Preface

This Guide was approved on December 4, 2002 by the University of New Hampshire (UNH) Institutional Review Board (IRB) for the Protection of Human Subjects in Research and last updated in August, 2013. It explains the pertinent regulations and ethical principles, and sets forth review procedures required for researchers using human subjects in research at UNH.

Nothing in this Guide shall be construed as limiting the authority of UNH, the Institutional Official, the Director of Research Integrity Services, the IRB Chair, IRB members or designees in their duty to protect the rights and welfare of human subjects, as provided in 45 CFR 46 and other pertinent regulations.

IRB requirements are subject to change. Changes will be reflected on the IRB webpage at http://unh.edu/research/human-subjects
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Section I

Introduction

The University of New Hampshire (UNH) assumes responsibility for encouraging research activities to benefit the advancement of knowledge of human conditions. At the same time, UNH assumes responsibility for ensuring the conditions for protecting human subjects as required by the National Research Act, public Law 93-348 and implemented by U.S. Department of Health and Human Services (DHHS) Title 45 Code of Federal Regulations Part 46 (45 CFR 46), Protection of Human Subjects (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html), as amended, and by other Federal agencies with appropriate jurisdiction. Additional requirements are imposed by the Food and Drug Administration (FDA) (http://www.fda.gov) when Investigational New Drugs and Medical Devices are used in research.

UNH operates a centralized program to review and approve all research involving human subjects. Before a research study involving human subjects may commence, it must be reviewed and approved by the Institutional Review Board (IRB). While the researcher has primary responsibility for the conduct of the study, the UNH IRB is responsible for protecting the rights and welfare of study participants. Through its Federalwide Assurance (Assurance), UNH is held accountable to federal agencies that have established guidelines for the use of human subjects in research.

Accordingly, UNH has developed this Guide to:

1. Provide the reader with an appreciation and basic understanding of the ethical principles, and regulatory process and means by which compliance can be assured, and the responsibilities that a researcher assumes when choosing to involve human subjects in a research activity,
2. Provide a concise, up-to-date accessible source of information about UNH's program for protecting people who are subjects of its research activities,
3. Facilitate communication between and among researchers, study personnel, and administrators in the interest of promoting the responsible conduct of research involving human subjects,
4. Document UNH's commitment to ensuring the protection of people who are subjects of its research activities, and
5. Document, in part, UNH's responsibility for ensuring that all personnel involved in human subjects research are appropriately informed, trained, and qualified to perform their respective duties.
Section II

Definitions


Assurance: UNH’s Federalwide Assurance of Protection for Human Subjects


Confidentiality: Treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Human Subject: “A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [45 CFR 46.102(f)].

Institutional Official (IO): The individual designated by the UNH President to ensure that research involving human subjects conducted under the auspices of UNH is in compliance with all applicable laws and regulations. This individual is the Senior Vice Provost for Research.

Institutional Review Board for the Protection of Human Subjects in Research (IRB): The committee established by the UNH President to oversee the use of human subjects in research conducted under the auspices of UNH.

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)].

Privacy: Having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Research: “A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” [45 CFR 46.102(d)].

Researcher: Any UNH faculty or staff member, or student who accepts responsibility for all aspects of the study. In the case of student studies, the Faculty Advisor and the student share responsibility for the study.

Risk: The probability of harm or injury (physical, psychological, social, legal, or economic) occurring as a result of participation in a research study.
Section III

Applicability

The Assurance, the UNH Policy on the Use of Human Subjects in Research (http://usnholpm.unh.edu/UNH/VIII.Res/F.htm), and the information in this Guide apply to all research activities involving human subjects that are:

Sponsored by UNH, or

Conducted by or under the direction of any employee, student, or agent of UNH in connection with his or her UNH responsibilities, or

Conducted by or under the direction of any employee, student, or agent of UNH involving the use of any UNH property or facility, or

Conducted by or involving any individual or institution working with UNH as part of a collaboration, subgrant, or subcontract.

Recipients of formal instructional activities are not regarded as human subjects for the purposes of this Guide or the UNH Policy on the Use of Human Subjects in Research, unless the students are also used as subjects in a research study.

A. Human Subjects

Federal regulations (45 CFR 46) provide the following definitions:

Human subjects: “Living individual(s) 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.”

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 (for example, 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.”

Using this definition of human subjects, all activities involving prospective collection of information about individuals via intervention/interaction are considered using human subjects and require UNH IRB approval before commencing.

When studies involve the use of secondary/existing data (data/information that exist(s) at the time the research project begins [e.g., previously collected survey data, school records, medical records]), UNH IRB approval is NOT needed to use such data for research purposes if the secondary/existing data do not contain private information. Some common examples of secondary/existing data that are not considered private information include, but are not limited to:
Some information on the Internet - comments on TripAdvisor; content of public tweets and blogs; information on public Facebook pages; census information; freely-available datasets (whether or not anonymous)

Archives - identifiable information about individuals in a public archive

Datasets - anonymous datasets, whether privately held or publicly available

Researchers should be aware that not all information on the Internet is considered publicly available and not all datasets that are characterized as anonymous actually are. Examples include, but are not limited to: Comments on a non-public chatroom or listserv; restricted-access datasets; or privately held datasets where individuals may be identified, either directly, through a code associated with a name, or through a combination of variables. As the UNH IRB DOES NOT give post-hoc approval, researchers must be certain that the secondary/existing data do not contain private information before use. Further, some journals require proof of IRB approval for research projects that the UNH IRB may not consider to involve human subjects (e.g., use of anonymous datasets). Researchers should check journal requirements before conducting the project and contact the IRB with any questions.

B. Research

When applying the definition of research to an activity, the IRB looks at the intent of the investigation, the researcher’s relationship with the subjects, and how the data will be used.

Activities at UNH involving human subjects commonly fall into the following categories:

Research - the purpose of the activity is to contribute to generalizable knowledge and data gathered may be shared with a research community or the public at large.

Evaluation/Assessment/Service/Reporting - the purpose of these activities is, upon request, to gather data to measure the current situation in regard to a specific phenomenon or set of factors. Data gathered may be shared only with the sponsor/client/requesting party and where appropriate, the faculty advisor, or used for internal decision making or informational purposes.

Classroom Assignments/Educational Inquiry/Practice - the purpose of these activities is the education of an individual student through an inquiry or experiential approach to discover known principles or phenomena. Data gathered may be shared only with the course instructor or faculty advisor, or in the case of an internship/practicum, the collaborating party.

Individuals gathering data from human subjects as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice abrogate their rights to publish data as research data; if they choose to share observations with others, their actions ought to be governed by the ethical standards of their discipline (e.g., American Psychological Association, American Anthropological Association).

Individuals who wish to gather data from human subjects as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice AND intend to use the data as research data for the purpose of publishing or sharing with a research community or the public at large must obtain IRB approval PRIOR to conducting the activity.
Activities conducted as part of an honor's thesis, master's thesis, or doctoral dissertation are considered research, and thus must be submitted to the IRB for review prior to commencing if they involve human subjects. The UNH Graduate School will not accept thesis or dissertation work that involves human subjects without proof of UNH IRB approval.

Activities involving human subjects within the context of research methods courses generally do not require IRB review, unless the results will be used for research purposes (e.g., presented at the UNH undergraduate or graduate research conferences, used in a thesis or dissertation, research conducted under the auspices of the Hamel Center for Undergraduate Research).

When students engage in research activities in the context of a class, the instructor should discuss the responsible conduct of research using human subjects and the IRB application materials (see the UNH IRB document, Application Materials for IRB Approval available at http://unh.edu/research/human-subjects), as they relate to the assignment BEFORE students begin collecting data. The instructor assumes responsibility for monitoring student research studies for human subjects concerns. This responsibility endures for the life of each study. Students and their instructors should fully understand and uphold the concepts of confidentiality, participant privacy, risk management, informed consent, and voluntariness of participation. The instructor must report to the IRB any unexpected or adverse events within one working day of occurrence. (See Section XI, A. Reporting Adverse Events.)
Section IV

Program Overview

UNH's program for protecting human subjects in research protects the rights and welfare of people who are the subjects of UNH research activities, and adheres to all applicable laws, standards, and policies affecting such use. The program applies to all involvement of human subjects in research at UNH, regardless of whether the study is funded.

All UNH research activities involving human subjects must be conducted in accordance with:

1. Federal, state, and local laws and regulations applicable to use of human subjects in research. These include, but are not limited to, Federal Policy for the Protection of Human Subjects, 45 CFR 46; FDA human subject protections regulations, Title 21 Code of Federal Regulations Parts 50 and 56; and, the principles set forth in The Belmont Report;
2. UNH Policy for the Use of Human Subjects in Research; and
3. UNH Assurance.

C. Regulations

UNH must comply with federal regulations in order to involve human subjects in research activities. The primary set of federal regulations pertaining to the protection of human subjects in research is the Federal Policy (Common Rule) for the Protection of Human Subjects. Per its Assurance, UNH is required to comply with DHHS regulations 45 CFR 46 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).

These regulations, promulgated in 1981 by the U.S. Public Health Service, consist of Subparts A, B, C, and D. Subpart A covers the duties of the IRB, requirements of an Assurance, required elements for informed consent, and other core aspects. The other Subparts cover research involving vulnerable populations: pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and, children (Subpart D). In 1991, sixteen other federal agencies and departments codified human subject protections regulations (Common Rule). Some federal agencies have regulations differing from DHHS Subparts B, C, and D protecting vulnerable populations.

D. Ethical Principles

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (http://www.hhs.gov/ohrp/policy/belmont.html) issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, is the basis for federal regulations. UNH regards these principles as the foundation for its program to protect the rights and welfare of human subjects in research. The principles in the Belmont Report are:

- “Respect for Persons -- Respect for persons incorporates at least two ethical convictions: First, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
Beneficence -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In [the Belmont Report], beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

Justice -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit" (The Belmont Report, April 18, 1979, 2-3.)

E. Assurance

UNH has provided DHHS with an Assurance that is administered by DHHS's Office of Human Research Protections (OHRP). This Assurance represents a legally binding commitment to DHHS and is critical in maintaining UNH's eligibility to receive federal and private funds for research involving human subjects. It states that UNH's program is guided by the ethical principles of the Belmont Report, and will comply with 45 CFR 46 for all federally funded human subjects research. It further commits UNH to complying with the federal regulations regardless of the source of funding, even when the research has no funding at all.

F. UNH Policy on the Use of Human Subjects in Research

UNH's policy (http://usnholpm.unh.edu/UNH/VIII.Res/F.htm) regarding the use of human subjects in research states: All UNH research activities proposing to involve human subjects must be reviewed and receive written, unconditional approval from the IRB before commencing. Failure to submit research involving human subjects to the IRB for review prior to commencing is a violation of UNH policy. (See Section XVI, Serious or Continuing Non-Compliance with Regulations and/or IRB Requirements.)

G. Other Guidance

Other guidance for protecting human research subjects is provided in the following sources:

- The Nuremberg Code
• American Psychological Association
• American Anthropological Association
Section V

Institutional Review Board for the Protection of Human Subjects in Research

UNH has one IRB authorized under its Assurance to review and to approve research involving human subjects. The IRB is a UNH standing committee responsible for protecting the rights and welfare of people who are the subjects of UNH research activities. The IRB has authority through UNH’s Assurance to interpret and apply federal, state, and local human subjects protections to UNH research studies.

The primary purpose of the IRB is to protect the rights and welfare of human research subjects by ensuring that physical, psychological, economic, legal, and/or social risks to subjects are minimized, and when present, justified by the importance of the research, and agreed to by subjects. Secondly, the IRB seeks to protect UNH and researcher(s) from possible adverse consequences of research with human subjects. The IRB seeks to assist the researcher to design her/his study so it is in compliance with federal and UNH requirements, thus the researcher can receive approval and conduct the study.

All research conducted by UNH agents, or by researchers of other institutions using UNH agents, living humans as subjects, or samples or data obtained from living subjects, directly or indirectly, with or without the subjects’ consent, must be approved in advance by the UNH IRB.

Per federal regulations, the IRB cannot approve a research study ex post facto.

Review and approval by another IRB does not negate the requirement for review and approval by the UNH IRB (if another IRB shares jurisdiction over a study, the UNH IRB requires a copy of that IRB’s determination).

The UNH IRB:

- Reviews all research studies involving human subjects,
- Reviews and addresses concerns involving the use of human subjects in research,
- Advises faculty, staff and students on the ethical conduct of research involving people,
- Conducts appropriate reviews of UNH's program and develops guidelines to ensure compliance with federal and state regulations,
- Participates in developing, reviewing, and providing educational opportunities for the UNH community on the use and protection of human subjects in research, and
- Serves in an advisory capacity to the Senior Vice Provost for Research.

Information about the IRB is available at [http://unh.edu/research/human-subjects](http://unh.edu/research/human-subjects). All correspondence with the IRB should be sent to Research Integrity Services office (RIS), Service Building, 2nd floor.
Section VI

Departmental Review Committees

In certain UNH departments, Departmental Review Committees (DRCs) carry out limited review activities on behalf of the IRB. DRCs are authorized by the IO and operate under the authority of the IRB. DRCs are authorized only to review and to approve research involving human subjects that can be classified as Exempt according to federal regulations.

The IRB has the authority to recommend, upon request, to the IO the establishment of DRCs at the department, school, or college level as an extension of the IRB for the purpose of reviewing and acting on proposals in the Exempt category where applicable. DRCs must comply with the procedures and requirements established for their operation by the IRB.

Contact the RIS office at 603/862-2003 or julie.simpson@unh.edu for more information about DRCs.
Section VII

Research Integrity Services

The RIS staff provide administrative support to the IRB and assist researchers with the IRB application and review process. RIS staff can be contacted at 603/862-2003 or 603/862-3536, or via the web at http://unh.edu/research/human-subjects
Section VIII

Responsibilities of Researchers and Advisors in Studies Involving Human Subjects

UNH faculty and staff members, and students may serve as directors of studies that involve human subjects. Students must arrange for a UNH faculty or staff member (usually their faculty advisor or instructor) to supervise them in their research activities and share responsibility for the study and welfare of the subjects.

A. Researchers

Responsibilities of a researcher conducting research involving human subjects include, but are not limited to, those specified in the Assurance and the following:

A. Researchers are responsible for complying with

I. UNH's Policy on the Use of Human Subjects in Research (http://usnholpm.unh.edu/UNH/VIII.Res/F.htm),

II. UNH's Federalwide Assurance, and


B. Researchers are responsible for gaining familiarity with, and adhering to, the ethical principles stated in The Belmont Report (http://www.hhs.gov/ohrp/policy/belmont.html).

C. Researchers must submit all proposed research activities involving human subjects to the UNH IRB for review before commencing. Researchers must not involve human subjects in research activities until the researcher has received written, unconditional approval from the IRB for the study.

D. Researchers are responsible for protecting the rights and welfare of human subjects in their research studies.

E. Researchers are responsible for keeping co-researchers and all research staff informed about the nature and goals of the study, and the need to adhere to ethical and responsible practices.

F. Researchers are responsible for adhering to the IRB-approved protocol and consent process, including providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. The researcher must retain all signed consent documents for at least 3 years after the end of the study.

G. Researchers must request IRB approval for proposed changes in previously approved human subject research activities before initiating them, except where necessary to eliminate apparent immediate hazards to the subjects.

H. Researchers are responsible for reporting progress of approved research to the IRB as often as, and in the manner, prescribed by the approving IRB on the basis of risks to subjects. For studies approved at the Expedited and Full Board review levels, this must be no less than once a year (365 days) from the last review date.
I. Researchers must report to the IRB any injuries or unanticipated problems involving risks to subjects and others within one working day of occurrence.

J. Researchers will not seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law. Such activities, however, will not be considered research nor may the data be used in support of research.

K. Researchers who collaborate with colleagues at other institutions/sites have additional responsibilities. Researchers will advise the IRB, RIS, and appropriate officials of other institutions of the intent to engage human subjects in research studies for which the UNH Federalwide Assurance or any related Inter-Institutional Amendment or Non-institutional Investigator Agreement applies. Institutions in the collaboration must possess an OHRP-approved Assurance prior to the involvement of human subjects in a research study.

B. Advisors

Dissertations, theses (graduate and undergraduate), master’s projects, independent research studies, and other research studies involving human subjects undertaken by students should be submitted to the IRB by the student-researcher. All student-researchers must have a faculty or staff member as an advisor of record for a study. The advisor must sign the IRB application form for the study as well as provide a letter of support for the study. In agreeing to be an advisor for a student research study, the faculty or staff member is responsible for, but not limited to, the following:

- Overseeing the design and conduct of the study,
- Protecting the rights and welfare of human subjects in the student research study,
- Informing student-researchers about the ethical principles for the protection of the human subjects of research, the ethical conduct of research involving human subjects, and applicable policies and procedures,
- Ensuring that student-researchers are well-trained and competent,
- Reviewing the application and protocol application prior to signature and submission to the IRB,
- Ensuring that projects are conducted in accordance with UNH’s Assurance, 45 CFR 46, and the IRB’s stipulations once IRB approval has been issued,
- Ensuring that IRB approval is requested for proposed changes in previously approved human subject research activities before initiating them, except where necessary to eliminate apparent immediate hazards to the subjects,
- Ensuring that progress of approved research is reported to the IRB as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once a year from the last review date,
- Reporting all deviations, noncompliance, adverse events, and injuries promptly to the IRB, and
- Promptly reporting to the IRB unanticipated problems involving risks to subjects and others.

Prior to planning or conducting a study involving human subjects, applicable faculty, staff, and students are expected to be familiar with the regulations and guidelines discussed in this manual.
C. Students as Research Study Personnel for an Instructor-Researcher as Part of a Class Activity

If an instructor requires students to conduct activities involving human subjects as part of the instructor’s research study (versus for academic inquiry or for the students’ own research study) as part of a class, students are acting as research study personnel on the instructor-researcher’s study. Accordingly, the instructor-researcher must ensure that the students’ involvement is fully described in the IRB protocol (either as part of the initial application or as a modification to the existing IRB-approved protocol) for the study. This should include, at a minimum, a brief description of the following (typically one to two pages):

- The names of the students involved in the research activities,
- Research activities that students will perform and duration,
- Scope and content of instruction in the protection of human subjects that the instructor will provide to students, and
- Training in the applicable research procedures that the instructor will provide to students commensurate with the students’ experience with such procedures.

The instructor must receive written approval from the IRB to include students in a class as research study personnel before having students engage in research activities involving human subjects on the instructor’s research study.
Section IX

Levels of Review

There are three levels of IRB review at UNH: Exempt, Expedited, and Full Board. At UNH, the IRB, not the researcher, determines the review level. Studies determined by the IRB to qualify for Exempt or Expedited review are reviewed by the IRB upon receipt; studies determined to qualify for Full Board review that are received by the published deadline are placed on the agenda for review at the next scheduled IRB meeting (http://unh.edu/research/irb-meeting-schedule). Studies received after the published deadline may be placed on the agenda for review at the next scheduled IRB meeting if it is determined there is adequate time for review.

A. Exempt Level Review

Federal regulations categorize certain human research activities as eligible for Exempt level review by the IRB. (When members of vulnerable groups are in the study population, the study must be reviewed at the Full Board level.) The Exempt review process may only be used for research involving no more than minimal risk. (For a definition of minimal risk, see Section II, Definitions.) At UNH, Exempt review is conducted by one voting IRB member or IRB authorized designee.

Research may be considered for Exempt level review if the only involvement of human subjects in the research falls into one of the following categories:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 45 CFR 46.101(b)(1).

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. 45 CFR 46.101(b)(2).

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not otherwise exempt if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. 45 CFR 46.101(b)(3).

- Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. 45 CFR 46.101(b)(4).
• Research and demonstration studies which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. 45 CFR 46.101(b)(5).

• Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. 45 CFR. 46.101(b)(6).

Certain studies involving adults that qualify for Exempt review cannot qualify for Exempt level review when children are involved.

B. Expedited Level Review

Federal regulations categorize certain research studies as eligible for Expedited level review by the IRB. Expedited review may only be used for research involving no more than minimal risk. (See Section II, Definitions for a definition of minimal risk.) At UNH, Expedited level review is conducted by two voting IRB members.

Expedited level 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.

Categories of research eligible for expedited review may be used only when the only involvement of human subjects in the research falls into one of the following categories:

• Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required. §46.110(b)(1)(1)

• Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (i) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (ii) 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 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. §46.110(b)(1)(2)

• Prospective collection of biological specimens for research purposes for noninvasive means such as: (i) Hair and nail clippings in a nondisfiguring manner; (ii) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (iii) permanent teeth if routine patient care indicates a need for extraction; (iv) excreta and external
secretions (including sweat); (v) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (vi) placenta removed at delivery; (vii) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (viii) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (ix) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (x) sputum collected after saline mist nebulization. §46.110(b)(1)(3)

- Collection of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve the 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, electro encephalography, 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). Studies intended to evaluate the safety and effectiveness of a medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. §46.110(b)(1)(4)

- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). §46.110(b)(1)(5)

- Collection of data from voice, video, digital, or image recordings made for research purposes. §46.110(b)(1)(6)

- 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. §46.110(b)(1)(7)" (45 CFR 46.110)

In addition, under certain circumstances, Expedited level review may be appropriate for continuing review of research previously approved by the convened IRB:

- "Research where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects. §46.110(b)(1)(8)(a)

- Research where no subjects have been enrolled and no additional risks have been identified. §46.110(b)(1)(8)(b)

- Research where the remaining research activities are limited to data analysis. §46.110(b)(1)(8)(c)

- Research not conducted under an investigational new drug application or investigational device exemption where the research does not otherwise qualify for exemption but the IRB has determined and documented at a convened meeting that the research involves no
greater than minimal risk and no additional risks have been identified §46.110(b)(1)(9)” (Federal Register at 63 Fed. Reg. 60364-60367 (November 9, 1998).

C. Full Board Level Review

The IRB conducts initial and continuing reviews of research studies determined not to qualify for Exempt or Expedited review at a convened IRB meeting. The UNH IRB meets biweekly during the academic year, and monthly in the summer. A schedule of upcoming IRB meetings is posted on the IRB webpage (http://unh.edu/research/irb-meeting-schedule). An IRB meeting may be canceled by the Chair due to an inability to secure a quorum of members or for other reasons that make a scheduled meeting not possible.

Researchers should submit studies requiring Full Board review to the RIS office at least two weeks before the next scheduled IRB meeting. Applications are placed on a meeting agenda in order of receipt in the RIS office. IRB members will not review studies that they have not had sufficient time to consider.

The IRB may require or invite a researcher (or representative) to attend a scheduled IRB meeting to address issues about a study. Researchers and guests present at the IRB meeting must leave the meeting room when requested to do so by the Chair to facilitate uninhibited discussion of the study, and may not be present for the vote on the study. Alternatively, the IRB may invite a researcher (or representative) to contact an IRB member to discuss any issues arising from the IRB meeting.
Section X

New Study Application and Review Process

A. Length of Review Process and Timing of Application Submission

Researchers may submit an application to the IRB for review at any time. If a study qualifies for Exempt or Expedited review and the application is complete, the review process normally takes 10-15 working days. If a study requires review at the Full Board level, the process may take up to a month. So that research is not delayed, the IRB strongly recommends that researchers submit applications at least one month prior to the desired study start date. Researchers may involve human subjects in studies ONLY after receiving written approval without contingencies from the IRB.

B. Application

All research studies proposing to involve human subjects must be submitted to the IRB (through the RIS office) for review and approval prior to commencing. Studies under the jurisdiction of the IRB must be directed by a UNH faculty or staff member, or student. Where a student is conducting the study, the faculty advisor must also sign the Request for IRB Review form AND submit a letter of support for the research, delineating the student’s experience with the research paradigm and the commensurate level of supervision to be provided by the faculty advisor. Study applications are reviewed by the IRB on a first come, first served basis, and must be complete in order to qualify for review. Applications for IRB review should include:

- Completed, signed two-page Request for IRB Review form (see the Application Materials for IRB Approval at http://unh.edu/research/human-subjects);
- Narrative of no more than 4 pages in length (single-space) detailing major study features (see the Application Materials for IRB Approval at http://unh.edu/research/human-subjects), and Guidelines for Writing a Research Protocol to Submit to the IRB at http://unh.edu/research/irb-application-resources;
- Certificate of completion of the UNH Web-based training on the ethical use and treatment of human subjects in research (training available at http://www.unh.edu/rcr/HumSubj-Title.htm). Applications missing this certificate will not be processed;
- Copies of advertising and/or recruitment materials (where applicable);
- Copies of informed consent document(s) and/or assent documents (see http://unh.edu/research/human-subjects for consent form templates and Child Assent Guidelines at http://unh.edu/research/irb-application-resources);
- Copies of the survey instruments, interview questions, debriefing materials, questionnaires (where applicable);
- Letters from collaborating sites (where applicable);
- Letter of support from the faculty advisor (for students); and
- Copies of other pertinent documents/information. These documents may be supplemented by additional information that either the researcher believes to be important or the IRB requests for review purposes.
C. Initial Review

Upon receipt of an application, RIS staff assign a protocol number and enter the application information into a database. The IRB protocol number remains with the study until the study is closed. The IRB protocol number appears on all correspondence from the IRB, and researchers should include the applicable IRB protocol number on all correspondence with the IRB. RIS staff then conduct an initial review of the application. RIS staff contact researchers if their application materials are incomplete, missing signature(s), or require clarification or revision. Once RIS staff determine that an application is ready for review, the RIS staff determine the appropriate review level. If a study qualifies for Exempt or Expedited level review, RIS staff forward the application to the appropriate IRB reviewer(s). Studies requiring Full Board level review are placed on the agenda for the next scheduled IRB meeting (in order of receipt).

D. Criteria for Approval of Studies

In order for the IRB to approve a study, the researcher must satisfy all of the following criteria, unless specifically waived by the IRB:

- Risks to subjects are minimized,
- Risks to subjects are reasonable in relation to anticipated benefits,
- Selection of subjects is equitable,
- Informed consent is adequate and appropriately documented,
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects,
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, and
- Appropriate safeguards have been included to protect vulnerable subjects.

E. Special Consultants

The IRB may designate consultants with special expertise to assist in the review of particular studies. Researchers are notified and offered the opportunity to show cause why a particular consultant may be inappropriate. If consensus cannot be reached, the IRB may refuse to act on a study.

F. Potential IRB Actions

The IRB may take the following actions with respect to a study submitted for review:

- Approval without comments or contingencies,
- Approval with comments (e.g., suggestions for minor changes),
- Approval subject to satisfaction of contingencies by the researcher, as determined by the IRB reviewers (Exempt and Expedited reviews) or an IRB subcommittee (Full Board reviews),
- Approval subject to satisfaction of contingencies by the researcher, as determined by the IRB (Full Board reviews). If major changes are needed, the modified Full Board study must be returned to the IRB for review at a convened meeting,
- Tabled (substantive questions and/or significant concerns need to be addressed by the
researcher), or
• Non-approval or disapproval (proposal does not meet requisite standards).

Researchers are notified in writing of the IRB’s action. If a study is not approved, the researcher should work with a member of the IRB to address the IRB’s concerns for resubmission to the IRB.

G. Notification of Review Results

Researchers, key research personnel, and faculty advisors (where applicable) are notified in writing of the results of review. When the IRB requests modifications in, or tables, a study, the researcher is informed in writing of the reasons for the IRB’s actions.

When a study is approved, researchers are notified of the following:

• Requirement to submit a progress report by the date at which the IRB has determined continuing review is required,
• Requirement to obtain approval of any changes to the study and consent form prior to initiation of the proposed changes,
• The protection of human subjects in the study is an ongoing process for which they hold primary responsibility. In receiving IRB approval for the study, they agree to conduct the study in accordance with the ethical principles and guidelines for the protection of human subjects in research, as described in the following documents: The Belmont Report; 45 CFR 46; and UNH’s Assurance, and
• Requirement to report to the IRB within one working day any serious or unexpected adverse events involving subjects.

H. Approval Term/Period

Studies reviewed at the Expedited and Full Board levels are approved for a term that does not exceed 365 days from the date of initial IRB approval. The study approval period/term is based on factors related to the level of risk posed by the research. Factors may include, but are not limited to: vulnerability of subjects; previously reported adverse events in related or similar research; and investigator/group experience with the subject population. The IRB approval letter states the term for which the study is approved.

I. Responses to IRB Reviews

The IRB may approve a study contingent upon specific major revisions to the study and/or consent form. To secure approval, researchers need to respond to the IRB’s written statement of contingencies (e.g., by providing additional information, consent form revisions). The researcher’s response is reviewed by the initial reviewer(s) if reviewed at the Exempt or Expedited review level, and the study approval date is the date the reviewer approved the researcher’s response. If reviewed at the Full Board level, the researcher’s response is either reviewed at the next convened IRB meeting or by a subcommittee of named IRB members (determined at the time of the initial review). For studies reviewed at the Full Board level, the study approval date is the IRB meeting date when the study was initially reviewed and approved with contingency.

The IRB may table approval of a Full Board study, postponing further discussion to another scheduled IRB meeting pending receipt of information from the researcher. The researcher should
respond to concerns raised by the IRB as soon as possible to expedite subsequent review by the IRB. The IRB will review the researcher's response at the next scheduled meeting after receipt if all required information is provided to the IRB in a timely manner. When the IRB approves, with or without contingencies, a previously tabled study, the study approval date is the IRB meeting date when the study was finally approved, not at which the study was originally tabled.

J. Appeals Process

Researchers wishing to appeal an IRB decision can do so by submitting a formal written statement to the IRB Chair. The IRB Chair will review appeals and issue a written response within five working days of receipt of an appeal.

K. Proposals for External Funding

Researchers seeking external funding for studies involving human subjects should coordinate the timing of the submission of their applications to the IRB for review with the prospective sponsors' application deadlines and Sponsored Programs Administration (SPA). All federal and many private sponsors require IRB approval at the time of award.

L. Review of DHHS Grant Proposals

Federal regulations require the IRB to review grant proposals for research involving human subjects submitted to DHHS to ensure the study involving human subjects in the grant does not deviate from that approved by the IRB. Therefore, researchers submitting proposals to DHHS must provide a copy of their funding proposal to the IRB at the time they submit an IRB application and study for review. If the researcher submits the application for IRB review before the proposal has been written, the researcher must forward a copy of the proposal to the IRB at the time the proposal is submitted for funding.
Section XI

After Initial IRB Approval

After obtaining IRB approval for a study, researchers have a variety of IRB communication and record-keeping responsibilities. Funding agencies and other regulatory agencies may place additional responsibilities on researchers.

A. Reporting Adverse Events

An adverse event is any unanticipated reaction or event contemporary with the study that has a harmful effect on a subject, including adverse physical, psychological, or social events. Researchers must report every adverse event to the IRB whether or not they believe the event to be caused by the study. Researchers should report any measures taken for the benefit of subject(s) and to mitigate the potential of recurrences.

Researchers are required to report adverse events to the IRB within one working day of occurrence. Researchers must submit a written report of the situation, one or more follow-up reports detailing how the situation was resolved, and a report of steps taken to prevent recurrence. The IRB Chair or designee evaluates each adverse event report and determines whether further action is needed beyond that taken by researchers. Further actions may include, but are not limited to:

- Modifying the study to minimize risks to subjects,
- Making consent form changes to accurately reflect the nature, frequency, or severity of the event,
- Requiring that subjects be asked to re-consent to participate in a study, or
- Temporarily suspending enrollment of new subjects in a study, and/or discontinuing study procedures because, based on the information available, the risk benefit ratio appears to be unfavorable to subjects.

Adverse event reports are reviewed by the IRB at convened meetings. Actions that may be taken by the IRB in response to the report include:

- Deciding that no further action is necessary (the research may continue),
- Requiring further investigation prior to the next IRB meeting by an IRB member or outside expert designated by the Chair,
- Requiring that additional information regarding risks be given to subjects, or
- Suspending or terminating approval.

Researchers are notified by the IRB of any action, including reasons for that action, in writing within 5 working days of receipt of the adverse event report and/or the convened IRB meeting at which the adverse event was discussed. The IO is copied on such correspondence. The IRB is required to report to the IO and the appropriate federal department or agency any unanticipated problems involving risks to subjects or others.
B. Continuing Review

The IRB is required to conduct a review of each approved Expedited and Full Board study at least once every 365 days. The IRB may, at its discretion, require more frequent reviews. The IRB may determine it appropriate or prudent to conduct more frequent review to ensure adequate protection of the rights and welfare of research subjects. The IRB's study approval letter to the researcher will specify the required study review frequency.

At UNH, continuing review is conducted at the same level at which the study was originally approved. For example, a study originally reviewed and approved at the Full Board level undergoes continuing review at the Full Board level. Exceptions to this procedure are those Full Board-approved studies that at the time of continuing review qualify for Expedited review. (See Section IX, B., Expedited Level Review.)

To prompt timely review, RIS staff send to researchers an Annual Continuing Review Questionnaire approximately 60 days prior to a study approval expiration date, as well as a reminder notice approximately 30 days later if no response is received from a researcher. Via the Annual Continuing Review Questionnaire, researchers must:

- Either request an approval extension (for another 365 days) or report study closure,
- Report the stage at which the research is currently,
- Report the number of months the research has been conducted,
- Provide the number of subjects involved to date,
- Specify whether or not the research has been conducted in accordance with the procedures reviewed and approved by the IRB,
- Report whether any problems have emerged and/or serious unexpected adverse subject experiences have been observed, and
- Submit a short report detailing findings to date and a copy of the current informed consent document(s) if subject recruitment is ongoing.

Researchers should complete the Annual Continuing Review Questionnaire and return it, along with the progress report and copy of the current consent document (if applicable) to the RIS office at least 30 days prior to the study approval expiration date. The RIS staff review completed Annual Continuing Review Questionnaires and reports, and route them for Full Board or Expedited level review, as appropriate.

If a researcher does not complete and submit an Annual Continuing Review Questionnaire and/or progress report for review by the IRB prior to the study approval expiration date, the IRB notifies the researcher in writing that approval of the study has expired and that:

- New subjects may not be enrolled in the study until the study and consent form are reviewed and approved by the IRB,
- All involvement of human subjects in the study must cease until a completed Annual Continuing Review Questionnaire and/or progress report are/is reviewed and approved by the IRB, and
- Continued research involving current enrollees will be considered and allowed only where the IRB Chair finds that it is in the best interests of the subjects already enrolled to do so.

In order to reinstate IRB approval for a study where approval has expired, researchers must complete and submit the study’s Annual Continuing Review Questionnaire along with a progress report and a copy of the current informed consent form (if applicable) to the IRB for review.
Researchers must receive written IRB approval without contingencies before resuming involvement of subjects in their studies.

C. Requests for Modifications to Previously Approved Studies

Researchers may not implement any changes to IRB-approved studies without prior IRB review and approval of the change, except when necessary to eliminate apparent immediate hazards to subjects. Researchers who are planning substantive changes in subject population, recruitment plans, advertising materials, consent requirements, research procedures, study instruments, study sites, or researchers or study personnel instrumental to the design or execution of the study, must submit a request to the IRB for approval of the modification(s) prior to implementing the modification(s). Researchers should submit the following information:

- Description of the proposed change(s),
- Description of the implications for the subjects,
- Revised consent documents if the change will affect subjects, and
- Explanation of why the change is needed (if the change is proposed by the sponsor or a national group), and provide the sponsor's formal notice of a change or revised study).

The IRB reviews requests for study modifications at the initial study review level (i.e., modifications to Full Board-approved studies are reviewed by the IRB at a convened meeting).

An exception for prior IRB approval of a modification can be made in rare circumstance when a change is necessary to eliminate apparent immediate hazards to subjects. In this case, the researcher must promptly inform the IRB of the change. The IRB will review the change to determine whether it is consistent with IRB policies and procedures and/or human subjects protections. New information that may affect the risk/benefit assessment must be reported promptly to, and reviewed by, the IRB to ensure adequate protection of human subjects.

D. Study Closure

When a study ends or is canceled for any reason, researchers must submit a closure report for the study. The report must address the same information required for continuing approval. (See Section XI, B., Continuing Review.) Researchers should not close IRB approval of a study until data collection is complete, and data analysis and interpretation have been concluded. Once researchers have formally closed a study, they may not collect any more data for that particular study until they receive in writing that the IRB has reactivated approval.

E. Record Keeping and Retention

Researchers are required by UNH policy (http://usnholpm.unh.edu/UNH/VIII_Res/C.htm) and federal regulations to maintain records of all documentation and data relating to the use of human subjects in each study. At a minimum, copies of the UNH IRB-approved application and research protocol, communication to and from the IRB, and signed informed consent documents (if applicable) must be maintained in researchers’ records. All records of human subject research are subject to inspection by federal authorities, the UNH IRB, and, in certain circumstances, UNH officials (e.g., in an investigation of an allegation of scholarly misconduct). Copies of all research
records must be kept for a minimum of three years after study closure. A prevailing sponsored agreement, contract, or other regulations may require longer retention periods.
Section XII

Informed Consent and Assent

Obtaining informed consent from each subject in a research study is a basic ethical obligation for researchers. Informed consent is an ongoing process of information exchange between a subject and a researcher throughout the study to provide potential subjects with sufficient information to make an informed and voluntary decision about either beginning or continuing participation in a study.

Prior to admitting a subject into a study, researchers must obtain the informed consent of the individual involved. Accordingly, no researcher may involve a human being as a subject in a research study unless the researcher has obtained the legally effective written informed consent of the subject or the subject’s legally authorized representative (unless the IRB has specifically waived consent and/or written documentation of consent). If a researcher has a relationship with potential subjects (physician-patient, instructor-student, employer-employee), the researcher should take special care to avoid recruitment methods that may be seen as coercive due to the relationship between the parties.

Informed consent involves a thorough briefing (orally or in writing) of each potential subject by the researcher, including all the required elements (see part B of this section). The amount of information and the manner of presentation is generally related to the complexity and risk involved in the study. Researchers must make every effort to ensure that each subject has fully understood what s/he agrees to and that they have answered all of the subject’s questions. Then researchers should obtain each subject’s signature on a consent form documenting that the subject has participated in the process of informed consent and has agreed to participate in the study. The informed consent document itself serves as a written source of information for the subject. A signature on a consent form does not by itself constitute informed consent.

Consent is a legal concept. Only legally competent adults can give legally effective informed consent. Minors and those individuals who are not competent to provide consent should be given the opportunity to assent to participate in a study (see parts A and C of this section). Assent is a knowledgeable agreement to participate in a study. Mere failure to object should not be construed as assent. Adequate provisions should be made for soliciting independent, non-coerced assent from minors or cognitively impaired persons who are capable of knowledgeable agreement (see part A of this section). If the person from whom assent is sought refuses, the person should not be enrolled, even if the parent or legal guardian gives permission. Alternatively, if a person from whom assent is sought agrees to participate, the person may not be enrolled if the parent or legal guardian does not give permission. In rare circumstances, depending on the nature of the study and the age and circumstances of the minor or person who has diminished capacity to consent, the IRB may waive the requirement for parental or legal guardian permission.

In cases where researchers plan to obtain assent from a minor or a subject who has diminished capacity to consent, researchers must also obtain permission from the legally authorized representative (e.g., parent, legal guardian). In studies involving minors, the legally authorized representative is the parent or court-appointed guardian. The IRB recognizes foster parents as having the authority to enter children in their care into studies. In studies involving cognitively impaired adults, the legally authorized representative is a designated proxy (e.g., a Durable Power of Attorney for Health Care), court-appointed guardian, spouse, adult child, parent, or adult sibling.

When conducting research in the U.S. and foreign countries, researchers must abide by any state or local laws and/or regulations pertaining to consent.
A. Obtaining Assent from Children

The IRB recognizes that much of the research involving children poses no more than minimal risk for them. (For a definition of minimal risk, see Section II.) Researchers whose procedures pose greater than minimal risk for their subjects can request additional assistance from the IRB in drafting procedures for obtaining assent.

The following are 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 students. In addition, because there are individual differences in the development of children's ability to understand a researcher's requests, there is a necessary age overlap in the categories listed below.

AGES 2-7 - For children between the ages of 2 and 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 the 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 through 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.

B. Required Elements of Informed Consent

Researchers must provide information to their subjects or a subject's representative in language understandable to subjects or the representative. No informed consent procedure may contain any exculpatory language through which a subject or representative is made to waive, or to appear to waive, any of the subject's legal rights, or releases, or appears to release, the researcher, the sponsor, or UNH or its agents from liability for negligence.

In administering informed consent, researchers must provide the following information to subjects or their representative:

- Statements that the study involves research, explanation of the purpose of the research, expected duration of participation, description of the procedures, and identification of any
experimental procedures,
- Description of any reasonably foreseeable risks or discomforts,
- Description of any benefits to the subject or to others that might be reasonably expected from the research,
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject,
- Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the sponsor, the IRB, University officials, the FDA, or other regulatory agencies,
- For research involving more than minimal risk, explanation as to whether any compensation and medical treatment are available if injury occurs and if, so, what they consist of or where further information may be obtained,
- Identification of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact if the subject sustains a research-related injury, and
- Statements that participation is voluntary, that the subject may discontinue at any time, and that withdrawal or refusal to participate or will not involve a penalty or loss of benefits to which the subject is otherwise entitled.

Where appropriate, the researcher must also provide the following information to the subject or representative:

- Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are known or currently unforeseeable.
- Anticipated circumstances under which the subject’s participation may be terminated by the researcher without regard to the subject’s consent.
- Any additional costs to the subject that may result from participation in the research, including whether such costs may be billed to a third party.
- Consequences of the subject’s decision to withdraw from the research and procedures for safe and orderly termination of participation.
- Statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue to participate will be provided to the subject.
- Approximate number of subjects involved in the study.

C. Altered or Waived Informed Consent

As some studies would not be feasible if written informed consent from subjects were required, researchers may request that the IRB approve a consent procedure that omits or alters some or all of the elements of informed consent. The federal regulations state that informed consent may be waived in full or in part if the IRB determines that:

- The research involves no more than minimal risk to the subjects,
- The waiver or alteration will not adversely affect the rights and welfare of the subjects,
- The research could not practically be carried out without the waiver or alteration, and
- Whenever appropriate, subjects will be provided with additional pertinent information after participation.
Examples of types of studies in which some or all of the elements of consent have been waived include certain types of ethnographic research, retrospective chart reviews, and studies involving elements of deception. In some situations, a written document is required, but that written document may not contain all of the required basic elements of consent. In other situations, no written document is required. If researchers seek a waiver of any or all of the elements of consent, the research protocol should describe the reasons for the request, paying particular attention to why obtaining written informed consent is not feasible.

D. Waiver of Documentation of Informed Consent

Researchers may request that the IRB waive the requirement for obtaining research subjects’ signature on a written document. Federal regulations state that documentation of consent (i.e., signature) may be waived if the IRB determines that:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Examples of types of studies that fall into the first category are survey or interview studies that contain highly sensitive questions (e.g., criminal behavior, sexual behavior). Studies that fall into the second category are mailed surveys about topics that could not reasonably damage a participant’s reputation or employability or otherwise be stigmatizing. In the case of minimal risk mailed surveys, the IRB may require a letter containing all of the basic elements of consent and a statement that indicates that return of the survey will be considered agreement to participate.

E. Informed Consent for Non-English Speakers and Persons with Limited Literacy

If a study involves subjects who do not speak or read English, or where the subject’s native language is not written, the IRB may require researchers to follow certain procedures in order to ensure that each subject gives fully informed consent to participate in the study.

In the case where subjects do not speak or read English, informed consent information must be presented in language understandable to subjects and in writing. Wherever possible, documents should be written in subjects’ preferred language and such that all the elements necessary for legally effective informed consent are presented. Researchers must submit to the IRB for review at the time of initial study submission all foreign language versions of consent forms and any other translated documents that will be presented to subjects. The IRB may review these documents with outside experts to ensure that translation is appropriate.

As some of the world’s languages are not written, researchers may present studies to the IRB for review involving subjects whose native language is only spoken. In these cases, researchers must ensure that informed consent is obtained from each subject in language understandable to the subject. Normally, each subject would be given an oral presentation of informed consent information in their native language. Researchers should submit to the IRB for review an English language version of the informed consent information that will be presented to each subject. At the time of consent, the IRB may require that the English language informed consent document be signed by the person obtaining consent, as authorized in the study, and a witness.
person obtaining consent is assisted by a translator, the translator may serve as the witness to the consent process.
Section XIII

Privacy and Confidentiality

Issues of primary importance in many studies are protecting subjects’ privacy and maintaining confidentiality of data collected. Researchers must delineate in research protocols submitted to the IRB for review all precautions to protect privacy and confidentiality, and consent forms must define any limitations on confidentiality.

It is the responsibility of researchers to be sensitive to privacy and confidentiality issues, and to consider them when designing studies. Under certain circumstances, an invasion of privacy or breach of confidentiality may present risk of serious harm to subjects (e.g., when the research would obtain information about subjects that could, if disclosed by the researcher, jeopardize employment or lead to prosecution of criminal behavior). Under other circumstances, an invasion of privacy or breach of confidentiality can be unethical, or, at least in theory, provide cause for legal action against a researcher or institution.

When designing a study, researchers must ensure that mechanisms have been devised to protect subjects’ privacy in the recruitment, intervention, data analysis, and reporting stages. In addition to protecting subjects’ privacy, researchers must delineate how they will maintain confidentiality of data, for example, storing data in a locked file cabinet in a private lockable office. Furthermore, researchers should describe who has access to the data and under what circumstances a code system may be broken. Without appropriate safeguards, problems may arise from long-term retention of records. In special circumstances requiring additional safeguards to prevent potential criminal prosecution of participating subjects, the IRB may require the destruction of all data that can identify the subjects.

Researchers, however, cannot guarantee absolute confidentiality to subjects, either verbally or in consent forms. Prospective subjects should be informed that, in rare instances, information from the study may be shared with UNH officials, designees of the sponsor(s), and other appropriate government agencies (such as OHRP). While participants’ identities generally must be kept confidential, participants also should be informed that researchers will report information in certain situations as required by law (see part B of this section).

When researchers are gathering data through video or audio tapes, or photographs, they must make sure that collection of data via these media is explained in consent information as these means provide additional potential means for subject identification. Researchers should also explain in consent forms plans for final disposition or destruction of such data.

A. Federal Certificates of Confidentiality

In those cases where data about sensitive issues (e.g., illegal behavior, alcohol or drug use, sexual practices or preferences, or genetic testing) are collected, protection of confidentiality consists of more than preventing accidental disclosure. Researchers should be aware of, and prepared to address, breaches of confidentiality when judicial or law enforcement agencies seek data through subpoena or other forms of forced disclosure. Under federal law, researchers can obtain a Certificate of Confidentiality that will provide protection against forced disclosure of identifying characteristics of subjects. Federal funding is not a prerequisite.
The Certificate of Confidentiality does not protect a researcher from the voluntary disclosure of identifying characteristics; therefore researchers must still adhere to state laws regarding mandatory reporting requirements, such as suspected child abuse and/or neglect. The full extent of protection provided by a Certificate of Confidentiality has not been contested in a court of law.

B. New Hampshire State Law

New Hampshire law mandates that all individuals must disclose certain information to law enforcement officials and/or other third parties, regardless of whether the individuals have entered into a legally-recognized confidential relationship with the information source. The following is a summary of the pertinent laws:

1) Any person who has reason to suspect that a child has been abused or neglected must report the information to the New Hampshire Department of Health and Human Services. RSA § 169-C:29.

2) Any person who has reason to believe that an incapacitated adult is being or has been subjected to physical abuse, neglect or exploitation, or is living in hazardous conditions must report the information to the Director of the Division of Elderly and Adult Services at the New Hampshire Department of Health and Human Services. RSA § 161-F:46.

3) Any person who is present or otherwise has direct knowledge of any student hazing must report the hazing to law enforcement or educational institution authorities. The educational institution is required to report the hazing information to law enforcement authorities. RSA § 631:7.

4) Any person who knowingly renders treatment or assistance to an individual for a gunshot wound or any other injury believed to have been caused by a criminal act must immediately notify law enforcement officials. (This reporting requirement does not apply to a victim of sexual assault who is over 18 years of age, objects to the release of any information, and has not been treated for a gunshot wound or other serious bodily injury.) RSA § 631:6.

In addition, in a recent court case, Schneider v. Plymouth State College, the New Hampshire Supreme Court indicated that employees of New Hampshire institutions of higher education have a duty to report situations where there is reason to suspect that a student is being or has been sexually harassed by a faculty or staff member. The report should be made to appropriate school officials in accordance with the institution’s sexual harassment policy. These reporting requirements create a duty of disclosure for faculty and staff who may obtain certain information during the performance of their duties, or as result of research. Therefore, it is important researchers understand the reporting requirements and the limitations on assurances of confidentiality. (The above information is based on a January 30, 2001 memorandum from the University System of New Hampshire General Counsel’s Office.)

To manage the risk of liability for failure to disclose any of the above situations by promising confidentiality to subjects in a research study where the researcher might reveal the above information, researchers must inform potential participants about their reporting responsibilities and the associated risks to participants. When reviewing a research study and accompanying informed consent document(s), the IRB will assess how well researchers clearly outline specific situations wherein they are mandated to disclose certain confidential information (i.e., cannot maintain confidentiality of responses), therefore potentially putting participants at risk for legal
 action. Ideally, researchers should present disclosure information in at least two places in informed consent documents: (1) Detailed as a potential risk to the participant; and (2) Detailed as a situation wherein confidentiality of responses cannot be maintained.

C. Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

Effective April 14, 2003, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 160 and 164) requires covered health care entities to obtain written authorization from individuals in order to use or disclose their protected health information for research purposes.

1. 45 CFR § 160.103 defines a covered entity as “(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.”

2. Use is defined as “with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such as information” (§164.501).

3. Use is defined as “with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such as information” (§164.501).

4. Protected health information is defined as “individually identifiable health information: (1) Except as provided in paragraph (2) of this definition, that is: (i) transmitted by electronic media; (ii) Maintained in any medium described in the definition of electronic media at §162.103 of this subchapter; or (iii) transmitted or maintained in any other form or medium. (2) Protected health information excludes individually identifiable information in: (i) Education records covered by the Family Educational Rights and Privacy Act as amended, 20 U.S.C. 1232g; (ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and (iii) Employment records held by a covered entity in its role as employer” (§164.501).

Health information is defined as “any information, whether oral or recorded in any form or medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual” (§160.103).

Individually identifiable health information is defined as “information that is a subset of health information, including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual” (§160.103).

The Privacy Rule considers the following as identifiers:

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
As research involving protected health information qualifies as human subjects research, such research conducted by UNH agents must be reviewed and approved by the UNH IRB prior to commencing. In addition, UNH researchers who plan to obtain protected health information from covered health care entities should check with those covered health care entities as early as possible to find out any requirements for review by their IRBs.

In order for researchers to access and use protected health information maintained by covered health care entities, in most situations researchers will have to either obtain written authorization from each subject for use or disclosure of her/his protected health information or approval of a waiver of authorization from the appropriate IRB(s). In other specified research activities involving use or disclosure of protected health information, researchers do not have to obtain written authorization but have to fulfill other requirements. The authorization requirement is in addition to human subject protections regulations\(^5\) requiring informed consent to participate in a research study.

A covered health care entity is permitted to use or disclose protected health information for research purposes with written authorization from individuals, or, in limited circumstances, without written authorization.

### 1. Use/ Disclosure with Individual Authorization

The Privacy Rule permits covered health care entities to use or disclose protected health information for research purposes when an individual authorizes the use or disclosure of information about him or herself in writing. Authorizations are required to be study-specific. In order to be valid, an authorization needs to include the following information:

- A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion [§164.508(c)(1)(i)], e.g., “laboratory results” or “height, weight, and diagnosis” rather than “all health information necessary for study purposes.”

- The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure [§164.508(c)(1)(ii)], i.e., the names of the hospital, physician, physical therapist, or health care provider who maintain the desired information.

- The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure [§164.508(c)(1)(iii)], i.e., the name of the researcher and any study personnel who will have access to the information.

- A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose [§164.508(c)(1)(iv)].

- An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for

\(^5\) 45 CFR § 46.116

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research, including for the creation and maintenance of a research database or research repository [§164.508(c)(1)(v)].

• Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual must also be provided [§164.508(c)(1)(vi)].

In addition to the above information, the authorization must contain the following “required” statements:

• Notice of the individual’s right to revoke the authorization in writing and the exceptions to the right to revoke. This can be accomplished either by describing the right to revoke and the exceptions in the authorization or by referring to the covered entity’s Notice of Privacy Practices [§164.508(c)(2)(i)]. (Each covered health care entity has to develop a Notice of Privacy Practices and make it available to individuals.)

A covered entity may continue to use and disclose protected health information that was obtained before an authorization was revoked in order to maintain integrity of the study (American Council on Education [ACE], 2002). A covered entity may not disclose protected health information obtained after the effective date of a revoked authorization. Only information gather by the covered entity before the effective date of a revocation may be disclosed. When an individual revokes her/his authorization, the researcher may continue to use the information previously received as long as it complies with the original authorization (ACE, 2002).

• The covered entity’s inability to make treatment, payment, enrollment, or eligibility for benefits conditional upon signing the authorization. One exception is where research involves treatment. If a participant elects to participate in a study involving research-related treatment and refuses to sign an authorization, the researcher does not have to enroll the individual in the study [§164.508(c)(2)(ii)].

• The potential for information disclosed under the authorization to be re-disclosed by the recipient and not protected by the Privacy Rule. The covered entity is not responsible for what researchers do with the protected health information after receiving it from the covered entity [§164.508(c)(2)(iii)].

In addition to the required elements and statements, the Privacy Rule states that:

• An authorization must be written in plain language

• A copy of the signed authorization must be provided to the individual who is permitting the use or disclose of her/his protected health information.

2. Authorizations and Informed Consent

Human subjects protections regulatory requirements for informed consent and Privacy Rule requirements for written authorization are different. Informed consent, as required by the Common Rule, is a consent to participate in the research study as a whole whereas the Privacy Rule’s authorization is for the use or disclosure of protected health information for research purposes. IRBs do not have to approve authorization forms per se. However, IRBs review

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authorization as information provided to subjects in the study and for consistency with the research protocol.

Although there are important differences between the Common Rule’s requirements for informed consent and the Privacy Rule’s requirements for authorization, the elements are compatible. Thus researchers have a couple of options when they are required to obtain authorization from subjects for the use or disclosure of protected health information in a research study:


- Use a consent form that includes the required authorization language. For a consent form to also function as a valid authorization for use or disclosure of protected health information, the information outlined above (Use/Disclosure with Individual Authorization) must be included. (See UNH IRB document, Sample Authorization Language for Consent Forms for Use or Disclosure of Protected Health Information available at http://unh.edu/research/sites/unh.edu.research/files/docs/RIS/hipaa_sample_consent_form_auth_language.rtf)

3. Use/Disclosure without Individual Authorization

There are four situations where a covered health care entity may use or disclose protected health information for research purposes without obtaining written authorizations from individuals:

1. IRB waivers
2. Reviews preparatory to research
3. Research on a decedent’s information
4. Limited data sets

Although all UNH research involving protected health information requires UNH IRB review, only the first situation involves specific action and findings by the IRB. The regulations governing the other situations are enforced by administrative units in the covered health care entity although the UNH IRB also has to approve the research.

a. Documented Approval of Waiver by IRB

A covered health care entity may use or disclose an individual’s protected health information for research purposes without obtaining a written authorization if it obtains documentation that an IRB has waived the written authorization requirement or has approved a modified authorization [§164.512(i)(1)(i)]. This might be used, for example, to conduct records research when researchers are unable to use de-identified information and the research could not practicably be conducted if individuals’ authorization were required.

If a researcher requests a waiver of written authorization by subjects, the IRB has to make the following findings in order to approve the waiver request:

- A determination that the alteration or waiver of authorization, in whole or in part, satisfies the following criteria:
a. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(i) An adequate plan to protect the identifiers from improper use and disclosure;

(ii) An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(iii) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research which the use or disclosure of protected health information would be permitted by the Privacy Rule.

b. The research could not practicably be conducted without the waiver or alteration; and

c. The research could not practicably be conducted without access to and use of the protected health information [§164.512(i)(2)(ii)].

In addition to the above, documentation of IRB approval of an alteration or waiver of authorization provided to the covered health care entity must include all of the following:

• Identification of the IRB and the date on which the alteration or waiver of authorization was approved [§164.512(i)(2)(i)];

• A brief description of the protected health information for which use or access has been determined to be necessary by the IRB pursuant to paragraph §164.512(i)(2)(ii)(C) [§164.512(i)(2)(iii)].

• A statement that the alteration or waiver of authorization has been reviewed and approved under either expedited review procedures or at a convened meeting of the IRB [§164.512(i)(2)(iv)].

• The signature of the chair or other member, as designated by the Chair, of the IRB [§164.512(i)(2)(v)].

When submitting a research protocol that involves a request for waiver of individual authorization for the use or disclosure of protected health information to the IRB for review, the researcher should make sure that s/he clearly addresses the criteria (a-c) in the first bullet above.

b. Reviews Preparatory to Research

A covered health care entity may use protected health information or disclose it to a researcher without obtaining written authorization if it obtains representations from the researcher that:

• The use or disclosure of the protected health information is solely to prepare a
research protocol or for similar purposes preparatory to research;
• The researcher will not remove any protected health information from the covered entity; and
• Protected health information for which access is sought is necessary for the research [§164.512(i)(1)(ii)].

This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study. This exception does not allow for the electronic transfer of protected health information from a covered health care entity to a researcher’s office (ACE, 2002).

c. Research on Protected Health Information of Decedents
A covered health care entity may use protected health information or disclose it to a researcher without obtaining a written authorization if it obtains representations from the researcher that:

• The use or disclosure being sought is solely for research on the protected health information of decedents;
• The protected health information being sought is necessary for the research; and,
• At the request of the covered entity, documentation of the death of the individuals about whom information is being sought [§164.512(i)(1)(iii)].

d. Limited Data Sets with a Data Use Agreement
A covered health care entity may use or disclose protected health information without obtaining a written authorization if it enters into a data use agreement with the limited data set recipient. Pursuant to this agreement, the covered health care entity may disclose the limited data set to the researcher for research, public health, or health care operations [§164.514(e)(1)].

In order to qualify as a limited data set, the following direct identifiers of the individual or of relatives, employers, or household members of the individual must be excluded:

• Names;
• Postal address (other than town/city, state and zip code);
• Telephone and fax numbers;
• Email addresses;
• URLs and IP addresses;
• Social security numbers;
• Medical record and health plan beneficiary numbers;
• Account numbers;
• Certificate/license numbers;
• Vehicle identification and serial numbers;
• Device identifiers and serial numbers;
• Biometric identifiers including finger and voice prints; and
• Full face photographic images [§164.514(e)(2)].

The data use agreement that a researcher enters into must:

• Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or
disclosure that would violate the Privacy Rule if done by the covered entity;

- Establish who is permitted to use or receive the limited data set; and
- Require the recipient to agree to the following:
  - Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
  - Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
  - Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
  - Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
  - Not to identify the information or contact the individual [§164.514(e)(4)].

When submitting a research protocol to the IRB for review that involves a limited data set, the researcher should make sure that s/he includes the data use agreement.

Under the Privacy Rule, a covered health care entity may use and disclose protected health information created or received for research, either before or after April 14, 2003, if it obtained any one of the following prior to the compliance date:

- An authorization or other express legal permission from an individual to use or disclose protected health information for the research;
- The informed consent of the individual to participate in the research; or
- A waiver of informed consent by an IRB in accordance with the Common Rule or an exception under FDA’s human subject protection regulations.

If a waiver of informed consent was obtained prior to April 14, 2003, but informed consent is subsequently sought after the compliance date, the covered health care entity must obtain the individual’s authorization as required at §164.508.

The Privacy Rule allows covered health care entities to rely on such express legal permission, informed consent, or IRB-approved waiver of informed consent, created or received before April 14, 2003, to use and disclose protected health information for specific research studies, as well as for future unspecified research that may be included in such permission.

Researchers will have to get written authorization from any subjects recruited into a study on or after April 14, 2003 in order for a covered health care entity to disclose protected health information about the individual, unless the researcher obtains an IRB approval of waiver of authorization.
Section XIV
Special 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 subjects directly, the regulations require that researchers implement special safeguards, particularly with respect to informed consent.

A. Children

The most common special research population at UNH is 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 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 UNH IRB requires subject assent and parental consent for all studies, unless a waiver is requested by the researcher and granted by the IRB.

Additional requirements apply to some research involving children who are wards of the state.

Federal regulations (45 CFR 46.409) require additional protections for wards of the state who are involved in certain research studies. The IRB recommends that researchers who anticipate involving children in research who are residing at the State of New Hampshire’s John H. Sununu Youth Services Center (SYSC) facility in Manchester, at other residential treatment centers, or in foster homes consider them, for research purposes, as wards of the state. When wards of the state are to be involved in a research study, the IRB may require the appointment of an advocate for the wards. This applies particularly to studies that present more than minimal risk. This individual cannot be the child’s legal guardian or serving in loco parentis. The advocate also cannot be a member of the research team, although he or she does need to understand the research and must be able to represent the children’s interests in terms of the study. The advocate may be one person for an entire group, for example a group of foster children being
included in a research project or a group of children at SYSC. Individuals who might be considered for this role are professionals involved in children’s lives such as Court Appointed Special Advocate (CASA) volunteers and Guardians ad litem. There may be some circumstances where SYSC residents, youth in residential centers or foster children may not be wards of the state. If the researcher can provide sufficient documentation to the IRB to demonstrate legal guardianship of the child is held by someone other than the state, the appointment of an advocate in these cases is not required.

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 UNH, any study that recruits prisoners must be reviewed at the Full Board level. If the study was not initially approved to recruit prisoners, then a 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 her/his 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 her/his 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 nonprisoner 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 her/his 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 neurologic, 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 her/his 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, researchers 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 researchers want to use required class assignments (e.g., journal entries or evaluations) in his or her research. Course syllabi should clearly state that 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 students' grades. 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 administrative assistant keeps informed consent documents until after the course grades have been handed in).
Section XV

Conflicts of Interest in Research Involving Human Subjects

In the research environment, a conflict of interest exists when a researcher’s personal interests, such as career, reputation, or finances, inherently conflict with her/his professional obligations to honest, objective, and responsible conduct of research activities. Where personal interests affect the professional obligations in research activities, the integrity of the research may be compromised.

In most cases, personal interests or professional obligations by themselves do not raise ethical issues. The relationship between the interests and the obligations, however, may raise ethical concerns that need to be addressed.

The possibility that financial interests might affect the integrity of research and harm human subjects has resulted in federal and institutional regulations that mandate that such conflicts be identified and then managed, mitigated, or eliminated.

A. UNH Policy

Regulations (e.g., Public Health Service [PHS], National Science Foundation) exist governing financial conflicts of interest of researchers who apply for external funds to conduct research. UNH has two policies on financial conflict of interest in research to protect the integrity of externally-sponsored research and to comply with federal regulations. The purpose of these policies is to identify and eliminate or manage any possible threat to research objectivity at UNH and, where conflicts could affect the rights and welfare of human subjects in research, to identify and eliminate or manage the conflicts that could lead to the unethical treatment of research subjects.

The first UNH policy on financial conflict of interest in research applies to all research funded, or proposed for funding, by any external source except for the PHS and organizations that require compliance with the PHS financial conflict of interest in research regulations. Effective August 24, 2012, UNH has a second financial conflict of interest in research policy that applies specifically to research funded, or proposed for funding, by the PHS and other organizations that require compliance with the PHS financial conflict of interest in research regulations (see http://unh.edu/research/financial-conflicts-interest-research-projects-funded-public-health-service-phs for more information).

The UNH policies apply to individuals who are responsible for the design, conduct, or reporting of research activities (investigators) funded or proposed for funding by external sources. The UNH policies require that investigators disclose any significant financial interests prior to UNH submitting an application for external funds to support research.

B. Researchers

A researcher submitting a study to the IRB for review that is sponsored by external funds must initial a statement on the Request for IRB Review form that s/he:
• Has read and understands the applicable UNH policy on financial conflict of interest in research and will abide by its terms;
• Has made all required financial disclosures;
• As project director, has made every effort to ensure that all individuals responsible for the design, conduct, or reporting of the research have submitted the required disclosures; and
• Prior to the expenditure of award funds will have reached an agreement with UNH that provides for conditions or restrictions necessary to manage, reduce, or eliminate any conflicts of interest under UNH policy.

Researchers who have financial interests related to a study need to consider the potential effects that a financial relationship of any kind might have on the research or on interactions with research subjects, and what actions to take. Such actions might include:

• Including information in the informed consent document, such as the source of funding and funding arrangements for the conduct and review of research, or information about a financial arrangement of an institution or an research and how it is being managed.
• Using special measures to modify the informed consent process when a potential or actual financial conflict exists, such as having a another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.
• Using independent monitoring of the research.

C. IRB Review

If a researcher discloses financial interests for a study involving human subjects that would reasonably appear to be affected by the research, the IRB will work with the UNH Disclosure Review Committee during the review of the study to ensure that the financial interests do not compromise the rights and welfare of human subjects.
Section XVI

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 UNH policy or federal regulations governing such research. The IRB reviews all allegations of non-compliance according to human subjects 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 UNH researchers or a project conducted under the auspices of UNH. 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 according to the procedure outlined in the IRB Procedures Manual at Section XI, Serious or Continuing Non-Compliance with Regulations and/or IRB Requirements (Manual available at http://www.unh.edu/research/human-subjects).

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 IO 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 IO is the final authority as to the course of action taken by UNH 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, UNH's Assurance, or the UNH Policy on the Use of Human Subjects in Research, 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 IO, with or without a recommendation for specific action.

All recommendations for sanctions, correction, or educational measures, if any, are established by the IO, usually in consultation with the IRB. The IO also determines whether to refer the matter to another more appropriate process or authority within UNH for resolution (e.g., inquiry/investigation through the UNH Policy on Misconduct in Scholarly Activity).
Repeated or willful violations of federal laws and UNH policy regarding use of human subjects in research are an extremely serious matter. 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.

The IRB may temporarily or permanently suspend approval of a study at any time. This suspension may not be overridden by the IO or at any level at UNH (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 UNH. The IRB must report a study suspension promptly in writing to the IO and to OHRP.

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

- IO,
- Researcher’s Department Chair,
- Researcher’s Dean,
- Graduate School Dean (if appropriate),
- IRB Chairs and IOs of other institutions involved in the research (if appropriate),
- OHRP, and
- The funding agency (if appropriate).
Section XVI

Miscellaneous

A. Subject Compensation

Researchers are permitted to compensate research subjects in return for participation providing that such compensation is not coercive in the context of the study environment. Compensation should be a form of recognition for the investment of the subject's time, loss of wages, or other inconvenience incurred. Accordingly, compensation may not be withheld contingent on the subject's completion of the study. In most cases involving continued participation, compensation should be given on a reasonable prorated basis to avoid the impression that the researcher is coercing the subject to continue in a study or is punishing the subject for non-compliance.

The researcher should consider the appropriateness of payment methods in regard to confidentiality issues (e.g., providing a social security number to UNH Accounts Payable for payment by check for participation in a study in which subjects are offered confidentiality). While not an IRB requirement, the IRB encourages researchers to consult their Business Service Center Director to ensure that proposed compensation arrangements comply with federal tax regulations.

B. Subject Recruitment Materials

Researchers must submit all advertisements and subject recruitment materials to the IRB as part of their initial application. In advertisements and letters of recruitment, researchers must inform prospective subjects that participation is voluntary and researchers must not use coercive language. The information provided must also accurately reflect the nature of the protocol. Audio/video tapes used for recruitment must be reviewed and approved by the IRB.

The following are guidelines for designing a study advertisement or recruitment letter:

- Include the purpose of the study and/or briefly state what is expected of the subject, including the anticipated time commitment.
- Include the researcher's UNH department affiliation and where the research will take place.
- Include a contact name and phone number.
- Do not include the name of commercial sponsors or products.
- Avoid phrases such as "help needed." The recommended wording is "invited."
- If participants will be paid for their time/effort, it is recommended that the wording "Compensation Available" be used, rather than specifying a specific amount. Compensation should not be excessive to the nature of the project. If the researcher wishes to include a specific amount of compensation in an advertisement, the researcher should justify why this is needed in the application materials.

C. Guide Updates

This Guide will be reviewed and updated by the IRB as necessary or as appropriate to ensure fulfillment of institutional responsibilities under the existing Assurance, reflect changes in regulations, improve operational efficiency, or address other concerns that may arise. All changes will be reflected in a revised and dated version of this manual.