



University of New Hampshire

Institutional Review Board
for the Protection of Human Subjects
in Research

PROCEDURES MANUAL

Preface

This document was initially approved on May 10, 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 regulations and sets forth operating procedures required for implementing a program of human research subjects protections at UNH.

Nothing in this document 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>

TABLE OF CONTENTS

SECTION I	1
Definitions	1
SECTION II	2
Introduction	2
A. Summary.....	2
B. Purpose and Scope	3
C. Federal Regulations.....	4
D. Statement of Principles	4
SECTION III	6
Membership	6
SECTION IV	7
Oversight, Administration, and Responsibilities	7
A. University/Institutional Official	7
B. Director, Research Integrity Services.....	7
C. IRB Chair and Vice Chair	8
D. IRB Members.....	8
E. Designees.....	9
F. Researchers.....	9
G. Advisors	10
SECTION V	11
Operations	11
A. Study Submission.....	11
B. Meetings	11
C. Study Review.....	12
1. <i>Exempt Review Procedures</i>	12
2. <i>Expedited Review Procedures</i>	14
3. <i>Full Board Review at a Convened IRB Meeting</i>	16
4. <i>Criteria for Approval of Studies</i>	16
D. Recusal	17
E. Minutes	17
F. Special Consultants	17
G. Action by the IRB.....	17
H. Study Approval Period/Term.....	18
I. Notification of Review Results.....	18
J. Responses to IRB Reviews	18
K. Appeal Process.....	19
L. Continuing Review.....	19
M. Requests for Modifications to Previously Approved Studies.....	20
N. Information Provided To Members For Review.....	21
O. Recordkeeping Requirements	22
P. Confidentiality of IRB Records.....	22

SECTION VI	23
Informed Consent and Assent	23
A. Required Elements of Informed Consent.....	23
B. Altered or Waived Informed Consent.....	24
C. Documentation of Informed Consent.....	25
D. Waiver of Documentation of Informed Consent.....	25
E. Informed Consent for Non-English Speakers and Persons with Limited Literacy.....	26
SECTION VII	28
Confidentiality and Privacy	28
A. Federal Certificates of Confidentiality.....	28
B. New Hampshire State Law.....	29
C. Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.....	30
1. <i>Use of Authorizations</i>	31
2. <i>Waiver of Authorization</i>	32
3. <i>Transition Provisions</i>	35
SECTION VIII	36
Special Populations	36
A. Children.....	36
1. <i>Wards of the State</i>	36
B. Prisoners.....	37
C. Persons with Diminished Capacity to Consent.....	38
D. Women and Minorities.....	39
SECTION IX	40
Adverse Event Reporting	40
SECTION X	41
Conflicts of Interest in Research Involving Human Subjects	41
A. UNH Policy.....	41
B. Researchers.....	41
C. IRB Review.....	42
D. IRB Members.....	42
SECTION XI	43
Serious or Continuing Non-Compliance with Regulations and/or IRB Requirements	43
A. Initial Inquiry.....	43
B. Formal Investigation and Decision.....	44
C. Action Prior to Decision.....	45
D. Coordination with Other Investigative Processes.....	45
E. Confidentiality.....	45
F. Retaliation.....	45
G. Reporting Serious or Continuing Non-Compliance to DHHS.....	45
H. Suspension and Termination.....	45

SECTION XII	47
Departmental Review Committees	47
A. Process for Establishing a DRC.....	47
B. DRC Membership Requirements	47
C. Policies Governing DRC Operation	47
SECTION XIII.....	49
Instructional Activities and Student Studies.....	49
A. Instructional Activities	49
B. Student Studies.....	49
C. Students as Research Study Personnel for an Instructor-Researcher as Part of a Class Activity	50
SECTION XIV	51
Miscellaneous.....	51
A. Payments to Subjects.....	51
B. Review of DHHS Grant Proposals	51
C. Study Closure	51
D. Updating Procedures Manual	51

Section I

Definitions

45 CFR 46: Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects
(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>)

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

The Belmont Report: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report titled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*
(<http://www.hhs.gov/ohrp/policy/belmont.html>)

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 II

Introduction

A. Summary

This Manual sets forth the basic operational procedures of the University of New Hampshire (UNH) Institutional Review Board (IRB) for the Protection of Human Subjects in Research. These procedures ensure the IRB operates in accordance with applicable regulations and guidance issued by the federal government, the Office for Human Research Protections (OHRP), and other federal agencies. Federal regulations are complemented by applicable state or local laws that provide additional protection for human subjects.

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, as amended, and by other Federal agencies with appropriate jurisdiction. Additional requirements are imposed by the Food and Drug Administration (FDA) when Investigational New Drugs and Medical Devices are used in research.

At UNH, there is one IRB authorized under an Assurance approved by DHHS 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. UNH's policy 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.** This policy applies to all research activities sponsored by UNH; conducted by or under the direction of any employee, student, or agent of UNH in connection with his or her UNH responsibilities; 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.

All 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 subjects 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.
3. UNH Assurance.

Failure to submit research involving human subjects to the IRB for review prior to commencing is a violation of UNH policy. (See Section XI, Serious or Continuing Non-Compliance with Regulations and/or IRB Requirements.)

The IRB has the responsibility and authority to:

- Approve, disapprove, or require modifications in studies, based upon consideration of human subjects protections,

- Require progress reports from the researchers and oversee the conduct of the study,
- Suspend or terminate approval of a study, and
- Place restrictions on a study.

The IRB has authority through UNH's Assurance to interpret and apply federal, state, and local human subjects protections to UNH research studies. The procedures in this Manual are intended to be consistent with the referenced documents.

In certain UNH departments, Departmental Review Committees (DRCs) carry out limited review activities on behalf of the IRB. DRCs are authorized by the Institutional Official (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. DRC operational procedures are delineated in Section XII.

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.

B. Purpose and Scope

The primary purpose of the IRB is to protect the rights and welfare of human research subjects by ensuring that physical, psychological, legal, economic, 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 researchers with designing their studies so they are in compliance with federal and UNH requirements, thus researchers can receive approval and conduct the studies.

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

Human subjects are defined as "living individual(s) about whom a researcher (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information" [45 CFR 46.102(f)].

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. 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 the University'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.

Per federal regulations, the IRB cannot approve a research study ex post facto. Conducting research with human subjects at UNH without IRB approval is a violation of UNH policy, and accordingly, researchers conducting studies without IRB approval are subject to the procedures outlined in Section XI of this manual.

C. Federal Regulations

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 subjects protections regulations (Common Rule). Some federal agencies have regulations differing from DHHS Subparts B, C, and D protecting vulnerable populations.

The FDA has traditionally retained human subject protection regulations that vary from DHHS regulations. Research involving FDA regulated substances or devices falls under 21 CFR 50 for consent requirements and 21 CFR 56 for general IRB regulations. While the differences are not many, they are substantive.

D. Statement of 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.)

Section III

Membership

Federal regulations require an IRB to have a minimum of five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted at UNH (45 CFR 46.107). In addition to possessing the professional competence necessary to review specific research activities, the membership as a whole must include, at a minimum:

- At least one member whose primary concerns are in scientific areas, such as a physician or scientist,
- At least one member whose primary concerns are in nonscientific areas, such as a lawyer, ethicist, or member of the clergy, and
- At least one member unaffiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.

When the IRB reviews research involving prisoners as subjects, federal regulations require that at least one member who participates in the review of such research must be a prisoner or prisoner representative/advocate [45 CFR 46.304(b)].

IRB members are appointed formally in writing by the IO for three year terms. Members should be representative of the departments where UNH research involving human subjects commonly occurs, and, where possible, include both men and women and members of minority groups. The membership list is updated to reflect changes and submitted to OHRP as required. When a member goes on sabbatical or takes a leave of absence, the IRB may find a replacement. Replacements can either serve for the term of the original member's sabbatical or leave of absence, or complete the remainder of the original member's term, as determined by the IRB.

Members are expected to attend meetings regularly (at least 50% of scheduled IRB meetings), review carefully all materials provided in connection with IRB activities, participate actively in convened meetings, and participate in continuing education opportunities. Members are provided continuing education, with particular attention to changes in regulations and agency guidance.

New members must complete an orientation prior to beginning their duties, including, but not limited to, the purpose and functions of the IRB, pertinent federal regulations, and the study review process.

Members who wish to resign from the IRB must submit a formal written resignation addressed to the IO, stating the date the resignation is effective. The IO, in conjunction with the IRB Chair, will make every attempt to fill the vacancy promptly.

Removal of a member from the IRB requires documented and substantiated just cause that demonstrates the member to be unfit or unable to serve on the IRB. Just cause for removal may include, but is not limited to, lack of regular attendance at meetings, a finding of misconduct, or an unresolved conflict of interest. The decision to remove a member is made by the IO and a majority vote of the IRB membership.

Section IV

Oversight, Administration, and Responsibilities

A. University/Institutional Official

The IO is UNH's official point of contact with OHRP, and bears ultimate responsibility for ensuring UNH's compliance with federal regulations. UNH's President has designated the Senior Vice Provost for Research as the IO.

UNH is required to vest in the IRB those powers required by 45 CFR 46. Accordingly, the IRB may disapprove, discontinue, suspend, or limit approved activities at any time it is deemed in the interest of protecting the rights and welfare of human subjects. UNH administrators and/or the IO may not overturn decisions of the IRB regarding study disapproval, or conditions for approval; however, UNH administrators and/or the IO may overturn IRB approvals. (UNH administrators may withhold funds for studies.) When disapproving an IRB-approved study, the IO will inform the investigator and the IRB about her/his decision.

UNH, through the IO, will notify OHRP in writing promptly of serious or continuing noncompliance with the terms of its Assurance or 45 CFR 46, or of any serious adverse events involving risk to subjects.

UNH must provide resources to the IRB sufficient for the IRB to carry out its duties/responsibilities.

The IO oversees the activities of the IRB and appoints IRB and DRC members. Upon request, the IRB shall report its actions to the IO, and shall report other such information as may be required by applicable law or UNH policy.

Where research involving human subjects has been conducted without IRB approval, the IO, upon receipt of a written recommendation from the IRB Chair, shall be the final authority as to the course of action taken by UNH, including administration of sanctions (see Section XI).

B. Director, Research Integrity Services

The IRB shall be supported by adequate administrative staff, including a staff member to oversee and manage the operations of the IRB (IRB Administrator). Appropriate staff members may serve as ex officio or voting members of the IRB. The IO has delegated to the Director, Research Integrity Services (RIS), the responsibility to manage the systems for IRB review and approval of research, including

- Providing adequate staffing, support, and space,
- Instituting and updating IRB operating procedures in compliance with 45 CFR 46,
- Preparing minutes of IRB meetings,
- Communicating IRB actions to researchers,
- Communicating to the IRB and the IO any serious or continuing instances of noncompliance with regulations or IRB requirements, any injuries to subjects or other problems involving risks to subjects, and any suspensions or terminations of IRB approval,
- Providing study application assistance to researchers,

- Ensuring all necessary information on research with human subjects is widely disseminated and available throughout the UNH community,
- Educating the UNH community about UNH requirements and issues regarding human subjects in research, and
- Ensuring necessary reviews of grant applications are performed, and appropriate approvals are obtained prior to commencement of research studies.

C. IRB Chair and Vice Chair

The IRB operates with a Chair and a Vice Chair, recommended by a majority vote of the IRB membership, and formally appointed in writing by the IO. The Chair and Vice Chair should be experienced members of the IRB who are familiar with regulatory requirements, the design and conduct of human research studies, and ethical issues. The Chair may authorize the Vice Chair to act in her/his absence. The Chair and Vice Chair may, from time to time, delegate certain duties to other members of the IRB in accord with IRB practice. Chair and Vice Chair's duties identified in this Manual may therefore also be performed by other members designated by the Chair.

The IRB Chair is responsible for

- Convening and presiding at meetings,
- Reviewing and approving minor changes to Full Board studies as permitted by 45 CFR 46,
- Temporarily suspending research not in compliance with IRB guidelines, when necessary, prior to review by the Full Board,
- Informing the Director of RIS of serious or continuing noncompliance problems in IRB approved studies, any injuries to subjects or other problems involving risks to subjects, and any suspensions or terminations of IRB approval,
- Advising researchers on requirements regarding research with human subjects,
- Remaining informed of the latest changes in federal, state and local regulations and guidelines concerning ethical considerations involved in research using human subjects, and assisting IRB members in similar efforts,
- Developing policies and procedures to implement the federal regulations and the Assurance,
- Making recommendations to the IO for new member appointments,
- Reviewing covered research involving human subjects conducted without IRB approval and making recommendations to the IO as to an appropriate course of action (see Section XI), and
- Participating in developing, reviewing, and presenting educational opportunities for the UNH community on the use and protection of human subjects in research studies.

D. IRB Members

Voting members are appointed formally in writing by the IO and are named in the Assurance. New members are reported to OHRP. IRB members are responsible for

- Reviewing studies and evaluating them in terms of the criteria for approval (45 CFR 46), as well as in any other terms that appear relevant,
- Determining studies are in compliance with 45 CFR 46 and the terms of UNH's Assurance,
- Attending IRB meetings with a reasonable frequency,
- Entering into a process of discovery and discussion concerning the issues inherent in each study,

- Making recommendations for reducing risk and improving the informed consent process, and otherwise to improve human subject protections,
- Voting to approve or disapprove studies, or recommending modification in studies to enable approval,
- Recommending improvements in policies and procedures to improve the integrity and adequacy of human subject protections,
- Advising researchers on requirements regarding research with human subjects,
- Informing the Chair of noncompliance problems of which they become aware,
- Participating in continuing education on human subjects protections, and
- Participating in developing, reviewing, and presenting educational opportunities for the UNH community on the use and protection of human subjects in research.

E. Designees

The IRB can designate qualified non-voting members to perform certain activities on its behalf, such as signing correspondence or performing study reviews. Any action to make an individual an official designee of the IRB must be approved at a regularly convened meeting of the IRB, be recorded in the minutes, and describe any restrictions on activities to be performed.

F. Researchers

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

- Complying with all applicable provisions of UNH's Assurance, 45 CFR 46, and stipulations of the IRB,
- Gaining familiarity with and adhering to the ethical principles stated in *The Belmont Report*,
- Keeping co-researchers and all research staff informed about the nature and goals of the study, and the need to adhere to sound ethical practices,
- Acknowledging and accepting responsibility for protecting the rights and welfare of human subjects in their research study,
- Adhering to the approved study 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. All signed consent documents are to be retained by the researcher for at least 3 years after the end of the study,
- Requesting 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,
- 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, 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.

No researcher obligated by the provisions of the UNH Assurance shall 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 (see 45 CFR 46.116[f]). However, such activities cannot be counted as research nor the data used in support of research.

G. 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.

Section V

Operations

A. Study Submission

All research studies proposing to involve human subjects must be submitted to the IRB (through RIS) for review and approval. Studies under the jurisdiction of the IRB must be directed by a UNH faculty or staff member, or student. At its discretion, the IRB may make exceptions, for instance in the case of unpaid adjunct appointees, or where studies originating externally use UNH resources, but UNH employees do not help to direct the study. 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. Study applications are reviewed by the IRB on a first come, first served basis, and must be complete in order to qualify for review. This means that each study should contain the following:

- 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.

These documents may be supplemented by additional information that either the researcher believes to be important or the IRB requests for review purposes.

B. Meetings

Meetings are convened by the Chair at least twice a year. At UNH, the IRB typically meets biweekly during the academic year, and once a month in the summer. A schedule is publicized throughout the UNH community to facilitate timely review of studies, and is on-line at <http://unh.edu/research/irb-meeting-schedule>. An emergency meeting may be called by the Chair, as necessary, with 24 hours notice. A meeting is convened if requested by any two voting IRB members to consider a specified topic that cannot await a scheduled meeting.

A quorum (a majority of the voting members) is required for study approval, with a majority of those present voting to approve. Per federal regulations, the nonscientific member must be present in order for the IRB to vote on studies [45 CFR 46.108(b)]. Should the quorum fail during a meeting (e.g., those with conflicts being excused, early departures, loss of the nonscientific member), the meeting is terminated from further votes unless the quorum can be restored.

C. Study 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 to qualify for Exempt or Expedited review are reviewed 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. 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.

1. Exempt Review Procedures

According to 45 CFR 46.101, certain human research activities may be eligible for determination of Exempt review by the IRB. The Exempt review process may be appropriate for research involving no more than minimal risk. Minimal risk means that "*the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily living or during the performance of routine physical or psychological examinations or tests*" [45 CFR 46.102(i)]. At UNH, Exempt review consists of review by one voting IRB member or IRB-authorized designee.

RIS forwards studies to IRB members for review based on the reviewer's background and/or expertise. After ensuring the study application is complete, the IRB member determines whether the study meets the criteria for Exempt review, and if so, whether it is advisable to perform an Exempt review. S/he may perform such review or refer the review to a member more experienced in the field. If the study poses more than minimal risk, the study cannot be considered for Exempt review.

The reviewer may take any action that the Full Board may take except disapproval of the research study. Thus a reviewer may approve or require modifications in the study and/or consent form to secure approval, or defer action pending additional information. When a reviewer concludes that a study does not qualify for Exempt review, the research study must be referred to the IRB for Expedited or Full Board review.

Also, when members of vulnerable groups are in the study population, the study must be reviewed by the Full Board.

If the reviewer determines that the study qualifies for Exempt review, the reviewer returns the completed Exempt/Expedited Classification Sheet to RIS to issue formal written approval to the researcher.

A list of studies determined to be Exempt since the IRB's last convened meeting is provided to all IRB members for review and discussion at the next convened meeting, or by mail thereafter.

Research may be considered for Exempt status 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. §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. §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. §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. §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. §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. §46.101(b)(6)” (45 CFR 46.101).

Certain studies involving adults that qualify for Exempt review can not qualify for Exempt review when children are involved. (See Section VIII.)

Studies that are reviewed and approved at the Exempt level do not have to undergo continuing review (annual review) by the IRB.

2. Expedited Review Procedures

Per 45 CFR 46.110, certain research studies may not require review by the Full Board but may be considered for Expedited review by the Chair or one or more experienced reviewers designated by the Chair. Expedited review may be appropriate for research involving no more than minimal risk (45 CFR 46.110). At UNH, Expedited review is conducted by two voting IRB members.

RIS forwards studies to IRB members for review based on the reviewer's background and/or expertise. After ensuring the study application is complete, the IRB member determines whether the study meets the criteria for Expedited review, and if so, whether it is advisable to perform an Expedited review. S/he may perform such review or refer the review to a member more experienced in the field. If the study poses more than minimal risk, the study cannot be considered for Expedited review.

The reviewer may take any action that the Full Board may take except disapproval of the research study. Thus a reviewer may approve or require modifications in the study and/or consent form to secure approval, or defer action pending additional information. When a reviewer concludes that a study does not qualify for Expedited review, the research study must be referred to the IRB for Full Board review. Also, when members of vulnerable groups are in the study population, the study must be reviewed by the Full Board.

If the reviewer determines that the study qualifies for Expedited review, the reviewer returns the completed Exempt/Expedited Classification Sheet to RIS to issue formal written approval to the researcher.

A list of studies determined to be Expedited since the IRB's last convened meeting is provided to all IRB members for review and discussion at the next convened meeting, or by mail thereafter.

Categories of research eligible for expedited review are set forth in the Federal Register at 63 Fed. Reg. 60364-60367 (November 9, 1998), and 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, electroencephalography, thermography, detection of naturally-occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves). 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 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).

3. Full Board Review at a Convened IRB Meeting

Initial and continuing reviews of research studies determined not to qualify for Exempt or Expedited review are reviewed at a convened IRB meeting at which a quorum of the membership exists and the nonscientific member is present.

Studies requiring Full Board review should be received by RIS at least two weeks before the next scheduled IRB meeting. IRB members will not review studies they have not had sufficient time to consider.

Materials for each scheduled IRB meeting are provided to each IRB member approximately one week in advance of the meeting. Materials include:

- Minutes of the previous meeting,
- Studies to be reviewed at the meeting,
- Full Board-approved study continuing reviews,
- Pending modifications to Full Board-approved studies,
- A list of Expedited and Exempt study activity (approvals, continuing reviews, modifications) since the prior convened IRB meeting, and
- Other pertinent information (e.g., educational materials).

Discussion, comments, and questions during the meeting are encouraged. The Chair accepts motions to approve, approve with contingencies, table, or disapprove studies. Studies with contingencies can be approved either by the Full Board at a subsequent meeting, or assigned to a subcommittee of members named at the time of Full Board review (and recorded in the minutes) for approval. A majority of voting members present is required to approve motions. Any member with a potential conflict of interest must excuse her/himself from the room before the discussion of and vote on the research study takes place, except that the member may remain long enough to answer any questions regarding the study. The absence of the member is documented in the minutes. Absent members cannot count as part of the quorum.

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, and members with a potential conflict of interest, 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 a representative to contact an IRB member to discuss any issues arising from the IRB meeting.

4. Criteria for Approval of Studies

Studies will not be approved unless all of the following criteria are satisfied, unless specifically waived by the IRB and documented in writing in the study file (Exempt and Expedited reviews) or the meeting minutes (Full Board review):

- 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.

D. Recusal

An IRB member who has a potential conflict of interest as a researcher or as an interested party in a study (e.g., advisor to student or a thesis/dissertation committee member), or holds a financial interest in a study, is required to disclose the conflict prior to the study's review. In this event, the member may not take an active part in study review, except to provide requested information, and must abstain from the final discussion and vote.

E. Minutes

Minutes of IRB meetings are maintained in the IRB records in RIS in accord with 45 CFR 46.115.

Handwritten notes and tape recordings are not official meeting records, and may be destroyed after the minutes have been ratified by the IRB; such materials are available only to those developing the formal minutes.

Minutes must list members attending and summarize the business of the meeting, including a brief listing or discussion of issues raised for each study reviewed, and the vote outcome (number for, against, and abstaining). Names of members making and seconding motions and the numerical votes are recorded in the meeting minutes. Names of members abstaining from study reviews and/or voting due to potential conflicts of interest are recorded. (See D. Recusal above.) Minutes are not intended to be an exhaustive or verbatim record of the proceedings.

F. Special Consultants

The IRB may designate a consultant with special expertise to assist in the review of a particular study [45 CFR 46.107(f)]. The researcher is 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 the study.

G. Action by the IRB

The IRB may take the following actions with respect to a research 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 researcher, as determined by the IRB reviewers (Exempt and Expedited reviews) or an IRB subcommittee (Full Board reviews). If specific minor changes or clarifications are needed, a modified Full Board study can be

- approved without further review at a convened IRB meeting once satisfied by researcher.
- 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).

H. Study Approval Period/Term

Studies reviewed at the Expedited and Full Board levels are approved for a term not to exceed 365 days from the date of initial IRB approval, with or without comments and/or contingencies. The study approval period/term is based on factors related to the level of risk posed by the research. These 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. In establishing the approval period/term, the IRB may also review and consider the researcher's history of research and prior IRB reviews at UNH and other institutions.

I. Notification of Review Results

Researchers, research staff, and faculty advisors (where applicable) are notified in writing of the results of review. When the IRB requests modifications or tables studies, researchers are informed in writing of the reasons for the IRB's actions.

When a study is approved, the researcher is 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 s/he holds primary responsibility. In receiving IRB approval for the study, s/he agrees 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 Federalwide Assurance, and
- Requirement to report to the IRB within one working day any serious or unexpected adverse events.

J. Responses to IRB Reviews

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. Responses to tabled studies are reviewed by the IRB at the next scheduled meeting (if possible, depending on deadlines) if all required information is provided to the IRB in a timely manner. When the IRB approves a previously tabled study (with or without contingencies), the study approval date is the IRB meeting date when the study was approved, not at which the study was tabled.

The IRB may approve a study contingent upon specific major revisions to the study and/or consent forms. To secure approval, the researcher is asked 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 approves 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 (as stipulated by the IRB at the time of 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.

K. Appeal Process

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

L. Continuing Review

Federal regulations [45 CFR 46.109(e)] require the IRB 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 will document such a determination in the IRB meeting minutes. In determining review frequency, the IRB may also consider the participation of vulnerable populations and other pertinent factors. 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 per 45 CFR 46.110(8) or 45 CFR 46.110(9). To prompt timely review, RIS, on behalf of the IRB, sends to the researcher an Annual Continuing Review Questionnaire approximately 60 days prior to the study approval expiration date, as well as a reminder notice approximately 30 days later if no response is received from the researcher. Via the Annual Continuing Review Questionnaire, the researcher 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.

The Annual Continuing Review Questionnaire should be completed and returned to the IRB at least 30 days prior to the study approval expiration date. The IRB Chair or designee reviews the completed

Annual Continuing Review Questionnaire and reports, and routes them for Full Board or Expedited review, as appropriate.

The IRB may request verification from sources other than the researcher that no material changes have occurred since the initial or previous continuing review if,

- (i) the study is complex, involving unusual levels or types of risk to the subjects,
- (ii) the researcher has failed previously to comply with the IRB's requirements or 45 CFR 46, or
- (iii) there exist reasons to have concerns about possible material changes occurring without IRB approval.

If a completed Annual Continuing Review Questionnaire and/or progress report are/is not submitted and reviewed 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.

Continuing review must be substantive and meaningful. The IRB applies the same criteria for continuing approval as it does in the initial review (i.e., acceptable risks, potential benefits, informed consent, and safeguards for human subjects). The same rules for deferral and stipulation of revisions apply to continuing review as described above for initial review. During a continuing review, the IRB considers the information provided by the researcher on the Annual Continuing Review Questionnaire, the report of findings to date, and the current informed consent document (if applicable), as well as any other requested information, to determine whether to extend approval for another 365 days (or any other stipulated time period up to 365 days in length). As a product of their review, the IRB may request modifications to the consent form. For example, new findings that may relate to a subject's willingness to continue participation should be provided to the subject, and the subject offered the opportunity to withdraw or to continue by signing the revised consent document. As part of continuing review, the IRB has the authority to appoint one or more individuals (other than the researcher) to observe the consent process or the research, and to report any findings to the IRB. The IRB shall appoint such an individual whenever the IRB determines (based on information available such as adverse event reports, deficiencies noted in the IRB files, media or scholarly reports of research activity) that monitoring is in the best interests of subjects.

M. Requests for Modifications to Previously Approved Studies

The IRB informs researchers that they cannot implement any changes to the study without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects, via information included in approval letters, information and materials posted on the IRB webpage, and in training sessions.

Researchers 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). Required

information includes:

- 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).

Requests for modifications to studies are reviewed at the initial review level (i.e., modifications to Full Board-approved studies are reviewed by the IRB at a convened meeting). If the IRB Chair determines that a requested modification to a Full Board study is minor in nature and thus can be reviewed at the Expedited level [45 CFR 46.110(b)(2)], the Chair can review and approve the requested modification. Minor modifications to Full Board studies may include, but are not limited to, addition of questions and/or instruments not presenting any additional risk to subjects, addition of subjects (in already-approved populations), or addition of research sites.

Each revision to a research study should be incorporated into the study protocol to ensure that there is only one complete protocol in the file.

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 subjects.

N. Information Provided To Members For Review

Prior to a scheduled IRB meeting or review action, each IRB member is provided with a copy of, and an opportunity to review, the following minimum information submitted by researchers or generated by IRB administrators:

1. Initial Review
 - Application
 - Proposed recruitment materials (letters, advertisements, postings, e-mail announcements, etc.)
 - Detailed study protocol
 - Proposed informed consent document(s)
2. Continuing Review
 - Completed Annual Continuing Review Questionnaire
 - Report of findings-to-date
 - Request for modification (if applicable)
 - Copy of the current informed consent form
 - Original study
3. Adverse Events
 - Written description of the adverse event(s), signed by the researcher
 - Revised consent form and revised study (if applicable), with rationale for changes

4. Requests for Modifications to a Previously-Approved Active Study
 - Detailed description of proposed changes, including rationale
 - Revised consent form (if applicable)

O. Recordkeeping Requirements

The IRB maintains records of its activities for at least three years after completion of the research and closure of the study. The records are available for inspection and copying by OHRP, other federal or state government agencies, or sponsors in the course of carrying out their respective duties. The following records are maintained:

- IRB Membership,
- Written policies and procedures, forms and other instructions,
- Meeting minutes that include: (i) members present, (ii) summary of discussion on study-related issues, (iii) actions taken by the IRB and the basis for those actions, (iv) record of voting (for, against, abstentions), on each agenda item, and (v) the time the meeting began and ended, and
- Copies of research studies reviewed, approved sample consent documents, continuing review progress reports, amendments to research studies, adverse event reports as well as any correspondence between the IRB and researchers.

Where federal regulations require specific findings on the part of the IRB, these findings are fully documented in the IRB minutes, including study-specific information justifying each IRB finding. Required documented findings include the following:

- Basis for approving a procedure which alters or waives the requirements for informed consent,
- Basis for approving a procedure which waives the requirement for obtaining a signed consent form,
- Basis for approving research involving prisoners, and
- Basis for approving research involving children

P. Confidentiality of IRB Records

The IRB maintains records of its activities, including records that document the review process, and research studies. IRB records and copies of research studies are confidential to the extent permitted by UNH policy, and local, state, and federal laws. However, these records are available for inspection and copying by OHRP, other federal or state government agencies, sponsors, or the IO in the course of carrying out their respective duties.

Section VI

Informed Consent and Assent

Informed consent must be an ongoing PROCESS. It involves a thorough oral briefing of each potential subject by the researcher, including all informed consent elements per 45 CFR 46.116, especially a discussion of any potential risks and potential loss of privacy; efforts to ensure that each subject has fully understood what s/he agrees to and has had all questions answered; and subject 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. Signature on a consent form does not by itself constitute informed consent.

Prior to admitting a subject into a research study, a researcher must obtain the informed consent of the individual involved. (See <http://unh.edu/research/human-subjects> for consent document templates.) 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).

Obtaining informed consent from special populations such as children and individuals with diminished capacity to consent may require additional procedures. (See Section VIII.) In addition to parental permission, assent is to be sought from minors in a manner commensurate with their maturity and ability to understand and to use language. (See UNH IRB document, *Child Assent Guidelines* available at <http://unh.edu/research/irb-application-resources>.) A minor may not be entered into a study without giving assent. The IRB recognizes foster parents as having the authority to enter children in their care into studies.

It is the IRB's responsibility to review proposed informed consent procedures to be used for all research involving human subjects. The informed consent requirements in this Manual, however, are not intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable laws and regulations [45 CFR 46.116(f)].

A. Required Elements of Informed Consent

In reviewing for approval an informed consent procedure, the IRB must first determine that the information to be provided to the subject or the subject's representative is in language understandable to the subject or representative. No informed consent procedure may contain any exculpatory language through which the subject or the 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 approving an informed consent procedure, the IRB must determine that the procedure provides adequate information to the subject or representative on the following basic elements of informed consent:

- 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.

When appropriate, the IRB will also consider whether the following additional elements of informed consent are adequately provided 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.

B. Altered or Waived Informed Consent

The IRB may approve a consent procedure that omits or alters some or all informed consent elements. Per 45 CFR 46, the IRB may alter or waive the requirement to obtain informed consent only if the IRB finds and documents in the IRB's file for the study (Expedited review) or the IRB meeting minutes (Full Board review) that:

- "(1) The research or demonstration study is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
- (i) Public benefit of 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, and
- (2) The research could not practicably be carried out without the waiver or alteration" [45 CFR 46.116 (c)].

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- “(i) The research involves no more than minimal risk to the subjects; and
- (ii) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (iii) The research could not practicably be carried out without the waiver or alteration; and
- (iv) Whenever appropriate, the subjects will be provided with additional pertinent information after participation” [45 CFR 46.116(d)].

C. Documentation of Informed Consent

Except as provided below, informed consent must be documented via a written consent form approved by the IRB and signed by the subject or representative. The researcher must provide a copy to the person signing the form. Signed informed consent forms must be kept in a secure location by the researcher for a minimum of three (3) years (or more if required by the FDA or sponsor of the research) following completion of the research.

Per 45 CFR 46, the IRB may approve informed consent documents that are either of the following:

- “(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
- (2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form” (45 CFR 46.117).

D. Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the researcher to obtain a signed consent form for some or all subjects if the IRB finds and documents in the IRB's file for the study (Expedited review) or the IRB meeting minutes (Full Board review) either that

- “(1) 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. Each subject will be asked whether s/he wants documentation linking her/him to the research,

and the subject's wishes will govern; or

- (2) 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" [45 CFR 46.117(c)].

For cases in which the documentation requirement is waived, the IRB may require the researcher to provide subjects with a written statement regarding the research.

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

Special issues arise where (1) subjects do not speak or read English, and (2) where the subject's native language is not written.

In the case where subjects do not speak or read English, informed consent information must be presented "in language understandable to the subject" (45 CFR 46.116), and in writing. Whenever possible, documents should be written in the subject's preferred language and such that all the elements necessary for legally effective informed consent are presented. Where an oral presentation of informed consent information is used with subjects who do not speak or read English,

- The oral presentation and the short form written document should be in a language readily understandable to subjects, and
- The English-language informed consent document approved by the IRB may serve as the summary.

At the time of consent

- (i) The short form document should be signed by the subject (or the subject's legally authorized representative),
- (ii) The summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized in the study, and
- (iii) The short form document and the summary should be signed by the witness.

When the person obtaining consent is assisted by a translator, the translator may serve as the witness to the consent process. The researcher must submit to the IRB for review all foreign language versions of the short form document and any other translated documents presented to subjects. The IRB may review these documents with outside experts to ensure that translation is appropriate. Expedited review of these versions is acceptable if the study, the full English language informed consent document, and the English version of the short form document have already been approved by the Full Board.

As some of the world's languages are not written, the IRB may review research involving subjects whose native language is only spoken. In these cases, informed consent information must be presented "in language understandable to the subject" (45 CFR 46.116). When an oral presentation of informed consent information is used with subjects whose native language is not written,

- (i) The oral presentation should be in a language readily understandable to subjects, and
- (ii) The English-language informed consent document approved by the IRB may serve as the summary.

At the time of consent, the IRB may also require that:

- The summary (i.e. the English language informed consent document) should be signed by the person obtaining consent as authorized in the study, and
- The summary should be signed by the witness.

When the person obtaining consent is assisted by a translator, the translator may serve as the witness to the consent process. The researcher must submit to the IRB for review all English language versions of information presented to subjects.

Section VII

Confidentiality and Privacy

Whenever there is no compelling reason to protect the identity of study participants, the IRB will consider whether a study need be anonymous or confidential. The researcher must document in the study precautions to protect confidentiality in confidential studies, and the consent form must define any limitations on confidentiality.

When reviewing a research study, the IRB reviewer should consider the possibility that research may invade the privacy of individuals or a breach of confidentiality may occur. Under certain circumstances, an invasion of privacy or breach of confidentiality may present a 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. It is the responsibility of the researcher to be sensitive to privacy and confidentiality issues, and to consider them when designing the study.

Researchers cannot guarantee absolute confidentiality to subjects, either verbally or in consent forms. Prospective participants 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 B. New Hampshire State Law.)

The IRB carefully reviews researchers' recruitment procedures to ensure protection of individuals' privacy. The IRB may require researchers to increase or decrease the level of intervention prior to contacting potential participants depending on the nature of the information to be obtained.

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:

- 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.
- 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.
- 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.
- 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, the IRB requires researchers to inform potential participants about the researcher's reporting responsibilities and the associated risks to participants. When reviewing a research study and accompanying informed consent document(s), the IRB assesses how well a researcher clearly outlines specific situations wherein s/he is 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

Through the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 160 and 164), effective April 14, 2003, a covered health care entity¹ must obtain written authorization from individuals in order to use² or disclose³ their protected health information⁴ for research

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 Disclose is defined as “the release, transfer, provision of access to, or divulging in any other manner information outside the entity holding the 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;
- Full face photographic images and any comparable images; and,
- Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section” [164.514(b)(2)(i)].

purposes. As research involving protected health information qualifies as human subjects research, such research conducted by UNH agents must be reviewed and approved by the IRB prior to commencing.

In order for researchers to access and use protected health information that is maintained by covered health care entities, in most situations researchers will have to either get a 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). The authorization requirement is in addition to informed consent requirements. In certain situations, such as when conducting research on protected health information of decedents, although researchers do not have to obtain written authorization, they have to comply with other regulatory requirements.

1. Use of Authorizations

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/herself in writing. Although IRBs do not have to approve authorization documents, IRBs should review authorization language that is incorporated into the consent form. Although there are important differences between the Privacy Rule's requirements for individual authorization and the Common Rule's requirements for informed consent, both sets of requirements can be incorporated into a single form (permitted by the Privacy Rule). When required to obtain authorization from subjects for use or disclosure of protected health information, researchers may:

- Use a consent form that includes the required authorization language. In this case, the IRB will review the authorization language as part of the consent form.
- Use separate consent and authorization documents. In this case, the IRB does not review the authorization form.

Authorizations are required to be study-specific and in order to be valid must 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 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 gathered 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 disclosure of her/his protected health information.

2. Waiver of Authorization

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

- i. IRB waivers
- ii. Reviews preparatory to research
- iii. Research on a decedent's information
- iv. De-identified information and 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 other administrative units in the covered health care entity although the UNH IRB will also have to approve the research.

i. 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)]. If a researcher requests a waiver of authorization by subjects, the IRB has to make the following findings in order to approve the waiver request.

- A. The use or disclosure of protected health information involves no more than 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, the documentation of IRB alteration or waiver of authorization must include the following:

- Identification of the IRB/Privacy Board 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/Privacy Board 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 or the Privacy Board [§164.512(i)(2)(v)].

ii. Reviews Preparatory to Research

A covered health care entity may use or disclose protected health information 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).

iii. Research on Protected Health Information of Decedents

A covered health care entity may use or disclose protected health information 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)].

iv. 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 which the covered health care entity may disclose a 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 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
 - ✚ 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)].

3. Transition Provisions

Under the Privacy Rule, a covered health care entity may use and disclose protected health information that was created or received for research, either before or after the compliance date, if the covered health care entity 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 the compliance date 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 entities to rely on such express legal permission, informed consent, or IRB-approved waiver of informed consent, which they create or receive before the applicable compliance date, 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 obtain written authorization from any subjects recruited into a study after the compliance deadline in order for covered health care entities to disclose protected health information, unless an IRB approves a waiver of authorization.

Section VIII

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 the subjects directly, the regulations require special safeguards, particularly with respect to informed consent. The specific requirements for these special populations must be reviewed by the IRB whenever subjects from these populations are proposed to be involved in a study. Applicable regulations are available through RIS.

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. Special considerations that apply to children are:

- Exempt review - Research involving survey or interview procedures or observation of public behavior with children cannot qualify for Exempt review, except for research involving observations of public behavior when the researcher(s) do not participate in the activities being observed.
- Consent and Assent - Where children are subjects, the study 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. Per 45 CFR 46.409, additional requirements apply to some research involving children who are wards of the state.

1. 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

"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)]. Special issues that apply to prisoners are

- Composition of IRB - At least one member of the IRB must be a prisoner or prisoner representative who participates in the review of the study. A majority of the IRB members must have no association with the prison or other facility as defined above.
- Review level – All research involving prisoners must be reviewed by the Full Board.
- Permissible Research - The IRB must find and document that the research is within a permissible category under 45 CFR 46.306(a)(2) as follows:
 - 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.
- Additional Findings - In reviewing the study, per 45 CFR 46.305 the IRB must make and document in the meeting minutes the following determinations:
 - 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

Where research is conducted using human subjects who suffer from conditions, whether temporary or permanent, that may diminish their capacity to consent to participate, additional protections are needed. 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.

Section IX

Adverse Event Reporting

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. Adverse events must be reported to the IRB whether or not the researcher believes the events to be caused by the study. The researcher should report any measures taken for the benefit of the 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. The IRB requires 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 will evaluate each adverse event report and determine whether further action is needed beyond that taken by the researcher. Upon receipt of an adverse event report, the Chair or designee decides if urgent action is necessary to eliminate apparent immediate hazards to the human subjects, including, but not limited to, the following:

- 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 the study, or
- Temporarily suspending enrollment of new subjects in the study, and/or discontinuing the study procedures because, based on the information available, the risk benefit ratio appears to be unfavorable to the subjects.

The Chair will discuss adverse event reports (and actions taken by the Chair or her/his designee upon receipt of the adverse event report) at the next convened IRB meeting. The IRB shall determine appropriate action in response to the report, including one or more of the following:

- 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.

The IRB will give written notice of any action taken to the researcher and IO, including reasons for that action, 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 IRB is required to report to the IO and the appropriate federal department or agency "any unanticipated problems involving risks to subjects or others" (UNH Assurance, 1997, Part 2, III, J. 1.). If the research study is suspended or terminated, additional notice will be provided. (See Section XI.)

Section X

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 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](http://unh.edu/research/financial-conflicts-interest-research-projects-funded-public-health-service-phs) applies to all research funded, or proposed for funding, by any external source except for the PHS and organization that require compliance with the PHS financial conflict of interest in research regulations. Effective August 24, 2012, UNH has a financial conflict of interest 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 in a study should 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 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. In reviewing such disclosures, the IRB may consider the following actions:

- Determining whether methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.
- Determining whether other actions are necessary to minimize risks to subjects.
- Determining the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

D. IRB Members

IRB members who have a potential conflict of interest as a researcher or as an interested party in a study (e.g., advisor to student or a thesis/dissertation committee member), or hold a financial interest in a study, are required to disclose the conflicts prior to the study's review. In these events, the members may not take an active part in study review, except to provide requested information, and must abstain from the final discussion and vote.

Section XI

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:

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

A. Initial Inquiry

Whenever a non-compliance allegation or complaint is made in regard to an IRB-approved study, the Chair will either investigate the allegation or refer the investigation to another IRB member with appropriate expertise. The Chair also will send written notice of the allegation to the researcher and request a response. The Chair (or designated member) will review the allegation of non-compliance, the researcher's response, and any other information necessary to determine whether a full investigation is warranted. At the conclusion of her/his inquiry, the Chair (or designated member) will report findings to the IRB and the IO. Findings will address:

- Substance of the allegation or complaint,
- 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 these procedures (e.g., informed consent),
- Where the allegation or complaint appears founded and is serious, whether a formal IRB investigation is warranted, and,
- Recommendations, if any, for corrective action.

Recommendations for sanctions, correction, or educational measures will be established by the IO in consultation with the IRB. The IO will also determine 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), or for formal investigation by the IRB.

In consultation with the IO, the IRB will act promptly upon the Chair's or designated member's recommendations and notify the researcher in writing of the inquiry outcome, including a statement of the reasons for the IRB's decision. Depending on the nature of the allegations and the extent of the review required, the inquiry phase is generally completed within thirty days of receipt of the allegation of non-compliance. The IRB may extend this time frame if warranted.

In cases where non-compliance involves human subjects research conducted without prior IRB approval, the Chair will review 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 will then make 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 shall be the final authority as to the course of action taken by UNH on the matter.

B. Formal Investigation and Decision

For allegations of non-compliance in IRB-approved studies, the IO, in consultation with the IRB, may decide to conduct a formal investigation when s/he determines that an allegation appears founded and is serious. The investigation normally is conducted by an ad hoc panel of two IRB members and the Chair (or designated member). Panel members are IRB members whose areas of expertise are suited to reviewing the complaint and area of study. The panel may use any and all materials and reports gathered during the initial inquiry phase, may obtain documents and other records relevant to the investigation, and may interview any persons who may have relevant information. The individual under investigation will be given an opportunity to submit written comments and to appear before the panel on at least one occasion prior to the panel issuing its report. Based on its investigation, the panel prepares a report summarizing the information considered and outlining its conclusions and recommended actions. The panel sends the report to the IRB and to the IO. The investigation phase is expected to be completed within 60 working days, but this may vary depending on the case.

In reaching a decision, the IRB will consider the panel's report and any comments submitted by the researcher. Actions the IRB may take include, but are not limited to the following:

- Dismissal of the complaint as unjustified,
- Monitoring of future activities by the researcher in the study at issue,
- Increased reporting requirements for the researcher of her/his human subjects research activities in the study at issue,
- Restrictions on research practice, such as limiting the privilege to conduct research involving human subjects to minimal risk or supervised studies,
- Suspension of approval for one or more of the researcher's studies,
- Termination of approval for one or more of the researcher's studies, or
- Referral to other UNH administrators/committees for possible further review and action.

The IRB sends a copy of its decision to the researcher and the IO. If IRB approval is suspended or terminated, additional notice is provided. (See H. Suspension and Termination below.) The IO decides upon and administers any sanctions warranted for non-compliance with human subjects protections regulations.

C. Action Prior to Decision

At any time during the inquiry or investigation processes, the IRB may determine that it is necessary to suspend recruitment or engagement of research subjects. Except in cases of imminent harm to research subjects or others, the IRB will not suspend approval of research studies until the researcher has had an opportunity to respond satisfactorily to the initial allegation of non-compliance. Notice of suspension or termination is provided. (See H. Suspension and Termination below.)

D. Coordination with Other Investigative Processes

Some complicated cases require review by other institutional or external authorities. The IRB cooperates in the review of allegations of conflicts of interest, misconduct in scholarly activity, financial mismanagement, FDA inspections, etc. In cases that appear to involve academic misconduct, the IRB may report allegations of such misconduct to the appropriate UNH administrator(s). Where academic misconduct and IRB investigations are pending against the same researcher, the IRB will coordinate its activities closely with others to avoid duplication of effort and to minimize competing use of resources.

E. Confidentiality

Consistent with applicable UNH policies, the Chair determines whether the identity of those persons making allegations should be provided to the researcher being reviewed.

F. Retaliation

The IO will assist the IRB in protecting complainants from retaliatory actions.

G. Reporting Serious or Continuing Non-Compliance to DHHS

The IRB is required to provide written reports promptly to the IO, OHRP, and other appropriate federal departments or agencies of any serious or continuing noncompliance with the regulations governing the protection of human subjects or the requirements or determinations of the IRB.

H. Suspension and Termination

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.

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. The IO may then determine appropriate sanctions.

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. A study suspension must be reported 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 XII

Departmental Review Committees

Deriving its authority from the IRB, a Department Review Committee (DRC) facilitates the IRB's responsibility for protecting human subjects by reviewing minimal risk research studies generated within a department. Such authority, when granted, extends only to studies classified as Exempt per 45 CFR 46.101. Permission to form a DRC should not be construed as a lessening of IRB authority or responsibility as delineated in UNH's Assurance and federal regulations.

The IO permits formation of a DRC upon the positive recommendation of the IRB. The IRB recommends the formation of a new DRC when:

- There is evidence of substantial activity in human subjects review in the department requesting the DRC,
- It is clear that a DRC would facilitate the timely review of Exempt research studies, and
- The IRB is confident that the requesting department would have sufficient staffing, and its DRC members would have sufficient expertise and seniority to manage human subjects review in accordance with UNH policy and federal regulations.

A. Process for Establishing a DRC

1. A request to establish a new DRC is made by the Department Chair to the IRB Chair, and includes:
 - The reason for the request, and
 - A list of faculty members who would serve on the DRC, including a brief summary of their qualifications to review human subject research studies.
2. The IRB will review the request at a regularly convened IRB meeting.
3. Upon a positive recommendation by the IRB, the request is forwarded to the IO.

B. DRC Membership Requirements

1. An approved DRC consists of three (3) faculty members with rank of at least Assistant Professor.
2. The Department Chair presents DRC nominees to the IRB for recommendation to the IO for appointment terms of no longer than three (3) years. (Appointment terms may be renewed.)
3. The Department Chair presents changes in DRC membership to the IRB for recommendation to the IO.
4. Following approval of DRC membership by the IRB, DRC members receive an orientation from the IRB and participate in continuing education as stipulated by UNH policy and federal regulations.

C. Policies Governing DRC Operation

1. DRCs may review a study to determine if the study meets the criteria for Exempt status. If the study meets the criteria as outlined in 45 CFR 46.101, DRCs may grant approval for the use of human subjects in the proposed study. If a study does not meet requirements for Exempt status,

and/or the DRC raises doubts about a study's Exempt status, the study must be forwarded to the IRB for review.

2. DRCs may not approve the following (and must forward such studies to the IRB for action):
 - Research studies involving children, prisoners, pregnant women, or other vulnerable populations,
 - Research studies for students or faculty that originate outside the department,
 - Research studies for sponsored studies (especially those that require sponsor verification of human subjects approval),
 - Research studies for which there exists any ambiguity about the appropriate classification,
 - Research studies that have already been conducted prior to the request for DRC review (i.e., post-hoc requests for approval), or
 - Research studies originally approved by the IRB at the Expedited or Full Board review levels.
3. DRCs shall maintain written records of all actions, minimally, the *Exemption Classification Sheet*, the proposed study title, researcher(s) name(s), statement of risk to human subjects and action taken.
4. An IRB member designated by the IRB is assigned to review each DRC's actions each semester to ensure compliance with UNH's Assurance and federal regulations.
5. The IRB reviews each DRC's activity annually, at minimum, as a prerequisite to renewing that DRC's mandate. The IRB reserves the right to recommend to the IO removal of any DRC mandate any time.
6. Actions and information issuing from the IRB to the DRC are addressed to the Department Chair.

Section XIII

Instructional Activities and Student Studies

A. Instructional Activities

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

B. Student Studies

As students progress through their academic programs they may engage in research activities. Student research conducted within an academic course usually falls within one of two broad categories: academic inquiry, or research for dissemination (contribution to generalizable knowledge).

Academic inquiry customarily involves data collection and interpretation to acquaint students with particular methodologies, paradigms or general pedagogy. Inquiry is limited to the single course environment. That is, data are not disseminated beyond the classroom, are not the basis for nor do they contribute to other studies, and the inquiry is not designed to contribute to generalizable knowledge (the advancement of a particular discipline). The purpose of the activity is for the specific edification of the student.

Research for dissemination often involves data collection and interpretation with the goal of presenting findings to an audience beyond the classroom. It may be the foundation or part of other research, and may well contribute to generalizable knowledge. Examples of dissemination beyond the classroom might include presentation at a conference or poster session, publication in a journal or other resource, or presentation of the research data for funding of further research.

If students engage in research for dissemination, the class instructor should forward the studies to the IRB (or DRC if one is established in the instructor's department) for review. The IRB/DRC will review the studies according to the procedures set forth in this Manual. (Any student research studies reviewed by a DRC that represent greater than minimal risk to subjects, i.e., not qualifying for Exempt review, must be forwarded to the IRB for Expedited or Full Board review.) The instructor must receive written approval from the IRB/DRC before allowing student research studies to commence.

When students engage in research activities, the class instructor should discuss the responsible conduct of research using human subjects and the IRB Request for Review form, as related 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 IX.)

C. Students as Research Study Personnel for an Instructor-Researcher as Part of a Class Activity

On occasion, 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. In such cases, 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 XIV

Miscellaneous

A. Payments to Subjects

The IRB may permit payments to research subjects in return for participation, providing that such payments are not coercive in the context of the study environment. The IRB will offer guidance to the researcher regarding payment method (i.e., cash versus check) if the method poses risk to the subject as a study participant (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 will encourage researchers to consult their Business Service Center Director to ensure that proposed compensation arrangements comply with federal tax regulations.

B. Review of DHHS Grant Proposals

Per 45 CFR 46, the IRB is required to review grant proposals 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 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.

C. Study Closure

A closure report is required on all studies approved by the IRB. The report must address the same information required for continuing approval. A study cannot be considered for closure by the IRB until data collection is complete, and data analysis and interpretation have been concluded.

D. Updating Procedures Manual

This Manual will be reviewed and updated by the IRB periodically, as necessary or 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.