



UNIVERSITY OF  
SOUTHERN MAINE

# **The University of Southern Maine Policies, Procedures and Guidance For Human Subjects Research**

***Office of the Provost and Vice President  
for Academic Affairs***

***University of Southern Maine  
Institutional Review Board***

***Office of Research Compliance***

Revised: 2007

Original Approval Date: December 10, 2001

IRB Registration # IRB00001953  
FederalWide Assurance # 00001748

# CONTENTS

<b>I. INTRODUCTION</b>	<b>4</b>
<i>A. Ethical Principles Governing Human Subjects Research</i>	4
1. Respect for Persons	4
2. Beneficence	4
3. Justice	5
<i>B. Purpose</i>	5
<i>C. Scope</i>	5
<i>D. Applicability</i>	5
<i>E. Assurance</i>	6
<i>F. Definitions and Operational Concepts</i>	7
<b>II. THE INSTITUTIONAL REVIEW BOARD (IRB)</b>	<b>12</b>
<i>A. The Role of the IRB</i>	13
<i>B. Institutional Review Board Responsibilities</i>	13
<i>C. IRB Authorized Powers</i>	15
<i>D. Categories of Review</i>	16
<i>E. Withdrawal or Termination of Research</i>	21
<i>F. Foreign Research</i>	21
<i>G. Collaborative Research</i>	21
<i>H. Application Requirements for Research Involving Human Subjects</i>	22
1. Contents of the Research Proposal Summary:	22
<i>I. Informed Consent: General Requirements</i>	22
<i>J. Informed Consent in Vulnerable Populations</i>	24
1. Research Involving Minors (subjects under 18 years of age)	24
2. Research Involving Subjects with a Diminished Capacity to Consent	25
3. Research Involving Experimental Biological or Behavioral Interventions	25
4. Research Involving Pregnant Women, Fetuses and Products of Labor and Delivery	26
5. Research Involving Non-English Speaking Populations	26
6. Research Involving Prisoner Populations	27
7. Research Involving University of Southern Maine Students	29
8. Use of Specimens for Future Research	29
<i>K. Documentation of Informed Consent</i>	29
1. Written Consent Forms:	29
2. Full Form Written:	30
3. Short Form – Written (Oral Summary):	30
4. Alteration or Waiver of Informed Consent Requirements	30

<i>L. IRB Procedure for Protocol Violations</i>	31
<i>M. Procedure for Adverse Research Events</i>	34
<i>N. IRB Membership</i>	35
1. Board Composition	35
2. Appointment to the IRB	35
3. Chairperson	36
4. Vice Chairperson	36
5. Membership Terms and Voting Rights	36
a) General Members	36
b) Chairperson	36
6. General Member Responsibilities and Obligations	37
7. IRB Member Education	37
8. IRB Registration with the Department of Health and Human Services (DHHS)	37
9. Termination of Membership	37
a) Voluntary	37
b) Involuntary	38
<i>O. IRB Meetings</i>	38
<i>P. Meeting Minutes</i>	38
<i>Q. IRB Policy Updates, Changes and Additions</i>	39
1. Strict regulatory/statutory requirements	39
2. Discretionary Regulatory/Statutory Requirements	39
3. Emergency Changes	40
4. All Other Requirements	40
<b>III. The Office of Research Compliance</b>	<b>40</b>
<i>A. Administrative Support</i>	40
<i>B. Record Keeping, File Retention and File Destruction</i>	41
<i>C. ORC Granted Powers</i>	41
<i>D. IRB Annual Report</i>	42
<i>E. Human Protections Administrator (HPA)</i>	42
<i>F. Complaints, Adverse Events, Privacy Breaches and Allegations of Research Misconduct</i>	42

## I. INTRODUCTION

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

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

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

### A. Ethical Principles Governing Human Subjects Research

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

#### 1. Respect for Persons

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

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

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

#### 2. Beneficence

This guiding principle requires that researchers maximize the potential benefits to the participants or to society, while minimizing the potential risks of harm. The extent of protection depends on the risks and benefits of the proposed research to the participants and to society. All participants should be treated in an ethical manner. Ideally, direct benefits to the subjects should always outweigh the risks of participating in the research. At a minimum, proposed research must present sufficient benefits to society at large to outweigh the risks the research presents to the research participants.

### 3. Justice

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

## B. Purpose

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

## C. Scope

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

1. Sponsored by the University of Southern Maine (USM);
2. Conducted by or under the direction of any employee or agent of USM, including any faculty, staff or administration members, and students, in connection with their responsibilities;
3. Conducted by or under the direction of any employee or agent of USM, including any faculty, staff or administration members, and students, using any property or facility of this University;
4. Involving the use of USM's non-public information to identify or contact human research subjects or prospective subjects;
5. Conducted by students and includes, but is not limited to:
  - a) Student classroom projects involving human subjects or information protected under other applicable laws (such as HIPAA);
  - b) Graduate level thesis, dissertation, capstone project; or
  - c) Any project that would normally be treated as reviewable research in a non-class setting.
6. Presented by an outside entity, not otherwise covered, to the USM IRB for review under the terms of an External Review Agreement as set forth in the USM Policy on IRB External Review of Non-USM Research Protocols. The USM Policy on IRB External Review of Non-USM Research Protocols is incorporated herein by reference.

## D. Applicability

When applying the definition of research and determining the applicability of human subjects protections to a research protocol, the ORC and the IRB will consider:

1. The intent of the investigation;
2. The subject population;
3. Type of information being used or sought;
4. The source of information being used or sought;
5. The source of funding, if any;
6. The researcher's relationship to the participants;
7. The researcher's status (e.g., student, faculty, employee of a state agency, etc.);
8. The interaction with other federal or state laws or regulations (e.g. HIPAA);
9. The primary or intended use of the data;
10. Secondary beneficiaries of the research results;
11. The dispensation of the data at the protocol's conclusion; and
12. Privacy, confidentiality and security measures being utilized.

#### **E. Assurance**

USM entered into a legally binding agreement with DHHS concerning research involving human subjects. This Assurance (**FederalWide Assurance # 00001748**) is administered by DHHS's Office of Human Research Protections (OHRP) and governs all human subjects research receiving, or eligible to receive, federal (DHHS) funds. This agreement is guided by the ethical principles of the *Belmont Report* and requires, at a minimum, compliance with 45 CFR 46 (The Common Rule). In addition, the following Federal Agencies have adopted the requirements of the DHHS Common Rule and as such any research that complies with the OHRP FederalWide Assurance, will also meet their requirements.

Department of Agriculture	7 CFR 1c
Department of Energy	10 CFR 745
National Aeronautics and Space Administration	14 CFR 1230
Department of Commerce	15 CFR 27
Consumer Product Safety Commission	16 CFR 1028
Agency for International Development	22 CFR 225
Department of Housing and Urban Development	24 CFR 60
Department of Justice	28 CFR 46
Department of Defense	32 CFR 219
Department of Education	34 CFR 97
Department of Veterans Affairs	38 CFR 16
Environmental Protection Agency	40 CFR 26
National Science Foundation	45 CFR 690
Department of Transportation	49 CFR 11
Central Intelligence Agency	By Executive Order 12333
Department of Agriculture	By Statute

In addition, USM has voluntarily agreed to apply all the Common Rule requirements and all subparts found under 45 CFR 46 (The Common Rule ) to **all** human subjects research regardless of funds, funding source or governing Federal Agency. Furthermore, USM has voluntarily agreed to apply heightened standards to **all** human subjects research involving pregnant women, neonates, prisoners, and/or children.

## **F. Definitions and Operational Concepts**

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

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

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

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

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

**Coercion:** To bring about participation in research by force or threat, actual or perceived, or through any other imbalance of power.

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

**Generalizable Knowledge:** Formerly, the Office of Human Research Protection had counseled USM that "generalizable knowledge" meant knowledge gained with the intent to disseminate in any manner. In an effort to further clarify this point, the ORC considered three alternative definitions of "generalizable knowledge":

Intent to disseminate or actual dissemination of knowledge;

The ability to make general, real-world inferences from statistical models; or

The ability to use conclusions from particular study scenarios or conditions to infer or generate broader real world inferences.

Currently, OHRP **does not** have a formal position on what does and does not constitute "generalizable knowledge" beyond the language of the Common Rule. There is no official Federal written policy statement or published guidance on the topic. Federal officials take the position that each institution is responsible for developing its own rationally based standards and definitions. Each individual institution is responsible for adopting a reasonable, well grounded definition of "generalizable knowledge" and research. Dissemination is **not** the fundamental defining characteristic of research, nor is a statistically based model an acceptable indicator of research under current OHRP policies. In keeping with the positions articulated by OHRP senior staff, USM has adopted the following definition of generalizable knowledge:

Generalizable knowledge is information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

Thus, a case study, designed to illuminate the course of a single individual's experience generally **will not** be considered to be developing or contributing to generalizable knowledge. A series of case studies, intended to lead to improvements in the management of a particular circumstance or condition, generally **will** be considered generalizable knowledge.

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

1. Data through intervention or interaction with the individual, or
2. Identifiable private information." 45 CFR 46.102.f

**Identifiable Private Information:** Includes (but is not limited to)

1. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. [45 CFR 46.102(f)]
2. Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). [45 CFR 46.102(f)]
3. Private information which is individually identifiable. [45 CFR 46.102(f)]
4. Information of a nature that the identity of the subject is or may readily be ascertained by the investigator or associated with the information. [45 CFR 46.102(f)]

5. Information which was collected specifically for the proposed project through intervention or interaction with living individuals and is of a nature that the investigator can readily ascertain the identity of the individuals.

**Institutional Review Board (IRB):** The USM research review committee whose primary purpose is to review all research involving human subjects and to provide oversight of human subjects protections.

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

**Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

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

**Minimal Risk:** "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily living or during the performance of routine physical or psychological examinations or tests". 45 CFR 46.102.i

**Minor:** An individual under the age of 18 years.

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

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

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

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

**Private information:** "Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the

information) in order for obtaining the information to constitute research involving human subjects.” 45 CFR 46.102.f

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

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

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

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

**Protocol Violation, Major:** A major protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the Institutional Review Board and the actual activities being performed. Major protocol violations include violations that:

1. Cause or pose a significant risk of substantive harm to research participants;
2. Damage the scientific integrity of the data collected;
3. Show evidence of willful or knowing misconduct on the part of the investigator, or
4. Demonstrate a serious or continued noncompliance with federal, state or local research policy, laws or regulations.

**Protocol Violation, Minor:** A minor protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the Institutional Review Board and the actual activities being performed. Minor protocol violations:

1. Have no substantive effect on the risks to research participants;
2. Do not impact the value of the data collected (meaning the violation does not confound the scientific analysis of the result); and
3. Do not result from willful or knowing misconduct on the part of the investigator(s).

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

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

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

1. Fabrication is making up data or results and recording or reporting them.
2. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
4. Research misconduct does not include honest error or differences of opinion.

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

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

**Signatory/Institutional Official:** The signatory/institutional official (IO) is the highest institutional official who has the legal authority to represent USM's Assurance filed with the Office of Human Research Protection, and is responsible for the provisions of this policy.

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

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

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

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

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

## II. THE INSTITUTIONAL REVIEW BOARD (IRB)

The USM IRB is the primary institutional body legally vested and charged with protecting the rights and welfare of persons participating in human subjects' research conducted at, or affiliated with, USM, or submitted to the USM IRB under the External Review Policy approved by the IRB. The IRB is responsible for:

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

USM has only one IRB (Registration# IRB00001953) authorized under its Assurance to review and approve human subjects research. The USM IRB has sole authority through the USM Assurance to interpret and apply federal, state, and local human subjects protections to USM research protocols and proposals.

All potential research that proposes interaction or intervention with human subjects must be prospectively reviewed and either approved or exempted by the IRB or its designee prior to the onset of data collection. All human subject research, even if found exempt from IRB review, must follow the USM policies for the protection of human research subjects and guiding principles of the Belmont Report.

The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

## A. The Role of the IRB

The IRB is charged with two primary roles:

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

## B. Institutional Review Board Responsibilities

1. Review, approve or reject protocol applications submitted by the USM community or agents of USM; Review,
2. Review, approve or reject protocol applications submitted by an outside entity, not otherwise covered, to the USM IRB under the terms of an External Review Agreement as set forth in the USM Policy on IRB External Review of non-USM Research Protocols.
3. Monitor approved protocols;
4. Report to appropriate USM officials any action to suspend or terminate a research protocol that fails to meet compliance standards. Appropriate officials include the Institutional Official (IO), the Director of the ORC, the Privacy Officer for Research, the Research Integrity Officer or any other official deemed necessary by the IRB or the Provost's Office and report to OHRP;
5. Act as an informational resource to the USM community;
6. Assist peer review committees, where applicable;
7. Submit semi-annual reports of IRB activities to the Provost;
8. Ensure that legally effective informed consent of human research subjects will be obtained in a manner and method that meets the requirements of federal, state and local rules and laws, USM and University of Maine System policies; and to
9. Make one of the following findings in order to approve research involving children. The IRB MUST determine that the research meets one of the following categories:

### **45 CFR 46.404 - Research not involving greater than minimal risk to the children.**

To approve this category of research, the IRB must make the following determinations:

- The research presents no greater than minimal risk to the children; **and**
- Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

**45 CFR 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.**

To approve research in this category, the IRB must make the following determinations:

- The risk is justified by the anticipated benefits to the subjects;
- The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; *and*
- Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

**45 CFR 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.**

In order to approve research in this category, the IRB must make the following determinations:

- The risk of the research represents a minor increase over minimal risk;
- The intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
- The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; *and*
- Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

The IRB may make a fourth finding, which triggers review by the OHRP before approval can be granted:

**45 CFR 46.407 - Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.**

If the IRB believes that the research does not meet the requirements of 45 CFR 46.404, 46.405, or 46.406, but finds that it presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, it may refer the protocol to HHS for review. The research may proceed only if the Secretary, HHS, or his or her designee, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, determines either: (1) that the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406, or (2) the following:

- The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- The research will be conducted in accordance with sound ethical principles; **and**
- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR.

### **C. IRB Authorized Powers**

1. Approve the research as submitted;
2. Approve the research contingent upon specific revisions;
3. Table the protocol for substantive changes;
4. Disapprove the research;
5. Recommend the protocol be jointly reviewed by another committee that has the expertise or authority over a particular subject matter (e.g., the Institutional Biosafety Committee for research involving human blood samples);
6. Require a primary investigator to apply for a Certificate of Confidentiality from the National Institutes of Health (for more information see <http://grants1.nih.gov/grants/policy/coc/>).
7. Randomly monitor approved protocols for compliance with IRB recommendations by any appropriate and reasonable means.
  - a) Monitoring methods include, but are not limited to:
    - (1) Observation of the consent process,
    - (2) Observation of the data collections process;
    - (3) Appointment of a third party to undertake such observation;
    - (4) Appointment of a third party to independently evaluate the PI's compliance;
    - (5) Independent review of research documents, including but not limited to, consent forms (both blank and completed) and research instruments;
    - (6) Appointment of an IRB subcommittee charged with the monitoring process;
    - (7) Request that the PI(s) appear before a fully convened IRB for an update, etc.; and
    - (8) Request that the PI(s) submit what data or analysis has been done to date to the IRB for review.

- b) Potential triggers for monitoring include, but are not limited to:
  - (1) Principal Investigators with prior adverse events;
  - (2) Novel or new interventions in a biomedical study;
  - (3) Investigators submitting protocols requiring expedited or full board review who have no prior research experience;
  - (4) Especially high risk protocols (as determined by the IRB and/or the ORC);
  - (5) Protocols involving especially high risk/vulnerable populations and/or groups highly susceptible to coercion;
  - (6) Protocols that substantially overlap with major Privacy Rights statutes, such as HIPAA and FERPA;
  - (7) A protocol to be conducted over an unusually long period of time;
  - (8) Principal Investigators who are chronically late in filing for continuing review; and
  - (9) Principal investigators who:
    - (a) Submit multiple drafts of informed consent forms;
    - (b) Submit standardized or “form” informed consent forms;
    - (c) Submit informed consent forms which clearly do not apply to the study being reviewed; or
    - (d) Submit informed consent forms from other sites or facilities.

8. Suspend or terminate any research project that:

- a) Is not conducted in accordance with the IRB’s approval;
- b) Results in a minor or major protocol violation;
- c) Has been associated with an unexpected harm to human subjects;
- d) Is the focus of an initiated investigation (assessment, inquiry or formal investigation); or
- e) When ordered to by a State or Federal agency or granting organization.

**D. Categories of Review**

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

### 1. **Not Research**

Certain types of activity do not qualify as research. When the ORC makes a determination that a proposed project is not research, no IRB oversight is required. The Principal Investigator will receive a "Not Research Letter" from the ORC. **Only** the Office of Research Compliance can determine if a proposed project qualifies as not research.

### 2. **Student Classroom Project**

Certain projects, conducted in the context of an assigned class activity, may be deemed to constitute a Student Classroom Project under the term of the University of Southern Maine Policy on Student Classroom Projects. Faculty who submit such projects will receive a letter indicating IRB general approval of the proposed activities from the Office of Research Compliance. **Only** the Office of Research Compliance can determine if a proposed project qualifies as a Student Classroom Project.

### 3. **Exempt**

The Common Rule outlines certain types of research which are exempt from IRB oversight. 45 CFR 46.101.b; 21CFR 50 and 56 (FDA research). **Only** the Office of Research Compliance can determine if a proposed project qualifies as Exempt. Research presenting greater than minimal risk, or involving children, pregnant women, fetuses, prisoners, mentally disabled, or subjects with a diminished capacity to give consent is subject to special restrictions, and is ineligible for exemption. Principal Investigators whose research which is exempt will receive an Exemption letter, and are not required to have any further interaction with the IRB or the Office of Research Compliance unless adverse events occur, or there is a substantial change to the protocol.

#### a) Exempt Categories (45 CFR 46.101(b):

- (1). Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - (a). Research on regular and special education instructional strategies, or
  - (b). Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2). Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - (a). Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - (b). Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3). Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures,

interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

- (a). The human subjects are elected or appointed public officials or candidates for public office; or
  - (b). Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4). Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5). Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
- (a). Public benefit or service programs;
  - (b). Procedures for obtaining benefits or services under those programs;
  - (c). Possible changes in or alternatives to those programs or procedures; or
  - (d). Possible changes in methods or levels of payment for benefits or services under those programs.
- (6). Taste and food quality evaluation and consumer acceptance studies,
- (a). If wholesome foods without additives are consumed or
  - (b). 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.

b). Procedure for Requesting an Exemption from IRB Review

Investigators may request an exemption from IRB review by completing a [Request for Study Exemption from IRB Review form](#) that includes a brief description of the protocol. This form is available through the IRB Web Site or the Office of Research Compliance. Completed applications will be reviewed by the Administration and evaluated according to the criteria listed above. The Office of Research Compliance and the IRB will attempt to process and review the application within 5 working days of receipt. The official assessment of exempt or not exempt will be conveyed to the investigator in writing.

#### 4. Expedited

Proposed activities which do not qualify for exemption may be subjected to Expedited Review, 45 CFR 46.110 in accordance with designated expedited categories set forth in [63 FR 60364-60367, November 9, 1998](#), but only if the procedure or activities involve no more than minimal risk to the research subjects. Expedited review does not mean that the process takes less time. It means that the review and approval process rests with a single IRB board member or member of the ORC staff. In general, protocols involving vulnerable populations, sensitive information, or higher than usual risk, do not qualify for Expedited Review. Researchers whose projects qualify for expedited review will receive an approval letter stating that the proposed research was reviewed using Expedited Review. **Only** the Office of Research Compliance can determine if a proposed project qualifies for Expedited Review.

##### a. Expedited Review Procedure

Investigators may request an IRB review of their protocol by submitting a [Request for IRB Review Form](#), a [brief protocol summary](#), and an outline of investigator qualifications. All protocols that the IRB review will be analyzed for eligibility to use an expedited review procedure in accordance with the above Expedited Review Criteria. The ORC and the IRB will attempt to act on a request for IRB review that qualifies for an expedited review procedure within 20 working days of receipt of a complete application. Expedited reviews are conducted by at least one experienced IRB member assigned by the IRB Chair or the Chair's designee. In an expedited review, a reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. If the reviewer does not find that the proposal meets the criteria for expedited review, the proposal will be reviewed using a full review procedure at the next convened IRB meeting.

#### 5. Full Board

All protocols which do not fall under one of the four categories listed above will undergo full board review at a duly convened meeting of the IRB with a quorum present. The full board will discuss the protocol, and may take one of several actions including:

- Approving the Protocol outright;
- Approving the Protocol with changes;
- Tabling the protocol until the next meeting to allow the Principal Investigator to address IRB concerns; or
- Rejecting the protocol.

The IRB's actions will be communicated to the Principal Investigator in a letter which details the IRB's decision, sets forth any required changes, requests more information, or invites resubmission after the protocol is revised.

##### a. Full Board Review Procedure

Investigators may request IRB review of their protocol by submitting a [Request for IRB Review Form](#), a [brief protocol summary](#), and an outline of investigator qualifications. All protocols that require IRB review that are not eligible for an expedited review procedure (see Section IV C above) will be reviewed by the IRB at a convened IRB

meeting in accordance with the terms of this policy and the rules outline in 45 CFR 46. The University of Southern Maine will attempt to act on a request for IRB review approximately 30-45 days after receipt by the IRB office if no revisions are required.

#### 6. **Educational Requirements for Protocol Approval**

All researchers who intend to collect data involving human subjects (whether these projects are exempted or reviewed by the IRB) are required to complete the National Institutes of Health (NIH) online training module on Human Subject's Protection (<http://cme.nci.nih.gov/>). Upon completion, a copy of the certificate of completion must be filed in the Office of Research Compliance. **Protocols may only be exempted or approved if the Primary Investigator and key personnel have fulfilled and documented the completion of the above educational requirements.**

In addition to completing the NIH training module, researchers must also attend a USM educational session regarding Conflict of Interest, Research Misconduct, and the USM procedures for Human Subject Research. These informational sessions will be held on a periodic basis or, in some circumstances, on an individual basis by the Office of Research Compliance. This education must be updated at least every 36 months in order for investigators to continue research activities.

#### 7. **Continuing Review Process**

Review of research must occur not less than once per year. Some high-risk protocols may require more frequent review as deemed necessary by the IRB review process and federal regulations. At their discretion, the ORC/IRB may require research protocols that extend 5 years from the initial IRB review date to be reviewed de novo (as new) every 5 years from the initial IRB review.

Sixty days prior to the initial or continuing IRB approval expiration date, investigators must submit an [IRB Continuing Review Form](#) and a summary of the study that includes the following information:

- a). Number of subjects enrolled in the study to date;
- b). Withdrawal of subjects from the research;
- c). Any unexpected events or complaints about the research and a method for monitoring the safety of research participants;
- d). Information regarding any amendments or modifications to the research since the last review;
- e). Any findings of the research;
- f). Reports on multi-center trials or cooperative research;
- g). An update of the initial literature review;
- h). Any other relevant information, especially information about risks associated with the research;
- i). A copy of the current informed consent document.

The researcher should deliver 2 copies of the continuing review summary to the Office of Research Compliance. Under no circumstances may an investigator continue data collection beyond the IRB approval date, nor may any researcher use an expired research instrument (such as surveys, questionnaires, or tests). Upon continuing approval the researcher must update all forms used in the research project to reflect the new IRB approval date. The IRB may require unannounced observation of research activities either by the IRB members, a designee or a third party observer.

Researchers found to be collecting data without IRB approval may be required to expunge the data upon IRB request, and all research activities will be suspended by the IRB pending continuing IRB review and approval of research activities.

### **E. Withdrawal or Termination of Research**

When a study is withdrawn or completed the investigator must notify the IRB, in writing, and indicate provisions to protect confidential information or indicate plans for destroying it. All records of IRB communications must be kept on file for three years following termination or completion of research studies. Protocols are considered to be active as long as identifiable private information exists and will require at least yearly IRB continuing approval. Consequently all information that links identities of subjects to data gathered should be destroyed as soon as possible in accordance with the specific aims of the study. In the case of Oral Histories, once data is permanently archived a study may be closed and considered completed for IRB purposes.

### **F. Foreign Research**

All of the USM human subject research activities will be guided by statements of ethical principles of the Belmont Report including research performed in foreign countries by USM Employees or Agents. The investigator will abide by that country's laws or regulations or 45 CFR 46 whichever provides the greatest degree of protection to human research subjects.

### **G. Collaborative Research**

The activities of individual research investigators who are not employees or agents of the institution may be covered under the USM Federalwide Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. (OHRP's sample Unaffiliated Investigator Agreement may be used for this purpose. <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/unafisup.rtf>) USM will maintain such commitment agreements on file and provide copies of them to OHRP upon request.

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

## H. Application Requirements for Research Involving Human Subjects

Investigators are invited to use the downloadable [Request for IRB review](#) form available on the USM IRB web site, <http://www.usm.maine.edu/orc/irb/forms.htm>, when requesting approval for research proposals.

### 1. Contents of the Research Proposal Summary:

It is essential that all questions on the Request for IRB review form be answered fully and in sufficient detail to allow IRB reviewers to discuss the criteria for Approval (see section III. B. Criteria for IRB Approval).

- a) Introduction;
- b) Specific aims;
- c) Methods of data collection (including copies of instruments) and analysis;
- d) Subject population, research setting, subject recruitment procedures;
- e) Informed consent procedure;
- f) Provisions for subject and data confidentiality;
- g) Statement of potential research risks to subjects;
- h) Statement of potential research benefits to subjects; and
- i) Investigator experience.

## I. Informed Consent: General Requirements

Unless specifically authorized or waived by the IRB, all research requires written informed consent in non-exculpatory language understandable to the subject.

Informed Consent is a process not a single event. Since subjects always retain the right to withdraw from a research project, it is imperative that the investigator maintain subject's continuing, voluntary informed consent at all times. The application for IRB Review must describe the procedures for gaining and documenting the informed consent of the subjects.

The investigator shall seek informed consent only under circumstances that provide the prospective subject and or subject's legal representative sufficient opportunity to consider whether or not to participate without undue influence or coercion. The information given to the subject or the subject's legal representative will be in a format understandable to that subject or representative and it shall not be misrepresentative of the research or methods. An informed consent may not include any exculpatory language that waives the subject's legal rights or appears to release the investigator, the University or its agents from liability or negligence.

### 1. Informed consent must include the following elements:

- a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's

participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

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

## **2. Additional elements of informed consent**

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

- a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- c) Any additional costs to the subject that may result from participation in the research;
- d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- f) The approximate number of subjects involved in the study.

## J. Informed Consent in Vulnerable Populations

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

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

In all human subject research, the agreement of the subject to participate is an essential protection of the subject's rights and welfare. Minors, by definition, cannot give legal "consent". Therefore, a combination of "assent" (agreement) of the minor and "permission" (agreement) of the parent(s) or legal guardian(s) is generally deemed an adequate substitute. If either parent refuses permission or the minor subject refuses assent, the minor should not be enrolled in the research project.

- a) Parental Consent: The USM IRB requires the permission of both parents be given for research involving minors, unless:
  - (1) One parent cannot reasonably be found or contacted in a reasonable time period (typically 60 days);
  - (2) One parent is deceased;
  - (3) One parent has lost or surrendered all legal parental rights;  
or
  - (4) If one parent has been granted by the court sole custody and all parental rights

There may be exceptions to this general policy that the IRB will determine on a case-by-case basis.

- b) Legal Guardians vs. Caregivers: The permission of caregivers and/or service providers is not sufficient to conduct research with minors. Only parents and legal guardians have that authority and responsibility. School principals, teachers, clinic personnel, etc., do not have the authority to give "blanket" permission for their students/patients/clients to participate in research. They do have the authority to permit the research to be conducted in the facility under their auspices. (This permission should be made part of the study submission.) In classroom research, it must be made clear that the research is not part of the regular educational program and that the student's grades or standing will not be affected by not participating.
- c) Child (minors) Assent: Adequate provision must be made for soliciting the assent of those children capable of providing a meaningful agreement. The process must be appropriate to the study as well as the age, maturity and psychological state of the child. Information must be presented in language and format that is understandable to the child. The children should have an understanding of the research procedures and it should be clear that their participation is voluntary. An investigator may not include a minor as a research subject without his or her assent unless the minor is not capable of giving assent and the assent is waived by the

IRB because the research holds out a prospect of benefit for the child or provides important research information.

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

## **2. Research Involving Subjects with a Diminished Capacity to Consent**

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

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

Consent procedures must be proportional to the research risk, as impairment increases, so does risk and discomfort associated with the study and the safeguards should increase on a sliding scale. When a researcher is determining a participant's capacity for decision-making, a key factor is the participant's appreciation of how the risks, benefits and alternatives to participation apply to them personally. It is advisable that the consent processes actually include the researcher asking the participant; "Do you understand the risks and benefits of participation?" or "Do you have any questions about the study or process?" Options for additional safeguards include the use of an independent monitor, use of a legally authorized representative, use of assent and a legally authorized individual, use of an advance directive as local laws permit, or use of a waiting period.

In addition, researchers may need to write their informed consent forms at a lower reading level in order to compensate for potential diminished capacity. For example, a mentally challenged individual who is their own legal guardian and has full control over their own activities of daily living (ADL's), may still only have a 4<sup>th</sup> Grade reading level.

## **3. Research Involving Experimental Biological, Medical or Behavioral Interventions**

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

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

#### **4. Research Involving Pregnant Women, Fetuses and Products of Labor and Delivery**

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

#### **5. Research Involving Non-English Speaking Populations**

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

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

All foreign language versions of the short form document must be submitted to the IRB with the Request for IRB Review Form. Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

## 6. Research Involving Prisoner Populations

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

The following criteria must be used when including prisoners as research subjects:

### a) Acceptable Categories of Prisoner Research

The proposed research must fall into one of the following categories for USM IRB approval:

- (1) 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; or
- (2) 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.

The following categories of research may only be conducted if, in addition to USM IRB approval, the Secretary of DHHS has consulted appropriate experts and published notice in the Federal Register of his/her intent to approve such research:

- (3) 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); and
- (4) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject.

### b) Acceptable Conditions for Prisoner Research

- (1) Any possible advantages accruing to the prisoner through his or her participation in the research are not of such a

magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

- (2) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner subjects.
- (3) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research study, unless the principal investigator provides to the IRB justification, in writing, for following some other procedure.
- (4) The information is presented in language that is understandable to the subject population.
- (5) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
- (6) If there is a need for follow-up examination or care of participants after participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact.

## **7. Research Involving University of Southern Maine Students**

Use of USM students presents a special set of concerns that are applicable in any study that could potentially recruit USM students. This includes not only pools that specifically recruit students, but also studies that are advertised on campus. Undergraduates at USM may be below the age of consent in Maine. As such, the special requirements for studies involving minors apply to studies using these students. One solution is to limit inclusion to individuals over the age of 18 years.

An additional concern in studies that involve USM students is the possibility of undue influence. Recruitment of a subject by his or her advisor or faculty member holds the potential for undue influence. This also holds true whenever a student's participation will be made known to someone who holds power over that student's academic status or extra credit for course grading purposes.

Since participation in a research study is completely voluntary, there may not be any loss of academic status if a student chooses not to participate. If academic benefits are offered as compensation for participation in a study, an equivalent alternative activity must be offered (with the same academic benefit offered) to students who choose not to participate.

The above issues must be addressed in all research studies involving USM students.

## **8. Use of Specimens for Future Research**

If specimens are to be stored for use in future research, this information must be included in the informed consent process and the informed consent documentation. Further, it is the policy of the USM IRB to require that a specific consent statement be included in consent forms that ask subjects to grant permission to store specimens for future research use. The purpose of the extra consent statement is to clearly indicate that the subject can participate in the current research study without agreeing to have specimens stored for future research. The only case where the separate consent line is not required is when the purpose of the current research study is to collect specimens for the purpose of storing them for future research or use.

## **K. Documentation of Informed Consent**

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

### **1. Written Consent Forms:**

Informed consent shall be documented (unless the IRB has given approval for a waiver, alteration, or exception) by the use of a written consent form approved by

the IRB and signed by the subject or the subject's legally authorized representative. A copy of the consent form shall be given to the person signing the form. The consent form may be either a full form written or a short form written.

## 2. Full Form Written:

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

- a) The subject or the representative signs the full form.
- b) The subject or the representative receives a copy of the form.

## 3. Short Form – Written (Oral Summary):

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

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

- a) There must be a witness to the oral presentation.
- b) The researcher must provide the IRB a written summary of what will be said to the subject or the representative **and** the researcher must obtain IRB approval of the summary before it is implemented.
- c) The subject or the representative signs only the short form.
- d) The witness must sign both the short form **and** a copy of the IRB approved summary.
- e) The person actually obtaining consent (the researcher) must sign a copy of the summary.
- f) The subject or the representative receives a copy of the summary **and** a copy of the signed form.

## 4. Alteration or Waiver of Informed Consent Requirements

There are only two circumstances in which the IRB may waive the required consent. The first waiver authority is applicable only to research activities designed to study certain aspects of public benefit or service programs; the conditions under which this waiver may be authorized by an IRB are detailed at 45 CFR 46.116(c)(1-2) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - (1) Public benefit or service programs;
  - (2) Procedures for obtaining benefits or services under those programs;
  - (3) Possible changes in or alternatives to those programs or procedures; or;
  - (4) Possible changes in methods or levels of payment for benefits or services under those programs; and
- b) The research could not practicably be carried out without the waiver or alteration.

The second waiver authority is described at 45 CFR 46.116(d). An 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:

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

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

#### **L. IRB Procedure for Protocol Violations**

A protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the Institutional Review Board and the actual activities being performed. Violation may be minor or major in nature. All incidents of alleged or known protocol violations will be investigated using the following procedures.

- 1. Minor protocol violation:** In the event of a reported minor protocol violation, an investigation will be launched which will include the following steps:

- a) The IRB chairperson will initiate a fact finding inquiry, either directly or by delegating to the Director and/or Associate Director of the Office of Research Compliance.
- b) The designated investigator(s) will analyze all information gathered regarding the protocol violation and compare it to the approved protocol. When necessary, the designated investigator(s) will consult with experts in the particular area of research in order to make definitive, unbiased and educated decisions regarding the violation. A conclusion will then be made regarding the seriousness of the violation.
- c) If the findings support all three criteria listed in the definition of a minor protocol violation, the IRB chairperson or the designated investigator(s) will notify the principal investigator, in writing, indicating:
  - (1) What corrective actions must be done (if anything) to correct the conditions creating the violation;
  - (2) What (if anything) must be communicated to the research participants; and
  - (3) The notification of a formal investigation being initiated, if warranted or required by law.
- d) The IRB chairperson or designated investigator(s) will present a summary of the violation, process, facts, and conclusions at the next scheduled convened IRB meeting.
- e) The IRB chairperson or the designated investigator(s) will prepare the appropriate report for the Institutional Official to file with the Office of Human Research Protection (OHRP) and, if appropriate, the research protocol's sponsor.
- f) If the IRB chairperson or the designated investigator(s) determine that no violation has occurred, the investigation will be closed with no further action.

## **2. Major Protocol Violation**

In the event of a reported major protocol violation, an investigation will be launched which will include the following steps:

- a) The IRB chairperson will initiate a fact finding inquiry, either directly or by delegating to the Director and/or Associate Director of the Office of Research Compliance.
- b) The designated investigator(s) will analyze all information gathered regarding the protocol violation and compare it to the approved protocol. When necessary, the designated investigator(s) will consult with experts in the particular area of research in order to make definitive, unbiased and educated decisions regarding the violation. A conclusion will then be made regarding the seriousness of the violation.
- c) If the findings support all three criteria listed in the definition of a major protocol violation, the IRB chairperson will convene a formal

hearing committee to consider all the facts of the case and to meet the investigator (s). The hearing committee will consist of:

- (1) IRB Chairperson, IRB Vice-Chairperson or their official designee;
- (2) The assigned Investigator(s);
- (3) 1-3 IRB members; and
- (4) Any required or assigned specialists;

As a general practice, the hearing committee will always consist of an odd number of people should any votes be required.

- d) If the hearing committee finds a reasonable basis to believe that any of the elements of the definition of a major protocol violation exists, the IRB chairperson or the designated investigator(s) will immediately suspend the protocol. (Note: this does not preclude the IRB chairperson or the designated investigator(s) from suspending the protocol in advance of the hearing if, in the chair's assessment, the conditions in 45 CFR 46.113 have been met and warrant an emergency protocol suspension).
- e) If suspension of the protocol or study procedures would result in harm to the enrolled research participants, the IRB chairperson or the designated investigator(s) will request that the Principal Investigator's department chair assign Principal Investigator's duties to another qualified person and submit a Project Revision Amendment Form explaining this substitution and indicating temporary closure of the study. In this situation the official action will be the suspension of the investigator (45 CFR 46.109 (d)).
- f) In the event of a protocol or investigator suspension, the IRB chairperson or the designated investigator(s) will prepare the appropriate report for the Institutional Official to file with the Office of Human Research Protection (OHRP) and, if appropriate, the research protocol's sponsor.
- g) Depending on the nature or the seriousness of the violation, the hearing committee may elect to direct the IRB and/or the Office of Research Compliance to audit all protocols involving the Principal Investigator in question. The IRB chairperson may delegate this duty to the ORC Director, the ORC Associate Director, or the Human Protections Administrator.
- h) If the findings of the hearing committee support research misconduct (as defined under federal regulations) or professional misconduct (as defined under USM's policy for "*Alleged Misconduct in Research and Other Professional Activities*"), the provost will be notified and a USM Misconduct Investigation will ensue.
- i) A summary of the issue, process, facts, conclusions and actions will be presented at the next scheduled IRB meeting. A written summary will be forwarded to the Principal Investigator, the Principal Investigator's department chair, and the appropriate dean or director. A copy will be retained in the IRB study file, maintained by the Office of Research Compliance.

## M. Procedure for Adverse Research Events

The chair of the IRB and the Director of Research Compliance will review all reports of adverse events (See Section II Definitions). All adverse events will be communicated to the IRB at the next IRB meeting at which time the IRB may require additional protocol safeguards to protect human research subjects.

1. In the event of a death or life-threatening research event, a full IRB meeting will be convened to discuss the adverse event. In such cases the following procedure will be followed:
  - a) The adverse event report form, the original IRB review forms, the original approval letter, continuing approvals, and any IRB or ORC protocol monitoring notes will be reviewed by the IRB for possible links of the event with the research procedure. As necessary, an advisor or expert in the field will be consulted if such expertise is not available from among the IRB board members or a perceived or actual conflict of interest exists for IRB members with such expertise.
  - b) The IRB will discuss the protocol in light of the adverse event(s) using the [Criteria for Protocol Approval](#) (See Section 4. A. of this Policy) to assure that the protocol adequately protects research participants. The IRB may require additional safeguards and/or changes in the informed consent procedure to prevent additional adverse events or inform participants of the adverse events associated with the study to date. If the IRB finds the risks of the protocol are unacceptable the board may vote to suspend or terminate the protocol with a majority IRB vote.
  - c) For adverse events related to minor or major protocol violations, the procedures for protocol violation(s) will be followed. For adverse events related to misconduct or alleged misconduct (see USM Policy on Alleged Misconduct) the procedures for Alleged Misconduct will be followed.
  - d) The Investigator will be notified in writing of the Scheduled IRB review of adverse events and any changes or actions taken by the IRB as a result of the adverse event. Unforeseen adverse research events will be reported to the Office of Human Research Protections and all funding sources. Adverse research events that involve Alleged Misconduct or Misconduct will be reported to the Public Health Service Office of Research Integrity.
  - f) The Investigator must submit a follow-up adverse event report 30 days following IRB review of the adverse event. This report will be reviewed by the IRB at the next convened IRB meeting to assess the adequacy and effectiveness of the protocol protections. If necessary the IRB may require additional changes. The investigator will be notified in writing if any additional changes are required.

## **N. IRB Membership**

### **1. Board Composition**

The IRB will consist of at least 9 voting members with varying backgrounds that promote complete and adequate review of research conducted at USM. At a minimum the USM IRB will be composed of:

- a) IRB Chairperson (Tenured faculty or Provost approved staff only)
- b) Human Protections Administrator (HPA)
- c) One person from the USM community (faculty or staff only)
- d) Two community members not affiliated with the University;
- e) One scientist (MD, Ph.D. or other appropriate scientific degree);
- f) One non-scientist (Ph.D., JD, MS or other appropriate degree);
- g) One person serving as the official IRB Prisoner Representative; and
- h) One person serving as the official IRB Child Representative.

All other members are appointed at the discretion of the IRB Chairperson and/or the USM Provost. Additional members include, but not limited to:

- a) IRB Vice-Chairperson
- b) Additional voting members
- c) ORC administrative staff (voting)
- d) Alternate board members
- e) Alternate board members representing special knowledge areas or protected population groups (voting and non-voting)
- f) Alternate board members representing specific ethnic, cultural, or religious groups (voting and non-voting)
- g) Two student members (one undergraduate and one graduate; non-voting)

### **2. General IRB Membership Appointment**

All IRB members are selected and appointed to the Board either:

- a) By direct appointment of the USM Provost; or
- b) Voted onto the IRB by a simple majority vote and then formally confirmed by the Provost.

In either case, all members of the IRB will receive an appointment letter from the Provost stating their appointment date, term, and basic responsibilities. All IRB

members will also receive, within 60 calendar days from their appointment date, a letter from USM outlining the University of Maine Systems Indemnification Policy and a Letter of Indemnification covering their term of service on the IRB.

### **3. Chairperson**

The Provost appoints the IRB Chairperson to the Board. The Chairperson will be either a tenured faculty person or an appointed staff person.

### **4. Vice Chairperson**

The Vice Chairperson is appointed at the discretion of the IRB Chairperson and/or the USM Provost and serves in lieu of the Chairperson in cases of conflict or illness. Please note that this is not a “chairperson elect” position. The Vice Chairperson has the prerogative of seeking the Chairperson position in the future, but is not obligated to do so.

### **5. Membership Terms and Voting Rights**

#### **a) General Members**

The Provost of the University of Southern Maine (or his/her authorized representative) will appoint members to the IRB for a period of 1, 2 or 3-year terms. New members will be allowed a 1 year appointment, but can accept a longer term if they so agree. All other members are requested to commit to either a 2 or 3 year term after their first term or initial 1 year appointment. This reduces the effect of turn over and insures a consistent voting membership.

Reappointment terms can be for 2 or 3 years and must be by mutual consent of the member, the IRB Chairperson and the Provost.

All general members have full voting rights and privileges.

#### **b) Chairperson**

The IRB Chairperson is appointed by the USM Provost (or their authorized representative) and is appointed for a period of 2 years. This is renewable with the consent of the IRB Chairperson and Provost.

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

## 6. General Member Responsibilities and Obligations

- a) Attend 50% or more of regularly scheduled meetings per year (based on appointment date) in order to maintain membership status.
- b) Complete the National Institutes of Health's *Human Participant Protections Education for Research Teams* (also known as the NIH Training) or CITI Training once every three years.
- c) Maintain any special or required credentials for those serving in specialized roles.
- d) Attend either some form of continuing IRB education annually or the annual IRB Retreat provided by the Office of Research Compliance.
- e) Serve as a reviewer for expedited protocols and/or serve as primary reviewer for Full-Board reviews
- f) Take an active part in the voting process when present for board meetings
- g) Recuse oneself from voting or participating in IRB business when the member has a clear or perceived [conflict of interest](#) concerning the matter at hand
- h) Recuse oneself from voting or participating in IRB business when the member is the topic of business, including when the member is the PI on a Full Board review.

## 7. IRB Member Education

All IRB members are required to complete the NIH training module (available at the following link: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>) or other training program as may be designated from time to time. New IRB members must submit documentation of completion of these training modules to the Office of Research Compliance prior to voting on any submitted research projects. All IRB members will also be expected to attend a yearly IRB educational retreat provided by the Office of Research Compliance or the equivalent, for continuing education.

## 8. IRB Registration with the Department of Health and Human Services (DHHS)

All voting IRB member names and qualifications must be registered with DHHS at least once per year or when voting board membership changes. The ORC will notify OHRP within 15 business days of any changes to membership.

## 9. Termination of Membership

### a) Voluntary

An IRB member may voluntarily resign their membership at any time. As a matter of courtesy, it is requested that any member wishing to do so provide a written notice to the IRB Chair or the Director of the

ORC at least 60 days prior to leaving. No justification is required. Under USM and UMS policy voluntary termination cannot and will not be held against the resigning member.

**b) Involuntary**

**An IRB member may be involuntarily terminated from the IRB for:**

- (1) Professional misconduct;
- (2) Research misconduct (as defined under federal regulations);
- (3) Breach of membership duties;
- (4) Unethical or illegal activities related to their duties and obligations to the IRB; or
- (5) A supermajority (75%) vote of all IRB voting members (minus the member in question).

**O. IRB Meetings**

The IRB will meet at least once per month, or more frequently as needed, to conduct official business. The IRB Chair has the discretion to call for additional meeting sessions or for longer meeting times in order to meet IRB obligations.

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

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

**P. Meeting Minutes**

All IRB meetings will be recorded at each session. Copies of the meeting minutes will be made available to all IRB members, the USM Provost and all applicable State/Federal regulatory agencies.

All minutes will include, at a minimum:

1. Members in attendance and absent;
2. Report of adverse events since the last IRB meeting;
3. Summary of protocols (and numbers of) for the preceding month;
4. Update on any changes or revisions to a previously reviewed Full Board protocol;
5. Summary of discussions held during the meeting;
6. Notification of any IRB Investigation that has been initiated (if applicable);

7. Summary and/or status of any IRB investigation being conducted (if applicable);
8. Full statement of any motion made, subsequent discussions, any formal decisions;
9. Recommendations and a formal recording of votes made (for, against, and abstention);
10. Votes against a particular motion, including what the reasons were; and
11. Summary of any formal USM Policy changes, changes in Federal regulations or guidance, etc. about which the Full IRB Board needs to be informed.

The IRB Secretary, or other designated individual, will be the person responsible for documenting and maintaining all IRB meeting minutes.

## **Q. IRB Policy Updates, Changes and Additions**

The ORC Director, in conjunction with the HPA and the IRB Chairperson, is responsible for periodically updating this Manual in order to conform to changes in applicable laws and regulations. All policy updates or changes must meet regulatory requirements and conform to USM's Federalwide Assurance.

### **1. Strict regulatory/statutory requirements**

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

### **2. Discretionary Regulatory/Statutory Requirements**

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

### 3. **Emergency Changes**

The Institutional Official (IO-USM Provost), ORC Director, IRB Chairperson or other IO designated Official may implement any emergency Policies and Procedures necessary to:

- a) Prevent harm to research subjects;
- b) Correct a latent policy issue;
- c) Address known privacy, security or confidentiality breaches;
- d) Respond to emerging circumstances in a particular research program or category of research; or
- e) Respond to changes in State or Federal laws.

All emergency changes take effect immediately.

### 4. **All Other Requirements**

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

## **III. The Office of Research Compliance**

### **A. Administrative Support**

The Office of Research Compliance (ORC) provides administrative, technical and logistical support to the IRB and other research review committees (i.e. IBC, IACUC, RSC, etc.). As part of the general duties and responsibilities to the IRB, the ORC will:

1. Prepare and maintain records of IRB activities (meeting minutes, annual reports, training materials, etc.) for at least 3 years;
2. Set up and maintain all records related to protocols including:
  - a) Copy of protocols application (including any attached funding applications),
  - b) Informed consent documents
  - c) Research instruments used and any other supporting documentation;
  - d) Records of protocol review and continuing review activities; and
  - e) Copies of all correspondence between the IRB and investigators;

3. Maintain a current list of IRB members and their qualifications for serving on the board;
4. Periodically update this Manual and other Policies and Procedures effecting or involving human subjects;
5. Provide technical assistance to the IRB;
6. Update the IRB on current changes in federal policies and guidance; and
7. Provide educational sessions to IRB members, including hosting an annual retreat.

## **B. Record Keeping, File Retention and File Destruction**

The ORC is responsible for maintaining all protocol files, including applications, correspondences, approvals and other related information. Protocol files and records include both paper and electronic versions. Protocol files will be maintained and retained for a minimum period of time as follows:

1. Active Protocols will be maintained throughout the approval period plus any continuing reviews.
2. Disapproved protocols will be retained for a period of **2-years**.
3. Not Research and Exempt Protocols will be maintained for a period of **4-years** from the original submission/filing date (based on the IRB Protocol number). Each PI will be responsible after this time period for maintaining their own records. Student Classroom Project protocols approved for recurring classes may be retained indefinitely.
4. Completed Protocols (Expedited and Full-Board) will be maintained for a period of **6-years** from the original submission/filing date (based on the IRB Protocol number). Must be kept 3 years after the research ends.

The OHRP mentioned informed consent document must be kept by the PI for three years

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

## **C. ORC Granted Powers**

The ORC Director, Associate Director and the Human Protections Administrator (HPA) are official IRB designees with full power and authority to act on behalf of the IRB. With the approval of the IRB Chairperson, the Director, Associate Director and the HPA may sign protocol approval letters, conduct protocol reviews and assign primary reviewers to Expedited and Full-Board protocols.

The ORC's Operations Specialist is a regular IRB Board Member.

The IRB Chairperson, the ORC Director, the ORC Associate Director and the HPA are the only authorized persons at USM who can officially determine what is or is not research for purposes of human subjects research protections (as defined under the Common Rule).

The ORC is the only body authorized to review and approve Exempt level research.

#### **D. IRB Annual Report**

The ORC Director, in conjunction with the IRB Chairperson, will submit an annual report to the Institutional Official (USM Provost) and USM's President regarding the past year's activities. This report will include at a minimum:

1. The volume and status of protocols reviewed by the IRB;
2. Any adverse research events, regardless of type;
3. The status and disposition of any investigation (assessment, inquiry or formal investigation);
4. A synopsis of continuing education materials provided to the IRB members;
5. A summary of any Federal policy or guidance changes that went into effect during the year;
6. A summary of any pending or effective changes in the rules or regulations that may affect research during the next year and impact strategic planning;
7. At the discretion of the IRB chair, the IRB may make recommendations for procedural changes to facilitate or improve the IRB process; and
8. Any formal recommendations presented by the IRB or IRB Chair.

#### **E. Human Protections Administrator (HPA)**

The Human Protections Administrator is USM's primary institutional agent who exercises operational responsibility, on a day-to-day basis, for USM's IRB program. The HPA's duties and responsibilities include, but are not limited to:

1. Reviewing all human subjects research protocols in order to ensure that regulatory compliance requirements are met and appropriate ethical conduct standards are upheld;
2. Serving as primary reviewer for all Exempt level research and conducting an initial review for all other levels before assigning the protocol to a primary IRB reviewer;
3. Providing assistance in drafting and administering with the ORC Director, IRB Chairperson and IRB members USM's policies and procedures governing the ethical conduct of human subjects research and associated activities;
4. Serving as a voting member of the IRB;
5. Providing professional, technical, and educational assistance to faculty, staff, and students on all aspects of the ethical conduct of human subjects research and associated activities and
6. Performing initial detection/inquiry into possible protocol violations/adverse events and making preliminary recommendations for alleged policy violations;

#### **F. Complaints, Adverse Events, Privacy Breaches and Allegations of Research Misconduct**

The Human Protections Administrator and the Research Integrity Officer are the primary points of contact for registration of research related complaints; notification of adverse events; privacy, confidentiality and security related issues involving research protocols, and; allegations of research misconduct.

The USM Provost, ORC Director, IRB Chairperson, Human Protections Administrator, Research Integrity Officer (RIO), and/or Privacy Officer for Research are responsible for initially assessing any claim made and for responding appropriately to the claim. USM and the ORC will apply any or all applicable regulations and guidance in assessing and addressing any claim made, including but not limited to:

1. USM's Policies and Procedures;
2. USM Policies and Procedures for Conducting Investigations and Reporting Events;
3. The Office of Research Integrity's policies for responding to an allegation of research misconduct;
4. Office for Human Research Protections (OHRP) policies;
5. US Public Health Service (PHS) policies;
6. Other applicable federal and state statutes, regulations and/or policies.

The Department of Health and Human Services (DHHS) must be notified, in writing, of any unexpected adverse events in all non-exempt Human Subject research and is not limited to only Human Subject Research which is federally-funded. This notification must be made by the IO, though the ORC Director or the Research Integrity Officer has been authorized to make this notification on the IO's behalf.