



Institutional Research Review Board
for the Protection of Human Subjects

POLICIES AND PROCEDURES MANUAL

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I. GENERAL POLICY

A. Statement of Applicability and General Policies:

1. Southern New Hampshire University has established the Institutional Research Review Board (IRB) for the Protection of Human Subjects to develop and implement procedures to ensure the ethical treatment of human subjects. These policies are guided by the ethical principles regarding all research involving human subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Belmont Report: Ethical Guidelines for the Protection of Human Subjects of Research* (1978) in compliance with the Code of Federal Regulations, Department of Health and Human Services, *Protection of human subjects: 45 CFR 46*. The policies outlined below are intended to foster a positive climate for scholarly research for the university while establishing guidelines for research involving human subjects.
2. The Southern New Hampshire University IRB was established to review, monitor and approve research projects. The IRB has the responsibility and authority to review, approve, disapprove or require changes to appropriate research activities involving human subjects. The primary purpose of the IRB is to oversee the inclusion of human subjects and the ethics of the research process. The SNHU IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the SNHU IRB's decisions, conditions and requirements or that has been associated with unexpended serious harm to subjects.
3. This policy will apply to research, as defined in this policy, as conducted by university personnel (faculty or administrators) or students when that research involves human subjects.
4. Southern New Hampshire University acknowledges and accepts its responsibility for protecting the rights and welfare of human research subjects.
5. Southern New Hampshire University assures that before human subjects are involved in research, proper consideration will be given to:
 - a. the risks to the subjects;
 - b. the anticipated benefits to the subjects and others;
 - c. the importance of the knowledge that may reasonably be expected to result;
 - d. the informed consent process to be employed;
 - e. the provisions to protect the privacy of subjects; and
 - f. the additional safeguards for vulnerable subjects.
6. Southern New Hampshire University encourages and promotes constructive communication among the institutional officials, research administrators, deans,

department heads, research investigators, clinical care staff, human subjects and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of subjects.

7. Southern New Hampshire University will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.
8. All research must be certified on an annual basis. Work that was approved in a previous year may be recertified through an expedited review process.

B. IRB Structure

9. The IRB is comprised of the following members: the Vice President for Academic Affairs (ex officio); one External Member (appointed by the President); one faculty member with research experience from each of the schools/departments – School of Liberal Arts, School of Business, School of CED, School of Education, School of Professional and Continuing Education; one professional staff member (appointed by the President); plus a grant writer (appointed by the President). Unless a member of the IRB serves ex-officio, IRB members are appointed for three year, renewable terms. In order to ensure continuity, three of the first IRB appointees will serve one time only for a four year term.
10. IRB members must be sufficiently qualified through their research expertise and experience and sensitivity to such issues as community attitudes and issues related to vulnerable populations to safeguard the rights and welfare of human subjects.
11. Members are expected to participate effectively and consistently in the IRB's work. Failure to do so, or failure to attend three consecutive meetings, may result in removal from the board.
12. No IRB member may participate in the initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB.
13. The committee will conduct an annual review of research to assess risks to subjects and other ethical considerations of the research process. Meetings for IRB approval of research will be called as needed.
14. The contact person for the IRB shall be the chairperson.
15. Copies of this policy and operating procedures will be available at <http://www.snhu.edu/5703.asp>.
16. No member of the IRB will be allowed to review his or her own research. In situations where a full committee is needed for review an IRB member's research, an alternate will be assigned in place of that member.

II. DEFINITIONS

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)).

Human Subject is a “living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” (45 CFR 46.102(f)).

Minimal Risk is when “the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (CFR 46.102(i)).

III. DETERMINING WHEN TO SUBMIT A PROPOSAL TO THE IRB

A. FACULTY AND STAFF RESEARCH OR ANY RESEARCH DONE UNDER THE AUSPICES OF SNHU

The IRB will only review research, defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR part 46 s. 102d).¹ Generalizable knowledge is knowledge that you want to apply to people outside of your sample of subjects. For example, if a psychology professor wants to examine memory with the intention of presenting it at a regional psychology conference, then this is a study that must be reviewed by the IRB. Because the study involves the “testing and evaluation” of memory and is intended to contribute to “generalizable knowledge,” it is subject to IRB review. As a second example, if the enrollment manager wants to collect information about the GPA of freshmen at SNHU to see how it relates with their retention rates, that is not subject to IRB review. This is because it is not intended to lead to knowledge beyond SNHU college freshmen.

IRB review of research includes any research done under the auspices of SNHU, including any of its resources and facilities (unless the research is done as a classroom activity as described below). Any affiliates of SNHU need to follow the same review criteria as faculty and staff of SNHU if their research is done under the auspices of SNHU.

Any research proposal that is potentially funded by external grants or sponsored by an outside agency meets the definition of generalizability and is therefore subject to IRB review. A draft of the grant proposal, providing the goals, methods and expected outcomes of research should be provided before submission of the grant proposal to an outside agency. Submissions must be received two weeks before the grant deadline. Exceptions to this must be discussed with the IRB chair.

¹ The IRB will not grant retrospective reviews (i.e., IRB reviews will not be conducted *after* research is conducted).

In cases involving shared research of collaborating investigators at various institutions, the IRB will review all proposals submitted by investigators from SNHU.

B. STUDENT RESEARCH²

As defined above, only research is subject to review by the IRB. Since class work assignments are usually not intended to or likely to lead to generalizable results, the IRB does not normally include these projects under its operational definition of research. Rather, they are viewed as practicum resources or teaching.

1. Subject to paragraphs 2. and 3. hereof, student projects:
 - a. which are all research practica (usually in the form of course related research projects and/or directed studies); and
 - b. which do not involve physically or psychologically invasive, intrusive, or stressful procedures; and
 - c. which, in the judgment of the instructor, do not have the potential for placing the subjects at more than minimal risk (see definition above)

do not require review by the IRB.

For example, if a business faculty member instructs students to interview company executives with their informed consent, this is not necessarily subject to IRB. However, the faculty member, in this case, would need to ensure that the interviews are not physically or psychologically invasive, intrusive, or stress-inducing, and that the interviews involve no more than minimal risk.

2. Student research, including classroom and independent study projects, theses and dissertations, that may place the subject at more than minimal risk is subject to IRB review. In clinical courses, subjects will be considered to be at greater than minimal risk if the procedures used and/or the questions asked do not fall under what is construed as being ordinary practice. Consideration should be given to the research setting when assessing risk.
3. Special populations including pregnant women, fetuses, prisoners, mentally disabled, economically or educationally disadvantaged or minors are considered vulnerable research subjects and projects involving such subjects are subject to IRB review.

The following procedures are to be followed for all student research projects:

A. Instructors are responsible for screening individual research projects and making the initial determination as to whether the project is research as defined above, thus requiring IRB review.

² The Student Research section is based on the Student Research Policy at Indiana University.

B. If an instructor determines that a research project is assigned for the purpose of producing generalizable knowledge or that it may involve greater than minimal risk, an application for the project must be submitted to the IRB.

C. If there is any doubt as to whether the project should be reviewed by the IRB, the IRB should be contacted for assistance.

D. In the event the IRB review is not needed for a particular classroom research project, the student researcher and the instructor are not relieved of the obligation for ethical use of human subjects. Consequently, the researchers should adhere to ethical standards and use informed consent when appropriate.

E. If there is reasonable expectation on the part of the instructor and the student that the study will be funded (regardless of source) and/or published, IRB approval must be obtained.

F. In instances where a class of students will be conducting group or individual research projects as a part of the classroom instruction, and the instructor believes that, under our guidelines, IRB approval is required, the instructor shall present for Committee approval one form setting forth the parameters of the research being conducted by the students. The instructor should describe the types of research to be undertaken by the students, the nature of the subjects used, and the kinds of procedures to be used in the research projects. This means that individual forms are not to be filled out by each student researcher as long as the research falls within the parameters described in the “umbrella” form. Any research not within the described parameters would require separate approval.

IV. CATEGORIES OF RESEARCH

The IRB recognizes three categories for review:

1. Full Review. Research that presents more than minimal risk and/or involves vulnerable populations. Consent is required unless waived by the IRB.
2. Expedited Review. Research that is minimal risk and falls into one of six categories. Consent is required unless waived by the IRB.
3. Exempt Review. Research that is minimal risk and falls into one of six categories. Consent is not required, although some information is advisable.

All three categories of research must be presented to the IRB for review, and not begin prior to written approval being received from the IRB chair.

A. Exempt Review

Exempt Review shall be conducted by the SNHU IRB chairperson or by his/her designee.

Research is exempt when the only involvement of human subjects falls within one or more of the categories below and involves only minimal risk to the human subject:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (such as cognitive, diagnostic, aptitude, and achievement tests), survey procedures, interview procedures or observation of public behavior, unless a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (such as cognitive, diagnostic, aptitude, achievement tests), survey procedures, interview procedures, or observation of public behavior that is not otherwise exempt if: a) The human subjects are elected or appointed public officials or candidates for public office; or b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects designed to study, evaluate or otherwise examine: (a) public benefit or service programs (b) procedures for obtaining benefits or services under those programs (c) possible changes in or alternatives to those programs or procedures or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if: (a) wholesome foods without additives are consumed or (b) foods consumed contain a food ingredient at or below the level found to be safe and for a use found to be safe, or agricultural chemical or environmental contaminants are at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Research can be considered exempt, *unless*:

1. Human subjects are prisoners.
2. Human subjects are minors in survey/interview research.
3. Human subjects are minors in observation of public behavior where the investigator(s) participate(s) in activities being observed.
4. Human subjects are other vulnerable populations.

For additional information on vulnerable populations, see Section VII.

B. Expedited Review

Expedited review may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless the researcher has documented that reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Expedited Review shall be conducted by the SNHU IRB chairperson and by at least one other member of the Research Review Board, designated by the chairperson to conduct the review.

Research is eligible for expedited review when the only involvement of human subjects falls within one or more of the categories below and involves only minimal risk to the human subject:

1. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required. (see 63 FR 60364-60367 (1))
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in a 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
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 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. It also includes such procedures as 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 (for example, x-rays, microwaves)
4. Collection of data from voice, video, digital, or image recordings made for research purposes.
5. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
6. In addition, under certain circumstances, expedited review may be appropriate for continuing review of research previously approved by the convened IRB:

Research where

- a) the research is permanently closed to the enrollment of new subjects;
- b) all subjects have completed all research-related interventions; and
- c) the research remains active only for long-term follow-up of subjects, or research where no subjects have been enrolled and no additional risks have been identified, or research where the remaining research activities are limited to data analysis.

C. Full Committee Review:

1. If research does not satisfy the guidelines of exemption or expedited review and/or external funding is being sought, SNHU IRB full-board review shall be conducted. A majority of the members of the SNHU IRB must participate in the review.
2. Research protocols scheduled for review shall be distributed to all members of the SNHU IRB in advance. When the SNHU IRB determines that consultants or experts will be required to advise the SNHU IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the review.

V. APPEALS AND GRIEVANCE PROCEDURES

If the IRB denies approval, the principal investigator may file a request to resubmit the proposal for a second review by the IRB. Researchers may not submit the same proposal more than twice.

VI. AMENDMENTS TO THE POLICY

The policy will be reviewed every five years and any amendments will be incorporated into the policy statement. In cases of changes in state and federal laws and emerging institutional needs, an earlier review will be called for, or when otherwise determined to be necessary.

VII. VULNERABLE POPULATIONS

Federal regulations require that special consideration be given to protecting the welfare of particularly vulnerable study participants, such as children, prisoners, persons with diminished capacity to consent, institutionalized individuals, or economically or educationally disadvantaged persons. Although the regulations allow approval of research involving these populations if it is of minimal risk or if it will benefit the subjects directly, the regulations require that researchers implement special safeguards, particularly with respect to informed consent.

A. Children

According to federal regulations, "children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the

applicable law of the jurisdiction in which the research will be conducted' [45 CFR 46.402(a)]. In New Hampshire, individuals under the age of 18 are considered children for research purposes.

There are special considerations to take into account when using children as research subjects. Federal regulations define the types of studies that may be reviewed at the Exempt level by the IRB. Specifically, all Exempt categories may be used for studies involving children except parts of exemption 46.101(b)(2). That is, studies involving survey or interview procedures may not be reviewed at the Exempt level when children are subjects. Further, observations of public behavior where the researcher is a participant in the activity may not be reviewed at the Exempt level when children are subjects. Researchers working in educational and/or clinical/therapeutic settings must ensure that the subjects know that the research is separate from any instruction or intervention.

Where children are subjects, the researcher must provide for obtaining the consent of the child's legal representative (parent or guardian) and the child's assent. Only in very limited circumstances may the IRB waive the requirement for parental/guardian consent or child assent. When the IRB requires both the parent's consent and the child's assent in a research project, the researcher **MUST** obtain parental consent **PRIOR** to seeking the child's assent or participation. The SNHU IRB requires subject assent and parental consent for all studies, unless a waiver is requested by the researcher and granted by the IRB.

Federal regulations also address research involving children who are wards of the state. Wards of the state may be subjects in a study only if the research is:

- (1) related to their status as wards; or
- (2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards (45 CFR 46.409(a)).

Where a study involves children who are wards of the state, the regulations require that the researcher appoint an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis [45 CFR 46.409(b)]. One individual may serve as advocate for more than one child. The advocate should be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the researcher, or the guardian organization. Researchers should delineate in their application materials the study specific procedures addressing this requirement.

B. Prisoners

Because incarceration could affect a person's ability to make a truly voluntary and uncoerced decision whether or not to participate in a study, federal regulations provide additional safeguards for the protection of prisoners. "Prisoner" is defined to include any individual involuntarily confined or detained in a penal institution. The term encompasses individuals sentenced to such an institution under a criminal or civil statute; detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; and/or detained pending arraignment, trial, or sentencing [45 CFR 46.303(c)].

At SNHU, any study that recruits prisoners must be reviewed at the Full Board level. If the study was not initially approved to recruit prisoners, then the researcher may not enroll a prisoner. The rules also apply for a subject who at a later date becomes a prisoner, because it is unlikely that the IRB review of the research study contemplated the constraints imposed by incarceration. Therefore, if a researcher determines that a subject has become a prisoner at some later date after enrollment, and the study involves additional research interventions or interactions with that subject, the subject must either be dropped from follow-up, or the researcher must submit a modification request prior to further interaction with the prisoner subject(s).

Four categories of research involving prisoners are permitted under the federal regulations. They are:

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects,
- Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects,
- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after DHHS has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of its intent to approve such research, or,
- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

In reviewing the study, in addition to the usual criteria for approval, the IRB must find the following:

- Any possible advantages accruing to the prisoner(s) through his/her participation in the study, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his/her ability to weigh the research risks against the value of such advantages in the limited choice environment of the prison is impaired,
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers,
- Procedures for subject selection within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal researcher provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the

group of available prisoners who meet the characteristics needed for that particular research study,

- The informed consent information is presented in language understandable to the subject population,
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making parole decisions, and each prisoner is clearly informed in advance that participation in the research will have no effect on his/her parole, and
- Where the IRB finds there may be a need for follow-up examination or care of participants after their participation ends, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

C. Persons with Diminished Capacity to Consent

Individuals in a wide variety of situations may have diminished capacity to make decisions, including giving consent to participate in a study. For example, impairment may occur at times of great stress. Diminished capacity can be temporary or permanent, and is not limited to individuals with neurological, psychiatric, or substance abuse problems; conversely, individuals with neurologic, psychiatric, or substance abuse problems should not be presumed to have diminished capacity to consent.

Subjects with diminished capacity are considered vulnerable and therefore researchers need to employ additional protections. Considerations include

- Research studies should not target persons with mental disorders as subjects when such research can be done with other subjects,
- Research studies must include a thorough justification of the research design used, including a description of procedures designed to minimize risks to subjects,
- Studies designed to provoke symptoms, withdraw subjects rapidly from therapies, use placebo controls, or otherwise to expose subjects to risks that may be inappropriate are subject to heightened scrutiny,
- No person who has the capacity to consent may be enrolled in a study without his or her informed consent,
- When potential subjects are capable of making informed decisions about participation, they may accept or decline participation without involvement of third parties,
- Any potential or actual subject's objection to enrollment or continued participation in a research study must be heeded in all circumstances,

- A researcher, acting with a level of care and sensitivity that will avoid the possibility or appearance of coercion, may approach people who previously objected to ascertain whether they have changed their minds,
- For research studies that present greater than minimal risk, the IRB may require that an independent, qualified professional assess the potential subject's capacity to consent. The study should describe who will conduct the assessment and the nature of the assessment. The IRB may permit researchers to use less formal procedures to assess potential subjects' capacity if there are good reasons for doing so,
- A person who has been determined to lack the capacity to consent to participate in a research study must be notified of that determination before permission may be sought from his/her legally authorized representative to enroll that person in the study. If permission is given to enroll the person in the study, s/he must then be notified. Should the person object to participating, this objection must be heeded,
- Persons determined to lack the capacity to consent should not be enrolled in a study which is not likely to result in direct benefit to them, unless the study presents no more than minimal risk, and
- For research studies involving subjects who have fluctuating or limited decision-making capacity or prospective incapacity, researchers should establish and maintain ongoing communication with involved caregivers, consistent with the subjects' autonomy and with medical confidentiality.

D. Women and Minorities

All research involving human subjects should be designed and conducted to include members of both genders and of minority groups, unless a clear and compelling rationale and justification establishes that such inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion except when such a study would duplicate data from other sources. Studies should employ a design with gender, racial and/or age representations appropriate to the known incidence/prevalence of the disease or condition being studied. If subjects of a certain gender, race or age group are to be excluded, such exclusion must be clearly explained and justified by the researcher. For example, if inclusion of women is impossible or inappropriate with respect to the purpose of the research, the health of the subjects, or other reasons, or if there is a disproportionate representation of one gender in the only study population available, these reasons for excluding women or men, or for not including either gender in numbers appropriate to the incidence/prevalence of the disease, must be well explained and justified by the researcher.

It is not expected that every minority group and subpopulation will be included in each study. However, broad representation and diversity are the goals, even if multiple sites are needed to accomplish it. The Office of Management and Budget (OMB) Directive No. 15 defines the minimum standard of basic minority racial and ethnic categories, and which are used by the National Institutes of Health, (NIH) as

- American Indian or Alaskan Native: a person having origins in any of the original peoples of North America, and who maintain cultural identification through tribal affiliation or community recognition,
- Asian or Pacific Islander: a person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent or the Pacific Islands and Samoa,
- Black, not of Hispanic origin: a person having origins in any of the black racial groups of Africa, and
- Hispanic: a person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin regardless of race.

Each minority group may contain subpopulations which are delimited by geographic origins, national origins and/or cultural differences. The minority group or subpopulation to which an individual belongs is determined by self-reporting.

E. Students

Consistent with an overall concern that no research subject should be coerced, researchers should take particular precautions to avoid the unintentional coercion that may occur when a potential research subject is also a student. For this reason, researchers should be cautious about using their own students as research subjects. Researchers who wish to use their own students should be able to provide a good scientific reason, rather than convenience, for selecting those students as research subjects.

In instances where researchers use their own students in their research, the IRB generally requires that someone other than the researcher/instructor obtain informed consent and collect the data. When this is not possible, the IRB will consider other methods for obtaining consent and collecting data that would not reveal to the researcher/instructor whether or not a student participated in the research project until after final grades have been determined. The students should be informed of what these procedures are in the informed consent document.

Researchers may propose to give extra credit to students who participate in a research project only when alternative means of obtaining equivalent extra credit with equivalent effort are made available to students who do not wish to volunteer as research subjects. The researcher should make sure that students are not being coerced into participating. For example, if volunteering for a survey takes 30 minutes and the student's output is not evaluated for its quality to determine whether extra credit is given, the alternative should involve 30 minutes of effort and the output should not be evaluated (beyond assurance that a good faith effort was made). The informed consent document should make clear the consequences of withdrawing from a study prior to completion (e.g., dispensation of extra credit). In general, the researcher should give the extra credit even if the subject withdraws, unless the student withdraws immediately or there is clear evidence of bad faith on the part of the student.

There may be circumstances when a researcher wants to use required class assignments (e.g., journal entries or evaluations) in his or her research. The course syllabus should clearly state that the assignments are required for the course, but that at the end of the semester, the researcher/instructor will ask the student for permission to use the assignments for research purposes. It should be clear that participation will not affect a student's grade. The students should understand procedures to be used to ensure that the researcher/instructor does not know who has consented until after final grades have been determined (e.g., department secretary keeps informed consent documents until after the course grades have been handed in).

VIII. SERIOUS OR CONTINUING NON-COMPLIANCE WITH REGULATIONS AND/OR IRB REQUIREMENTS

Non-compliance means conducting research involving human subjects in a manner that disregards or violates SNHU policy or federal regulations governing such research. The IRB reviews all allegations of non-compliance according to human subject protections regulations and its own requirements. Any individual or organization may submit to the IRB a written complaint or allegation of non-compliance related to SNHU researchers or a project conducted under the auspices of SNHU. The IRB may also initiate a complaint based on information available to the IRB (e.g., deficiencies noted in IRB files, media or scholarly reports of research activity subject to IRB jurisdiction). Non-compliance can include, but is not limited to the following:

1. Failure to obtain IRB approval for research involving human subjects prior to commencing such research,
2. Failure to satisfy contingencies set by the IRB prior to commencing research,
3. Failure to conduct research as delineated in the IRB-approved study,
4. Failure to follow recommendations made by the IRB to ensure the safety of subjects,
5. Failure to obtain informed consent from each prospective subject according to the IRB-approved study,
6. Inadequate supervision of personnel during the conduct of research,
7. Failure to report promptly adverse events involving harm to subjects,
8. Failure to obtain approval for modifications to a study prior to implementation, or
9. Failure to provide ongoing progress reports as requested by the IRB

Whenever a non-compliance allegation or complaint is made in regard to an IRB-approved study, the IRB investigates the allegation. In cases where non-compliance involves human subjects research conducted without prior IRB approval, the IRB Chair reviews a written statement from the researcher explaining the reasons why IRB approval was not sought, and, where applicable, a copy of the research findings. The Chair then makes written recommendations to the VPAA as to the appropriate course of action based on a variety of factors, including whether subjects were put at risk, the need for

immediate action to protect subjects' welfare, and the procedures for protecting subjects implemented by the researcher and the adequacy of those procedures (e.g., informed consent). The VPAA is the final authority as to the course of action taken by SNHU on the matter.

If the IRB determines that a researcher is deliberately or continuously out of compliance with the procedures stated in this manual, with 45 CFR 46, SNHU's Assurance, has failed to adhere to stipulations of the IRB, or is found to have placed the welfare of subjects at unnecessary risk, the IRB will report the matter promptly to the VPAA, with or without a recommendation for specific action.

All recommendations for sanctions, correction, or educational measures, if any, are established by the VPAA, usually in consultation with the IRB. The VPAA also determines whether to refer the matter to another more appropriate process or authority within SNHU for resolution.

Repeated or willful violations of federal and state laws as well as SNHU policy regarding use of human subjects in research are extremely serious matters. In such circumstances, the IRB has the authority to suspend or terminate approval of a study, or refuse to approve further research with human subjects by a researcher.

Policy violations could lead to violation of federal and state laws. In these cases the IRB will refer the matter to the SNHU legal counsel.

The IRB may temporarily or permanently suspend approval of a study at any time. This suspension may not be overridden by the VPAA or at any level at SNHU (45 CFR 46.112). The IRB may take such action in a wide variety of circumstances, including serious concern for the well-being of subjects or for the reputation of SNHU. The IRB must report a study suspension promptly in writing to the VPAA.

When the IRB suspends or terminates approval of a study for any reason, the following individuals, in addition to the researcher(s) listed on the study, are notified in writing within five working days of such suspension or termination:

- VPAA
- Researcher's Department Chair
- Researcher's Dean
- IRB Chairs and VPAA's of other institutions involved in the research (if appropriate)
- The funding agency (if appropriate).

IX. APPLICATION INSTRUCTIONS

Any student, faculty or staff of Southern New Hampshire University who is planning to conduct research involving human subjects must submit an application for Research Review to the SNHU Review Board. A complete application will consist of the following:

- 1) A cover letter requesting a review, including an introduction to the investigator(s) and the title of the proposal;
- 2) A completed form entitled "Assurance of the Principal Investigator";
- 3) A "Research Review Notification" form bearing the investigator's name and mailing address;
- 4) An electronic copy of the complete research proposal (including the purpose and rationale of the research, a description of the participants to be used in the study, and a description of the methodology and procedures used to answer the research question, with numbered pages) emailed as an attachment to Ron Biron at r.biron@snhu.edu;
- 5) An informed consent form (or a description of how children's assent will be achieved and a parental consent form for studies involving children).
- 6) Application Checklist

Upon completing the review, the SNHU IRB may do one of several things:

- 1) Approve the proposal as submitted, forwarding the application to the chairperson for notification to the principal investigator and/or faculty advisor;
- 2) Approve the proposal on the condition that it be revised according to recommended changes, in which case the application is returned to the principal investigator and/or faculty advisor for revision. A clean copy of the revised proposal must then be resubmitted to the SNHU IRB. Data collection from human subjects may not begin until the investigator is notified by the chairperson that the revised proposal has been approved.
- 3) If the SNHU IRB concludes upon reading the application that the type of review requested is not appropriate for the proposed research the application may be returned to the investigator, with the suggestion that it be resubmitted in the correct category.
- 4) The SNHU IRB may disapprove of the proposal, based on inadequate protection of human subjects. The application for research review and reviewer evaluation will be forwarded to the Chair, who will notify the investigator of the Board's decision. The application will be kept on file, along with a copy of the reviewer evaluation. A revised proposal may be

resubmitted to the Board and the author(s) of the proposal may meet with the IRB for consultation.

ADDITIONAL REQUIREMENTS ASSOCIATED WITH PROPOSALS FOR FULL REVIEW

If neither of the streamlined reviews are possible, the IRB may request from the principal investigator additional copies of the completed proposal included with the complete application, less any appended material not necessary to an understanding of the project as part of the application for Research Review. The complete application should be forwarded to the chairperson of the Institutional Research Review Board.

The chairperson will assign one principal reviewer for each proposal. Each member of the Institutional Research Review Board will have a proposal and associated materials for review. The principal investigator could be asked to clarify relevant issues, attend the Institutional Research Review Board meeting or submit additional materials. The principal investigator is encouraged to attend the Institutional Research Review Board meeting.

At the Institutional Research Review Board meeting, the principal reviewer is encouraged to present the proposal to the Board with his/her recommendations. Following a discussion of the proposal the Board will determine the status of the proposal. The reviewers will return the proposal and materials to the chairperson with a signed report of action indicating the outcome of the review. The chairperson of the Review Board will notify the principal investigator of the decision. (Materials and Institutional Research Review Board decisions will be placed on file in the Office of the Vice President for Academic Affairs.)

NOTIFICATION OF THE STATUS OF THE RESEARCH PROPOSAL

For all reviews, the IRB will notify the principal investigator of the status of the application. From the time of submission of the a completed application, a maximum of two weeks will be necessary for exempt and expedited reviews and a maximum of four weeks will be necessary for a full review. A copy of the decision is forwarded to the dean or staff supervisor.

X. APPLICATION CHECKLIST

Please make sure you send the following IRB application materials to the VPAA's office, c/o Ron Biron.

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	1. A cover letter requesting a review, including an introduction to the investigator(s) and the title of the proposal
	2. A completed form entitled "Assurance of the Principal Investigator"
	3. A "Research Review Notification" form bearing the investigator's name and mailing address
	4. An electronic copy of the complete research proposal sent to Ron Biron as an attachment (send to r.biron@snhu.edu).
	5. An informed consent form (or a description of how children's assent will be achieved and a parental consent form for studies involving children)
	6. This Application Checklist

SOUTHERN NEW HAMPSHIRE UNIVERSITY

INSTITUTIONAL RESEARCH REVIEW BOARD

X. ASSURANCE OF PRINCIPAL INVESTIGATOR

Principal Investigator: _____

Department: _____

Title of Proposal/Project

I CERTIFY as follows concerning the above named research proposal in which I am the principal investigator:

- (1) The rights and welfare of the subjects will be adequately protected.
- (2) Risks or discomfort (if any) to subject(s) have been clearly indicated and it has been shown how they are outweighed by potential benefits to the subject or by the importance of the knowledge to be gained.
- (3) The informed consent of subjects will be obtained by appropriate methods which meet the requirements of the university's general assurance procedures.
- (4) Any proposed changes in research activity will be reported to the Institutional Research Review Board. Those changes may not be initiated without Institutional Research Review Board review and approval except where necessary to eliminate apparent immediate hazard to the subjects.
- (5) Any unanticipated problems involving risks to human subjects or others will promptly be reported to the Institutional Research Review Board.
- (6) If the study is approved, a report on the progress of the research will be submitted to the Institutional Research Review Board after one year, and each year until completion of the project. The Status Report Form will be used for this purpose.

Signature: _____ Date: _____

Principal Investigator

Acknowledged: _____ Date: _____

Dean/Vice President

XI. GENERAL REQUIREMENTS FOR INFORMED CONSENT

1. Informed consent must be obtained only under such circumstances that provide the prospective subject, or the subject's representative, sufficient opportunity to consider participation in the research project and where the possibility of coercion or undue influences is eliminated.
2. The Informed Consent Statement
 - a. must be written in language understandable to the subject or representative;
 - b. shall not contain any language by which the subject waives any of his or her rights;
 - c. shall not contain any language that releases the principal investigator, the university or the sponsoring agency from liability for negligence.
3. The Informed Consent Statement should follow the format given in this section. When the subject is a minor and the parent's or guardian's consent is sought, space for the parent's or guardian's signature should be provided. If the subject is an adult requiring guardian consent, space for the guardian's signature should be provided. Alternatively, where it is necessary to separate the consent of the parent/guardian from the assent of the minor or non-consenting adult, separate forms should be used for each.
4. In cases where it is appropriate to obtain written consent, two copies of the Informed Consent statement must be signed; one copy is to be retained by the individual (or his/her representative/guardian), and one copy is to be kept by the principal investigator. (NOTE: the signature page may not be completely separated from the text of the informed consent.)

XII. GENERAL REQUIREMENTS FOR OBTAINING ASSENT FROM CHILDREN

1. There are special considerations to take into account when using children as research subjects. Federal guidelines (Title 45, Part 46) have defined the types of studies that may be classified as exempt from IRB review. Specifically, all types of exempt categories can be used for projects involving children except for projects involving survey or interview procedures or observations of public behavior are not exempt when children are the subjects unless the researcher is not a participant in the activity.
2. OHRP (the Office of Human Research Protections in the U.S. Department of Health and Human Services, formerly OPRR) has stated that the decision belongs to the institutional IRB whether to require subject assent/parental consent for research projects involving children for any level of IRB review. When the IRB requires both the parent's consent and the child's assent in a research project, the investigator **MUST** obtain parental consent prior to seeking the child's assent or participation. The SNHU IRB requires subject assent and parental consent for all studies, unless a waiver is requested by the researcher and granted by the IRB.
3. The IRB recognizes that much of the research involving children poses no more than "minimal risk" for them. These suggestions are designed to assist researchers in drafting protocols for gaining children's assent to participate in research studies. Researchers whose procedures pose greater than minimal risk for their subjects can request additional assistance from the IRB in drafting protocols for assent.
4. What follows includes the definition of assent and guidelines for obtaining the assent of children of different ages. Because the ability of children to understand the elements of assent generally increases with age, researchers will likely provide less detailed explanations to younger children and more detailed explanations to older children. In addition, because there are individual differences in the development of children's ability to understand the researcher's requests, there is a necessary age overlap in the categories listed below.

Definition of Assent: "Assent" means a child's affirmative agreement to participate in research. *Mere failure to object should not be construed as assent.*

Ages 2-7

For children between the ages of 2 to 7, the request for assent should be kept simple and direct. For example, the researcher might ask the child if he or she would join the researcher in the next room to look at pictures. If the child were to say "yes," that would imply assent for this age group. If the child were to say "no," the researcher should respect the child's wishes. It should be possible, however, to ask the child once again several minutes later. Sometimes children may not communicate verbally their refusal to participate. For example, a child may begin working on another task unrelated to the research activity. The researcher should be aware of such a cue and end the activity.

Ages 6-14

For children between ages of 6 and 14, the request for assent should include: (1) a general description of the purpose of the child's participation; (2) a brief description of the experimental tasks; (3) an assurance that the child's participation is voluntary and that he or she may withdraw from the study at any point; and (4) an offer to answer questions. A researcher studying reading comprehension might say the following: "I am studying how fourth grade students read. I am going to ask you to read a few stories for me and answer questions about the stories when you are finished. You don't have to read if you do not want to do so. If at any point you want to stop, that is fine; you may stop and go back to class."

Ages 12-17

For children ages 12 to 17, the request for assent should include the elements of informed consent presented to adults, but this request should be presented in language appropriate to the child's level of comprehension.

Researchers working in educational and/or clinical settings should ensure that the subjects know the research is separate from any instruction or intervention.

XIII. INFORMED CONSENT CHECKLIST

The following checklist is to help you design your informed consent documents. The documents may be in the form of a letter or in the form of a consent document (seen in the example that follows). In either form, the document must be written in language understandable to the subject, and in a layout that allows easy reading (i.e., regular font size, sufficient white space, etc.)

Basic elements (required):

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	A statement that the study involves research
	An explanation of the purpose of the research
	The expected duration of the subject's participation
	A description of the procedures that will be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks/discomforts to the subject OR a statement indicating that there are no foreseeable risks if the study is a minimal risk study.
	A description of any benefits to the subject or to the others which may reasonable be expected from the research
	A statement describing the extent, if any, of which confidentiality or records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available, if injury occurs. If compensation/treatment are available, details of what is available, and how further information may be obtained should be included.
	An explanation of whom to contact for answers to pertinent questions about the research (name and phone number) and the rights of research subjects
	An explanation of whom to contact in the event of a research-related injury to the subject
	A statement that participation is voluntary; Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
	A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which (s)he is otherwise entitled

Additional elements, as appropriate (could be required by the IRB):

√

	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	A statement that any significant new findings developing during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	The approximate number of subjects involved in the study

SOUTHERN NEW HAMPSHIRE UNIVERSITY³

DEPARTMENT OF: _____

Title of Project

CONSENT FORM FOR RESEARCH

Introductory section should begin with words to this effect:

I have been asked to take part in a research project described below. The researcher will explain the project to me in detail. I should feel free to ask questions. If I have more questions later, I can contact { Name of principal investigator }, the person mainly responsible for this study, at { Phone and email}. I can also contact the chair of the Institutional Research Review board, { Name of IRB Chairperson }, at { Phone and email }, with questions or concerns.

Description and purpose of the project:

I have been asked to take part in the study that { describe the nature of the study and the purpose of the research here }.

What will be done:

If I decide to take part in this study here is what will happen: { explanation of the procedures, how long the subject will be involved in the study, and which portions of the study are experimental}.

Risks or discomfort:

{ Explain any risks or discomfort that might reasonably be expected to happen. If there are no physical, mental, or social risks/discomforts, state that there are no foreseeable risks. An explanation of whom to contact in the event of a research-related injury to the subject should also be included. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available, if injury occurs. If compensation/treatment are available, details of what is available, and how further information may be obtained should be included. }

Benefits of the study:

{ Describe potential benefits to the subject or to others in this study. If there is no direct benefit to the subject, include a sentence to the following effect: } Although there will be no direct benefit to me for taking part in this study, the researcher may learn more about _____. (NOTE: payment given to the subject for participation in the study is not

³ This informed consent form was adopted with revision from the Institutional Research Review Board Manual at Rivier College.

considered a benefit.) { Describe any alternative procedures or courses of treatment, if any, that might be advantageous to the subject }

Confidentiality:

{ Describe the way confidentiality of records identifying the subject will be maintained. Use words to the following effect, if appropriate: } My part in this study is confidential. None of the information will identify me by name. All records will { Describe how to be maintained }. { Or, if the study involves information that legally must be reported to government agencies, then include the following: } My part in this study is confidential within legal limits. The researchers at Southern New Hampshire University will protect my privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify me by name. All records will be { Describe how to be maintained }.

{ Alternatively, if the study is anonymous, then this should be stated here. Indicate to the subject how anonymity will be preserved. }

Decision to quit at any time:

{ Use words to the following effect: } Participation in this study is voluntary. I do not have to participate. If I decide to take part in the study, I may quit at any time. Whatever I decide will in no way penalize me { affect my grade, status as a student, etc. } If I wish to quit I simply inform { name of principal investigator and phone number } of my decision.

Debriefing

{inform the subjects that they will be debriefed about the study when it is completed and a summary of the research will be provided if the subject wants }

I have read the Consent Form. My questions have been answered. My signature on this form means that I understand the information and I agree to participate in this study.

Signature of Participant

Signature of Researcher

Typed/Printed Name

Typed/Printed Name

Date

Date

XIV. MONITORING PROCEDURES

The Code of Federal Regulations empowers the Institutional Research Review Board (IRB) to "conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and to observe or have a third party observe the consent process and research."

Approved projects are assigned a monitoring date. All investigators will receive a monitoring form in advance of that date that must be completed and returned to the Institutional Research Review Board ten days before the designated date. In addition, you will be asked to submit a copy of the consent form you are currently using, or most recently used, and a summary of the project or the annual report to a funding agency. The IRB will review these documents with federal and state regulations as well as the research policies of the university. Continuing research or changes in ongoing research must be monitored and approved for continued IRB approval annually using the Status Form. Upon completion of the study the IRB will be notified by the investigator(s), using the change/renewal/termination form.



XV. RESEARCH REVIEW NOTIFICATION
Issued by the IRB

The following is to be filled out by the principal investigator of the proposed study.

Researcher(s) involved with proposed study:

Date: _____

Address of principal investigator:

Title of proposal:

Type of Review: Exempt Expedited Full

The decision of the Committee is as follows:

Approved

Approved with the following recommendations/comments:

Disapproved

Comments:

Reviewer(s) Signature(s):

Chair, IRB

Date

Vice President for
Academic Affairs

Date

Cc : Department Chairperson and Dean/Divisional Vice President

XVI. REFERENCES

Code of Federal Regulations (1993). *Protection of human subjects: 45CFR46*. Washington, DC: Department of Health and Human Services.

Indiana University. (2002). *Student research policy*. [Manual]. Bloomington, Indiana: Author.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978). *Belmont report: Ethical principles and guidelines for research involving human subjects*. Washington, DC: US Government Printing Office.

Rivier College. (2000). Institutional research review board policies and procedures manual. [Manual]. Nashua, New Hampshire: Author.

University of New Hampshire. (2002). Institutional review board for the protection of human subjects in research: Guide for researchers. [Manual]. Durham, New Hampshire: Author.

SOUTHERN NEW HAMPSHIRE UNIVERSITY
INSTITUTIONAL RESEARCH REVIEW BOARD

XVII. STATUS REPORT FORM

According to SNHU's policy regarding research involving human and animal subjects, this form is to be submitted to the Institutional Research Review Board annually by investigators until the research is completed. The purpose of this status report is to monitor the protection of human subjects by ongoing research. Any changes in recruitment, informed consent, instrumentation, or methods, which may have resulted in increased risk to subjects, should be reported, and a request for renewed approval must be submitted. Renewal of approval for ongoing research, which remains unchanged since the initial proposal should be noted. If the research has been completed, please make the appropriate notation.

Completed forms are to be returned to the IRB Chair in care of the VPAA's Office, within 30 days.

Principal Investigator: _____

Title of Project:

Leave a check mark next to the current status of project:

Research is ongoing, and changes regarding human subjects have been made.
(Documentation of revisions must be attached.)

Research is ongoing, no changes regarding human subjects have been made.

Research is completed or project terminated. Date of completion or termination:

Discovery of unanticipated risks to human subjects. (Documentation of any identified risks must be attached.)

Thank you for taking the time to complete and return this form.

Signed: _____ Chairperson

Date: _____

SOUTHERN NEW HAMPSHIRE UNIVERSITY
INSTITUTIONAL RESEARCH REVIEW BOARD
XVIII. CHANGE/RENEWAL/TERMINATION FORM

Date: _____

Please complete Questions 1 through 4.

1. Project Director: _____ Department: _____

2. Project Title: _____

3. Committee on Research Participation No.: _____ Date Originally Approval: _____

4. Date Project Initiated: _____

Of the following matters, please complete only those pertinent to the current status of this research project.

5. _____ Change in procedure as follows: (Attached revised Status Form for changes)

6. _____ Renewal of project last approved on _____ with changes shown in 5.
Date

7. _____ Renewal of project last approved on _____ with no changes in procedure.
Date

8. _____ Project Termination: _____
Date

9. _____ Description of unexpected risks to subjects that may have developed since previous review. (Use reverse of this Form or Attached separate sheet.)

Project Director: _____ Date: _____

Dean/Divisional vice president: _____ Date: _____

Complete the form and return to the IRB Chairperson in care of the VPAA's Office.