertise.

IRB - Abbreviation for Institutional Review Board.

IRB Approval - The determination of the IRB that a research activity has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Justice - An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in research activity that are no greater than those encountered in daily life or the performance of routine physical or psychological examinations or tests.

Nonaffiliated Member - Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker).

Normal Volunteers - Volunteer subjects used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with subjects who do have the condition. "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease.

Nuremberg Code - A set of principles for human experimentation set as a result of the Nuremberg trials at the end of the Second World War. Specifically, they were in response to the inhumane Nazi human experimentation carried out during the war.

Privacy - Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Private information - 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). Private information must be individually identifiable (i.e., the

identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Respect for Persons - An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Review (Of Research) - The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis.

Risk - The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (See also: *Minimal Risk*.)

Surveys - Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

Voluntary - Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Vulnerable Subjects - Human subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Vulnerable subjects must be afforded special safeguards in a study to protect their rights and welfare.