GUIDEBOOK of

POLICIES and PROCEDURES

For

RESEARCH INVOLVING

HUMAN SUBJECTS

The College of New Jersey

INSTITUTIONAL REVIEW BOARD

Updated July 2018

1. INTRODUCTION

The Institutional Review Board of The College of New Jersey ("TCNJ" or "College") 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 policy governing the use of human subjects in research and the Federalwide Assurance for the Protection of Human Subjects ("FWA00004576", "FWA00023311", or "TCNJ FWA") maintained with the Department of Health and Human Services ("DHHS"), Office for Human Research Protections ("OHRP"), all research involving human subjects 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 (herein referred to as 45 CFR Part 46). In addition, the actions of the College's IRB will conform to all applicable federal, state and local laws and regulations.

In connection with research conducted or proposed to be conducted on human subjects the Institutional Review Board of the College (the "IRB") performs critical oversight functions to ensure applicable scientific, ethical, and regulatory standards are met. The IRB reviews and monitors biomedical and behavioral research conducted by TCNJ faculty, staff and students. It is charged with the responsibility and authority of reviewing research study p

roposals and granting approval, denying approval or granting approval subject to modifications or conditions for those proposals; requiring the cessation of unapproved or non-compliant research; periodically monitoring the progress of long-term records; and restricting research activities involving human subjects. The IRB is responsible for establishing and administering College policies and procedures related to the implementation of or compliance with federal, state and local regulations that govern the protection of individuals participating in research.

1.1 Applicability

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 by the IRB prior to such studies being undertaken. This policy applies to:

1. Any research whether new, ongoing, or proposed, regardless of funding status and source, whether conducted at The College of New Jersey or elsewhere, even if approved by an institutional review board of another institution of higher education or other entity, by anyone affiliated with the College i.e., faculty, staff, student);

2. Any investigator from outside The College of New Jersey that wishes to perform research on members of the TCNJ community or on the TCNJ campus must have a TCNJ 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 by a third party not affiliated with the College to do research off the TCNJ campus that is not related to the College and does not involve other TCNJ faculty, staff or students, and who performs the research outside of their capacity as an employee of The College of New Jersey.[1]

The terms of the TCNJ FWA (but not necessarily all of the policies and procedures in this Guide) apply to all subcontractors and non-TCNJ collaborators of research conducted by TCNJ faculty, staff and students. The TCNJ principal investigator is responsible for ensuring that appropriate human subjects protections are in place at any collaborating institution and, notifying the IRBof any deficiencies or noncompliance.

1.2 Membership

The IRB is directed by a chairperson, and is comprised of members with multidisciplinary expertise and backgrounds as required by federal policy. The IRB determines the role and responsibilities of its members and researchers in human subject protection. If appropriate, the IRB reports all violations of guidelines and regulations to the Research Integrity Officer. The IRB provides the Provost with an annual report of its activities and recommendations for IRB membership the following year. A current list of the IRB members is posted on the IRB website.

[1] Employees are cautioned that, with regard to such consultation, they must submit a completed Outside Activity Questionnaire for approval by their supervisor and the College Ethics Liaison Officer and comply with applicable College and State of New Jersey ethics laws and rules.

2. DEFINITIONS OF COMMON RESEARCH TERMS

Adverse event: An unwanted and unintended medically-related occurrence affecting a human subject 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, any applicable grantor and federal, state, or local agencies.

Assent: Affirmative 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 subjects.

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 subject (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 Federal department or agency component, in accordance with the requirements of 45CFR46, that a research project or activity involving human subjects 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 Part 46, and covers all federally funded research supported

by the Departments of Agriculture, Energy, Commerce, HUD, Justice, Defense, Education, Veterans Affairs, Transportation, and DHHS, 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 Part 46, Subpart A).
[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html]

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 research 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 research 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 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, research participant, human research participant, participant, human subject, research subject, human research subject, subject: These interchangeable terms refer to a living human individual about whom an investigator conducting research: (1) Obtains or seeks to obtain information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; (2) Obtains or seeks to obtain, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens..

Inclusion criteria: The list of elements in a person's medical history necessary to allow an individual to participate in a specific research 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 subject prior to participation in research. The information to be conveyed to the subject 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 subject 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 subjects in research studies prior to commencement of the study. The form is presented to and signed by the subject, who should have a chance to ask questions regarding the research prior to the commencement of the study.

Institutional Review Board: A specially constituted review body established to protect the welfare of human subjects in research. Federal law states that all institutions supported by a federal department or agency to which the Common Rule applies must establish an Institutional Review Board to review and approve research involving human subjects.

IRB 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.

Interaction: Includes communication or interpersonal contact between investigator and subject.

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 information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment performed for research purposes.

Institution: Any public or private entity, or department or agency (including Federal, state, and other agencies).

Investigator: In research studies, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the research 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 subject to his or her participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participations 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 research 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 subjects.

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 subjects. 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 subject 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.

Quorum: A simple majority of the IRB members qualified to vote.

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 subjects for a research study using proper inclusion criteria.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research does not include: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected; (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority[2]; (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes; and, (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Researcher: The individual who conducts and directs the research 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.

[2] Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from consumer products. Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

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 subjects considered against the potential benefits to the individual or to the research objectives of the research study.

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 subject'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 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 subjects/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 Part 46, Subpart B]; prisoners [45 CFR Part 46, Subpart C]; and children [45 CFR Part 46. Subpart D].

3. STATEMENT OF PRINCIPLES

The College of New Jersey 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, while upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers: for competence, for objectivity, for consideration of the best interests of the College and society, and for the welfare of every subject in a project. The College gives assurance that it will comply with the Common Rule in accordance with the guidance set forth by the OHRP of DHHS.
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.

1. 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 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.

2. 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.

3. All activities involving human subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be infringed.

4. The anticipated benefits to the subject or the importance of the knowledge gained must outweigh the risks to the individual inherent in the proposed research.

5. Participation in projects must be voluntary, and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the IRB. Methods that are in accordance with the requirements of 45 CFR§46.116 and 45 CFR §46.117 and appropriate to the risks of the project must be used to obtain the subjects' informed consent.

6. When required, consent must be obtained from the subjects themselves whenever possible. Further, if a subject is not legally or physically capable of giving fully informed consent, consent on that subject's behalf must be obtained from a legally authorized representative of the subject. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Representatives, for example, may not expose their child to more than minimal risk except for the child's direct benefit.

7. 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 during the informed consent process for all potential subjects.

8. The potential for a conflict of interest or coercion exists in an academic setting where subjects in research studies are also students in a course taught at the College or by an investigator connected with the research study. The Primary Investigator ("PI") is responsible for avoiding such conflicts and coercion in recruiting subjects.

9. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the Primary Investigator. The Primary Investigator is responsible to ensure compliance with the College's Information Privacy policy, Information Classification policy, and the Information Security policy, as well as any applicable privacy regulations, including for example the European Union General Data Protection Act ("EU GDPR"). 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:

    a. Explicit permission for the release of identifying data is given by the individual.

    b. Information about an individual is discussed only for professional purposes and only with persons directly involved in the research 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.

    c. The investigator is legally required to provide such information (e.g., child abuse, sexual abuse, or other illegal activities revealed by a subject).

10. An individual involved in the conduct or supervision of a specific project shall not participate in the IRB review of that project, except to provide information to the IRB.

4. PURPOSE OF IRB REVIEW OF PROPOSED RESEARCH STUDIES

The purpose of the IRB review is to ensure, both in advance and by periodic monitoring, that appropriate steps are taken to protect the rights and welfare of human subjects according to federal guidelines. To accomplish this process, the IRB uses a 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 subjects to risk.

2. The risks to human 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.

    a. For the purpose of IRB consideration, “risk” is defined as the probability of harm or discomfort (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).

    b. For the purpose of IRB consideration, "benefit" is defined as a valued or desired outcome, an advantage.

    c. 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 subject, or his/her legally authorized representative, in accordance with, and to the extent required by federal regulations and this IRB Policy and Procedures Manual.

5. The research plan, when appropriate, makes adequate provision for monitoring the data collected to ensure the safety of the human subject.

6. There are adequate provisions to protect the privacy of human research subjects and to maintain the confidentiality of research data.

Appropriate additional safeguards may be included in the research 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, individuals with impaired decision making ability, or economically or educationally disadvantaged persons).

5. TYPES OF IRB REVIEW OF PROPOSED RESEARCH STUDIES

The review and approval by the IRB of all research activities involving human subjects that fall within its jurisdiction is a prerequisite to the implementation of such research activities. There are four categories of IRB review of proposed studies:

5.1 Limited review,
5.2 Expedited review,
5.3 Full-Board review, and
5.4 Research exemptions from IRB review; Self determination.

Depending on the level of risk of the research protocol and the subject population, the IRB may conduct either Full-Board Review or Expedited Review.

5.1 Limited Review

For certain research exemptions listed in section 5.4 of this policy, the IRB must conduct a limited review in order to determine that there are adequate provisions to protect privacy of subjects and to maintain confidentiality of data (see 46.111(a)(7)), or that elements of broad consent meet federal requirements, that the consent process will be appropriate, that consent is documented as required and that privacy and confidentiality are protected (see 46.111(a)(8)).

5.2 Expedited Review

For certain kinds of research involving no more than minimal risk as authorized by 45 CFR 46.110, for minor changes in approved research, and for research which limited IRB review is a condition of exemption, 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 subjects to greater than minimal risk. Loss of confidentiality can cause harm to subjects, their relatives, and others.

5.3 Full-Board Review

When Full-Board Review is necessary, the research proposal is presented and discussed and voted upon 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.)

A research proposal that includes a vulnerable subject, or population, of research subject(s) requires a Full-Board Review. However, while the use of minors in research usually requires a Full Board Review, Expedited Review is allowed in research that would otherwise be considered Exempt if not for the inclusion of minors as research subjects.

5.4 Research Exemptions from IRB Review; Self determination

Under 45 CFR 46.101(b), certain research may be determined exempt from review by the IRB. If a research study falls into one of the exempt categories, researchers still have ethical responsibilities to protect subjects' rights. For some research, a Principal Investigator is permitted to self-determine exemption based on responses to key questions within qualifying human subjects exemption categories. The

IRB does not review self-determined projects. The IRB will implement a post-determination validation process for self-determinations to ensure that the exemption criteria are being applied in accordance with regulatory requirements and that the potential risk to human subjects remains minimal.

The following categories of research are exempt from full IRB review:

1. Research conducted: in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if at least one of the following criteria is met:

    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to them;

    b. Any disclosure of the human subject's responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement or reputation; or

    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written response or audiovisual recording if the subject prospectively agrees to intervention and information collection and at least one of the following criteria is met:

    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to them;

    b. Any disclosure of the human subject's responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement or reputation; or

    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

   a. The identifiable private information or identifiable biospecimens are publicly available;

   b. Information is recorded by the investigator in such a maner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

   c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under the Health Insurance Portability and Accountability Act, for the purposes of "health care operations", or "research" as those terms are defined at 45 cfr 14.501 or for "public health activities and purposes as described under 45 CFR 164.512(b); or,

   d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads and that are designed to study, evaluate, improve, or otherwise examine: (i) public health benefit or service programs, (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food-quality evaluation and consumer acceptance studies, (i) if whole- some foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environment Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

    a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;

    b. Documentation of informed consent or waiver of documentation of consent was obtained;

    c. An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent; and

    d. The investigator does not include returning individual research results to subjects as part of the study plan.

These exemptions do not apply to research involving prisoners. Further, the exemption in item 2 above does not apply to children, except in research involving educational tests or the observations of public behavior when the researcher(s) do not participate in the activities being observed.

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. 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 the IRB.

6. IRB COMPOSITION AND MEMBERSHIP

6.1 IRB Composition

The membership of the IRB shall include: (i) at least one community representative not otherwise affiliated with the College, (ii) the Provost or his/her designated representative who shall serve ex-officio, and (iii) a minimum of six College 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).The IRB should include members from a variety of disciplines on campus. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its 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.[3]

The IRB may, on a case by case basis 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 IRB. These individuals shall have no voting rights.

6.2 IRB Membership

1. Appointments to the IRB shall be made by the Provost on recommendation from the current sitting IRB members. An IRB must:

    a. At least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;

    b. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;

    c. Include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and

    d. Not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Please see the regulations at 45 CFR 46.107 for complete information on all of the required qualifications to properly compose an IRB (45 CF 46.107).

2. Faculty representatives shall serve three-year terms. Non-faculty representatives shall also serve for a three year term. The Chair, Vice-Chair and Recorder (collectively “Officers”) shall be elected from among the IRB members by a majority vote of the IRB. 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.

[3] 45 CFR §46.107(a)

3. 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.

7. IRB OPERATIONS

1. 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 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 school or department internal review committee (if any). A copy of the letter of approval will be maintained by the IRB.

    a. Departments and schools may continue to operate internal review committees. If a department is interested in or planning an internal review process, it should coordinate this process with the IRB Chair. Departmental review committees shall provide preliminary reviews of their department's proposals prior to review by the IRB, but shall not replace the review of the IRB.

2. Any member requesting minor changes may authorize the Chair of the IRB to request such changes, with or without requiring that they personally approve the revisions prior to the issuance of the approval letter. If an IRB member has a major objection to such a proposal, that member may call for a meeting of the full IRB to review the changes.

3. The principal investigator (and co-principal investigators, if appropriate) may attend the IRB meeting held to consider the PI's 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.

4. If the IRB does not approve an application, reasons for this negative decision will be provided in writing to the principal investigator. If the PI decides to modify the proposed research in such a way as to overcome the objections of the IRB, the PI may resubmit the proposal for consideration and/or have the Chair call an IRB meeting during which the PI may defend the proposal or the modifications. The PI has 60 days to re-submit a proposal that has been modified to address the requested changes, along with an MS Word document that describes the PI's responses. If the PI does not respond within 60 days of the issuing of the IRB's response, the proposal will have to be re-submitted as a new proposal.

5. When granting initial approval of a proposal, the IRB will indicate the minimum intervals needed for continuing review of the project in order to assure continued acceptance of the proposal. Research projects are reviewed at not less than yearly intervals; more complex and/or potentially dangerous projects can be reviewed at a greater frequency commensurate with the related risks. Renewal projects should include a progress report as well as a description of any anticipated design changes. Projects may also be reevaluated if someone 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(s) and may interview both the research staff and persons at risk. Unless the IRB determines otherwise, the following circumstances does not require continuing review:

a. Research eligible for expedited review in accordance with 46.110;
b. Research reviewed by the IRB in accordance with the limited IRB review required by exempted research;
c. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study;
    i. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    ii. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

6. An IRB member must recuse her/himself from the review, monitoring, or oversight of any research proposal or project with which s/he is affiliated. If the Chair of the IRB submits a research proposal for review, the Vice-Chair of the IRB will manage the review process. Additionally, the Vice-Chair's contact information will replace the Chair's information on the affiliated consent document, and any other places in the submission where the Chair of the IRB's contact information is required.

7. The IRB does not provide retroactive approval for research studies.

8. The IRB will communicate with the primary investigator, co-investigator, or a designee assigned by the primary or co-investigator. All e-mail and written correspondence between authors of proposals and reviewers (both department review committees and the IRB) will be maintained for a period of three years in the IRB file.

9. The IRB shall prepare and maintain adequate documentation of IRB activities, including:

    a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

    b. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

    c. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in Section 7.5. above.

    d. Copies of all correspondence between the IRB and the investigators.

    e. A list of IRB members.

    f. Written procedures for the IRB.

    g. Statements of significant new findings provided to subjects.

h. The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy.

8. PROPOSAL PROCEDURES

1. All human subject research proposals affiliated with the College, even if previously approved at another institution, must be submitted to TCNJ's IRB prior to the start of the research project (including, without limitation, the collection of any subject data). All research proposals must be electronically submitted for review and tracking under one of three categories: Expedited, Full-Board, and Exempt. The IRB will determine the category of review. Researchers cannot exempt from review their own research study 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.

2. The expected review process is based on the review type required for the submitted research proposal by the IRB:

    a. 'Exempt' proposals – a minimum of two weeks;

    b. 'Expedited' proposals – a minimum of three weeks;

    c. 'Full-Board' proposals – must be electronically submitted to the IRB a minimum of two weeks prior to the next occurring scheduled IRB meeting. Duration of the review process will vary according to the specifics of the research proposal.

3. 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.

4. Ongoing projects modified to include human 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.

5. Adjunct faculty who submit a research proposal to the IRB must include a non- TCNJ email address on the submission. This email must be valid for a period of no less than three years after the start of the IRB approved research study.

6. Research proposals that include research conducted at a site other than TCNJ must include a letter of collaboration/support from the proposed site, on site letterhead, and signed by an appropriate administrator of that site. Some exclusions, such as public locations or private residences, may be possible.

7. The IRB will only review complete research proposals. Proposals submitted that do not contain all of the required components will not be reviewed.

8. The electronic submission procedures, along with these policies and procedures the IRB Policy and Procedure Manual, 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. The most current version of the IRB Policies and Procedures Manual is available at the IRB website (http://irb.pages.tcnj.edu/).

8.1 Amendment to a Currently Approved Proposal

Prior to the expiration of an approved proposal, the Primary Investigator may request a change to any aspect of the previously approved proposal. The amendment request must be electronically submitted, and provide a clear and concise description of the requested changes. Upon review by the IRB Chair (or designated representative), the amendment may be accepted (and approved), further clarification may be requested, or if the changes are considered significant, the proposal may need to be formally re-reviewed.

Once accepted, amendments do not change the original expiration date of a research proposal (the original expiration date designated when the research proposal was first approved will remain effective).

8.2 Renewal of a Proposal

If a primary investigator wishes to renew a research proposal (this is only available prior to the expiration of the proposal, else a resubmission is necessary), the renewal request must be electronically submitted at least 45 days before the expiration date of the research.

9. IRB ROLES AND RESPONSIBILITIES

1. The IRB has the authority to approve or disapprove all research using human subjects. "Human research" includes, for example, undergraduate research, graduate thesis research, faculty and staff research, and research conducted at or in connection with the College by external investigators. Human subject research may not be conducted on campus under any circumstance without the approval of the IRB. Individuals connected with the College must have their off campus human research approved or exempted if the researcher indicates to subjects or other subjects 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.

2. The Primary or Co-Primary Investigator(s) of any research proposal submitted to the IRB may not be a student (undergraduate or graduate). Only TCNJ faculty or staff may submit a research proposal to the IRB. The responsibility for the submission of the IRB application and the conduct of this research and the supervision of human subjects lies with the Primary Investigator of the research study.

3. Outside investigators (non-TCNJ 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 requirements set forth in this guidebook. In addition, outside investigators must have TCNJ faculty or staff sponsor their research, acting as the PI.

4. For multi-center research, or research where the primary research activity will occur under the regulation of a federally registered institutional review board with a Federalwide Assurance other than TCNJ's FWA, the inter-institutional authorization agreement may be appropriate. This determination lies with the IRB.

5. All primary investigators, co-investigators, research assistants/students, and any other person affiliated with the proposed research study that have access to the human data must complete an online human research subject training program. The IRB accepts training certificates from the National Institute of Health (https://phrp.nihtraining.com/users/login.php) or CITI (https://www.citiprogram.org/).

   Training certificates must be renewed not less than every three years. Researcher's certificates submitted with a proposal must be less than three years old at the intended time of the beginning the research study.

6. In the event of the emergence of any problems or development of hazardous conditions for subjects, the PI must immediately so notify the IRB chair and seek and obtain IRB approval of an amended protocol before the research may continue.

7. Primary responsibility for adherence to high ethical standards, to Federal and State laws, and to College policies and procedures remains with the individual faculty and staff members who are involved in the research. After carefully reviewing the Common Rule and this Guidebook, 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 required that the investigator seek the advice of the IRB Chair or the appropriate internal review committee.

8. The 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[4]. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action, shall be reported promptly to the investigator and appropriate College officials and the department or agency head.

[4] 45 CFR §46.113

10. CRITERIA FOR IRB APPROVAL OF RESEARCH

10.1 General Requirements[5]

In order to approve a research proposal, the IRB must determine that protocols are specified in the proposal to meet all of the following requirements:

1. Risks to subjects are minimized: (i) by using procedures consistent with sound research design that do not unnecessarily expose subject s to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from risks and benefits of therapies those subjects would receive even if not participating.

3. Selection of subjects 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. Subjects should share equally in foreseeable benefits and risks.

4. Informed consent is sought and obtained from each prospective subject or the subject's legally authorized representative in advance of the subject's involvement in the research in accordance with, and to the extent required by 45 CFR §46.116.

5. Informed consent is appropriately documented or appropriately waived in accordance with, and to the extent required by 45 CFR §46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data in compliance with TCNJ policies and applicable regulations (e.g., EU GDPR).

8. For purposes of conducting the limited IRB review required by 46.104(d)(7), the IRB need not make the determinations preceeding determinations (1 – 7), and rather make the following determinations:

    a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);

    b. Broad consent is appropriately documented or waiver of documentation is appropriate, in

[5] 45 CFR §46.111

accordance with §46.117; and

c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Additionally, when some or all of the subjects are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision making capacity, economically disadvantaged, or educationally disadvantaged persons) additional safeguards are included in the research study to protect the rights and welfare of these subjects.

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 ensure that approved protocols are identified to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participation in the research study.

10.2 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 subjects—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 subjects 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 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.[6]

The concept of minimal risk has 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. Third, the concept is used to decide when documentation of subject consent may be waived.

The IRB must ensure that risks to subjects 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. The IRB should determine whether the researchers are competent in the proposed scientific 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 subject. The IRB should also assess whether

[6] 45 CFR §46.102

the research design will yield useful data, so that research subjects are not exposed to risks without sufficient justification.

The IRB must be notified of any unanticipated problem involving risks to subjects or others, including physical or psychological injury to subjects, improper disclosure of private information, economic loss, or other potentially harmful occurrences. The PI shall have primary responsibility to provide that notice, but all investigators on a research project shall share the obligation to ensure that the IRB is notified.

11. REPORTING TO THE IRB

The PI of each approved research 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 research study during the year.

Principal Investigators must promptly report to the IRB, appropriate institutional officials, the relevant department or agency head, any applicable regulatory body, and any applicable granting or funding agency or entity any unanticipated problems involving risks to subjects or others.

The PI must promptly report any changes in approved research protocols 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.

12. INFORMED CONSENT

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 subject. It is a process that involves conveying accurate and relevant information about the research study and its purpose; disclosing known risks, benefits, alternatives, and procedures; answering questions; and enabling the potential subject to make an informed decision about whether to participate.

General requirements for informed consent are described in 45 CFR.§46.116. Certain states have additional statutes regulating research.

12.1 Process

Once the researcher has a carefully defined research question, and a valid design and protocol for a research project, it is time to plan to obtain the informed consent of those recruited to participate as human subjects. Planning involves determining:

1. What information to provide to potential subjects, both in writing and in discussions;
2. Deciding who is going to present the information and at what point in your interactions with subjects;
3. How the subjects' understanding of the information included in the informed consent will be assessed; and
4. Who will obtain the subject's signature or agreement.

This plan must be reviewed and approved by the IRB before approaching potential subjects.

12.2 Elements of Consent

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

1. The subject must be COMPETENT to begin the informed consent process. If the subject is not competent because of age, illness, incapacity, or any other reason, special provisions apply, or

the subject may not be included in the research.

2. The research team must DISCLOSE all relevant information to the potential subject. The information must be sufficient to allow the potential subject to discuss and consider whether to participate. The potential subject must be given the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This includes the following information:

    a. The purpose of the research and the expected duration of the subjects participation;
    b. The nature of the procedures to be followed and identification of any procedures which are experimental;
    c. A description of reasonable alternatives to the proposed intervention;
    d. A description of the risks, potential discomforts, benefits, and uncertainties expected of the research
    e. A description of the extent to which confidentiality of records identifying the subject will be maintained;
    f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs;
    g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights.

    h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

    i. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
        i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative; or
        ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

    One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

    j. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable; (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

k. Any additional costs to the subject that may result from participation in the research;
l. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; (
m. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and (6) The approximate number of subjects involved in the study. ;
n. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
o. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
p. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

3. The subject must COMPREHEND the information. Information must be presented in sufficient detail related to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. The research teams must evaluate the potential subject's ability to understand the proposed intervention in the research study.

4. The subject must AGREE to the proposed intervention in the research study.

5. The subject's agreement must be VOLUNTARY and free from undue influence and coercion.

6. If the subject is located in the European Union, a separate data use consent form must be completed in addition to the informed consent.

12.3 Broad Consent

Broad consent may be obtained in lieu of informed consent only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. If the IRB is seeking broad consent from a subject or legally authorized representative the following must be provided to:

1. The information required in paragraphs 46.116 (b)(2), (b)(3), (b)(5), (b)(8) and, when appropriate, (c)(7) and (9);
2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
4. A description of the period of time that the identifiable private information or identifiable

biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

12.4 Screening, Recruiting, or Determining Eligibility

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

12.5 Preparation of Consent Document

The first step in the process of informed consent is preparing the written consent document for presentation to the IRB. Sample consent forms can be found on the IRB webpage.

Informed consent documents should be written in nontechnical language that can be understood by the proposed subject 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 shall not include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. In some cases, the researcher may request that the IRB approve a modification or waiver of the elements of informed consent permitted under 45 CFR §46.116(b) and (c).

Advertisements, fliers, or brochures prepared to recruit and inform potential subjects about a research

study are considered part of the informed consent process and, as such, also require review and approval by the IRB.

12.6 Implementation of Consent to Research Subjects

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 subject s. In this regard, after receipt of IRB approval of the informed consent plan, there are several essential steps to take in the process of informed consent. The researcher and responsible research team members should:

1. Feel confident that the potential subject has the capacity to understand the information provided, make informed decisions, and provide informed consent for the particular research study.

2. Provide both written (as described above) and oral information about the details of the research study in a way that is understandable to the subject.

3. Be satisfied that the subject understands the information provided and has had an opportunity to ask questions, have those questions adequately answered and deliberate about participation.

4. Be satisfied that the subject is in a position to make a voluntary decision and has not been coerced or unduly influenced by circumstances or other people.

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

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

12.7 Waiver or Alteration of Consent

As mentioned, the IRB may waive the requirement of obtaining written informed consent and approve a consent procedure that omits some, or alters some or all, of the elements of informed consent, under the following essential conditions:

1. The research poses no more than minimal risk to subjects.

2. The research could not practicably be carried out without the requested waiver or alteration;

3. If the research involves identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

4. There are no adverse effects as a result of the waiver or alteration.

5. Pertinent information will be provided after participation is completed, if appropriate.

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, then the IRB cannot waive consent for the storage, maintenance, and secondary use of the identifiable private information or identifiable biospecimens.

12.8 Special Issues in Informed Consent

12.8.1 Third Party Consent or Consent by Proxy (Legally Authorized Representative)

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

If the prospective subject is identified as incompetent to provide informed consent, and if the condition of being incompetent is temporary, (if for example, potential subjects 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 subject is cognitively impaired, the subject's legally authorized representative is responsible for deciding whether the subject should participate in the research. This person may, if participation is so decided, sign the consent form on behalf of the subject 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 subject has indicated refusal to take part in the research.

12.8.2 Research with Children and Assent to Research

Legally, children have not attained an age at which they can consent to their own participation in human subject research. Therefore, special provisions for agreement to participate in research are established in 45 CFR §46.408. 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 research study. Permission means the agreement of parent(s) or guardians(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 also indicate willingness to participate by assenting to the research study. Assent means a child's affirmative agreement to participate in research. By law, failure to object may

not be construed as assent. The IRB shall make the final determination if sufficient protections exist for children and how assent should be documented.

12.8.3 Language Barriers

Information relevant to participation in research must be communicated to subjects "in language understandable to the subject," and in most situations, such informed consent must be documented in writing.[7]

Written consent documents must include all elements necessary for legally effective informed consent in a language comprehensible to the intended subjects. Thus, subjects who are not native or fluent English speakers should be provided with a consent document in their native language, written at a level that makes the information comprehensible.

Researchers may propose 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 subject must receive copies of the short-form document and the summary. The witness must be fluent in both languages.

[7] See 45 CFR §46.116, 117

13. Guidance for Involvement of College Students

13.1 Using College Students as Research Subjects and 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 or coercion by faculty 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.

1. 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).

2. 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.

3. 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 of the subjects 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.)

4. 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.

5. 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.

6. Whenever possible, researchers should avoid data collection during regular class meetings. When research study participation consumes a significant portion of a class section, loss of instructional time for both subjects and non- subjects 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.

7. The plan for handling consent forms and research data should 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 subjects may view as personal or sensitive, data should be collected in a manner that minimizes the chance of one subject learning the response of another.

8. 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.

9. Like other research volunteers, students who become research subjects must be allowed to withdraw from the research 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.

10. 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.

13.2 Deception Guidance

When deception[8] 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 presented 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 research study, the process of data collection, and intent of the researcher. In exceptional circumstances, the full or true purpose of the research may be withheld from 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 research 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.

For an outline of things to consider when using student subject pools, see Appendix C.

13.3 Students Involved in or Leading Research

Since only TCNJ faculty and staff are permitted to act as the Primary Investigator to a research proposal submitted to the IRB, TCNJ students, undergraduate or graduate, can only be listed as 'student researchers'. This policy does not prevent students from conducting research at TCNJ; however, it ensures that TCNJ faculty or staff members will be the Primary Investigator on the IRB application. It is important that research subjects have access to the PI of a study, for several years after a study has completed. After a student graduates, it could be a difficult process for a research subject to locate the student who acted as a Primary Investigator. Having a TCNJ faculty or staff member acting as the Primary Investigator greatly reduces the likelihood of this issue.

Class projects conducted for educational purposes and not as research might 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 the IRB does 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.

[8] Deception is defined as "misleading research participants about the research purpose or procedures" (NIH Protecting Human Research Participants).

14. Research on Vulnerable Populations

Vulnerable subjects are persons who are susceptible to undue influence or coercion or 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. Vulnerable subjects include:

1. Children
2. Individuals with impaired decision making ability
3. Prisoners
4. Fetuses
5. The terminally ill
6. Students/employees
7. 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 federal guidelines (http://www.hhs.gov/ohrp/archive/irb/irb_chapter6.htm).

14.1 Research with Children[9]

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 complex 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 subjects is found in 45 CFR 46, Subpart D. Risk/benefit categories found in this regulation include those:

1. Not involving greater than minimal risk.
2. Involving greater than minimal risk but presenting the prospect of direct benefit to the child.
3. Involving greater than minimal risk and no prospect of direct benefit to the child, but likely to

[9] 45 CFR §46 Subpart D

yield knowledge about the child's disease.

4. 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 subjects 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.

14.2 Research of Subjects with Questionable Capacity

Research involving individuals with questionable capacity to consent requires careful consideration in order to provide these subjects 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, in which case informed consent must be given by a legally authorized representative of the subject and assent obtained, if possible.

14.3 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 subjects may believe 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. Refer to 45 CFR §46, Subpart C, for additional requirements when conducting research with prisoners as human subjects.

14.4 Equitable Recruitment and Selection

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 subjects may be either patients of the principal researcher or patients in the clinic or hospital in which the researcher conducts the research study should not preclude them from the opportunity to choose to participate as often as they wish.

15. 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 requires 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. The OHRP maintains an education website (http://www.hhs.gov/ohrp/education/index.html) that contains links to training material such as webinars, YouTube videos, and PDF documents.

In addition to the training provided by the IRB, researchers applying for federal funding through NIH must complete the NIH On-line Educational Module prior to beginning the research 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/.

Appendix A: Instructions for Submitting a Human Projects Proposal

1. Human subjects proposals are submitted for approval by using the electronic form located on the IRB website. Before completing the electronic proposal form, the principal investigator and/or project director should be familiar with the IRB Policy and Procedures Manual. 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.

2. Supporting materials such as questionnaires, approval letters from cooperating institutions, consent forms, etc., must be included.

3. If the investigator's school or department maintains an internal review committee, the approval and remarks of that or those committees must be submitted to the IRB. The IRB Chair will notify each applicant of the IRB's decision.

4. Investigators must electronically submit proposals for full IRB 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.

5. 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.

6. 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.

7. Proposals considered for Full-Board review must be submitted a minimum of two weeks before the next IRB meeting for proper review. The IRB calendar is posted on its website.

Appendix B: Providing Information to Potential Subjects

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

The provision of information about a research study usually involves more than just furnishing the written consent document to the potential subject 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 research study or clinical research in general are helpful. If the researcher delegates the function of oral presentation and discussion of a research study to members of the team, the researcher must be sure those delegates 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 subject's understanding?

The researcher should feel satisfied that after the detailed information has been presented and discussed, the potential subject 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 subject understands. Sometimes it is clear at the end of a discussion; other times, having a subject answer questions about the research study, either informally or even in writing, may be appropriate. The best method may depend on the complexity and risk level of the research study as well as on the potential subjects.

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

Individuals who feel "coerced" into making a decision about research participation or individuals who 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.

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.

How does the researcher determine if a subject 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 research 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 research 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 subjects or groups of subjects, 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.

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 subject 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 not necessary and possibly inappropriate. According to the federal regulations at 45 CFR.46.117(c), the IRB may waive this requirement if it determines:

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

Appendix C: 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 subject 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
    c. Minor must assent in most instance

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 subjects
    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