



Nashua Community College Policies, Procedures, and Guidance For Human Subjects Research

Ethical Research Board

Approval Date: 5/12/2017

IRB Registration # IRB00010441 (expiration
date: 06/21/2020)

FWA # 00023868 (expiration date:
06/19/2022)

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INTRODUCTION

Nashua Community College (NCC) requires that researchers respect and protect the rights, privacy and welfare of individuals recruited for and participating in research. In 1974 the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission in turn published [The Belmont Report](#), which articulated the ethical principles that guide human subjects research and served as the foundation for Title 45, Code of Federal Regulations, Part 46 (45 CFR 46).

NCC's policies, procedures and guidance involving human subject research are designed to comply with the Code of Federal Regulations and state and local laws to protect individuals from harm, provide equitable selection of subjects, and maximize the benefits and minimize the risks of research participation.

NCC and its administration, faculty, staff, and students share in the collective responsibility for the protection of human research participants and, more broadly, for the ethical conduct of research. This collaboration must operate in a culture of trust, mutual assurance, and integrity by upholding the highest ethical principles in the conduct of research and the pursuit of knowledge.

1. Ethical Principles Governing Human Subjects Research

NCC is guided by the three ethical principles of research set forth in the *Belmont Report*. These principles are: respect for persons, beneficence, and justice.

A. Respect for Persons

All researchers are required to seek and obtain, whenever possible, voluntary, written informed consent from all potential human subject participants. Informed consent must provide potential participants with sufficient information to;

- Understand what they are participating in;
- Understand the voluntary nature of their involvement;
- Understand that they are not under duress; and
- Provide sufficient information to allow the person to decide if they wish to participate or not.

The consent process must be written or explained in an easy-to-understand/easy-to-read nature. Respect for persons also includes honoring the privacy of individuals and maintaining their confidentiality.

B. Beneficence

This guiding principle requires that researchers maximize the potential benefits to the participants or to society, while minimizing the potential risks of harm. The extent of protection depends on the risks and benefits of the proposed research to the participants and to society. All

participants should be treated in an ethical manner. Ideally, direct benefits to the subjects should always outweigh the risks of participating in the research. At a minimum, proposed research must present sufficient benefits to society at large to outweigh the risks the research presents to the research participants.

C. Justice

This guiding principle requires that participants be selected fairly and that both the risks and benefits of research are distributed evenly among the subjects. Researchers should always take precautions not to select participants simply because of convenient availability, manipulability, compromised positions, or based on social, racial, sexual, economic, or cultural biases institutionalized in society.

2. Purpose

The *Policies, Procedures, and Guidance Manual for Human Subjects Research* is designed as an official policy manual and reference guide for ERB personnel and researchers. This manual details the policies, procedures, regulations and protocol submission requirements governing human subjects research at NCC.

3. Scope

This Manual and the ethical principles governing human subjects research will apply to all research:

- Sponsored by Nashua Community College (NCC);
- Conducted by or under the direction of any employee or agent of NCC, including any faculty, staff or administration members, and students, in connection with their responsibilities at NCC;
- Conducted by or under the direction of any employee or agent of NCC, including any faculty, staff or administration members, and students, using any property or facility of this College;
- Involving the use of NCC's non-public information to identify or contact human research subjects or prospective subjects;
- Conducted by NCC students may include:
 - **Student classroom projects involving human subjects or information protected under other applicable laws (such as HIPAA or FERPA);**
 - **Capstone project; or**
 - **Any project that would normally be treated as reviewable research in a non-class setting.**
- Presented by an outside entity, not otherwise covered, to the NCC ERB.

4. Applicability

This policy applies when NCC becomes "[engaged](#)" in human subjects' research regardless of funding or funding source. Engagement is defined by the OHRP [guidance](#).

5. Assurance

NCC entered into a legally binding agreement with DHHS concerning research involving human subjects. This Assurance (**Federalwide Assurance #00023868**) is administered by DHHS's Office of Human Research Protections (OHRP) and governs all human subjects research receiving, or eligible to receive, federal (DHHS) funds. This agreement is guided by the ethical principles of the *Belmont*

Report and requires, at a minimum, compliance with 45 CFR 46 (The Common Rule).

NCC's institutional policy requires the application of all Common Rule requirements and subparts found under 45 CFR 46 to **all** human subjects research regardless of funding or governing Federal Agency. In order to maintain an active Federalwide Assurance (FWA), the institution must update its FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official or every 5 years, if no changes have occurred.

6. Definitions and Operational Concepts

Adverse Event, Serious: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.

- Serious Adverse Events include those that:
 - Are fatal or life threatening;
 - Result in significant or persistent disability;
 - Require or prolong hospitalization;
 - Result in a congenital anomaly/birth defect; or
 - Represent other significant hazards or potentially serious harm to research subjects or others, in the opinion of the investigators.
- Unexpected Serious Adverse Events are those that have not been described in the:
 - Package insert for a given drug or investigator's brochure (for FDA investigational agents);
 - Approved protocol; or
 - Informed consent document. [21 CFR 312.32(a)]

Adverse Research Event: Adverse research events include a wide spectrum of events. Adverse events include, but are not limited to:

- Physical or psychological harm or injuries,
- Threats to privacy or safety,
- Unusual attrition of human subjects, and/or
- Breaches of confidentiality or emotional harms such as the emotional distress that could be triggered by questions about traumatic life events or a subject's complaints about the experimental procedures or the conduct of the investigators.

Certificate of Confidentiality: A discretionary document procured from the National Institutes of Health which helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Further information is available at <http://grants1.nih.gov/grants/policy/coc/>.

Coercion: To bring about participation in research by force or threat, actual or perceived, or through

any other imbalance of power.

Common Rule: The federal regulation that is the primary source of human subjects' protections. Common reference for 45 CFR 46, PROTECTION OF HUMAN SUBJECTS.

Ethical Research Board (ERB): The NCC research review committee whose primary purpose is to review all research involving human subjects and to provide oversight of human subjects protections.

Generalizable Knowledge: Information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context. Thus, a case study, designed to illuminate the course of a single individual's experience generally **will not** be considered to be developing or contributing to generalizable knowledge. A series of case studies, intended to lead to improvements in the management of a particular circumstance or condition, generally **will** be considered generalizable knowledge.

Human Subject: "A living individual(s) about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyses the information or biospecimens; or
- Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens." [45 CFR 46.102(e)]

Identifiable Private Information may include:

- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; [45 CFR 46.102(f)]
- Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (*e.g.*, a medical record); [45 CFR 46.102(f)]
- Private information which is individually identifiable; [45 CFR 46.102(f)]
- Information of a nature that the identity of the subject is or may readily be ascertained by the investigator or associated with the information; [45 CFR 46.102(f)], and/or
- Information which was collected specifically for the proposed project through intervention or interaction with living individuals and is of a nature that the investigator can readily ascertain the identity of the individuals.

Institutional Official: The institutional official (IO) is the highest institutional official who has the legal authority to represent NCC's FWA filed with the OHRP, and is responsible for the provisions of this policy.

Interaction: A communication or interpersonal contact between investigator and subject for research purposes.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. This may include surveys, interviews, observations, and/or questionnaires.

Key Research Personnel: Persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects' identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or use subjects' personal information.

Minimal Risk: "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 living or during the performance of routine physical or psychological examinations or tests" [45 CFR 46.102(i)].

Minor: An individual under the age of 18 years.

Minor Changes: Minor changes have no substantive effect upon an approved protocol or reduce the protocol risk already approved by the ERB. Examples of minor changes are:

- Changes in research personnel that do not alter the competence of the research team to conduct the research, or
- Minimal changes in remuneration.

Principal Investigator (PI): Any NCC faculty, staff member, student, or individual so designated in an application for external review that is the primary person responsible for all aspects of the research project and assumes all responsibilities for the results.

Prisoner: Any individual, regardless of age, involuntarily confined or detained in a penal institution, or subject to supervision as a term of probation or parole from confinement. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This definition also includes data from non-publicly available databases and secondary sources.

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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects" [45 CFR 46.102(e)].

Note: For research involving health or medical information (and/or the electronic transmission of this type of information) the definition of "private information" is not the same as the definition of "protected health information" (PHI) as defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Protected population: (Also referred to as protected subject group). These groups of potential research subjects have specific regulatory compliance requirements and receive special protections under the Common Rule and/or other federal regulations. These groups include (but not restricted to):

- Children/Minors (Under the age of 18);
- Prisoners (now includes non-publicly available secondary data);
- Pregnant women;
- Fetuses and products of labor and delivery;
- People with diminished capacity to give consent; and/or
- Mentally or physically challenged individuals.

Protocol: Any type of research project that is submitted for ERB review (also known as a research project, proposal, submission, etc.).

Protocol Violation, Major: Any protocol violation that may impact subject safety, make a substantial alteration to risks to subjects, or any factor determined by the ERB Chair or designee as warranting review of the violation by the convened ERB. Examples of major violations may include, but are not limited to:

- Failure to obtain informed consent, i.e., there is no documentation of informed consent, or informed consent is obtained after initiation of study procedures;
- Failure to obtain a waiver of informed consent, if applicable.
- Intentional enrollment of a subject who did not meet all inclusion/exclusion criteria;
- Performing study procedure not approved by the ERB;
- Failure to report serious unanticipated problems/adverse events involving risks to subjects to the ERB and (if applicable), the sponsor;
- Drug/study medication dispensing or dosing error, or failure to perform a required lab test that, in the opinion of the ERB or consultants to the ERB, may affect subject safety or data integrity;
- Study visit conducted outside of required time frame that, in the opinion of the PI or ERB, may affect subject safety; and/or
- Failure to follow safety monitoring plan.

Protocol Violation, Minor: Any protocol violation that does not impact subject safety or does not substantially alter risks to subjects. Examples of minor violations may include, but are not limited to:

- Implementation of unapproved recruitment procedures;
- Missing original signed and dated consent form (only a photocopy available);
- Missing pages of executed consent form;
- Inappropriate documentation of informed consent, including:
 - missing subject signature;
 - missing investigator signature;
 - copy not given to the person signing the form;
 - someone other than the subject dated the consent form; and/or

- an individual obtaining informed consent not listed on ERB approved study personnel list;
- Use of invalid consent form, i.e., consent form without ERB approval stamp or outdated/expired consent form;
- Failure to follow the approved study procedure that, in the opinion of the PI, does not affect subject safety or data integrity;
 - Study procedure conducted out of sequence;
 - Omitting an approved portion of the protocol;
 - Failure to perform a required lab test;
 - Missing lab results;
 - Enrollment of ineligible subject (e.g., subject's age was 6 months above age limit); and/or
 - Study visit conducted outside of required timeframe;
- Over-enrollment;
- Failure of the PI to follow through with recruitment/retention incentives for subjects listed on consent;
- Enrollment of subjects after ERB-approval of study expired or lapsed; and/or
- Failure to submit continuing review application to the ERB before study expiration.

Research: NCC takes as its starting point the federal definition of research set forth in the Common Rule, 45 CFR 46.102(d):

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes (e.g., some demonstration and service programs may include research activities). ***Please note - risk assessment plays no role in the determination of whether a proposed activity constitutes research. See also the definition of generalizable knowledge, above.***

Research misconduct (42 CFR § 93.103): means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

Sensitive Information: According to the NIH Certificate of Confidentiality, sensitive information is that which, if disclosed, may reasonably pose a risk to the subject's psychological, social, medical, legal, or economic well-being or quality of life. Categories of sensitive information include (but are not limited to):

- Sexual attitudes, preferences, or practices;
- Use of alcohol, drugs, or other addictive products;
- Information pertaining to illegal conduct;
- Information that if released might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination;
- Health and medical information contained in a medical record, chart or insurance file (this category may also require a HIPAA review);
- Information pertaining to an individual's psychological well-being or mental health (this category may also require a HIPAA review); and/or
- Genetic information or tissue samples (this category may also require a HIPAA review).

Per NCC policy (FERPA: Student Rights and Responsibilities), directory information is NOT considered sensitive information (for information, see [here](#)). Directory information includes: Name, Address, Email Address (CCSNH), Telephone Number, Major Field(s) of Study, Dates of Attendance, Enrollment Status, Degrees, Honors and/or Awards, and Most recent educational institution attended.

Specimen: Specimen is used to refer to biological specimens (e.g., blood or tissue samples), as well as to other types of data "specimens" that could be stored for use in future research (e.g. audio tapes, video tapes, etc.).

Substantive Changes: Substantive changes are changes that may increase the research population's risk or are of questionable risk. Examples of substantive changes that are considered to increase the risk to the study/individual include:

- Increasing the length of time a study participant is exposed to experimental aspects of the study;
- Changing the originally targeted population to include a more at-risk population (example: previous exclusion for those with renal failure are now allowed to enroll, or adding children or pregnant women to the study); and/or
- Adding an element that may breach the confidentiality of the subject such as tissue banking or genetic testing.

Undue Influence: Inappropriate remuneration or any other form of compulsion offered to an individual that may unfairly compel that individual to participate as a human research subject, as determined by the ERB.

Unanticipated Problem: Any event that is not expected given the nature of the research procedures and the subject population being studied, and places subjects or others at greater risk or harm/discomfort related to the research than was previously known or recognized. An event which was previously unforeseeable based on the information provided to the ERB.

7. The Institutional Review Board (Nashua Community College Ethical Research Board)

The NCC ERB is the primary institutional body legally vested and charged with protecting the rights

and welfare of persons participating in human subjects' research conducted at, or affiliated with, NCC, or submitted to the NCC ERB under the External Review Policy. The ERB is responsible for:

- Determining how human subjects research can be conducted;
- Determining what constitutes appropriate safeguards;
- Reviewing researcher compliance; and
- Monitoring approved research.

NCC has only one ERB (Registration# IRB00010441) authorized under its FWA to review and approve human subjects research. The NCC ERB has sole authority through the NCC FWA to interpret and apply federal, state, and local human subjects protections to NCC research protocols and proposals.

Generalizable research with human subjects must be prospectively reviewed and either approved or exempted by the ERB or its designee **prior to initiation**, including activities related to recruitment of subjects and data collection. All research involving human subjects, even if found exempt from ERB review, must follow applicable NCC policies for the protection of human research subjects and guiding principles of the Belmont Report.

The NCC ERB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The ERB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, 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. Every nondiscriminatory effort will be made to ensure that the NCC ERB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the ERB on the basis of gender.

The NCC ERB may not consist entirely of members of one profession.

The NCC ERB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The NCC ERB shall 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.

The NCC ERB shall include at least one member who is a current student of the institution. The student must be over 18 years and can be nominated by any existing committee member.

The NCC ERB may not have a member participate in the ERB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the ERB.

The NCC ERB may, in its discretion, invite individuals with competence in special areas to assist in the

review of issues which require expertise beyond or in addition to that available on the ERB. These individuals may not vote with the NCC ERB.

8. ERB Membership

A. Board Composition

The ERB will consist of at least 5 voting members with varying backgrounds that promote complete and adequate review of research conducted at NCC. All members are appointed at the discretion of the ERB Chairperson and the NCC IO. At a minimum, the NCC ERB will be composed of:

- ERB Chairperson (full time faculty or IO approved staff only);
- One person from the NCC community (faculty or staff only);
- One community members not affiliated with Nashua Community College;
- One scientist (MD, Ph.D. or other appropriate scientific degree);
- One non-scientist; and
- One person serving as the official ERB Student Representative.

All other members are appointed at the discretion of the ERB Chairperson and the NCC IO. Additional members include, but are not limited to:

- Additional voting members;
- Alternate board members;
- Alternate board members representing special knowledge areas or protected population groups (voting and non-voting); and/or
- Alternate board members representing specific ethnic, cultural, or religious groups (voting and non-voting).

B. General ERB Membership Appointment

All ERB members are selected by the ERB Chair and NCC IO and appointed to the Board by the Chair.

All members appointed to the ERB will receive an appointment letter from the Chair stating their appointment date, term, and basic responsibilities. All ERB members will also receive, within 60 calendar days from their appointment date, notification in writing from the Chair. ERB members are covered under the CCSNH General Liability Policy (see [here](#)).

C. Chairperson

The IO appoints the ERB Chairperson to the Board. The Chairperson will be either a full-time faculty person or an appointed staff person.

D. Membership Terms and Voting Rights

1. Regular Voting and Alternate Members

The Chairperson of Nashua Community College (or his/her authorized representative) will appoint members to the ERB for a period of 1 or 3- year terms. New members will be allowed a 1 year appointment. All other members are requested to commit to a 3-year term including their first term or initial 1 year appointment. This reduces the effect of turnover

and ensures consistent voting membership.

Re-appointment terms can be for 3 years and must be by mutual consent of the member, the ERB Chairperson and the IO.

All regular, voting members have full voting rights and privileges. Alternate member appointments are based on the experience, expertise, background, professional competence and knowledge of the member being equivalent to that of a primary ERB member.

2. Chairperson

The ERB Chairperson is appointed by the NCC IO and is appointed for a period of 3 years. This is renewable with the consent of the ERB Chairperson and IO.

The ERB Chairperson has full voting rights and privileges. The ERB Chairperson's contributions will be acknowledged through a combination of annual course release, a stipend which may be adjusted from time to time, and/or membership in PRIM&R (Professional Responsibility in Medicine & Research).

Responsibilities may also include, but are not limited to:

- Reviewing all human subjects research protocols in order to ensure that regulatory compliance requirements are met and appropriate ethical conduct standards are upheld;
- Serving as reviewer for all Exempt level research and conducting an initial review for all other levels;
- Providing assistance in drafting and administering with the IO and ERB members NCC's policies and procedures and guidance governing the ethical conduct of human subjects research and associated activities;
- Providing professional, technical, and educational assistance to faculty, staff, and students on all aspects of the ethical conduct of human subjects research and associated activities; and
- Performing initial detection/inquiry into possible protocol violations/adverse events and making preliminary recommendations for alleged policy violations.

3. Alternate Membership

An alternate member(s) may be designated, as needed, for a regular voting member (s). An alternate member may vote only when the regular voting member is not voting. Each alternate ERB member who replaces a primary member at any given meeting will have experience, expertise, background, professional competence, and knowledge equivalent to that of the primary ERB member whom the alternate will replace. Whenever this occurs, the minutes of the ERB meeting will indicate clearly that the alternate ERB member has replaced the designated primary ERB member, and include the identity of the replaced primary and alternate members. If multiple alternate members serve at an ERB meeting, the pairing of primary and alternate members will be indicated.

E. General Member Responsibilities and Obligations

1. Attend 50% or more of regularly scheduled meetings per year (based on appointment date) in order to maintain membership status.
2. Complete the required Human Subjects Protection training once every four years. The certificate must be on file with the Chair prior to voting.
3. Maintain any special or required credentials for those serving in specialized roles.
4. Attend and/or complete the continuing ERB education annually as outlined by the Chair.
5. Serve as a reviewer for expedited protocols.
6. Take an active part in the voting process when present for board meetings.
7. Recuse oneself from voting or participating in ERB business when the member has a clear or perceived conflict of interest concerning the matter at hand.
8. Recuse oneself from voting or participating in ERB business when the member is the topic of business, including when the member is the PI on a Full Board review.

F. Termination of Membership

1. **Voluntary:** An ERB member may voluntarily resign their membership at any time. As a matter of courtesy, it is requested that any member wishing to do so provide a written notice to the ERB Chair at least 60 days prior to leaving. No justification is required. Under NCC and CCSNH policy voluntary termination cannot and will not be held against the resigning member.
2. **Involuntary:** An ERB member may be involuntarily terminated from the ERB for:
 - a. Professional misconduct;
 - b. Research misconduct (as defined under federal regulations);
 - c. Breach of membership duties;
 - d. Unethical or illegal activities related to their duties and obligations to the ERB; or
 - e. A supermajority (75%) vote of all ERB voting members (minus the member in question).

9. ERB Meetings

The ERB will meet quarterly, or more frequently as needed, to conduct official business. The ERB Chair has the discretion to call for additional meeting sessions or for longer meeting times in order to meet ERB obligations.

All meetings will be duly convened by the ERB Chairperson or his/her designee and must have a quorum in order to conduct business.

All meetings will be conducted in closed door sessions, unless non-ERB personnel are invited to attend.

10. Meeting Minutes

ERB meetings may be recorded. Copies of the meeting minutes will be made available to all ERB members, the NCC IO and all applicable State/Federal regulatory agencies.

All minutes will include, at a minimum:

- Members in attendance and absent;
- Report of adverse events since the last ERB meeting;

- Summary of protocols (and numbers of) for the preceding month;
- Update on any changes or revisions to a previously reviewed Full Board protocol;
- Summary of discussions held during the meeting;
- Notification of any ERB Investigation that has been initiated (if applicable);
- Summary and/or status of any ERB investigation being conducted (if applicable);
- Full statement of any motion made, subsequent discussions, any formal decisions;
- Recommendations and a formal recording of votes made (for, against, and abstention);
- Votes against a particular motion, including what the reasons were; and
- Summary of any formal NCC Policy changes, changes in Federal regulations or guidance, etc. about which the Full ERB Board needs to be informed.

11. The Role of the ERB

The ERB is charged with two primary roles:

- A. Determining and assuring that all research protocols conform to all federal and state regulations and policies regarding the health, welfare, safety, rights, privileges and confidentiality of human subjects; and
- B. Assisting researchers in conducting ethical and federally compliant research in such a way that permits the researcher to accomplish the research activity.

12. Responsibilities of the ERB

- A. Except when an expedited review procedure is used, review proposed research at convened meetings at which a majority of the members of the ERB 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;
- B. Review, approve, or disapprove protocol applications submitted by the NCC community or agents of NCC;
- C. Review, approve, or disapprove protocol applications submitted by an outside entity, not otherwise covered, under the terms of an External IRB Authorization Agreement as set forth in the NCC Policy on ERB External Review Policy of non-NCC affiliated Research Protocols;
- D. Monitor approved protocols;
- E. Report to appropriate NCC officials any action to suspend or terminate a research protocol that fails to meet compliance standards. Appropriate officials include the IO or any other official deemed necessary by the ERB and report to OHRP (as applicable);
- F. Act as an informational resource to the NCC community;
- G. Assist peer review committees, where applicable; and to
- H. Ensure that legally effective informed consent of human research subjects will be obtained in a manner and method that meets the requirements of federal, state and local regulations and laws, NCC and Community College System of New Hampshire (CCSNH) policies.

13. ERB Authorized Powers

- A. Decisions of the ERB are final. NCC administrators and/or the IO may not overturn decisions of the ERB;

- B. Approve research as submitted;
- C. Approval of Research with Conditions;
- D. Table the protocol until the next meeting to allow the PI to address ERB concerns;
- E. Disapprove the research;
- F. Require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116. The ERB may require that information, in addition to that specifically mentioned in 46.116, be given to the subjects when in the ERB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;
- G. Require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.117;
- H. Conduct continuing review of research covered by 45 CFR 46 at intervals appropriate to the degree of risk, but not less, than once per year, and shall have authority to observe or have a third party observe the consent process and the research;
- I. Require a primary investigator to apply for a Certificate of Confidentiality from the National Institutes of Health (for more information see <http://grants1.nih.gov/grants/policy/coc/>);
- J. Suspend or terminate any research project that:
 - Is not conducted in accordance with the ERB's requirements;
 - Results in a minor or major protocol violation;
 - Has been associated with an unexpected serious harm to subjects;
 - Is the focus of an investigation (assessment, inquiry or formal investigation); or
 - When ordered to by a State or Federal agency or granting organization.
- K. Randomly monitor approved protocols for compliance with the ERB approved protocol by any appropriate and reasonable means.

Monitoring methods include, but are not limited to:

- Observation of the consent process;
- Observation of the data collections process;
- Appointment of a third party to undertake such observation;
- Appointment of a third party to independently evaluate the PI's compliance;
- Independent review of research documents, including but not limited to, consent forms (both blank and completed) and research instruments;
- Appointment of an ERB subcommittee charged with the monitoring process;
- Request that the PI(s) appear before a fully convened ERB for an update, etc.; and
- Request that the PI(s) submit what data or analysis has been done to date to the ERB for review.

Potential triggers for monitoring include, but are not limited to:

- PIs with prior adverse events;
- Novel or new interventions in a biomedical study;
- Investigators submitting protocols requiring expedited or full board review who have no prior research experience;
- Especially high risk protocols (as determined by the ERB);

- Protocols involving especially high risk/vulnerable populations and/or groups highly susceptible to coercion;
- Protocols that substantially overlap with major Privacy Rights statutes, such as HIPAA and FERPA;
- A protocol to be conducted over an unusually long period of time;
- PIs who are chronically late in filing for continuing review; and/or
- PIs who:
 - Submit multiple drafts of informed consent forms;
 - Submit standardized or “form” informed consent forms;
 - Submit informed consent forms which clearly do not apply to the study being reviewed; or
 - Submit informed consent forms from other sites or facilities.

14. Categories of Review

A submitted protocol may be deemed to fall into one of five categories, each with a different level of review:

A. Not Research and/ or Not Human Subjects

Certain activities do not qualify as research and/or research with human subjects. When the ERB makes a determination that a proposed project is not research and/or not research with human subjects, no ERB oversight is required. The PI will receive a determination, in writing, from the ERB. Once the project is submitted, only the Ethical Research Board or ERB Chair can determine if a proposed project qualifies as not research and/or not research with human subjects.

Procedure for Requesting a Not Research Involving Human Subjects Determination

If an investigator would like to request a formal, written determination, from the ERB regarding whether a planned activity constitutes research with humans subjects he/she should complete the Determination of Research Involving Human Subjects Application Form in the ERB website. Only complete submission will be accepted for review.

B. Student Classroom Project

Certain projects, conducted in the context of an assigned class activity, may be deemed to constitute a Student Classroom Project under ERB SOP-003 Student Classroom Projects, incorporated herein by reference. Faculty who submit such projects will receive notification in writing indicating ERB general approval of the proposed activities. Only the Ethical Research Board or ERB Chair can determine if a proposed project qualifies as a Student Classroom Project.

C. Exempt

The Common Rule outlines certain types of research which are exempt from ERB oversight. 45 CFR 46.101.b. Only the Ethical Research Board or ERB Chair can determine if a proposed project qualifies as Exempt. Research presenting greater than minimal risk, or involving children, pregnant women, fetuses, prisoners, mentally disabled, or subjects with a diminished capacity to give consent may be ineligible for exemption. PIs whose research is exempt will receive an Exemption letter, and are not required to have any further interaction with the ERB unless adverse events occur, or there is a change to the protocol.

Procedure for Requesting an Exemption from ERB Review

Only complete submissions will be reviewed by the ERB. The official assessment of exempt or not exempt will be conveyed to the investigator in writing.

D. Expedited

Proposed activities which do not qualify for exemption may be subject to Expedited Review, 45 CFR 46.110 in accordance with designated expedited categories set forth in [63 FR 60364-60367, November 9, 1998](#), but only if the procedure or activities involve no more than minimal risk to the research subjects. Expedited review does not mean that the process takes less time. It means that the review and approval process rests with at least one, qualified, ERB member. Protocols determined to be more than minimal risk, do not qualify for Expedited Review. The ERB may also determine that a project involving the collection of sensitive information or the inclusion of vulnerable populations is not eligible for Expedited review. Researchers whose projects qualify for expedited review will receive notification in writing stating that the proposed research was reviewed using Expedited Review, the terms of approval, and the approval period. Only the ERB or ERB Chair can determine if a proposed project qualifies for Expedited Review.

Expedited Review Procedure

Only complete submissions will be reviewed. All protocols that the ERB review will be analyzed for eligibility to use an expedited review procedure in accordance with the Expedited Review Criteria. Expedited reviews are conducted by at least one experienced ERB member assigned by the ERB Chair or the Chair's designee. In an expedited review, a reviewer may exercise all of the authorities of the ERB except that the reviewer may not disapprove the research. If the reviewer does not find that the proposal meets the criteria for expedited review, the proposal will be reviewed using a full review procedure at the next convened ERB meeting.

E. Full Board

All protocols which do not fall under one of the expedited review categories, or are more than minimal risk, or otherwise determined to require full review will undergo review at a convened meeting of the ERB with a quorum present. The full board will discuss the protocol, and may take one of several actions including:

- Approving the Protocol outright;
- Approving the Protocol with conditions;
- Tabling the protocol until the next meeting to allow the PI to address ERB concerns; or
- Disapproving the protocol.

The ERB's actions will be communicated to the PI in writing which details the ERB's decision, sets forth any required changes, requests more information, or invites resubmission after the protocol is revised.

Full Board Review Procedure

Only complete submissions will be reviewed. Applicants seeking Full Board review must submit at least 30 days prior to the next convened ERB meeting. Submissions that are incomplete or in need of major revisions will be reviewed at the next available ERB meeting. The need for Full review will be determined by the Chair. PI's may be given the opportunity to attend the meeting at which their protocol will be reviewed to answer questions but will not be present for

deliberations.

F. Educational Requirements for Protocol Approval

All investigators, faculty advisors, and research staff* are required to have completed the appropriate Human Subjects Protection training. Applications will not be processed or reviewed until this requirement has been fulfilled.

In addition, so long as an approved protocol is active, investigators must also update their qualifications at least every 4 years. This qualification must be maintained in order for investigators to continue research activities.

If key personnel have completed training with another university, institution, organization, etc. within the last 4 years, then a completion certificate must accompany the application. Please contact nccerb@ccsnh.edu with questions. The previously completed training may be accepted at the discretion of the Chair.

**key personnel are considered to be persons who 1) obtain data about living individuals for research purposes through intervention or interaction with them; 2) obtain individually identifiable private information for research purposes; 3) obtain informed consent of human research participants; or 4) have access to records with individually identifiable private information.*

G. Continuing Review Process

Review of research approved through an Expedited or Full review procedure must occur not less than once per year. Some high-risk protocols may require more frequent review as deemed necessary by the ERB. The approval period is listed on applicable approval letters and it is the PI's responsibility to obtain continuing review of their project, if needed. At their discretion, the ERB may require research protocols be reviewed *de novo*.

Sixty days prior to the ERB approval expiration date, investigators must submit an ERB Continuing Review Form with all requested study documents. Only complete submissions will be reviewed.

Under no circumstances may an investigator continue data collection or analysis beyond the ERB approval date, nor may any researcher use an expired research instrument (such as surveys, questionnaires, or tests). Researchers found to be collecting or analyzing data without ERB approval may be required to expunge the data upon ERB request, and all research activities may be suspended by the ERB pending continuing ERB review and approval of research activities. PI's who allow a protocol to lapse will be required to submit *de novo* with an explanation regarding why the lapse occurred.

15. Completion, Withdrawal or Termination of Research

When a study is withdrawn or completed, the investigator must notify the ERB, in writing, if a project was previously approved through an Expedited or Full review procedure. A Principal Investigator Closeout Form must be completed at the time of completion or termination. Closure of projects is a requirement. New projects submitted by a PI will not be reviewed if existing projects have not been properly closed or renewed. Records relating to research which is conducted will be retained for at least 3 years after completion of the research. Protocols are considered to be "active" so long as they continue to involve human subjects (based on the regulatory definition). Note this includes the

ongoing analysis of collected data.

16. Foreign Research

All human subject research activities conducted by employees or agents of NCC or in which NCC is otherwise determined to be “engaged”, will be guided by the ethical principles of the Belmont Report and will comply with the requirements of 45 CFR 46, under the terms of the NCC FWA. The investigator will also abide by that country's laws, regulations, and requirements.

17. Cooperative Research Review

Review and approval by an outside IRB does not negate the requirement for review and approval by the NCC ERB (if an outside IRB shares jurisdiction over a study, the NCC ERB requires a copy of that IRB's determination as part of the application).

Whenever NCC relies upon an IRB operated by another institution or organization for review of research to which its FWA applies, NCC will ensure that this arrangement is documented by a written agreement between NCC and the other institution or organization operating the ERB that outlines their relationship and includes a commitment that the outside IRB will adhere to the requirements of NCC's FWA. NCC's External IRB Authorization Agreement will be used for such purpose. This agreement will be kept on file at both institutions and made available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.

The activities of individual research investigators who are not employees or agents of the institution may be covered under the NCC FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and ERB oversight. [OHRP's sample Unaffiliated Investigator Agreement](#) may be used for this purpose. NCC will maintain such commitment agreements on file and provide copies of them to OHRP upon request.

All collaborative research projects must receive ERB approval and appropriate continuing review at each participating institution. The NCC ERB requires documentation of such approval and must be obtained prior to the initiation of research activities that are governed by the collaborating institution's IRB.

18. Application Requirements for Research Involving Human Subjects

Only complete protocol submission will be accepted for review. The ERB will notify the PI listed (via email) when a submission to the ERB is received in its complete form. A submission is considered complete only when it satisfies all four of these requirements:

- Each submission must utilize the appropriate form on the NCC ERB website;
- Each submission must answer all questions fully with sufficient detail to allow reviewers to make the determinations required;
- Each submission must include all attachments requested in the form (as applicable); and
- Each submission must be submitted as a single, complete PDF file to nccerb@ccsnh.edu.

19. Informed Consent: General Requirements

Unless specifically authorized or waived by the ERB, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the

subject or the subjects legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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.

Informed Consent is a process not a single event. Since subjects always retain the right to withdraw from a research project, it is imperative that the investigator maintain the subject's continuing, voluntary informed consent at all times.

A. Informed consent must include the following elements:

1. A statement that participation is voluntary and that the subject may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
2. 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;
3. A description of any reasonably foreseeable risks or discomforts to the subject (if no foreseeable risk exists, then a statement to that effect is appropriate);
4. A description of any benefits to the subject or to others which may reasonably be expected from the research (if no foreseeable benefit exists, then a statement to that effect is appropriate);
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
6. A statement describing how confidentiality of records that identify the subjects will be maintained;
7. For research involving more than minimal risk, an explanation of any compensation and an explanation of any medical treatments that are available if injury occurs and, what they consist of, or where further information may be obtained; and
8. An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject.

B. Additional elements of informed consent

When appropriate the following information shall also be provided to each subject:

1. 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;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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
6. The approximate number of subjects involved in the study.

20. Documentation of Informed Consent

Consent documents serve as confirmation of the process of obtaining informed consent for research participation. Consent forms are not a substitute for the consent process. Consent documents must be clearly written and understandable to subjects. Researchers need to consider their audience in relation to the comprehension of the information presented. This may require translation into the preferred language of the participants. The language of the consent document must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical or medical terms must be plainly defined. The consent form or process may not include language that appears to waive subjects' legal rights or appears to release the investigator from liability or negligence.

A. Written Consent Forms:

Informed consent shall be documented (unless the ERB has given approval for a waiver, alteration, or exception) by the use of a written consent form approved by the ERB and signed by the subject or the subject's legally authorized representative. A copy of the consent form shall be given to the person signing the form. The consent form may be either a full form written or a short form written.

B. Full Form Written:

A full form written consent document embodies all the required elements of informed consent, as outlined above. This form may be read to the subject or the subject's legally authorized representative, but the investigator must still give the subject or the representative adequate opportunity to read the document before it is signed. When the full form is used, the following procedures must be implemented:

- **The subject or the representative signs the full form; and**
- **The subject or the representative receives a copy of the form.**

C. Short Form – Written (Oral Summary):

A short form written consent document is a statement indicating that the required elements of informed consent (Section 19.B of this Policy) have been presented in an oral summary to the subject or the subject's legally authorized representative.

When the short form is used, the following procedure must be implemented:

- There must be a witness to the oral presentation,
- The researcher must provide the ERB a written summary of what will be said to the subject or the representative *and* the researcher must obtain ERB approval of the summary before it is implemented,

- The subject or the representative signs only the short form,
- The witness must sign both the short form *and* a copy of the ERB approved summary,
- The person actually obtaining consent (the researcher) must sign a copy of the summary, and
- The subject or the representative receives a copy of the summary *and* a copy of the signed form.

D. Alteration or Waiver of Informed Consent Requirements

There are only two circumstances in which the ERB may waive the required consent. The first waiver authority is applicable only to research activities designed to study certain aspects of public benefit or service programs; the conditions under which this waiver may be authorized by an ERB are detailed at 45 CFR 46.116(c) (1-2) An ERB 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 ERB finds and documents that:

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:

1. Public benefit or service programs;
2. Procedures for obtaining benefits or services under those programs;
3. Possible changes in or alternatives to those programs or procedures; or
4. Possible changes in methods or levels of payment for benefits or services under those programs; and
5. The research could not practicably be carried out without the waiver or alteration.

The second waiver authority is described at 45 CFR 46.116(d). An ERB 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 ERB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration (note: mere inconvenience is not sufficient); and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

In cases in which the documentation requirement is waived, the ERB may require the investigator to provide subjects with a written statement regarding the research.

21. Informed Consent in Research Involving Vulnerable Populations

Informed consent practices in especially vulnerable populations are subject to extra considerations.

A. Research Involving Minors (subjects under 18 years of age)

In all human subject research, the agreement of the subject to participate is an essential protection of the subject's rights and welfare. Minors, by definition, cannot give legal "consent". Therefore, a combination of "assent" (agreement) of the minor and "permission" (agreement) of the legal guardian(s)/parent(s) is generally deemed an adequate substitute.

The NCC ERB requires the permission of one legal guardian/parent be given for research involving minors that is determined by the ERB to be minimal risk. There may be exceptions to this general policy that the ERB will determine on a case-by-case basis.

Legal Guardians vs. Caregivers:

The permission of caregivers and/or service providers is not sufficient to conduct research with minors. Only parents and legal guardians have that authority and responsibility. School principals, faculty, teachers, clinic personnel, etc.; do not have the authority to give "blanket" permission for their students/patients/clients to participate in research. They do have the authority to permit the research to be conducted in the facility under their auspices. (This permission should be made part of the study submission.) In classroom research, it must be made clear that the research is not part of the regular educational program and that the student's grades or standing will not be affected by not participating.

Child (minors) Assent:

Adequate provision must be made for soliciting the assent of those children capable of providing a meaningful agreement. The process must be appropriate to the study as well as the age, maturity and psychological state of the child. Information must be presented in language and format that is understandable to the child. The children should have an understanding of the research procedures and it should be clear that their participation is voluntary. An investigator may not include a minor as a research subject without his or her assent unless the minor is not capable of giving assent and the assent is waived by the ERB because the research holds out a prospect of benefit for the child or provides important research information.

Exempt categories for observation of public behavior of children must abide to additional protections except when the researcher is not directly involved in the observed activity.

B. Research Involving Subjects with a Diminished Capacity to Consent

Individuals in a wide variety of circumstances may have an impaired ability to make an informed decision. An impaired decision making capacity may not be limited to neurological, psychiatric, or substance abuse populations, nor should it be assumed that these populations automatically have diminished decision capabilities. Limited decision making capacity covers a broad spectrum, including a healthy person in shock or experiencing high stress, a severely mentally retarded individual since birth, or an individual in an acute psychotic state. Researchers must be sensitive to the fluctuating capacities of individuals and design the consent procedures accordingly.

Some research questions may only be answered in populations with an impaired decision making capacity. In these matters, PIs and members of the research team are responsible for protecting research participants.

Consent procedures must be proportional to the research risk, as impairment increases, so does risk and discomfort associated with the study and the safeguards should increase on a sliding scale. When a researcher is determining a participant's capacity for decision-making, a key factor is the participant's appreciation of how the risks, benefits and alternatives to participation apply

to them personally. It is advisable that the consent processes actually include the researcher asking the participant; "Do you understand the risks and benefits of participation?" or "Do you have any questions about the study or process?" Options for additional safeguards include the use of an independent monitor, use of a legally authorized representative, use of assent and a legally authorized individual, use of an advance directive as local laws permit, or use of a waiting period.

In addition, researchers may need to write their informed consent forms at a lower reading level in order to compensate for potential diminished capacity. For example, a mentally challenged individual who is their own legal guardian and has full control over their own activities of daily living (ADL's), may still only have a fourth-grade reading level.

C. Research Involving Nashua Community College Students

The following issues must be addressed in all research studies involving NCC students:

1. Use of NCC students presents a special set of concerns that are applicable in any study that could potentially recruit NCC students. This includes not only pools that specifically recruit students, but also studies that are advertised on campus. Since undergraduates at NCC may be below the age of consent in New Hampshire, special requirements for studies involving minors apply to studies using these students. One solution is to limit inclusion to individuals over the age of 18 years.
2. An additional concern in studies that involve NCC students is the possibility of undue influence. Recruitment of a subject by his or her advisor, department chair or instructor holds the potential for undue influence. This also holds true whenever a student's participation will be made known to someone who holds power over that student's academic status or extra credit for course grading purposes.
3. Since participation in a research study is completely voluntary, there cannot be any loss of academic status if a student chooses not to participate. If academic benefits are offered as compensation for participation in a study, an equivalent alternative activity must be offered (with the same academic benefit offered) to students who choose not to participate.

D. Research Involving Experimental Biological, Medical or Behavioral Interventions

If the study is delivering an experimental intervention (biological, medical or behavioral) the consent form must provide additional information. The consent must include:

- A statement of the particular treatment or procedure that may be involved;
- A statement of any potential risks from the procedure or known potential risks from the intervention/medication;
- The circumstances in which the subject's participation will be discontinued by the investigator;
- Any known alternative treatments/interventions that may be currently available;
- The costs (if any) for which he/she is responsible as a result of the research participation or any consequences of early withdrawal from the study; and
- The subject must also be informed of any recent significant findings discovered during the course of the research study.

E. Research Involving Pregnant Women, Fetuses and Products of Labor and Delivery

Participation of pregnant women in research that may compromise maternal health requires the consent of both the mother and the father of the fetus, unless the purpose of the research is to meet the health needs of the mother or the identity, or whereabouts of the father cannot be ascertained. Research activities involving products of labor and delivery or embryos including the dead fetus or placenta may only be conducted in accordance with federal, state and local laws and regulations. Upon request, a researcher (with ERB approval) may request a waiver for these requirements with the approval of the Ethical Advisory Board of the Department of Health and Human Services after a public comment period published in the Federal Register (Sect. 46.211). In addition to the regulations noted in Title 45 CFR Part 46, clinical studies with pregnant women as research participants must also abide by FDA regulations (21 CFR50, 21 CFR 56). However, pregnant women can also participate in categories of waived research specified in 21 CFR Sect. 56.104 and all exemptions listed in 45 CFR 46.101(b).

F. Research Involving Non-English Speaking Populations

Informed consent information must be presented in language understandable to the subject and be documented in writing. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. Alternatively, an oral presentation of informed consent information in conjunction with a short, written consent document (stating that the elements of consent have been presented orally) may be used (see Section 19.C of this Policy, Documentation of Informed Consent). A witness to the oral presentation is required and must sign a statement on the consent form.

When the short form, written procedure is used, the subject or the subject's legally authorized representative must sign the short form document. If the person does not read or write a witness may sign the consent form. If a translator assists the person obtaining consent, the translator may serve as the witness.

All foreign language versions of the short form document must be submitted to the ERB with the completed application.

G. Research Involving Prisoner Populations

Additional safeguards are applied to prisoner populations because prisoners may be under constraints because of their incarceration that could affect their ability to make a truly voluntary and uncoerced decision about participation as a subject in research. These protections apply whether the research involves prisoners or a person who at a later date becomes a prisoner. In the latter situation, it is unlikely that review of the research and the consent document contemplated the constraints imposed by incarceration. Researchers must contact the ERB for guidance should this situation arise.

H. Use of Specimens for Future Research

If specimens are to be stored for use in future research, this information must be included in the informed consent process and the informed consent documentation. Further, it is the policy of the NCC ERB to require that a specific consent statement be included in consent forms that ask

subjects to grant permission to store specimens for future research use. The purpose of the extra consent statement is to clearly indicate that the subject can participate in the current research study without agreeing to have specimens stored for future research. The only case where the separate consent line is not required is when the purpose of the current research study is to collect specimens for the purpose of storing them for future research or use.

22. ERB Procedure for Protocol Violations

The standard operating procedure (SOP) for protocol violations can be found in ERB SOP-002 Protocol Violations, incorporated herein by reference.

23. ERB Procedure for Noncompliance

The standard operating procedure (SOP) for violations can be found in ERB SOP-001 Noncompliance, incorporated herein by reference.

24. Procedure for Unanticipated Problems & Adverse Research Events

The standard operating procedure (SOP) for violations can be found ERB SOP-004 Unanticipated Problems & Adverse Events, incorporated herein by reference.

25. ERB Policy Updates, Changes and Additions

The ERB Chairperson is responsible for periodically updating this Manual in order to conform to changes in applicable laws and regulations. All policy updates or changes must meet regulatory requirements and conform to NCC's FWA.

A. Strict regulatory/statutory requirements

Policy and Procedure updates, changes or additions based on strict regulatory/statutory requirements do not require review or approval of the ERB. Example: The OHRP states that all IRBs will review a particular category of research using Full Board review, the Chair will inform the ERB of the new requirements, and will amend this Policy accordingly. The Chair will solicit feedback from the ERB regarding implementation of the new OHRP directive, to arrive at a best practices consensus. However, neither the Chair nor ERB can veto the new OHRP Directive. Such mandatory changes will take effect on either the date specified by OHRP, or if no date is specified, as determined by the Chair.

B. Discretionary Regulatory/Statutory Requirements

Policy and Procedures updates, changes or additions that are based on discretionary regulatory/statutory requirements must be reviewed and approved by the ERB. Example: The OHRP states that all IRBs must implement one of five listed measures in order to comply with a particular requirement, but each IRB can determine which one best suits their institution. The Chair will consult with the ERB to determine which of the five listed measures is appropriate for NCC. The Chair will then revise this Policy and submit the draft revisions to the ERB for approval. Approval will require a simple majority vote of the ERB. Discretionary changes will take effect on either the date specified by OHRP or if no date is specified, as determined by the Chair.

C. Emergency Changes

The IO, ERB Chairperson or other IO designated Official may implement any emergency Policies and Procedures necessary to:

1. Prevent harm to research subjects;
2. Correct a latent policy issue;
3. Address known privacy, security or confidentiality breaches;
4. Respond to emerging circumstances in a particular research program or category of research; or
5. Respond to changes in State or Federal laws.

All emergency changes take effect immediately.

D. All Other Requirements

All other Policy and Procedures updates, changes or additions that are not based on regulatory/statutory requirements per se (i.e., those which exceed regulatory requirements, are strictly NCC based Policies & Procedures, etc.) must be discussed at a regularly scheduled ERB meeting and approved by a simple majority vote. Based on the minutes of the meetings and other materials, the Chair will prepare changes to this Policy. These changes take effect either 60 calendar days from the approval date or as established by the ERB.

26. Record Keeping, File Retention and File Destruction

The Chair will provide administrative, technical and logistical support to the ERB. As part of the general duties and responsibilities to the ERB, the Chair will:

- A. Prepare and maintain records of IRB activities (meeting minutes, annual reports, training materials, etc.) for at least 3 years;
- B. Set up and maintain all records related to protocols including:
 - a. Copy of protocols application (including any attached funding applications);
 - b. Informed consent documents;
 - c. Research instruments used and any other supporting documentation;
 - d. Records of protocol review and continuing review activities; and
 - e. Copies of all correspondence between the ERB and investigators;
- C. Maintain a current list of ERB members and their qualifications for serving on the board;
- D. Periodically update this Manual and other Policies and Procedures effecting or involving human subjects;
- E. Provide technical assistance to the ERB;
- F. Update the ERB on current changes in federal policies and guidance; and
- G. Provide ongoing education to ERB members.

The ERB Chair is responsible for maintaining all protocol files, including applications, correspondences, approvals and other related information. Protocol files and records include both paper and electronic versions.

Protocol files will be maintained and retained for a minimum period of time as follows:

- A. Active Protocol records will be maintained throughout the duration of the study and for at least **3 years** after completion. If the protocol includes the obtaining or creating of PHI records will be kept for at least **6 years** after completion. Investigators must retain copies of signed consent

forms for at least 3 years after completion of the study;

- B. Disapproved protocols will be retained for a period of **3 years**; and,
- C. Not Research and Exempt Protocols will be maintained for a period of **3 years** from the original submission/filing date (based on the IRB Protocol number). Each PI will be responsible after this time period for maintaining their own records. Student Classroom Project protocols approved for recurring classes may be retained indefinitely.

Once the retention period has expired, the entire file and all corresponding records (paper and electronic) may be destroyed and/or purged. Paper files will be destroyed by any currently approved method. Electronic files and/or electronic storage media will be deleted and/or destroyed by any currently approved method. Some electronic information may be retained in ERB databases for purposes of historical tracking or other required obligations.

27. ERB Annual Report

The ERB Chairperson will submit an annual report to the IO regarding the past year's activities. This report will include at a minimum:

- A. The volume and status of protocols reviewed by the ERB;
- B. Any adverse research events, regardless of type;
- C. The status and disposition of any investigation (assessment, inquiry or formal investigation);
- D. A synopsis of continuing education materials provided to the ERB members;
- E. A summary of any pending or effective changes in the rules or regulations that may affect research during the next year and impact strategic planning;
- F. At the discretion of the ERB chair, the ERB may make recommendations for procedural changes to facilitate or improve the ERB process; and
- G. Any formal recommendations presented by the ERB or ERB Chair.