

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



The College of New Jersey

**INSTITUTIONAL REVIEW BOARD**

# TABLE OF CONTENTS

<b>I. INTRODUCTION .....</b>	<b>2</b>
<b>II. DEFINITIONS .....</b>	<b>4</b>
<b>III. STATEMENT OF PRINCIPLES .....</b>	<b>5</b>
<b>IV. IRB REVIEW OF PROPOSED RESEARCH STUDIES.....</b>	<b>7</b>
A. EXEMPT REVIEWS .....	7
B. EXPEDITED REVIEW .....	8
C. FULL BOARD REVIEW .....	10
<b>V. IRB MEMBERSHP: COMPOSITION, PROCESS, AND FUNCTION.....</b>	<b>10</b>
<b>VI. IRB PROCEDURES, INSTITUTIONAL RESPONSIBILITIES AND INVESTIGATORS' RESPONSIBILITIES .....</b>	<b>11</b>
<b>VII. IRB CRITERIA FOR EVALUATING AND APPROVING PROPOSALS.....</b>	<b>14</b>
A. BASIC REQUIREMENTS .....	14
B. ADDITIONAL FACTORS .....	14
<b>VIII. INFORMED CONSENT .....</b>	<b>15</b>
A. INFORMED CONSENT PROCESS .....	16
B. WRITTEN INFORMED CONSENT REQUIREMENTS.....	18
<b>IX. RESEARCH ON PREGNANT WOMEN, FETUSES, PARTS OF FETUSES, AND PLACENTAS, BIOMEDICAL AND BEHAVIORAL RESEARCH ON PRISONERS, AND STUDIES OF CHILDREN AND WARDS OF THE STATE .....</b>	<b>19</b>
<b>X. EDUCATION AND TRAINING .....</b>	<b>19</b>
<b>XI. REPORTING TO THE IRB.....</b>	<b>20</b>
<b>APPENDIX.....</b>	<b>21</b>
INSTRUCTIONS FOR SUBMITTING A HUMAN SUBJECTS PROPOSAL .....	21

## I. INTRODUCTION

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

The Institutional Review Board of The College of New Jersey is charged with the responsibility and authority to approve, require modification in, halt unapproved or non-compliant research, periodically monitor the progress of long-term records, or disapprove all research activities involving humans that fall within its jurisdiction. The IRB is responsible for establishing and administering institutional policies and procedures through which the College conforms to federal, state and local regulations that govern the protection of human subjects participating in research (human research subjects).

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

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

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

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

The college's IRB Committee is directed by a chairperson, and is comprised of members with multidisciplinary expertise and backgrounds as required by federal policy. The Committee determines the role and responsibilities of committee members and researchers in human subject protection. If appropriate, the Committee reports all violations of guidelines and regulations to the appropriate department chairperson or dean and to the Vice-Provost for Research. The

Committee provides the Vice-Provost for Research with an annual report of its activities and recommendations for Committee membership the following year. A current list of the IRB committee members is available from the IRB chairperson and is posted on the IRB website.

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

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

## II. DEFINITIONS

- A. **Research** is defined in the Common Rule as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” ([45 CFR §46.102\(d\)](#)) Under this definition some demonstration, service, and training projects may be considered to include research activities. Specific criteria that can be used to determine whether a planned activity is research include:
- The testing of a hypothesis or question for which an answer requires more information.
  - The prospective or retrospective collection of data from human subjects with the intent to publish such results.
  - The use of a standard procedure or an approved drug if its use is influenced by a consideration other than the direct welfare of the individual. For example: a selection between different, although widely-accepted, procedures or therapies according to a predetermined plan such as randomization; or the administration of a standard procedure of an approved drug to a healthy “control” subject.
  - The use of an experimental (investigational) drug, nutritional supplement, biologic, or device (e.g. a drug that is the subject of a FDA approval investigational new drug (IND) exemption or a device that is not FDA approved.
- B. **Human subjects** are living individuals about whom an investigator conducting research obtains data through intervention with the person or identifiable private information. Intervention includes both the physical procedures by which data are gathered (e.g. venipuncture) and manipulation of the subject or subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact (e.g. questionnaires, interviews) between the investigator and the subject.
- C. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual, which that individual can reasonably expect will not be made public (i.e., a medical record). It also includes information revealed by a primary research subject about another individual without the consent of that individual.
- D. **Minimal risk** means that the risks of harm anticipated in the proposed research are not greater in either probability or magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This also includes the normal exercise and training routine of athletes and athletic teams.
- E. **Informed assent** means the subject’s agreement to participate in the absence of full understanding. This concept commonly applies to individuals who have not attained legal majority and/or capacity.
- F. **Informed consent** means the knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under

circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

- G. **Legally authorized representative** means an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research procedure(s).

### III. STATEMENT OF PRINCIPLES

The College of New Jersey (hereafter, "the College") is committed to the pursuit of excellence in teaching, research, and public service. Concomitantly, the College seeks to protect the welfare of every person who may be involved in research and training projects. Members of the College community, although upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers: for competence, for objectivity, for consideration of the best interests of the College and society, and for the welfare of every participant in a project. The College gives assurance that it will comply with the federal policy for the Protection of Human Subjects (or "Common Rule," as it is sometimes called) (45 CFR §46, as amended) in accordance with the guidance set forth by the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services. The following principles are affirmed and should be interpreted in the broad context provided by the code of medical and general ethics promulgated by the World Medical Association as the Declaration of Helsinki, by the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research known as the Belmont Report, and for funded research, any additional human subjects regulations and policies of the supporting Department or Agency.

- A. The basic ethical principles set forth in the Belmont Report, respect for persons, beneficence, and justice underlie the requirements for the ethical conduct of research involving human subjects at The College of New Jersey. Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. Justice requires that the benefits and burdens of research be distributed fairly.
- B. Because the participation of humans in research and training projects may raise fundamental ethical and civil rights issues, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other College employees, on-campus or off-campus.
- C. All activities involving humans as subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be infringed.
- D. The direct or potential benefits to the subject or the importance of the knowledge gained must outweigh the risks to the individual inherent in the proposed research.

- E. Participation in projects must be voluntary, and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the College's Institutional Review Board (IRB). Methods that are in accordance with the requirements of 45 CFR [§46.116](#) and 45 CFR [§46.117](#) and adequate and appropriate to the risks of the project must be used to obtain the subjects' informed consent.
- F. When required, consent must be obtained from the participants themselves whenever possible. Further, if a subject is not legally or physically capable of giving fully informed consent, a legally authorized representative should do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Parents, for example, may not expose their child to more than minimal risk except for the child's direct benefit.
- G. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or to refuse to participate, without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue physical risk, embarrassment, discomfort, anxiety, and harassment. These rights need to be clearly defined for all potential subjects.
- H. The IRB acknowledges the potential for a conflict of interest or coercion in an academic setting where participants in research studies are also students in a course. The primary investigator is responsible for minimizing these effects in recruiting subjects.
- I. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. Investigators should detail to the IRB what security measures will be taken to ensure that privacy will be maintained. Records containing personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project. Specific subject information shall not be communicated to others unless one of the following conditions is met:
- Explicit permission for the release of identifying data is given by the individual.
  - Information about individuals may be discussed only for professional purposes and only with persons clearly involved in the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid a breach of confidentiality.
  - The investigator is legally required to provide such information (e.g., child abuse, sexual abuse, or other illegal activities revealed by a subject).
- J. An individual involved in the conduct and/or supervision of a specific project shall not participate in the IRB review, except to provide information.

## IV. IRB REVIEW OF PROPOSED RESEARCH STUDIES

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

1. exempt review,
2. expedited review, and
3. full board review.

### A. Exempt Review

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Research studies to which the only involvement of human subjects will be in one or more of the categories listed below are exempt from the Common Rule including the requirement to obtain informed consent. However, federal and college policies require IRB review of human research activities appearing to meet these exempt criteria so as to ensure respective regulatory compliance. Research protocols qualifying for exempt review are reviewed in an expedited manner by the IRB chairperson or his/her designee. Following an initial determination of exempt status, exempt research activities are not subject to annual renewal requirements.

Categories of exempt review are:

1. **Educational practices:** Research conducted in established or commonly accepted educational settings involving normal educational practices such as:
  - Research on regular and special education instructional strategies, or
  - Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods. This exemption does not apply to prisoners.
2. **Surveys, questionnaires, interviews, observational studies:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior; unless;
  - Information obtained is recorded in such a manner that subjects can be identified by the investigator or others, directly or through identifiers (codes) linked to the individuals, and
  - Any disclosure of the human research subjects' response outside the research could reasonably place the individuals at risk of criminal or civil liability or be damaging to the individuals' financial standing, employability, or reputation. This exemption does not apply to research involving children, except for research involving the use of educational tests or research involving observation of public behavior of children (i.e. provided that the investigator does not participate in the activities being observed. This exemption does not apply to research involving prisoners.
3. **Existing data or specimens:** Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens. To qualify for this exemption these sources must be publicly available or the information must be recorded

by the investigator in such a manner that the human research subjects cannot be identified (by the investigator or others), directly or through identifiers (codes) linked to the individuals. The data, documents, records or specimens must have been obtained independent of the research study. This exemption does not apply to research involving prisoners.

- For research protocols limited to the collection and study of existing data the principal investigator must provide written assurance in the protocol submission that:
    - the individual responsible for data collection is authorized (i.e. by College policies) access to the respective data;
    - the research is limited to the collection and study of data obtained initially for purposes other than the proposed research study, and
    - the instrument/form used for data collection will not contain any information (e.g. name, initials) that can potentially identify the subject.
    - If it is not possible to perform the research protocol under these conditions, then the investigator must submit for an expedited review or for a full board review.
  - For research protocols limited to the study of existing pathological specimens or diagnostic specimens the principal investigator must provide written authorization in the research protocol submission that:
    - use of respective specimens for research has been generally authorized (i.e., that use of the respective specimens is not restricted to a specific research activity or specific investigators as a result of conditions imposed by prior subject consent);
    - the research is limited to the study of specimens obtained initially for another purpose than the proposed research study.
    - The specimens and data related to the specimens provided to the investigators of the proposed study will not contain any information (i.e. names, initials) that can possibly identify the subjects, either directly or indirectly.
4. **Research and demonstration projects** which are conducted by or subject to the approval of respective federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
- public benefit or service programs
  - procedures for obtaining benefits or services under those programs
  - possible changes in or alternates to those programs or procedures
  - possible changes in methods or levels of payment for benefits or services under these programs.

## **B. Expedited Review**

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IRB regulations recognize that there are certain categories of research which involve procedures that pose no more than minimal risks to subjects and for which clear standards can be set (63 FR 60364). Accordingly, research projects that fall within one of these categories listed below will be reviewed by the Chair of the IRB and, if deemed necessary, by one or more IRB member.

All members involved in an expedited review must agree that the protocol falls under one of the expedited categories. Any member engaged in an expedited review may object to the application of the expedited review procedure or may have further questions that the investigator must answer. Similarly, each member has the option of referring the application to the IRB for full review. Investigators should be aware that even though applications for expedited review are less complicated to review and, if there is no need for revision or modification, are generally approved more quickly than other proposals, there can be no guarantee that this will be the case. If the application is approved using expedited review procedures, the IRB Chair will issue an approval letter as with any other approved proposal.

Listed below are eleven research categories which, by federal regulations, are eligible for expedited review. *Only* research protocols that fall in one of these categories are eligible for expedited review:

1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction;
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;
3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. (These procedures include weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (i.e., x-rays and microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant;
5. Collection of both supra- and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
6. Voice recordings made for research purposes such as investigations of speech defects;
7. Moderate exercise by healthy volunteers;
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens;

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects;
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
11. Minor modifications or additions to existing approved studies.

### **C. Full Board Review**

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Research protocols that do not qualify for exempt or expedited reviews under the above stated categories must be reviewed and approved by the full IRB committee at a regularly scheduled meeting.

## **V. IRB MEMBERSHIP: COMPOSITION, PROCESS, AND FUNCTION**

- A. The membership of the IRB shall include at least one community representative, the Vice Provost or his/her designated representative who shall serve ex-officio, and a minimum of six faculty members. Faculty members will be selected according to the College's research needs, but shall include at least one member whose primary expertise is in a non-scientific area (e.g., law, religion, or ethics). Ideally, the Committee should include members from a variety of disciplines on campus. The Committee shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. (45 CFR §46.107(a))

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

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

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

- B. A quorum of the members of the IRB, including at least one member whose primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Final approval by the IRB shall then require a two-thirds vote by members present. If the IRB agrees that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of approval. A letter of approval will be sent to the investigator with copies to the faculty advisor (if appropriate) and to the school or department internal review committee (if any). A copy of the letter of approval will be maintained by the IRB.
- C. Departments and schools may establish, or continue to operate internal review committees. These internal review committees shall provide preliminary reviews of their divisions' proposals prior to review by the College's IRB, but shall not replace the review of the College's IRB. The College's IRB will not consider a proposal originating from within those schools or departments that maintain internal review committees unless the proposal first has been approved by that committee.
- D. All e-mail and written correspondence between authors of proposals and reviewers will be maintained for a period of three years by the IRB chair.

## **VI. IRB PROCEDURES, INSTITUTIONAL RESPONSIBILITIES AND INVESTIGATORS' RESPONSIBILITIES**

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

- Outside investigators (non-College of New Jersey students or employees) conducting human subject research on The College of New Jersey campus or conducting research associated with the College are subject to the principles, procedures, and responsibilities outlined in this manual. In addition, they must have a sponsor from the College of New Jersey faculty or staff.
- C. The IRB recognizes the need for a thorough and prompt assessment of proposals. To expedite proposal review the Chair may choose the most efficient procedure for processing a particular proposal. All proposals that require a full board review shall be presented at a convened meeting of the IRB at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Any member requesting minor changes may authorize the Chair to negotiate such changes, with or without requiring that they personally approve the revisions prior to the issuance of the approval letter. If a committee member has a major objection to such a proposal, that member may call for a meeting of the full committee to review the changes.

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

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

- G. Investigators may submit proposals acknowledging that human subjects will be involved with the project, although plans for the involvement are indefinite. Such proposals will be reviewed and guidance will be provided. For IRB approval, however, formal review and approval will be required once complete plans are made, but before utilizing human subjects. In the case of an externally funded project, this later review and approval must precede the beginning of any grant budget period during which human subjects would be utilized.

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

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

the start date of the study. Those to be reviewed using the expedited procedures must be submitted at least two weeks before the start date, and proposals requiring full committee review must be submitted at least four weeks before the start date. Additional time may be needed if a proposal must be reviewed using more than one review procedure.

## VII. IRB CRITERIA FOR EVALUATING AND APPROVING PROPOSALS

Consistent with the Common Rule §46.111 Criteria for IRB Approval of Research, the IRB of The College of New Jersey will determine that the following requirements are satisfied in order to approve research covered by this policy (45 CFR §46.111(a)(1-7)):

### A. Basic Requirements

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1. Risks to subjects are minimized:
  - by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
3. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).
4. Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](#).
5. When appropriate, the research plan makes adequate provision for monitoring the data collected, to ensure the safety of subjects.
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

### B. Additional Factors

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1. *That all rights and welfare of the subjects will be adequately protected.* Each project will be scrutinized with the interests of the subjects foremost in consideration. Safeguards and emergency measures must be provided as appropriate. The IRB is concerned with the maintenance of proper records and the protection of anonymity and confidentiality of all data collected. Furthermore, the IRB will attempt to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participation

in a study. In short, the IRB shall make every effort to ensure that both the mental and physical well-being of the subjects are adequately protected.

2. *That the risks to the subjects are reasonable in relation to anticipated benefits.* The project protocol will be evaluated to determine whether risks to subjects are reasonable relative to the anticipated benefits, if any, to the subjects and/or to the importance of the knowledge that may reasonably be expected to result. The IRB will not allow the use of human subjects in poorly designed projects that are unlikely to elicit meaningful results. The primary responsibility for research design quality lies with the faculty sponsor. When necessary, the IRB will withhold project approval until an adequate design is adopted by the investigators.
3. *That the informed consent of subjects will be obtained by adequate and appropriate methods.* Except in rare instances when some degree of deceit is essential to the experimental design, all subjects will be fully informed by the investigator of the procedures to be followed including discomforts, risks, and possible benefits. Risks must be well defined in terms understandable by the subjects. Written informed consent must be obtained from all subjects, unless specifically waived by the IRB in accordance with 45 CFR §46.117 (c) (1) or (2):
  - that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, or
  - that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.”

## VIII. INFORMED CONSENT

Informed consent means the knowing, legally effective consent of any individual or the individual’s legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Informed consent is more than a signed document, it is a process. Written informed consent documents this process, but cannot serve as a substitute for it.

The information given to the subject, or the subject’s legally authorized representative, must be in simple, easily understood language. If the subject does not speak English, the informed consent must be presented in the appropriate language.

In most cases, written documentation of the consent process (i.e. a cover letter or cover sheet) is required. Unless consent is specifically waived by the IRB, the subject or the subject’s legally authorized representative must sign the consent document. If the subject is a minor (under age 18) or mentally incompetent, written consent of a parent, guardian, or legally authorized representative is required, unless waived by the IRB. Such a waiver, in accordance with 45 CFR §46.116, will be granted only if the investigator can provide adequate justification for the request. In addition to obtaining parental consent, the investigator must obtain assent of the child

unless the child is incapable of giving assent and the IRB has waived the requirement. Informed assent is the subject's agreement to participate in the absence of full understanding and commonly applies to individuals who have not attained legal majority and/or capacity.

In the case of certain surveys in which the only record linking the subject to the research or data would be a written signed consent form, the IRB may waive the use of a signed consent form. Nonetheless, a statement describing the procedures and objectives of the research must be supplied to the subjects in a written format. For example, the IRB may waive the use of a signed consent form for a project using a questionnaire that is distributed and returned anonymously through the mail. A cover letter sent with the questionnaire would include all the elements of informed consent listed in this section. If informed consent is to be obtained orally (i.e. prior to a telephone interview), a written summary of what subjects will be told must be provided to the IRB for review and approval. Under no circumstance may informed consent, whether oral or written, waive or limit in appearance or in fact the subject's legal rights, including any release of the institution or its agents from liability or negligence.

### **A. Informed Consent Process**

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The general requirements for the informed consent process as they appear in 45 CFR §46.116 (a) through (f) are outlined below.

1. Basic elements of the informed consent process. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent, the following information shall be provided to each subject:
  - a. A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
  - b. A description of any reasonably foreseeable risks or discomforts to the subject;
  - c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
  - d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - e. A statement describing the extent, if any 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 and, if so, what they consist of, or where further information may be obtained;
  - g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
  - 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.

2. Additional elements of informed consent: When appropriate, one or more of the following elements of information shall also be provided to each subject:
  - a. 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), which are currently unforeseeable;
  - b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
  - c. Any additional costs to the subject that may result from participation in the research;
  - d. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;
  - e. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and
  - f. The approximate number of subjects involved in the study.
3. An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:
  - a. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine:
    - public benefit or service programs;
    - procedures for obtaining benefits or services under those programs;
    - possible changes in or alternatives to those programs or procedures; or
    - possible changes in methods or levels of payment for benefits or services under those programs; and
  - b. The research could not practicably be carried out without the waiver or alteration.
4. An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:
  - a. The research involves no more than minimal risk to the subjects;
  - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - c. The research could not practicably be carried out without the waiver or alteration; and
  - d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
5. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws, which require additional information to be disclosed, in order for informed consent to be legally effective.

6. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

## **B. Written Informed Consent Requirements**

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Unless waived by the IRB, the following information shall be supplied in all written informed consents:

1. A statement that the project is research, a brief explanation of the scope, aims, and purposes of the research, and the experimental procedures to be followed, including the expected duration of the subject's participation. This statement should include a description of any anticipated benefits the subject or others might reasonably expect.
2. Identification of the responsible investigator, as well as the name of any sponsoring or funding source supporting the research. The College of New Jersey shall be identified as the, or one of the, responsible institution(s).
3. The following statement will be included in ALL written informed consents (including cover letters). This statement should be inserted at the bottom margin of the form, letter, or portion of the form to be retained by the subject.

THIS PROJECT WAS APPROVED BY THE COLLEGE OF NEW JERSEY  
INSTITUTIONAL REVIEW BOARD (609-771-3255) ON [INSERT DATE]  
AND EXPIRES ON [INSERT DATE].
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A description of any reasonable, foreseeable risks or discomforts to the subject (including likely results if an experimental treatment should prove ineffective). If the potential risk is currently unknown or unmeasurable, a statement to that effect will be required.
6. A statement regarding the availability of compensation and/or medical treatment, if injury occurs, will be required for research which involves more than minimal risk. If compensation or medical treatment will be provided, information about how it may be obtained or where further information may be secured will be required.
7. A statement that any new information developed during the course of the research which may relate to the subject's willingness to continue participation will be provided. Similarly, an offer to answer any questions the subject (or the subject's representative) might have regarding the subject's rights shall be included. This statement should include the name, address, and telephone number of the principal investigator as the contact point if questions or problems should occur.

8. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
9. A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled. This statement should include a description of the consequences, if any, that would accompany such a decision to withdraw.
10. In studies where deceit is essential to the experimental design, the IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent (45 CFR §46.116(d)). In such studies, honest debriefings must be held following the subjects' participation.

A copy of the informed consent shall be supplied to the subject or the subject's legally authorized representative. Federal law mandates that copies of all informed consents be retained for a minimum of three years after the completion of the research. The principal investigator is responsible for the maintenance and retention of such records. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance of these records. If the investigator leaves the institution within this 3-year period, all records must be forwarded to the OAGSR for retention.

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

The federal regulations dealing with studies on the above categories of human subjects are complex. Before submitting a proposal, investigators contemplating research utilizing these populations should obtain a copy of the most recent revision of the Code of Federal Regulations (45 CFR §46, Protection of Human Subjects), Subparts: B – Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in vitro Fertilization; C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and D – Additional Protections for Children Involved as Subjects in Research. These regulations may be obtained from the DHHS web site: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>.

#### **X. EDUCATION AND TRAINING**

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

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

## **XI. REPORTING TO THE IRB**

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

## APPENDIX

### Instructions for Submitting a Human Subjects Proposal

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

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

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

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

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

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

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

Proposals for proper review must be submitted in a timely fashion. Proposals expected to be exempted from formal review must be submitted at least one week before the start date of the study. Those to be reviewed using the expedited procedures must be submitted at least two weeks before the start date, and proposals requiring full committee review must be submitted at least four weeks before the start date. Additional time may be needed if a proposal must be reviewed using more than one review procedure.