

**A GUIDEBOOK OF
POLICIES AND PROCEDURES
FOR
RESEARCH INVOLVING
HUMAN SUBJECTS**



**The College of New Jersey
INSTITUTIONAL REVIEW BOARD**

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I. INTRODUCTION

The Institutional Review Board (IRB) at the College of New Jersey is an appropriately constituted administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities. In accordance with The College of New Jersey policy governing the use of human subjects in research and the Federalwide Assurance (FWA) (FWA00004576) maintained with the U.S. Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP), all human subjects research conducted by or under the auspices of The College of New Jersey will be performed in accordance with Title 45 Code of Federal Regulations, [Part §46 \(45 CFR §46\)](#). In addition, the actions of the College's IRB will conform to all applicable federal, state and local laws and regulations.

The IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory. The committee is formally designated to review and monitor biomedical and behavioral research that takes place on campus. It is charged with the responsibility and authority of approving, requiring modification in, halting unapproved or non-compliant research, periodically monitoring the progress of long-term records, or disapproving all research activities involving human subjects that fall within its jurisdiction.

The IRB is responsible for establishing and administering institutional policies and procedures through which the College conforms to federal, state and local regulations that govern the protection of human subjects participating in research (human research subjects).

All research involving the collection of information, data or specimens/samples from or about human subjects or information, data, specimens/samples gathered from humans at some prior time either by the researchers themselves or someone else, must be reviewed and approved prior to such studies being undertaken. This policy applies to:

- any research whether new, ongoing, or proposed, regardless of funding status and source, whether conducted at the College of New Jersey or elsewhere, by anyone affiliated with The College (i.e., faculty, staff, student).
- any investigator from outside The College of New Jersey that wishes to perform research on members of the TCNJ community or on its campus must have a College of New Jersey faculty or staff member serve as sponsor or co-investigator.

The policy does not apply to a faculty or staff member of The College of New Jersey who is hired as a consultant to do research outside of the college, and who performs the research outside of their capacity as an employee of The College of New Jersey.

The terms of the TCNJ FWA (but not necessarily all of the policies and procedures in this Guide) apply to all subcontractors and collaborators of research conducted by TCNJ personnel. The TCNJ principal investigator is responsible for assuring that appropriate human subjects protections are in place at the collaborating institution and, when they are not, bringing those protocols to the TCNJ IRB for approval.

The college's IRB Committee is directed by a chairperson, and is comprised of members with multidisciplinary expertise and backgrounds as required by federal policy. The Committee

determines the role and responsibilities of committee members and researchers in human subject protection. If appropriate, the Committee reports all violations of guidelines and regulations to the IRB chair. The Committee provides the Provost with an annual report of its activities and recommendations for Committee membership the following year. A current list of the IRB committee members is posted on the IRB website.

The purpose of the IRB review is to assure, both in advance and by periodic monitoring, that appropriate steps are taken to protect the rights and welfare of human research subjects. To accomplish this process, the IRB uses a group deliberation process to review and approve research protocols and related material (e.g., informed consent documents, investigator brochures, questionnaires). The focus of the process is to ensure that:

1. The risks to human subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the research participants to risk.
2. The risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.
 - For the purpose of IRB consideration, "risk" is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. In evaluating risk, the IRB is to consider the conditions that make the situation dangerous, per se (i.e., as opposed to those chances that specific individuals are willing to undertake for some desired goals).
 - For the purpose of IRB consideration, "benefit" is defined as a valued or desired outcome, an advantage.
 - In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research.
3. The selection of human subjects for research projects is equitable.
4. Human research subjects are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research; and that informed consent is obtained from each prospective human research subject, or his/her legally authorized representative, in accordance with, and to the extent required by federal regulations and IRB policies.
5. Informed consent of human research subjects is obtained in advance of research participation and appropriately documented in accordance with, and to the extent required by federal regulation and IRB policies.
6. The research plan, when appropriate, makes adequate provision for monitoring the data collected to ensure the safety of the human research subject.
7. There are adequate provisions to protect the privacy of human research subjects and to maintain the confidentiality of research data.
8. Appropriate additional safeguards have been included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g. children, prisoners, pregnant women, mentally or physically challenged persons, or economically or educationally disadvantaged persons).

II. DEFINITIONS

Adverse event:

An unwanted and unintended occurrence affecting a human participant during research. Adverse events may be unexpected or expected.

Adverse event reports:

Researcher reports of all serious adverse events, injuries, and/or deaths given to the sponsor, the IRB, the FDA, and the NIH.

Assent:

Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

Assurance:

A written, binding commitment filed with a Federal agency by an institution that wishes to conduct human research. The institution promises to comply with applicable regulations governing human subject research and stipulates the procedures through which compliance will be achieved.

Autonomy:

Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

Belmont Report:

The report entitled Ethical Principles and Guidelines for the Protection of Human Participants of Research generated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The ethical principles identified in this document: respect for persons, beneficence, and justice became the cornerstone of Federal regulation of protection for research participants.

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 no harm; and (2) protect from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Benefit:

A benefit in research is a valued or desired outcome enjoyed by the participant (therapeutic benefit), or accruing to a group under study, or to their family members, or to scientific knowledge (nontherapeutic benefit).

Certification:

The official notification by the institution to the supporting Department or Agency, in accordance with the requirements of 45CFR46, that a research project or activity involving human participants has been reviewed and approved by an Institutional Review Board in accordance with an approved assurance.

Child or children:

Persons who have not attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction in which the research will be conducted. Special rules and protections govern the participation of children in research.

Common Rule:

The “Common Rule” refers to Federal statutes governing the protection of human subjects in research, enacted in 1991 and adopted by 17 Federal agencies. The Common Rule is set forth in the Code of Federal Regulations, 45 CFR 46, and covers all federally funded research supported by the Departments of Agriculture, Energy, Commerce, HUD, Justice, Defense, Education, Veterans Affairs, Transportation, and HHS, as well as NSF, NASA, EPA, AID, Social Security Administration, CIA, and the Consumer Product Safety Commission. The provisions are identical to the DHHS Regulations (45 CFR 46, Subpart A).

Data:

Multiple facts (usually, but not necessarily, empirical) used as a basis for inference, testing, analysis, etc. or used as the basis for decision-making.

Data and Safety Monitoring Plan:

A plan with a general description of data and safety monitoring of a clinical research study. The plan is developed by the researcher, included in the protocol, and submitted to the IRB for review and approval before the study begins. An appropriate plan reflects the risks of the study, including its size and complexity.

Declaration of Helsinki:

Statement of ethical principles for human participation in biomedical research. The Declaration was first adopted in 1964 by the World Medical Association. It has been revised five times, most recently in 2000. Like the Nuremberg Code that preceded it, the Declaration

of Helsinki makes consent a central requirement of ethical research. The Declaration initially established a distinction between the standards for therapeutic and non-therapeutic research; however, this has been eliminated in recent revisions.

Double Masked Design or “Double Blind” Design:

A study design in which neither the investigators nor the subjects know the treatment group assignments of individual subjects.

Embryo:

The developing organism from conception or implantation until approximately the eighth week of pregnancy.

Epidemiology:

A scientific discipline that studies the factors determining the causes, frequency, and distribution of diseases in a community or specified population.

Expedited Review:

Review of proposed research by the IRB Chair or a designated voting member or group of voting members rather than the entire IRB.

Exclusion Criteria:

The list of elements in a person’s medical history that would prevent an individual from participating in a specific study.

Fetus:

The product of conception from the end of the eighth week of pregnancy until birth or expulsion.

Food and Drug Administration (FDA):

An agency within the Department of Health and Human Services (DHHS) that monitors the manufacture, import, transport, storage, and sale of goods regulated under the Food, Drug and Cosmetics Act and related Federal public health laws.

Guardian:

An individual entitled or authorized to make decisions affecting the health or medical care of another, including the ability to consent.

Human participant (subject):

A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction, or (2) identifiable private information.

Inclusion criteria:

The list of elements in a person's medical history necessary to allow an individual to participate in a specific study.

Informed consent:

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. Informed consent also refers to the process of information exchange between researcher and participant prior to participation in research. The information to be conveyed to the participant is factual information, including an assessment of the risks of participation, eight specific elements required by Federal regulations, a description of the procedures that will be performed, and the persons responsible. The information conveyed by the participant to the researcher is an indication of his or her comprehension of the process, the voluntary nature of participation, and understanding of his or her rights, including the right to withdraw.

The informed consent form is a written document, signed by participants in research studies prior to commencement of the study. The form is presented to and signed by the participant, who should have a chance to ask questions regarding the research prior to the commencement of the study.

Institutional Review Board (IRB):

A specially constituted review body established to protect the welfare of human participants in research. Federal law states that all institutions supported by a federal Department or Agency to which the Common Rule applies must establish an IRB to review and approve research involving human subjects.

Institutional Review Board approval:

The determination of the IRB that the research 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.

Intervention:

An action that produces an effect or that is intended to alter the course of a pathologic process. Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment performed for research purposes.

Institution:

Any public or private entity or Agency (including Federal, state, and other agencies); location of research.

Investigator:

In research studies, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the Investigator.

Justice:

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

Legally authorized representative:

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to his or her participation in the procedure(s) involved in the research.

Minor:

A person who has not attained the age of majority in a particular jurisdiction.

Minimal risk:

The probability and magnitude of harm or discomfort normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. This also includes the normal exercise and training routine of athletes and athletic teams.

National Institutes of Health (NIH)

The federal government's primary agency for advancing knowledge in biomedical and behavioral sciences intended to understand and treat human diseases. The NIH is part of the U.S. Public Health Service (PHS) within the Department of Health and Human Services.

National Research Act:

The law that authorized the creation of the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research in 1974 and mandated review of research studies by institutional review boards.

Normal “Control” Volunteers:

Volunteer subjects used to study normal physiology and/or behavior or who do not have the condition under study in a particular protocol. Normal volunteers may be studied for comparison with subjects who have the condition under study.

Nuremberg Code:

A code of research ethics developed during the trials of Nazi war criminals following World War II. This code became the first international standard for the conduct of research and began the modern era of protection for human research participants.

Office for Human Research Protection (OHRP):

The office within the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects. The OHRP has direct oversight and educational responsibilities wherever DHHS funds are used to conduct or support research involving human participants. Additionally, it serves as a research, guidance and educational resource for all institutions involved in conducting research that involves human partnership, regardless of the funding status of the research.

Parent:

A person’s biological or adoptive parent. In the conduct of research, the permission of the parent is generally necessary if the potential participant is a minor.

Permission:

The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Pregnancy:

The state of a female after conception or implantation until the birth of a baby or expulsion of the fetus.

Randomization:

Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

Recruitment:

The act of selecting and enrolling research participants for a study using proper inclusion criteria.

Research:

Federal research regulations and the Health Insurance Portability and accountability Act of 1996 (HIPAA) define research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” There are two key elements of this definition: (1) the project involves a systematic investigation, and (2) the design – meaning goal, purpose, or intent – of the investigation is to develop or contribute to generalizable knowledge.¹

Qualitative research may be exempt if the only procedures involve the use of...survey procedures, interview procedures or observation of public behavior, unless:

- (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and**
- (ii) 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.¹**

Researcher:

The individual who conducts and directs the study and carries the primary responsibility for the research. The Researcher is referred to as the Principal Investigator when acting as the leader of a research team.

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.

Risks:

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.

Risk/Benefit Analysis:

An analysis of the potential risks to participants considered against the potential benefits to the individual or to the research objectives of the study.

¹ Bankert, E.A. & Amdur, R.J. (2005). Institutional Review Board: Management and Function, pg. 101 and 397.

Sponsor:

An individual, company, institution, or organization that initiates and finances a research study. A sponsor is not necessarily the entity that conducts the research.

Therapy:

Treatment intended and expected to alleviate a disease or disorder.

Toxicity:

Having to do with poison or something harmful to the body. Toxic substances usually cause unwanted side effects to an organ system and/or to the participant's subjective status produced by therapy. Toxicities are graded numerically, with the lowest number representing no toxicity (e.g., 0 = none) and the highest number highest representing lethal toxicity (e.g., 5 = lethal).

Unexpected adverse event:

An adverse event not described in the Package Insert, Investigator's Brochure, published medical literature, protocol, or informed consent document.

Universal Declaration of Human Rights:

An international declaration adopted in 1948 by the United Nations as the first comprehensive agreement among nations as to the specific rights and freedoms of all human beings.

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 participants/population:

Individuals or groups of subjects who, by reason of disability, illness, age, or other status exhibit diminished personal autonomy. Neither the Federal regulations nor ethical codes, including the Belmont Report, proscribe inclusion of vulnerable persons as research subjects. However, DHHS regulations mandate special justification for research involving fetuses, pregnant women, and human in vitro fertilization [45 CFR 46 Subpart B]; prisoners [45 CFR 46 Subpart C]; and children [45 CFR 46 Subpart D].

III. STATEMENT OF PRINCIPLES

The College of New Jersey (hereafter, "the College") is committed to the pursuit of excellence in teaching, research, and public service. Concomitantly, the College seeks to protect the welfare of every person who may be involved in research and training projects. Members of the College community, although 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 College and society, and for the welfare of every participant in a project. The College gives assurance that it will comply with the federal policy for the Protection of Human Subjects (or "Common Rule," as it is sometimes called) (45 CFR §46, as amended) in accordance with the guidance set forth by the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services. 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, by the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research known as the Belmont Report, and for funded research, any additional human subjects regulations and policies of the supporting Department or Agency.

- A. The basic ethical principles set forth in the Belmont Report, respect for persons, beneficence, and justice underlie the requirements for the ethical conduct of research involving human subjects at The College of New Jersey. Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. Justice requires that the benefits and burdens of research be distributed fairly.
- B. Because the participation of humans in research and training projects may raise fundamental ethical and civil rights issues, 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 College employees, on-campus or off-campus.
- C. 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.
- D. The direct or potential benefits to the subject or the importance of the knowledge gained must outweigh the risks to the individual inherent in the proposed research.
- E. Participation in projects must be voluntary, and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the College's Institutional Review Board (IRB). 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 subjects' informed consent.

- F. When required, consent must be obtained from the participants themselves whenever possible. Further, if a subject is not legally or physically capable of giving fully informed consent, a legally authorized representative should 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 more than minimal risk except for the child's direct benefit.
- G. 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 to refuse to participate, 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 physical risk, embarrassment, discomfort, anxiety, and harassment. These rights need to be clearly defined for all potential subjects.
- H. The IRB acknowledges the potential for a conflict of interest or coercion in an academic setting where participants in research studies are also students in a course. The primary investigator is responsible for minimizing these effects in recruiting subjects.
- I. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. Investigators should detail to the IRB what security measures will be taken to ensure that privacy will be maintained. Records containing personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project. Specific subject information shall not be communicated to others unless one of the following conditions is met:
- Explicit permission for the release of identifying data is given by the individual.
 - Information about individuals may be discussed only for professional purposes and only with persons clearly involved in 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 a breach of confidentiality.
 - The investigator is legally required to provide such information (e.g., child abuse, sexual abuse, or other illegal activities revealed by a subject).
- J. An individual involved in the conduct and/or supervision of a specific project shall not participate in the IRB review, except to provide information.

IV. IRB REVIEW OF PROPOSED RESEARCH STUDIES

The IRB of the College of New Jersey must review and approve all research activities involving human subjects that fall within its jurisdiction prior to the implementation of such research activities. There are three categories of IRB review of proposed studies:

1. Expedited review,
2. Full board review, and
3. Research exemptions from IRB review.

Types of IRB Review

Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either full board review or expedited review.

Expedited Review

For certain kinds of research involving no more than minimal risk, and for minor changes in approved research, the IRB Chair or a designated voting member or group of voting members review the proposed research rather than the entire IRB. It cannot be assumed that research poses minimal risk because it involves only interview or survey data collection. Sensitive questions may lead to distress that exposes participants to greater than minimal risk. Loss of confidentiality can cause harm to participants, their relatives, and others.

Full Board Review

When full board review is necessary, the research proposal is presented and discussed at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those voting members present. (Note that, in effect, an abstention counts as a negative vote.)

Research Exemptions from IRB Review

Under Federal regulations [[45 CFR 46.101 \(b\)](#)], certain categories of activity are considered research but may be declared exempt from review by the IRB. Certain low-risk research is exempt from the requirements in the Federal regulations concerning IRB review and approval. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights. The researcher should not make the final determination of exemption from the applicable Federal regulations or the provisions of the institution. This determination should be made by someone other than the Principal Investigator. The College of New Jersey, in accordance with federal policy, requires that exempt status must be confirmed by the IRB. These confirmations are conducted by the IRB chair and/or his/her designee(s).

Following initial determination of exempt status, exempt research activities are not subject to annual renewal requirements.

The following are the six exempt categories listed in [45 CFR 46.101\(b\)](#):

- 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices. Research on the effectiveness of, or the comparison among, 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, unless:
 - (a) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to them and
 - (b) Any disclosure of the human participant's responses outside the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
- 3) 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 (2) of this section, if:
 - a) The participants are elected or appointed public officials or candidates for public office.
 - b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.
- 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified, directly or through identifiers linked to them. To qualify for this exemption these sources must be publicly available or the information or the information must be recorded.
- 5) Research and demonstration projects conducted by or subject to the approval of Federal department or agency heads and designed to study, evaluate, or otherwise examine public health benefit or service programs.
- 6) Taste and food-quality evaluation and consumer acceptance studies.

These exemptions do not apply to research involving prisoners, fetuses, pregnant women, or newborns. Further, the exemption in item 2 above does not apply to children, except in research involving observations of public behavior when the researcher(s) do not participate in the activities being observed. Interviews, surveys, and interactive observations are not exempt, while educational tests and noninteractive observations are.

Note that when research is conducted in countries outside the United States by foreign Principal Investigators, the rules for IRB review and exemption may differ if the bases for the institutional assurances are founded upon documents other than the Belmont Report and the Common Rule. Note that research conducted in countries outside the United States by U.S.-based Principal Investigators is not affected by this potential modification. Researchers should review the section covering international research for further information and always consult with their institution's IRB.

V. IRB MEMBERSHIP; COMPOSITION, PROCESS, AND FUNCTION

- A. The membership of the IRB shall include at least one community representative, the Provost or his/her designated representative who shall serve ex-officio, and a minimum of six faculty members. Faculty members will be selected according to the College's research needs, but shall include at least one member whose primary expertise is in a non-scientific area (e.g., law, religion, or ethics). Ideally, the Committee should include members from a variety of disciplines on campus. The Committee 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 subjects. ([45 CFR §46.107\(a\)](#))

The Committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the Committee. These individuals shall have no voting rights.

Appointments to the Committee shall be made by the Provost on recommendation from the IRB. Faculty representatives shall typically serve three-year terms, with one-third rotation each year. Non-faculty representatives shall also serve for a three year term. The Chair, vice-chair and recorder shall be elected from among the committee members by a majority vote of the committee. Officers of the IRB will maintain their position until the end of their term or for a three-year period, whichever comes first. An officer of the IRB may be reelected, and there are no limits to the number of terms they may serve.

IRB members are expected to attend all meetings. It is acknowledged that at times conflicts may arise that prevents attendance. However, it is expected that members will make every effort to attend each meeting. If an IRB member does not attend more than half of the meetings in an academic year, they will be removed from the IRB committee.

- B. A quorum of the members of the IRB, including at least one member whose primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Final approval by the IRB shall then require a two-thirds vote by members present. If the IRB agrees that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of

approval. A letter of approval will be sent to the investigator with copies to the faculty advisor (if appropriate) and to the school or department internal review committee (if any). A copy of the letter of approval will be maintained by the IRB.

- C. Departments and schools may continue to operate internal review committees. The TCNJ IRB is working on guidelines for such committees. If your department is interested or planning an internal review process, please contact the IRB Chair to begin conversation. These internal review committees shall provide preliminary reviews of their divisions' proposals prior to review by the College's IRB, but shall not replace the review of the College's IRB. The College's IRB will not consider a proposal originating from within those schools or departments that maintain internal review committees unless the proposal first has been approved by that committee.
- D. All e-mail and written correspondence between authors of proposals and reviewers will be maintained for a period of three years in the IRB file.

VI. IRB PROCEDURES, INSTITUTIONAL RESPONSIBILITIES AND INVESTIGATORS' RESPONSIBILITIES

- A. All human subject research proposals affiliated with The College of New Jersey will be electronically submitted for documentation and tracking under one of three categories: Expedited, Full, Exempt. The IRB will determine the category of review. Researchers cannot exempt from review their own study or research for which they are responsible. Similarly, individuals involved in the conduct and/or supervision of a research project cannot participate in its review, except to provide information to the IRB.
- B. The College's IRB has the authority to approve or disapprove all research using human subjects. "Human research" includes undergraduate research (e.g. Honors), graduate thesis research, faculty and staff research, and research conducted by external investigators. Unapproved research may not be conducted on campus under any circumstance. Individuals connected with the College must have their off campus human research approved or exempted if the researcher indicates to subjects or other participants an affiliation with the College, if College funds or equipment are used, or if the research will be used to fulfill a degree requirement at the College.
- When the investigator is a student, ultimate responsibility for the conduct of this research and the supervision of human subjects lies with the faculty sponsor. Following project approval, the faculty sponsor must provide proper oversight and review to ensure that subject recruitment, informed consent procedures, and subsequent contact with subjects are in conformity with approved guidelines.
 - Outside investigators (non-College of New Jersey students or employees) conducting human subject research on The College of New Jersey campus or conducting research associated with the College are subject to the principles,

procedures, and responsibilities outlined in this manual. In addition, they must have a sponsor from the College of New Jersey faculty or staff.

- C. The IRB recognizes the need for a thorough and prompt assessment of proposals. To expedite proposal review the Chair may choose the most efficient procedure for processing a particular proposal. All proposals that require a full board review shall be presented at a convened meeting of the IRB at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Any member requesting minor changes may authorize the Chair to negotiate such changes, with or without requiring that they personally approve the revisions prior to the issuance of the approval letter. If a committee member has a major objection to such a proposal, that member may call for a meeting of the full committee to review the changes.

The principal investigator (and faculty sponsor, if appropriate) may be invited to meetings held to consider the proposal. Even if the consensus of the IRB is favorable, the IRB may elect to impose additional restrictions or recommendations under which the project shall be conducted.

- D. If the IRB does not approve an application, reasons for this negative decision will be provided in writing to the principal investigator or project director. If the researcher decides to modify the proposed research in such a way as to overcome the objections of the IRB, the investigator may resubmit the proposal for consideration and/or have the Chair call an IRB meeting during which the investigator may defend the proposal or the modifications.
- E. Principal investigators must immediately report to the IRB chair any emergence of problems or development of hazardous conditions for subjects. The IRB must approve an amended protocol before the research may continue.
- F. When granting initial approval of a proposal, the IRB will indicate the minimum intervals needed for re-evaluation of the project in order to assure continued acceptance of the proposal. Routine projects will be reviewed at yearly intervals; more complex and/or potentially dangerous projects will be reviewed at a frequency commensurate with the related risks. Projects that are determined to be exempt will not require additional review. Renewal projects should include a progress report as well as a description of any anticipated design changes. Projects may also be reevaluated if someone involved in the research lodges a complaint with the IRB or if the principal investigator reports problems with the research. In the latter case, the IRB may elect to review the data accumulated by the investigator and may interview both the research staff and persons at risk.
- G. Investigators may submit proposals acknowledging that human subjects will be involved with the project, although plans for the involvement are indefinite. Such proposals will be reviewed and guidance will be provided. For IRB approval, however, formal review and approval will be required once complete plans are made, but before utilizing human

subjects. In the case of an externally funded project, this later review and approval must precede the beginning of any grant budget period during which human subjects would be utilized.

Ongoing projects modified to include humans as subjects must be submitted to the IRB for review and approval prior to the use of human subjects. In the case of an externally funded project, the granting agency would be notified of IRB action before the appropriation cycle for a budget period during which human subject involvement is proposed.

- H. In the case of a proposal submitted to an external funding agency, one copy of the complete proposal must be submitted to the IRB along with the IRB application. The IRB will make every effort to review and provide IRB approval in time for the proposal submission deadline. However, it is recommended that all completed materials be submitted to the IRB at least one month before the proposal deadline (additional lead time is needed over the summer).
- I. Primary responsibility for adherence to high ethical standards, to federal and state laws, and to College regulations must remain in the hands of the individual faculty, staff members and students who comprise this institution. They must make the initial decision as to whether their activities are or are not "human research" subject to review by the IRB. At times, this decision is not easily made. If any investigator is unclear as to whether proposed research is subject to review, it is recommended that the investigator seek the advice of the IRB Chair or the appropriate internal review committee, if any exists.
- J. As set forth in [45 CFR §46.113](#) Suspension or Termination of IRB Approval of Research, "an IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action, and shall be reported promptly to the investigator and appropriate institutional officials and the department or agency head.
- K. The electronic submission procedures, along with these policies and procedures, sample consent forms, and links to information concerning the use of human subjects in research may be found on the IRB web site. This site is maintained by the IRB under the direction of the Provost.
- L. Proposals must be submitted at least two weeks before the next IRB meeting for proper review. The IRB calendar is posted on its website.

VII. CRITERIA FOR IRB APPROVAL OF RESEARCH

In order to approve research, the IRB must ensure that the following requirements are satisfied:

- Risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from those participants would receive even if not participating.
- Selection of participants is equitable. The IRB should consider the purposes of the research and the setting in which the research will be conducted and be particularly mindful of the special problems of research involving vulnerable populations. Participants should share equally in foreseeable benefits and risks.
- Informed consent is sought, and will be obtained, from each prospective participant or the participant's legally authorized representative in accordance with, and to the extent required by 45 CFR 46.116.
- Informed consent is 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 participants.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- Additionally, when some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, or mentally disabled, economically disadvantaged, or educationally disadvantaged persons) additional safeguards are included in the study to protect the rights and welfare of these participants.

The IRB is concerned with the maintenance of proper records and the protection of anonymity and confidentiality of all data collected. Furthermore, the IRB will attempt to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participation.

Assessment of Risks and Benefits

When approving research, the IRB must assess whether the anticipated benefit of the research—either new knowledge or improved health for the research participants—justifies inviting anyone to undertake the risks. The IRB should not approve research in which the risks are judged unreasonable in relation to the anticipated benefits.

Risks to individuals are classified as physical, psychological, social, legal, and economic. In the process of determining what constitutes a risk, only those risks that may result from the research, as distinguished from those associated with therapies participants would undergo even if not engaged in research, should be considered.

Once risks have been identified, the IRB must assess whether the research poses minimal or greater than minimal risk. Minimal risk (defined in 45 CFR 46.102) is defined such 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.

The concept of minimal risk is used in the Federal policy for three purposes. First, the concept guides the IRB to determine if the proposed research should be reviewed by the entire Board or if it may qualify for expedited review. Second, it is used to determine what research can proceed without consent, and third, the concept is used to decide when documentation of subject consent may be waived.

IRBs must ensure that risks to participants are minimized. Researchers should include strategies for reducing risks in the protocol. For example:

- Precautions, safeguards, and alternatives should be incorporated into the protocol to reduce the probability of harm or to limit its severity or duration.
- IRBs should determine whether the researchers are competent in the planned area and whether they serve dual roles (e.g., as clinician and researcher) that may result in conflicts of interest and lead to a “therapeutic misconception” being held by the research participant. For student research, primary responsibility for research design lies with the faculty sponsor.
- IRBs should assess whether the research design will yield useful data, so that research participants are not exposed to risks without sufficient justification.

The IRB must be notified of any unanticipated problem involving risks to participants or others, including physical or psychological injury to participants, improper disclosure of private information, economic loss, or other potentially harmful occurrences.

VIII. INFORMED CONSENT

Once the researcher has a carefully defined research question, a valid design and protocol for a research project, it is time to plan for the informed consent for those invited to participate. Planning involves deciding:

- What information to provide to potential participants, both in writing and in discussions;
- Deciding who is going to present the information and at what point in your interactions with participants;

- How the participants understanding will be assessed; and
- Who will obtain the participant's signature or agreement.

This plan must be reviewed and approved by an IRB before approaching potential participants.

Informed consent, as a legal, regulatory, and ethical concept, has become widely accepted as an integral part of research. Current requirements for informed consent owe much to the legal system, but the underlying values are deeply embedded in American culture and the American character. Fundamentally, informed consent is based on respect for the individual, and, in particular, the individual's autonomy or capacity and right to define his or her own goals and make choices designed to achieve those goals in life. This right is well established in American jurisprudence and medical practice and applies to all types of medical interventions and clinical research.

Informed consent in research means more than simply obtaining the signature of the potential research participant. It is a process that involves conveying accurate and relevant information about the study and its purpose; disclosing known risks, benefits, alternatives, and procedures; answering questions; and enabling the potential participant to make an informed decision about whether to participate.

General requirements for informed consent in federally funded research are spelled out in the *Code of Federal Regulations*, [45CFR.46.116](#). Certain states have additional statutes regulating research.

Elements of Consent

In order for consent to be valid, it should be based on the following critical elements:

- The participant must be **COMPETENT** to begin the informed consent process. If the participant is not competent because of age, illness, incapacity, or any other reason, special provisions apply, or the participant may not be included in the research.
- The research team must **DISCLOSE** all relevant information to the potential participant. The information must be sufficient to allow the potential participant to decide whether to participate. IT is generally accepted that the potential participant must be given the following information: the purpose of the study; nature of the procedure; reasonable alternatives to the proposed intervention; and risks, benefits, and uncertainties of each possible intervention.
- The participant must **COMPREHEND** the information. The research teams must evaluate the potential participant's ability to understand the proposed intervention in the study.

- The participant must **AGREE** to the proposed intervention in the research study.
- The participant's agreement must be **VOLUNTARY** and free from coercion.

Finally, participants must be informed that even after they have made a voluntary agreement to participate in the study, they may **WITHDRAW** such agreement at any time without penalty.

Preparing the Consent Document for IRB Review

The first step in the process of informed consent is preparing the written consent document for presentation to the IRB. This document should include all the elements listed in Table 1 in Appendix D (and required by 45CFR.46.116), as well as any other information prospective participants might need to make an informed decision about participation. Consent documents should be written in nontechnical language that can be understood by the proposed participant population—consistent with their educational level, familiarity with research, and cultural views.

The consent document must make clear that participation in research is voluntary, and it should not include any language waiving or appearing to waive participants' rights. In some cases, the researcher may want to request that the IRB approve a modification or waiver of the elements of informed consent as spelled out in the regulations.

Advertisements, fliers, or brochures prepared to recruit and inform potential participants about a study are considered part of the informed consent process and, as such, also require review and approval by the IRB.

Approaching Research Participants

Researchers and members of the research team are responsible for making sure that the process of informed consent conforms to the value of respecting individuals' right to make informed and voluntary decisions about research participation, as well as to the regulations guiding research with human participants. In this regard, after receipt of IRB approval of the consent plan, there are several essential steps to take in the process of informed consent. The researcher and responsible research team members should:

- Feel confident that the potential participant has the capacity to understand information, make decisions, and provide informed consent for the particular study.
- Provide both written (as described above) and oral information about the details of the study in a way that is understandable to the participant.
- Be satisfied that the participant understands the information provided and has had an opportunity to ask questions and deliberate about participation.
- Be satisfied that the participant is in a position to make a voluntary decision and has not been coerced or unduly influenced by circumstances or other people.

- Be satisfied that the participant agrees to participate, as indicated in most cases by signing an informed consent document.

How does the researcher determine if a participant has the capacity to consent?

Adults have the capacity to consent when they possess sufficient mental capability to understand the information provided, appreciate how it is relevant to their circumstances, and make a reasoned decision about whether to participate in a particular study. Children (in most jurisdictions those under 18 years of age) do not have the legal capacity to consent independently.

Capacity can be affected by several things, including age, cognitive impairment, illness, and treatments. Capacity to consent for a study is study-specific. For example, a person may have sufficient capacity to carry out daily activities and make decisions, but not sufficient capacity to appreciate how the particulars of a given protocol might be relevant.

For some participants or groups of participants, the researcher or the IRB may decide that an independent capacity assessment is a good idea. This may involve consulting with a psychiatrist or neurologist to make a determination about an individual's cognitive ability and should include an independent assessment of the person's ability to understand the details and implications of the protocol being presented.

If a person is unable to provide his or her own consent, a legally authorized representative can in some cases give permission for participation in research. A legally authorized representative is a legal guardian; a parent (for children only); and in some cases, a validly designated durable power of attorney for health care (the latter is an evolving area). The researcher should check with institutional policies or assurance and the IRB.

What should the researcher consider when providing information to potential participants about the study?

The provision of information about a study usually involves more than just furnishing the written consent document to the potential participant to read. Oral presentation of information and the opportunity to discuss and answer questions and concerns are important parts of the process, usually in addition to giving the person time to read the written consent form. Educational materials about the study or clinical research in general are helpful. If the researcher delegates the function of oral presentation and discussion of a study to members of the team, he or she must be sure they have sufficient knowledge of the protocol to answer questions appropriately. Delegation may have to be approved by the institution's IRB.

How does the researcher assess the participant's understanding?

The researcher should feel satisfied that after the detailed information has been presented and discussed, the potential participant understands it well enough to make a decision. Of course, some studies are more complicated and involved than others. Researchers use many different strategies in determining whether or not a research participant understands. Sometimes it is

clear at the end of a discussion; other times, having a participant answer questions about the study, either informally or even in writing, may be appropriate. The best method may depend on the complexity and risk level of the study as well as on the potential participants.

How does the researcher know whether the participant's decision is voluntary?

Individuals who feel “coerced” into making a decision about research participation or are in a position in which it is impossible or extremely difficult for them to say “no” should not be enrolled into research. Coercion occurs if there is some threat of harm or punishment for refusal to participate. Individuals in relationships of unequal power or dependence have historically been particularly vulnerable to coercion. Examples might include telling students they would fail a course, employees they would not be promoted, or soldiers they would be reprimanded if they refused to participate in research. Coercion in research is rare due to the vigilance of research teams and IRBs.

All decisions, including decisions about research participation, are subject to the influences of one's previous experiences and circumstances. Sometimes, understanding an individual's reasons for considering participation is helpful in assessing how voluntary a decision is. The goal is to be sure that individuals understand research participation as a choice or an option among other—albeit in some cases, limited—options. Being sure that individuals understand that they can freely refuse to participate and/or withdraw at any time without penalty is critical to ensuring voluntary consent.

Must the researcher always obtain an individual's written signature?

In most cases, consent to research participation is documented by obtaining the signature of the participant or a legally authorized representative on the written informed consent document. A copy of this document should be given to the person signing the form. By Federal regulation, a signature is required on the written document containing all the required elements of information—or on a short form and written summary of the information when the information has been presented orally, as spelled out in [45 CFR.46.117\(b\)\(2\)](#).

In some cases, a signed consent document is inappropriate. According to the Federal regulations at [45 CFR.46.117\(c\)](#), the IRB may waive this requirement if it determines:

- There is a confidentiality risk, and the only link between the participant and the research would be the consent document.
- The research presents no more than minimal risk of harm and involves no procedures that normally require informed consent outside of research.

Consent by Proxy and Implied Consent

Proxy consent, or consent to participate in research by one competent adult on behalf of another, may be appropriate under certain circumstances. All uses of proxy consent must be approved by an institution's IRB.

If the prospective participant is identified as incompetent to provide informed consent, and if the condition of being incompetent is temporary, (if for example, potential participants have received sedating or pain-relieving medications and consent must be obtained before the effects wear off), the duration of the incompetence is unknown (for example, when a potential subject is in a coma resulting from traumatic injury), or the potential participant is cognitively impaired, the subject's legally authorized representative is responsible for deciding whether the subject should participate in the research. This person will sign the consent form on behalf of the participant and will indicate his or her relationship to the subject.

Consent from the subject's legally authorized representative should be obtained by the researcher in person and documented on the approved consent form.

Consent provided by a proxy should never be accepted if the potential participant has indicated refusal to take part in the research.

Research with Children and Assent to Research

Legally, children have not attained an age at which they can consent to research or treatment. Therefore, special provisions for agreement to participate in research are established in Section 46.408 of the Federal regulations. This section establishes the requirements for obtaining permission from parents or guardians and assent from children. The parent or guardian may provide "permission" for the child to participate in a study. Permission means the agreement of parent(s) or guardian(s) to the participation of their children or wards in research. Valid permission can be given only following an explanation incorporating the information currently required for informed consent.

In most cases, the child must indicate willingness to participate by assenting to the study. Assent means a child's affirmative agreement to participate in research. By law, failure to object may not be construed as assent. IRBs make the final determination if sufficient protections exist for children and how assent should be documented.

The inclusion of children in research studies poses many ethical and legal questions. For further information, link to: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

Waiver of Consent

Federal law (see Title 45 CFR 46.116(d)) permits an IRB to waive the requirement of obtaining written prospective informed consent under the following essential conditions:

- The research poses no more than minimal risk to subjects.
- There are no adverse effects as a result of the waiver or alteration.
- Without the waiver or alteration, the research in question could not be carried out.
- Information will be provided after participation is completed, if appropriate.

Special Issues In Informed Consent

Language Barriers

Information relevant to participation in research must be communicated to participants “in language understandable to the subject,” and in most situations, such informed consent must be documented in writing (45 CFR §46.116 and §46.117).

According to the statute [§46.117(b)(1)], the written consent document must include all elements necessary for legally effective informed consent in language comprehensible to the intended participants. Thus, participants who are not native English speakers should be provided with a consent document in their native language, written at a level that makes the information comprehensible.

The statute also provides for an alternative method of obtaining informed consent via oral presentation, accompanied by a short-form written consent document (stating the necessary elements and a written summary of what is presented orally). In that event, a witness to the oral presentation is required, and the participant must receive copies of the short-form document and the summary. The witness must be fluent in both languages.

Community Consent and Cross-Cultural Issues

Researchers conducting studies in multicultural settings have found that it sometimes is not enough to obtain individual consent using traditional concepts and rules. For example, among some ethnic groups, the role of the individual is secondary to the individual’s role as part of a community, and there is no distinct concept of individual will or identity. In other groups, women will defer to the decisions of their husbands, fathers, or other male relatives and will not express their own wishes. In still other groups—and depending on the nature of the research—the implications of participating in research extend beyond the individual and affect the entire group or community.

Community may be defined as a group living in proximity, a group related by blood or marriage, or a group with a common religious, ethnic, or racial heritage or identity.

The concept of community consent has developed, largely in response to research involving identifiable groups. Research with these groups, which are sometimes related by blood as well as living in proximity, requires a reconsideration of traditional concepts of consent. Traditionally, consent was a private matter between an individual patient and a treating physician. Today, the implications of participation in research may involve information that affects family and community members as well. For example, members of one group may feel stigmatized if a number of members of that group participate in research that reveals unpopular or dangerous traits. This may be true for behavioral research that indicates certain behaviors (such as alcoholism or violence) that portray others in the community unfavorably. Moreover, the conduct of clinical research may reveal general information that renders a group less desirable genetically, potential marriage prospects or employment opportunities. As a result, some believe that community consent should be an additional or at least an issue

addressed as part of education provided to participants—individual consent as a requirement for the ethical conduct of research.

IX. GUIDANCE FOR ENROLLING COLLEGE STUDENTS AS RESEARCH SUBJECTS & USING STUDENT SUBJECT POOLS

In some research situations, use of students is integral to a research protocol. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning. In the social and behavioral sciences course credit is commonly offered for research participation.

An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary and based upon full and accurate information. The student-faculty relationship raises the issue of voluntary participation. Students may volunteer to participate in the belief that doing so will place them in a favorable situation with faculty (e.g., better grade, good recommendation, employment possibilities), or that failure to participate will negatively affect their relationship with the investigator or faculty (e.g. lower grade, less favorable recommendation, being “uncooperative” and not part of the scientific community).

Care should be taken to eliminate or reduce the risk that undue influence of faculty or coercion affects student participation in research. The following guidelines are offered to assist departments and faculty who engage in research projects in which students will be asked to be research subjects:

Students should be of the age of majority in the state of New Jersey (18 years old). Research involving minors (under 18 years of age) as subjects, (16 or 17 year old college students) in most instances requires a signed parental (or legal guardian) consent, as well as the signed assent of the student. Some types of research may qualify for a Waiver of consent (parental permission).

Generally researchers may not access classroom performance evaluations, grades, and information in a (current) student's records without prior written permission from the student, regardless of the access an investigator may have in his/her academic role.

When research activities to be done by the students are not part of the required class activities, the instructor should arrange to have the data collected by an independent third party, so that the instructor does not know who participated and does not have access to the identifiable data or identity participants for any purpose until grades have been assigned and entered. For instructors using pre- and post- tests to determine efficacy of a particular curriculum, a colleague or third party should obtain the consent forms and distribute the tests when the instructor is not present (a graduate assistant in the class in which the student/subject is enrolled does not qualify as a third party for collecting the data on behalf of the instructor).

When course credit or extra credit is given to students who participate in research as part of a course requirement, students are to be given other options for fulfilling the research component, for example; short papers, special projects, book reports, and brief quizzes on additional readings, research seminars, or completing a similar project. These projects must be comparable in terms of time, effort and educational benefit to participation as a research subject to insure that students are not being coerced into becoming subjects. Alternatives offered to student subjects need prior IRB approval. Departments seeking to use student subject pools and offering projects including pre- and/or post- testing also require IRB approval.

Solicitation of volunteer student subjects for research must be done in a non-coercive manner. To avoid undue influence, subjects should be recruited by a general announcement, central posting or announcement mechanism and should include a clearly written description of the project and a statement of the proposed student participation. In addition to being provided with the traditional information and consent forms, the student should also be provided with the name and contact information of a neutral third party to contact should they feel coerced at any time during the process.

Whenever possible, researchers should avoid data collection during regular class meetings. When study participation consumes a significant portion of a class section, loss of instructional time for both participants and non-participants may be considered a loss of benefits. Also when research participation is expected during the same session at which participation is invited students may be unduly influenced to take part due to peer pressure, perceived stigmatization from non-participation, or a sense of having otherwise wasted time by attending that day's class.

Since there are special risks of confidentiality in the close environment of the college, special attention should be given to full disclosure of these risks in the consenting of a student to participate. The plan for handling consent forms and research data should also be designed to minimize the risk that confidentiality will be breached (e.g., signed consent forms can be collected and filed separately from the anonymous test instrument). When instruments call for the disclosure of information which participants may view as personal or sensitive, data should be collected in a manner that minimizes the chance of one participant learning the response of another.

The use of mass testing (classroom scenario) is strongly discouraged. Whenever possible, students should be allowed to access web-based research related activities via designated or personal computers. Using an application such as *Qualtrics* is also desirable because it allows the student to register for participation in specific research activities outside of the view of others at the time and place of their choosing.

Like other research volunteers, students who become research participants must be allowed to withdraw from the study at any time. The informed consent statement should make clear the consequences of withdrawing from a project prior to completion. In general it is favorable to give credit if the subject withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.

If the research is one where data are collected from a group project or perhaps a videotape of the group interaction, each student's consent is necessary for the use of that data in the instructor's research. If one student does not consent, the data may be used only if the non-consenting student's data can be effectively excluded.

When deception is used students have the right to full disclosure as soon as possible. **Two consenting presentations are required**, the **first** of which will normally take place during the pretesting period; the **final informed consent** will be presenting at the *debriefing*. Whenever possible a teaching opportunity in the form of an "educational debriefing" should be employed. Students should know something about the rationale for the study, the process of data collection, and intent of the researcher. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the completion of data collection. In such cases, students must not be subjected to undue stress or embarrassment and must have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected. During the debriefing students must be given an opportunity to decide whether the researcher(s) can use the data collected.

Research conducted by graduate students in a class in which the researcher teaches, assists in the class or does any grading should be subject to the same restraints described above.

INDIVIDUAL (UNAFFILIATED) INVESTIGATORS (non-TCNJ employees) seeking to enroll TCNJ students into human subject research protocols are subject to the principles, procedures, and responsibilities outlined in the TCNJ Institutional Review Board Guidebook of Policies and Procedures for Research Involving Human Subjects. They must contact the IRB Chair and have a sponsor from the TCNJ faculty or staff. **Prospective enrollment of TCNJ students into research without the written approval of the TCNJ Institutional Review Board is strictly prohibited.**

DEPARTMENTAL CONSIDERATIONS When Using Student Subject Pools

1. What is a Subject Pool?
 - a. Chance for students to earn credit
 - b. Opportunity for students to learn about the experiences of human subject research
 - c. Easy recruitment method for investigators

2. What are the Issues Surrounding the Use of Subject Pools?
 - a. Voluntary participation
 - b. Research volunteer versus student rights of participation
 - c. Coercion (mass teaching)
 - d. Breach of confidentiality
 - e. IRB oversight
 - f. Institutional Responsibilities

3. Maintaining Documentation of Participation

- a. Maintaining records to obtain credit
 - b. Maintaining data records
 - c. Maintaining records to document payment per IRB reporting requirements
4. What are the IRB Responsibilities for the Use of a Subject Pool?
- a. Satisfactory risk/benefit ratio
 - b. Equitable selection of subjects
 - c. Satisfactory informed consent process
 - d. Protection from coercion due to mass testing
 - e. Comparable alternative activity(s)
 - f. Adequate privacy and confidentiality guarantee
5. What are the Main Risks in Using Subject Pools?
- a. Coercion due to in-class (mass) testing
 - b. Breach of Confidentiality
 - c. Lack of comparable alternative activity(s)
 - d. Position as a research participant overrides position as student, during research participation
6. How to Minimize Risks?
- a. Comparable alternatives
 - b. Sign-in form kept separate from consent form (agreement with institution/department)
 - c. Must be able to withdraw at any time without penalty
 - d. Use of anonymous, minimal risk studies
 - e. Appropriate role of undergraduates as research staff
 - f. Excludes students <18 years of age; or (if exclusion is not appropriate), assent student and consent legal parent or guardian, or
 - g. Students <18 years of age may participate (e.g., for the education or experience), but their data cannot be used in the research
7. Parental Consent and Child's Assent for Participation
- a. All subjects must consent
 - b. Parents must give permission for minors
8. Requirements for the Use of Subject Pools
- a. Only exempt or minimal risk research will be permitted
 - b. Parental consent for those under 18, if the data is intended for research use
 - c. Students fully informed of their rights as participants
 - d. Documentation of participation to receive credit remains separate from documentation for participation in the research
 - e. Studies must have IRB approval prior to initiation
 - f. Must provide comparable alternatives
 - g. Decrease presence of coercion
9. Recruitment vs. Informed Consent
10. Special Issues in Prescreening and Database Management of Subject Pools

- a. Student access to student (identifiable) information
- b. Privacy and confidentiality

X. IRB GUIDANCE FOR STUDENTS INVOLVED IN OR LEADING RESEARCH

Federal regulations and college policies require Institutional Review Board (IRB) approval for research with human subjects. Research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” There are two key elements: (1) the project involves a systematic investigation, and (2) the design – meaning goal, purpose, or intent – of the investigation is to develop or contribute to generalizable knowledge. This applies whether the research is conducted by faculty or students, by individuals or a group. *Failure to obtain proper approval in advance may jeopardize your data, prevent you from publishing the results, and place you and the college in violation of federal regulations.* At the same time, many class projects are conducted for educational purposes and not as research, and will not require IRB approval. This guidance will help you determine whether you need to get approval from the IRB before conducting a given activity. Please note that IRBs do not have the option of granting “retroactive” approval after research is done; you should err on the side of submitting or consulting with the IRBs if there is any doubt. All forms and additional guidance are available at www.tcnj.edu/~irb.

STUDENT-LED RESEARCH

Student research activities include, but are not limited to class related projects, projects that result in undergraduate honors theses, masters theses, and Mentored Undergraduate Summer Experience (MUSE) projects. *IRB approval is generally required if human subjects are involved, either directly or through use of identifiable data about them... AND... the intent is to develop new or expanded knowledge that is generalizable.* Student researchers have the same submission options as any investigator. They may submit as Principal Investigator (PI) with a faculty advisor* as co-signator, which may be appropriate for new projects where the student has a leading role. Alternatively, it may be appropriate for the student researcher to be included on an existing faculty-led project that already has IRB approval, if the student activity is (or will be, after modification) subsumed under that existing study. This latter option precludes the need for a separate IRB application from the student. Each research scenario has its own set of circumstances that will dictate handling.

*The **Faculty Advisor** is responsible for reviewing and insuring compliance with IRB proposal submission, integrity, and conduct of research process and ultimately responsible for insuring that TCNJ policies and procedures are followed.

Here are some common scenarios, with likely processing requirements:

RESEARCH that involves **direct interaction** with individuals (e.g., in person, via mail, email, web survey, or telephone), or **data from human subjects for which the researchers will have access to identifiers**.

→ **IRB approval required** → **Submit eIRB application, either with student as PI or listed as study personnel on faculty application; or modify existing study if student project is directly related.**

Student researcher, co-investigators (if a group) and faculty advisor are required to have current research ethics certification

RESEARCH that is limited to **secondary analysis** of data, records or specimens that are either **publicly available, de-identified or otherwise impossible to be linked to personal identities**.

→ **IRB approval may be required** → **Submit eIRB application either with student as PI or listed as study personnel on faculty application.**

If IRB approval is not required, a data use agreement between the researcher and the data custodian may still be required to verify that the researcher will not have access to identifying codes. It is this “de-linking” of data from personal identifiers that allows the IRB to make this determination.

If the IRB determines that this project is not human subjects research, research ethics certification of the student(s) is not required by IRB, but may be required by the faculty advisor.

RESEARCH-like activities using departmental subject pools (e.g., Psychology, Business, Political Science, Journalism and Communications) even when the activity is conducted for educational purposes as a class requirement.

→ **IRB approval required unless IRB approved departmental internal review processes are in place (see guidance for enrolling TCNJ students as Research Subjects & Using Student Subject Pools)** → **submit an eIRB application for each activity by an individual or small group.**

Student researcher, co-investigators (if a group) and faculty advisor should have current research ethics certification.

CLASS PROJECTS
(EXCLUDING HONORS THESES, INDEPENDENT RESEARCH PROJECTS,
MASTERS THESES)

Class projects are generally conducted for educational purposes and not as research, excluding honors theses, independent research projects, and masters theses. While some require submission of an **IRB application** or a **determination that IRB approval is not required**, many class projects require neither. Instructors and departments are encouraged to contact the IRB for guidance about ways to handle topics such as privacy, confidentiality, informed consent, and professional ethics when class projects are part of the course syllabus. IRB members can share expertise related to managing risks of deductive disclosure, coercion-free recruiting, informed consent, and special consideration for projects that include potentially vulnerable individuals. These issues may still remain even when IRB approval is not required, in which case instructors, advisors, departments and schools play an even greater role in providing the appropriate guidance and oversight. Common scenarios:

CLASS PROJECTS involving **secondary data analyses** that are assigned and conducted as educational exercises, using data that are either publicly available, de-identified or otherwise impossible to be linked to personal identities.

→ **No IRB action required (neither approval nor determination of human research status)**

CLASS PROJECTS involving **secondary data analyses** that are assigned and conducted as educational exercises, and that use datasets that include private information and codes that link to identifiers, but the students do not have access to the identifiers.

No IRB action required (neither approval nor determination of human research status)

Class instructor and department are responsible for providing the necessary training in respecting the confidentiality of the data.

CLASS PROJECTS or PRACTICA that involve **direct interaction** (e.g., in person, via mail, email, web surveys, or telephone), but where the purpose is training, an educational exercise or professional development, and **not research**. The project or practicum is not “research” even if students ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform “in-house” evaluations as requested by the practicum site.

→ **No IRB action required (neither approval nor determination of human research status)** → but may be requested if instructor or students are unsure, or if documentation is required by gatekeepers (e.g., schools, businesses) for access to participants.

Class instructor and department are responsible for providing the necessary training in respecting the privacy of the individuals and the confidentiality of any resulting information, along with training in the relevant professional ethics.

Instructor provides information about the assignment for the students to distribute to people who participate in these class projects. List the instructor as the

appropriate contact person should questions arise.

CLASS PROJECTS or PRACTICA that involve **direct interaction** or **secondary analyses of private identifiable data** and are undertaken as **both an educational experience and as research** (e.g., results of these activities will be presented publicly or otherwise disseminated, or the data will be stored and used by the students or others as research data).

Submission Tip: Such projects may be very similar to one another. For example, each student may interview one or more persons for a group of oral histories, or conduct telephone surveys as part of a yearly poll, but all in the class follow the same general script or guidelines. If class projects follow different protocols, a table or chart can describe these more individualized activities, under the umbrella of a single IRB application.

→ **IRB approval required** → When there are several students in a class doing similar projects, a **single IRB application may be submitted by the course instructor as PI**, listing all students who will be involved. If projects vary greatly, then it may be preferable to submit individual IRB applications with the student(s) as PI.

The PI must have research ethics certification. Taking into account the sensitivity of the information to be collected, the instructor can require that students complete an ethics certification course, or the instructor may provide comparable training, with the approval of the IRB.

XI. RESEARCH ON PREGNANT WOMEN, FETUSES, PARTS OF FETUSES, AND PLACENTAS, BIOMEDICAL AND BEHAVIORAL RESEARCH ON PRISONERS, AND STUDIES OF CHILDREN AND WARDS OF THE STATE

Vulnerable Populations

Vulnerable research participants are persons who are relatively or absolutely incapable of protecting their own interests. The researcher and research team should be cognizant of the special problems of research involving vulnerable populations, justify the proposed involvement of these populations in the research, and include additional safeguards for their safety and welfare. These populations include:

- Children.
- Individuals with questionable capacity to consent.
- Prisoners.
- Fetuses and pregnant women.
- The terminally ill.
- Students/employees.
- Comatose patients.

Brief information about the regulations on research with children, individuals with questionable capacity to consent, and prisoners are presented, but the researcher and team should be familiar with all of the policies.

Research with Children

Research involving children demands a particularly high level of care and consideration by investigators. In recent years, ethical and legal standards have changed, and investigators who conduct research in this area should consult with the IRB.

The issue of children as research subjects is a complex one since they are not considered able to make informed choices independently. Further, exposure of children, particularly healthy children, to more than minimal risks must be weighed carefully.

When including children in research, the role of the family should be considered in devising the protocol as well as in obtaining informed consent from the parents or guardians. If the research is based in schools, appropriate involvement and permission must be obtained from the school. Adequate measures must be developed to protect children's privacy and to ensure that their participation does not stigmatize them in the present or future.

The regulation pertaining to children as research participants is found in [45 CFR 46, Subpart D](#).

Risk/benefit categories found in this regulation include those:

- Not involving greater than minimal risk.
- Involving greater than minimal risk but presenting the prospect of direct benefit to the child.
- Involving greater than minimal risk and no prospect of direct benefit to the child, but likely to yield knowledge about the child's disease.
- Not otherwise approvable, but presenting an opportunity to understand, prevent, or alleviate a serious problem for children.

In 1998, the NIH wrote a policy and Guidelines on the Inclusion of Children as Research Participants in all studies supported and/or conducted by the NIH. The goal of this policy is to increase the participation of children in research so that adequate data will be developed to support the treatment modalities for disorders and conditions affecting adults that may also affect children. Proposals for research involving human participants must include a description of plans for including children or an explanation for their exclusion. This policy is found at <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>. The FDA has published an Interim Rule entitled "Additional Safeguards for Children in Clinical Investigations of FDA-regulated products" (21 CFR Parts 50 and 56). This rule can be found at the following address: <http://www.fda.gov/ohrms/dockets/98fr/042401a.htm>

Research With the Decisionally Impaired

Research involving individuals with questionable capacity to consent requires careful consideration in order to provide these participants with additional safeguards. This vulnerable population may include persons with psychiatric illnesses, neurologic conditions, substance use history, and various metabolic disorders. Some individuals may not be able to

give informed consent, so “permission” for certain kinds of research can be given by a legally authorized representative and “assent” of the participant is substituted.

Research with Prisoners

Prisoners are confined under the strict control of people whom they must please and to whom they must appear cooperative if they are to earn their release. These potential participants may believe, probably as a result of their dependent situation, that their agreement to participate in research will be viewed positively by their wardens. In addition, such individuals are readily available in large numbers. In the past, prisoners have accepted the risks of research in disproportionate numbers, while the benefits of the research in which they participated went to all segments of the population. Therefore, special regulations are in place that restrict the involvement of prisoners in research. For example, it is appropriate to include a prisoner as a voting member of the IRB when decisions are made for studies that involve prisoners.

With these caveats and an understanding of the Federal regulations in mind, researchers must also be careful not to overprotect vulnerable populations to the extent that they are excluded from participating in research in which they wish to participate, particularly where the research involves therapies for conditions with no available treatments. So, too, patients with serious or poorly understood disorders may want to participate repeatedly in research designed to provide a better understanding of their conditions. The fact that participants may be either patients of the principal researcher or patients in the clinic or hospital in which the researcher conducts the study should not preclude them from the opportunity to choose to participate as often as they wish.

XII. EDUCATION AND TRAINING

The IRB will establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

In addition to the TCNJ required training, researchers applying for federal funding through NIH must complete the NIH On-line Educational Module prior to beginning the study. The certification of completion from this module must be forwarded to the OAGSR. The NIH On-line Educational Module can be accessed at: <http://cme.nci.nih.gov/>.

XIII. REPORTING TO THE IRB

- A. Each approved study is expected to submit a brief report annually to the IRB (unless a more frequent renewal cycle is required). The report should summarize all procedures and interactions with human subjects in the study during the year.
- B. Principal Investigators must promptly report to the IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any unanticipated problems involving risks to subjects or others.
- C. Changes in approved research protocols must be reported promptly to the IRB, and the changes may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

APPENDIX

Instructions for Submitting a Human Subjects Proposal

Human subjects proposals are submitted for approval by using the electronic form located on the institutional review board website insert new URL Before completing the electronic proposal form, the principal investigator or project director should be familiar with the policies and procedures of The College of New Jersey as described in a guidebook of policies and procedures for research involving human subjects (hereafter referred to as Guidebook). Investigators may not initiate any research involving humans until they have received notification of IRB approval and have agreed to comply with all contingencies made in connection with that approval.

The investigator must complete the electronic proposal form. If the investigator is a student, the application must be approved by the student's faculty sponsor.

Supporting materials such as questionnaires, approval letters from cooperating institutions, consent forms, etc., must be included. Any investigator who has submitted or plans to submit a project to an external agency for funding must forward one complete copy of the external proposal to the Committee as soon as it is available. The external proposal should be considered as a supplement or appendix to the IRB application.

If the investigator's school or department maintains an internal review committee, their approval and remarks should be submitted to the IRB Chair will notify each applicant of the committee's decision.

Investigators must electronically submit proposals for full committee review, expedited review, or exemption from review. Investigators must indicate the "Level of Review" on the electronic proposal form and the applicable category justifying this request. However, the IRB reserves the right to change the level of review required.

A written informed consent form documents the consent process. This process consists of a description of the specific research project, the procedures each subject will undergo, and a delineation of the individual's rights as a research subject.

Informed consent must normally be obtained in a written format that requires the subject's signature or that of the subject's legally authorized representative. The IRB may grant a waiver of this requirement if the investigator provides adequate justification for the request. In all cases a copy of the written informed consent must be given to the subject unless the IRB specifically waives this requirement.

Proposals for proper review must be submitted in a timely fashion. Proposals are expected to be submitted at least two weeks before the next scheduled IRB meeting.