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1.0 - MISSION STATEMENT

The University of Rhode Island, investigators and their research staff, and the Office of Research Integrity, must share a collaborative responsibility and commitment to maintain the highest ethical standards in our research endeavors. Human Subjects protection is not the responsibility of one office, or one individual. All individuals involved in Human Subjects research are equally responsible to ensure that all research is in compliance with federal regulations and 's policies and procedures. Human Subjects research is constantly evolving and the research community will be notified of regulatory or procedural changes through the website. This will ensure that Human Subject researchers will receive the most up-to-date regulatory and procedural standards.

The University of Rhode Island is guided by the ethical principles regarding all research involving humans as subjects set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report,")

The University of Rhode Island has established the institutional review board (IRB) responsible for the institution's obligations to review research involving human research. Researchers are allowed to involve human subjects in their research under the terms and conditions set forth by the Office of Human Research Protections (OHRP) of the Federal Government Department of Health and Human Service (DHHS) and the Food and Drug Administration (FDA). All employees, students, faculty and staff must comply with these regulations, as well as state and local laws, and institutional policies. Failure to comply with the required rules and regulations can result in loss of funding for human subjects research for the entire institution.

All research projects involving human subjects conducted by University faculty, staff and students or done under the sponsorship or auspices of the institution must be reviewed and approved by the prior to the commencement of “engaged” human subjects research. This includes research involving subjects from outside the university and research that is not funded.

The University of Rhode Island becomes “engaged” in research as defined by the Department of Health and Human Services

(1) Obtain data about living individuals for research purposes through intervention or interaction with them,
(2) Obtain individually identifiable private information for research purposes (45 CFR 46.102(d), if or(3) Obtain the informed consent of human subjects.

Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

In general, an institution is considered to be engaged in human subjects research whenever it receives a direct HHS award to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution. In general, simply informing potential subjects about a research study is not considered engagement in research. Also, providing written information about a research study, including how to contact the investigators for information and enrollment, and seeking and obtaining prospective subjects’ permission for investigators to contact them are not considered engagement in research. However, seeking or obtaining informed consent from a research participant is considered engagement in research.

Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.
1.1 Institutional Authority under which the is Established and Empowered

The University of Rhode Island’s IRB is guided by ethical principles, Federal, State and local laws regarding all research involving humans as subjects. The Nuremberg Code of 1947, the Declaration of Helsinki of 1964 and the Belmont Report Ethical Principles and Guidelines have set these guiding ethical principles, forth for the Protection of Human Subjects of Research of 1979.

The Federal Regulations include:

- The Office of Human Rights and Protection, the Department of Health and Human Services United States Code of Federal Regulations (CFR) Title 45 CFR 46
- Food and Drug Administration (FDA) Title 21 CFR 50 and 56. This also includes:
  - Investigational New Applications - IND 312;
  - Radioactive Diagnostic Drugs 361;
  - Investigational Device Exemptions IDE 812
- Department of Education 34 CFR Part 97, 98, 99, 350 and 356
- Department of Defense (DOD)-Department of Navy (DON) 3216.02, 3210.7, 6200.2, Title 10 USC 980

The University of Rhode Island has secured from the U.S. Department of Health and Human Services, Office for Human Research Protections, a Federal Wide Assurance (FWA) that is valid from through. The FWA is an assurance of compliance with the federal regulations for the protection of human subjects in research. The Assurance defines the responsibilities of the Institution, the IRB, the IRB administrative office and staff, and the investigator to protect human research subjects.

1.2 Purpose of the IRB

The primary responsibility for protecting the rights and welfare of human subjects rests with each individual who initiates, directs, or engages in research. It is the responsibility of IRB to insure that the rights and welfare of the human research subjects recruited to participate in research activities conducted under auspices are protected.

1.3 The Principles that Govern the IRB

The University of Rhode Island has established the Institutional Review Board (IRB) as responsible for the institution’s obligations to review research involving human subjects. This committee has been established under an assurance of compliance negotiated with the U. S. Department of Health and Human Services and is governed by the ethical principles outlined in the Belmont Report (The Ethical Principles and Guidelines for the Protection of Human Subjects, 1979).
2.0 THE AUTHORITY OF THE IRB

2.1 Types of Studies that must be Reviewed

All research projects involving human subjects conducted by University faculty, staff and students or done under the sponsorship or auspices of the institution must be reviewed and approved by the IRB prior to commencement of the research.

This includes research-involving subjects from outside the university and research that is not funded. This includes the following types of research (this is not an exhaustive list):

- All surveys and questionnaires distributed on-campus for research purposes
- Behavioral and social science research
- Clinical research
- Human genetic research
- Pilot studies

The University of Rhode Island allows research to those participants requiring additional protection outlined in the federal regulations:

- Pregnant Women
- Viable Neonates
- Prisoners
- Children
- Research involving human fetuses

The University of Rhode Island does not have the faculty, staff or facilities to conduct research involving the following subject population:

- Research involving nonviable neonates
- Research involving planned emergency waivers of informed consent

2.2 Disapproving, Modifying or Approving Studies based on Human Subject Protection Aspects

Actions on Protocols Reviewed by the IRB. By regulation, action on protocols that require full IRB review may be taken only at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it must receive the approval of a majority of those members present.

The Full Committee may act on a protocol in one of five ways:

1. It may be approved
2. It may be approved with conditions (requested modifications)
   o This option may not be used when the IRB requests modifications or clarifications that is directly relevant to the regulatory criteria for approval.
For the IRB Chair or an IRB member will review modifications and clarifications that are not relevant to the regulatory criteria designated by the IRB Chair to approve.

3. It may approve some components of the proposed research study and defer taking action on the other components
   o The IRB may approve components of the proposed research and allow the investigator to initiate research activities only related to those components. In such circumstances, the IRB must ensure that the approved components of the research study are scientifically valid and satisfy all criteria required for IRB approval, even if the other components are never approved and conducted. (OHRP Guidance November 10, 2010)

4. It may be tabled, needing substantial revisions or clarifications (such protocols will need to be re-reviewed by the full committee)

5. It may be disapproved (in this case, the study may be re-written to address all concerns and re-submitted for full committee review).

In cases where a study is disapproved - the IRB will provide its rationale for the action taken. The investigator may request an appearance before the Committee to present arguments for reversal of the decision or propose a change in the protocol based on the advice and counsel of the Committee.

2.3 Progressive Reports

The IRB may require progress reports or summary of findings from the investigator at any time and may determine a need to oversee the conduct of the study. The IRB has the authority to observe, monitor or request that an audit be performed to ensure that proper scientific, ethical and regulatory requirements are followed.

2.4 Monitoring for Compliance

Monitoring of ongoing studies may include the following:

- Determining whether the investigator has current, complete copies of all informed consents in his/her files for subjects enrolled in the study
- Determining whether the investigator has a copy of the current protocol and a blank copy of the most recent informed consent document
- Determining whether the investigator has complete and current copies of correspondence from the IRB and, if applicable, the study sponsor
- Determining whether the investigator has adhered to inclusion/exclusion criteria
- Determining whether the investigator has reported all unanticipated problems and adverse events to the IRB

2.5 Authority to Termination or Suspend Approval of a Study

The IRB has the authority to determine if a research project should be suspended or terminated for cause. The action will be reported to appropriate institutional officials, the head of any supporting Federal Department or Agency (if applicable), the Office of Human Research Protections under DHHS, and the corporate study sponsor (if applicable). If the project that is suspended or terminated involves a drug, device, or biologic regulated by the Food and Drug Administration, the FDA shall also be notified of the suspension/termination.
3.0 THE IRB ORGANIZATIONAL STRUCTURE

3.1 Administration of the Institution

For matters relating to the execution of their duties and responsibilities, the IRB staff reports directly to the Authorized University Institutional Official, the Vice President of Research and Economic Development.

The following are reported to the Vice President of Research and Economic Development who in turn communicates with the Office of Human Research Protections (OHRP) with the Federal Department of Health and Human Services (DHHS)

- Changes in IRB membership
- Serious or continuing noncompliance with federal regulations, within three (3) business days, upon verification.
- Any unanticipated problems involving risks to subjects or others, within three (3) business days, upon verification
- Any suspension or termination of IRB approval for a project, within three (3) business days, preceding the convened meeting.

Reports of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations of the IRB are also made to:

- The IRB as an information item in the agenda in the next scheduled meeting.
- Other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to the Office of Human Rights Protection (OHRP), within 14 business days of suspension or termination of research protocol.
- The Food and Drug Administration (FDA), when the research is FDA regulated, within fourteen days of suspension or termination of research protocol.

3.2 Other Committees

The IRB works in collaboration with other committees and with the campus community as a whole to ensure the protection of human subjects. The following is a list of other offices and committees that may be involved in collaboration. When research involves one of these committees, the IRB process requires review and approval from these other committees. Letters of review and approval must be received and reviewed by the convened IRB. This review requirements and process is outlined in the IRB Application.

- Institutional Official
  - The Vice President of Research and Economic Development is URI’s Institutional Official responsible for the oversight of research and the IRB office functions. The Institutional Official signs our Federal Wide Assurance and agrees to uphold the responsibilities and commitments with the requirements set forth in the Federal Wide Assurance and the regulations for the protection of human subjects at 45 CFR Part 46, the Food and Drug Administration 21 CFR 50 and 56, State and Local laws concerning Human Subjects research.
  - Biosafety Committee
    - The National Institutes of Health require that universities maintain the highest level of scientific integrity and community safety in the review of research involving genetic engineering, the splicing together of DNA from different organisms. Strict rules have
been established regarding types of experimentation allowable and under what circumstances different classes of experiments can be conducted. The Institutional Biosafety Committee reviews all such research.

- **Radiation Safety Committee**
  - The use of radioactive materials on campus is governed by the Rhode Island State Department of Health. The Radiation Safety Committee advises members of the university in matters involving radiological procedures and safety; establishing procedures pertaining to the ordering, receipt, use and disposal of radioactive materials; and advises faculty on specific problems related to the use of radioactive materials in research and instruction.

- **Institutional Animal Care and Compliance**
  - To provide for the care and well-being of animals used for research, training and education at The University of Rhode Island; To support the animal-related needs of University researchers, educators and students; To ensure compliance with all standards mandated by federal and state law, accrediting bodies and the Institutional Animal Care and Use Committee.

### 3.3 The Research Investigators

The IRB communicates to the Principal Investigator and ensures that the following requirements are adhered to:

- All members of the research team comply with the findings, determinations, and requirements of the IRB.
- Research does not commence until the human subject research conducted under their name has received review and approval by the IRB.
- The informed consent document and the informed consent process complies with the IRB reviewed and approved and stamped document.
- Continuing review and approval of the research has been conducted within the requirements set by the IRB.
- No modifications or revisions have been initiated without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects.
- No research is continued beyond the IRB designated approval period.
- Any unanticipated problems involving risks to subjects and any serious adverse events are reported to the IRB within 5 business days, or sooner depending on the severity as outlined in section Ensuring prompt reporting to the IRB, appropriate institutional officials, the OHRP and FDA unanticipated problems/adverse events/complaints.
- The P is required to report all allegations and finding of non-compliance within 5 business days to the IRB Office.
- Conflict of Interest forms and/or conditions must be reported to the IRB.
- The Principal Investigator is required to follow the Department of Education regulations regarding access to instructional material used in a research or experimentation program:
  - All instructional material - including teachers’ manuals, films, tapes, or other supplementary instructional material - which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.
  - Research or experimentation programs or projects mean any programs or projects in any research that is designed to explore or develop new or unproven teaching methods or techniques.
  - Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age of 18.
3.4 Research Records

Although regulations require that all human subjects' research records be retained for three years following the completion of the research 45 CFR 46.115(b). The investigator must maintain all research records (including a copy of the entire protocol, consent form, amendments, and copies of signed consent forms for each research participant if applicable) in the lab or office of the investigator.

If the investigator leaves The University of Rhode Island, the records must be kept at the University in the Office of Research Integrity or with a designated investigator. The office must be informed of this transfer of records prior to the investigator’s departure. The records will be accessible for inspection and copying by authorized representatives of the DHHS and FDA and the university.

When a student graduates, or otherwise leaves the University, the faculty advisor is then responsible for retaining the human subject documentation. Students may retain the original protocol; while a copy of all research documentation including all signed informed consent forms must be maintained in the areas listed above.

The IRB will retain all records required by the regulations (e.g. minutes, correspondence between the IRB office and investigators, IRB rosters, and written procedures required by regulations) for at least six years, and retains all records relating to research that has been conducted or cancelled for at least six years after completion or cancellation of research.

The IRB makes records accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

3.5 Closing a Protocol

Closure of a protocol should occur when the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, or all research activities and data analysis is complete. A Protocol Closure Form can be found on our website.

3.6 Other Institutions

All research that is being conducted in collaboration with another institution must receive approval from the other institution’s IRB, if one exists. If the collaborating institution does not have an IRB then a letter of permission from an individual who has authority must be obtained. If the research will be conducted in an educational environment, permission must be obtained from the Superintendent of the School District. All letters of permission must be received before research can commence. This may also include research sponsors, other IRBs with which we have a review relationship, and community and special interest advocacy groups.

These collaborating institutions must provide a letter of understanding that outlines that all applicable laws and regulations will be abided by and adhered to.

3.7 Regulatory Agencies

The University of Rhode Island’s IRB is required to communicate with Federal, State and local authorities regarding all information that is outlined in the Federal Guidelines. We also strive to maintain positive and productive relationships with regulatory agencies, local and state legislators.
4.0 THE MEMBERSHIP OF THE IRB

4.1 Number of Members

The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at The University of Rhode Island.

The IRB will consist of individuals who have expertise in the areas of research reviewed and have sufficient expertise and diversity to evaluate ethical issues involved in research. The IRB has at least one non-scientist, and at least one person who is not affiliated with the university, both represent the perspective of the research participants.

The committee will not have a member participate in the committee’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The IRB will invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

4.2 Qualification of Members

The IRB Chairperson in collaboration with the IRB Administrator will identify those areas of research which IRB member’s expertise is required. Recommendations for appointment to the IRB are requested from individuals in the research community. Community members may be identified through various sources and depending on the area of expertise required. The IRB conducts an initial contact to gauge the willingness of the individual. Individual names of those that express an interest and desire are forwarded to the Institutional Official. The Institutional Official appoints the individual.

4.3 Diversity of Members

The IRB membership will not consist entirely of men or entirely of women; it will include qualified persons of both sexes. The IRB will not consist entirely of members of one profession.

The University of Rhode Island’s IRB evolves and changes to ensure that the committee has the expertise to professionally evaluate the research protocols and to ensure the protection of human subjects. Our board members represent a wide range of professions and laymen and women. These always include a Physician, Professors in various fields, a community advocate, and a prisoner advocate. The compilation of various backgrounds brings to the committee the ability to assess risk from differing perspectives.

The University of Rhode Island IRB has called on in the past, individuals who are expert in a field that the committee lacks or does not include.
5.0 MANAGEMENT OF THE IRB

5.1 The Chairperson

The Chair has direct responsibility for assuring that the IRB operates in full accordance with regulatory requirements and the highest ethical standards. The Chair works with IRB staff, committee members, institutional officials, and investigators to ensure that the rights and welfare of research participants are adequately protected, and that the benefits of the research justify the risks to the research participants.

5.1.1 Selection and Appointment

The Institutional Official (Vice President for Research and Economic Development) appoints the IRB Chairperson.

5.1.2 Length of Term/Service

The Chair of the IRB is usually appointed for a three-year term.

5.1.3 Responsibilities

The Chair should play a leadership role in establishing and implementing IRB policy. As a primary representative of IRB decisions, the IRB Chair should have shared authority over all IRB policy and procedures in collaboration with the Institutional Official and IRB Administrator.

- The Chair should represent the IRB in discussions with other segments of the organization.
- The Chair should represent the organization in discussion with federal authorities.
- The Chair should review all protocols presented to the full committee. The IRB Chair is expected to have read each full committee protocol and to communicate with other reviewers so that important IRB issues are identified or resolved before the full committee meeting.
- The Chair should direct the proceedings and discussion of the full committee meeting. This includes keeping the discussion focused on important IRB issues and seeing that the full-committee meeting process is both efficient and effective.
- The Chair should vote at full committee meetings.
- The Chair should have an in-depth understanding of the ethical issues, state law, institutional policy, and federal research regulations that are applicable to studies that are reviewed by the IRB.
- The Chair is not expected to be the only, or ultimate, authority on compliance issues. The IRB Administrator or other members of the IRB organization also take responsibility for compliance verification.
- The Chair should assist the IRB Administrator in the drafting of letters from the IRB to researchers regarding IRB decisions.
- The Chair should review protocols in a timely fashion.
- The Chair should review and make decisions about responses to condition for IRB approval of research in a timely fashion. This task is shared with the IRB Committee and the IRB Administrator.
- The Chair should serve as the reviewer for research that is reviewed by exempt or expedited process. This task is shared with the IRB Administrator.
- The Chair should represent the IRB in defending or discussing IRB decisions with researchers.
• The Chair should investigate instances of non-compliance in collaboration with the Institutional Official and develop a plan of action to address the non-compliance and oversee monitoring of any remedial action.
• The Chair should review all of the unanticipated problems/adverse events/complaint forms and take appropriate action as needed regarding revision or status of the protocol and informed consent.
• Report as needed to the Institutional Official.

5.1.4 Removal

The Institutional Official is empowered to remove the Chair, at any time, for cause in consultation with the President.

5.2 IRB Members Selection and Appointment

The Chair and review and identify areas in which expertise is required. The IRB obtains the willingness of the individual to serve on the IRB prior to recommending the prospective member to the Institutional Official.

5.2.1 Length of Term/Service

Members serve a two-year term and can be re-appointed at the end of their term. Members may resign at any time by submitting a letter of resignation to the Chair of the IRB.

5.2.2 Duties

• The IRB members are responsible for completing initial and ongoing educational requirements regarding protection of human subjects.
• Identifying any conflicts of interest at IRB meetings and removing themselves from the discussion and voting except to provide information requested by the IRB.
• Identifying any conflicts of interest when requested to conduct reviews using the expedited procedure and not being involved in the discussion and decision making except to provide information requested by the IRB.
• Reading all material provided to them and being informed and prepared for the meeting.
• Conducting reviews as requested
• Being an active member of the IRB and attending the meetings on time, participating in the discussion and planning to stay the length of the meeting.

5.2.3 Attendance Requirements

The IRB members in accepting their appointments are informed of the scheduled meetings and it is their responsibility to make every effort to attend each meeting. In the event that a member is not available for a period of three consecutive meetings in one semester or six meetings in a one-year period they will relinquish their membership of the committee.

5.2.4 Removal

The Institutional Official may remove members from the IRB prior to the end of their appointment. The IRB member removal may occur in the event that the member does not fulfill their duties or responsibilities in reviewing protocols or has displayed inappropriate behavior and has affected the
conduct of the meeting. Members cannot be removed based on their voting record, or in an attempt to alter the IRB membership to obtain approval for protocols.

5.3 Training of the IRB Chair and Members

5.3.1 Orientation

The IRB members are required to complete the on-line Collaborative IRB Training Initiative educational program. The CITI human subject’s research educational program consists of a Basic Course specifically prepared for Investigators conducting Social / Behavioral research and a course for IRB Members.

- The CITI Education (e.g., Basic Course or IRB Member Course) must be completed prior to the first convened meeting that the new appointee is scheduled to attend. CITI as well as the Office of Research Integrity staff will notify those members requiring Continuing Education. This continuing education must be completed by the expiration date of 3 years from the last certification date in order to maintain active in University of Rhode Island’s IRB.

- The Department of Defense regulations require initial and continuing research ethics education for all personnel who conduct, review, approve, oversee, support, or manage human participant’s research. Educational requirements will be outlined through correspondence (i.e. email) by the Department of Defense and these requirements will be forwarded to the appropriate personnel by the IRB staff (i.e. all personnel who conduct, review, approve, oversee, support, or manage human participant’s research). CITI as well as the IRB staff will notify those members requiring continuing Education. This continuing education must be completed by the expiration date of 3 years from the last certification date in order to maintain compliance with the Department of Defense funded research.

- The IRB Administrator will review with the new member the procedures for obtaining materials and the various forms used. This includes reviewing access to and the ability to retrieve documents.

5.3.2 Continuing Education

The IRB Administrator or IRB Chair will present training materials to the committee on a regular basis. Additional training materials will be sent to IRB members via email and IRBNet.

5.3.3 Reference Materials (Library)

All information is stored on the IRB. The committee members are free and encouraged to submit educational findings regarding human subjects for distribution through email or through project mail in IRNet.

The Office also has access to IRB Ethics and Human Research and The Hastings Center Report. These publications offer issues and/or concerns that are relevant to human subjects research. Articles are often shared and discussed among the IRB.

5.4 Compensation of Members

The University of Rhode Island’s IRB is a volunteer group of individuals who are donating their time and expertise for the benefit of’s research environment.
5.5 Liability Coverage for Members

The University of Rhode Island Office of Risk and Safety provides insurance to all URI groups and individual members for their work representing URI.

5.6 Use of Consultants

The IRB will call on consultants to provide to the IRB the additional expertise or cultural diversity that may arise.

Consultants are chosen by the IRB Chair in consultation with the IRB Administrator and input from other individuals knowledgeable in the area of study, based on their expertise and can be drawn from an institution, the community, or a colleague.

The consultant is required to sign a written confidentiality statement, provide a summary of expertise, and complete a questionnaire indicating their possible Conflict of Interest. Those individuals who have a conflict of interest in the research they are asked to review will not be allowed to serve as a consultant.

The consultant will provide an opinion to the IRB in layman terms. This may be accomplished through a written report that will be distributed to the IRB via IRBNet or they may attend a meeting and submit the report then and be available for questions. If the consultant attends the IRB meeting, they will not be involved in the discussion and decision-making except to provide information requested by the IRB. The Consultant must leave the meeting before final discussion and voting.

All consultant reports will be kept on file in the IRB Office and the information provided to the IRB by the consultant will be reflected in the minutes of the meetings.

5.7 IRB Administrator Responsibilities

The IRB Administrator has the following responsibilities to:

- Serve as the primary resource for investigators regarding the administrative review requirements for human research protocols
- Understand, interpret and document compliance with Federal and State research regulations
- Perform preliminary review of all research applications and determine protocol status and identify problems and issues on the submission based on the University of Rhode Island’s, the Federal Government Guidelines and Rhode Island State Laws
- Approve protocols based on Federal criteria for Exempt and Expedited protocols
- Track pending applications and advise investigators on the status of their protocols
- Identify and track approved research protocols, including implementing office-established procedures to assist investigators in complying with conditions imposed by the committee
- Review which members will be present at the convened meetings and determine that:
  - At least one member will have sufficient scientific or scholarly expertise related to the research
  - If the research involves vulnerable populations at least one member who is knowledgeable about or experienced in working with such subjects will be present
  - If the research involves other necessary expertise, such as knowledge of local context, at least one IRB member with such expertise will be present
- If the IRB members do not have the required expertise, the IRB Chair will be informed that an outside consultant is required
- Issue approval notices based on conditions imposed by the committee
- Design and create all databases and documents pursuant to Federal Guidelines
Supervise the updating of all databases and maintain correct records of confidential research protocols
Supervise and train the Senior Word Processing Typist (SWPT) and student interns
Provide educational training in Human Subjects Research to University of Rhode Island’s academic departments and the Washington County community
Create and modify all forms and applications required for protocol submissions
Update and revise Policy and Procedures pursuant to Federal Policy 45 CFR 46.116(b) (5). And 21 CFR 56.

5.8 Resources

The University of Rhode Island's IRB is provided resources pursuant to Federal Regulations 45 CFR 46.103(b)(2)

1. Space and office - The Office of Research Integrity is located in the basement of 70 Lower College Road on the Kingston Campus. Resources also include meeting space, office equipment and supplies, including technical support, file cabinets, computers, Internet access, and access to copy machines. These resources are reviewed during the annual budget review process.
2. Personnel - The IRB is provided adequate staffing for conducting IRB business. Personnel hires are bound by The University of Rhode Island and the state of Rhode Island, and federal regulations of all Affirmative Action and Equal Employment Opportunities requirements. The recruitment and hiring process follow the policy and procedures and works in collaboration with the Human Resource Office.
3. Human Subjects Education Program - All IRB staff and committee members are required to fulfill the Collaborative IRB Training Initiative (CITI) Group 1 (Basic Course). The office staff maintains records to ensure that the members are currently up-to-date on all training. The CITI program also sends out reminders to all CITI registered users of any refresher courses that are required. All IRB staff and members also are involved in additional training through the use of current events relevant to human subjects research discussed during convened meetings. All new federal regulations, policy and procedures revisions and other news that require immediate notification to the research community is accomplished through the newsletter.
4. Legal Counsel - The IRB relies on the University of Rhode Island's General Counsel for the interpretations and applications of law and the laws of any other jurisdiction where research is conducted as they apply to human subject research.
5. Conflicts of Interest - All IRB members are required to sign an annual conflict of interest statement.
6. Community outreach - The IRB participates in community information setting by being present or providing brochures and educational material for individuals who have or may participate in Human Subjects Research. For those community members who have questions, complaints or concerns regarding participation in human subjects research, our office contact information is made widely available through media and the informed consent documents. Our office maintains documentation of all community questions, comments or concerns that are relayed to the IRB via email and IRBNet and discussed during convened meetings.
7. The IRB - On an annual basis the IRB are requested to complete the Research Review Committee Survey. The purpose of this survey is to collect data to assess current effectiveness in the education of IRB members and the conduct of the IRB meetings. The survey is collected anonymously and is included in the annual IRB membership meeting discussion with the Institutional Official, the IRB Chair and the IRB.

5.9 IRB Chair, Member and Staff evaluations

The IRB Chair requests evaluations from the IRB committee members and requires that these evaluations be forwarded to the IRB Administrator who forwards these assessments to the Institutional Official. Positive assessments are included in the reappointment letter authored by the Institutional Official.

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• The IRB Chair meets with the Institutional Official on an annual basis where the anonymous surveys, attendance records, and any other issues related to the Chairs position are discussed. At this time the Institutional Official may start the procedure to extend the Chair’s position or select a new IRB Chair.

• The IRB Members are evaluated through an anonymous survey distributed to each member on an annual basis. The IRB Chair and the Institutional Official on a yearly basis then review the survey. Evaluations also include attendance, and member participation and preparation for meetings.

5.10 IRB Quality Monitoring Program

Purpose
The purpose of the Quality Monitoring Program for Human Subjects Research is to provide a systematic internal process that will increase compliance with federal, state, local and institutional requirements. This program will also promote human subjects protections through the ethical conduct of research. This program will be conducted on an annual basis and the plan measures and improves human research protection effectiveness, quality, and compliance with organizational policies and procedures and applicable local, state, and local laws.

The Internal Audits includes, but is not limited to the following:

• Review of the IRB minutes to verify that meeting discussion address issues relating the regulatory requirements in 45 CFR 46.111 and for subsections B, C and D for IRB approval of research.
• Review minutes to assure that quorum was met and maintained.
• Review Complaints/ Adverse Events and Unanticipated Problem reports.
• Review database, files and minutes to evaluate the continuing review discussions, and to ensure that the Continuing Reviews are reviewed on an annual basis pursuant to federal regulations 45 CFR 46.109(e).
• Review electronic and hard copy files to assure presence of all appropriate documentation.
• Verification of IRB Federal Wide Assurance and Institutional Review Board applications with the Department of Health and Human Services.

All reports will be filed with the Institutional Official and copies provided to the IRB. The Institutional Official and the IRB will review the reports and revise policy and procedures to accommodate the required actions found in the report.

Research Assessment Surveys

The IRB encourages a “teamwork” model between the University of Rhode Island Researchers and the IRB. In order to facilitate this environment it is important to communicate with the researchers and to allow the researcher the opportunity to provide feedback, both positive and negative to the IRB.
6.0 CONFLICT OF INTEREST POLICY

The University of Rhode Island's IRB policy states that IRB members will not review, participate in the discussion of, or vote upon any research protocol for which they have a conflict of interest. No IRB member can take part in the initial, amendment or continuing review of a protocol in which they have a conflict of interest other than to provide requested information.

6.1 Conflicts of Interest for IRB Members

The University of Rhode Island’s IRB policy prohibits IRB members from reviewing, participating in the discussion of, or voting upon any research protocol for which they, their spouse, dependent children, or partner are involved in the design, conduct, or reporting of the research.

The IRB policy prohibits IRB members from reviewing, participating in the discussion of, or voting upon any research protocol when the committee member, their spouse, dependent children, or partner holds a financial interest, meaning anything of monetary value, including although not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options, or other ownership interest); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights)

The University of Rhode Island’s IRB members with these types of conflicts of interest shall recuse themselves from the final discussion and vote of all such studies. All conflicted members must recuse themselves and leave the room for the vote and are not counted towards quorum. Absences of IRB Committee members, who have a conflict, from the deliberation and the vote are noted in IRB minutes.

When a member, or a member’s spouse, relative or partner, is an investigator on a study to be reviewed, IRB members must recuse themselves from the review, discussion of, and vote on the protocol.

Consultants are considered to have a conflict of interest when they, their spouse, dependent children, or partner are involved in the design, conduct, or reporting of the research.

Consultants are considered to have a conflict of interest when consultant, their spouse, dependent children, or partner holds a financial interest, meaning anything of monetary value, including although not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options, or other ownership interest); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights).

6.2 IRB Responsibility

IRB members are provided guidance about conflicting interest through the University of Rhode Island’s IRB policies, given to all members upon their acceptance of IRB membership, and throughout their tenure on the board.

Every IRB meeting agenda includes language that prompts members to leave the room during the discussion and vote if they have a conflict of interest related to a study on the agenda

Absences of IRB Committee members, who have a conflict, from the deliberation and the vote are noted in IRB minutes.
7.0 FUNCTIONS OF THE IRB

7.1 Conducting Initial Review

The IRB Chair or an individual who possess the qualification and is a current member of the IRB will review each application for compliance with federal and state regulations and institutional policies. The IRB Chair or designee will determine if the protocol is “Human Subjects Research”, as defined below, and is eligible for exempt/expedited review pursuant to 45 CFR 46.110 and 21 CFR 56.110 and 45 CFR 46.101(b).

Research involving “human subjects,” means any activity that either:

- Meets the Department of Health and Human Services (DHHS) definition of “research” and involves “human subjects” as defined by DHHS; or
- Meets the Food and Drug Administration (FDA) definition of “research” and involves “human subjects” as defined by FDA.

DHHS Definitions:

**Research:** a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge [45 CFR 46.102(d)]

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

  - “Intervention” as defined by DHHS regulations means 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. [45 CFR 46.102(f)]
  - “Interaction” as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]
  - “Private information” as defined by DHHS regulations means 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). [45 CFR 46.102(f)]
  - “Identifiable information” as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

FDA Definitions:

**Research** - any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations [21 CFR 50.3(c), 21 CFR 56.102(c)]
“Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act” means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]

“Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act” means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]

“Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]”

**Human Subject** means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g), 21 CFR 56.102(e)] A human subject includes an individual on whose specimen a medical device is used. [21 CFR 812.3(p)]

**Definitions:**

**Systematic Investigation** - one utilizing the observation of phenomena, the formulation of a hypothesis concerning phenomena, experimentation to demonstrate the truth or falseness of the hypothesis, and a conclusion that validates or modifies the hypothesis.

**Generalizable Knowledge** - information that is gathered to draw general conclusions beyond the context and/or subject from which the data is gathered.

Some research on specimens derived from living individuals may be considered human subjects research under both the DHHS and FDA regulations.

**Scientific Evaluation**

All Expedited and Full Board Review protocols will be reviewed by the initial reviewer(s) and the IRB to evaluate all research protocols for scientific or scholarly validity by determining that:

- The research procedures are consistent with sound research design
- The research is likely to achieve its objectives
- The knowledge expected to result has importance

**Department of Defense Regulations**

Surveys performed on Department of Defense personnel must be submitted, reviewed and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.

### 7.1.1 Exempt and Expedited Review

IRB Applications received that qualify for exempt/expedited review are reviewed for approval by the IRB Chair or an experienced member of the IRB designated by the Chair. Experience is defined as those committee members who having gained this knowledge of the subject beyond that of an average man through their education, training, skill, or experience.

The Chair will designate experienced IRB members by periodically updating a list of experienced IRB members designated to conduct review using the expedited procedure and the IRB staff will select reviewers from the list. If the chairman or designated member of the IRB questions the approval of the protocol, they will communicate their questions to the Principal Investigator. Comments, questions and the request for additional information will be returned to the Principal Investigator in writing. The
Principal Investigator must address all comments, questions and additional information requested in the review before the protocol can be approved.

The following should be submitted to the Office of Research Integrity for review through IRBNet:

- The IRB Application
- Research Protocol/Narrative Proposal
- Proposed consent documents and all other documents in the Research Protocol/Narrative Proposal
- Grant Abstract
- The DHHS-approved sample consent document (when one exists)
- The complete DHHS-approved protocol (when one exists)

The Review process includes:

*Initial Review:*

- The reviewers will review all materials that would have been reviewed by the convened IRB.
- The reviewers will review Federal Regulations 45 CFR 46.110, 21 CFR 56.110 and 45 CFR 46.101. The reviewers will also complete the URI IRB Reviewer Form to ensure that the research:
  - Meets all applicability criteria
  - Represents one or more approvable categories of research.

The convened IRB will use the URI IRB Reviewer Worksheet

*Continuing Review:*

The following should be submitted to the Office of Research Integrity for continuing review:

- Human Subjects Continuing Review Form
- Research Protocol/Narrative Proposal
- Proposed consent documents
- All other documents noted in the Research Protocol/Narrative Proposal
- Currently approved consent documents

The convened IRB will use the URI IRB Reviewer Worksheet to determine whether the research undergoing continuing review can be approved.

- The reviewers will review the initial protocol along with the Continuing Review application and all material that would have been reviewed by the convened IRB.
- The reviewers will review Federal Regulations 45 CFR 46.110, 21 CFR 56.110. URI IRB Reviewer Worksheet to ensure that the research:
  - Meets all applicability criteria
  - Represents one or more approvable categories of research.

*Modifications:*

- The reviewers will review the initial protocol along with the Modification application and all material that would have been reviewed by the convened IRB.
- The reviewers will review Federal Regulations 45 CFR 46.110, The reviewers will also complete the URI IRB Reviewer Form to ensure that the research:
All expedited research; initial, continuing review and modifications are posted on the agenda and presented to the IRB at the next convened meeting.

Department of Defense

Modifications require that substantive amendments to approved research must undergo scientific review prior to IRB review or have scientific review conducted by the IRB.

7.1.2 Full Committee Review

By regulation, action on protocols that require full IRB review may be taken only at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it must receive approval of a majority of those members present. In the event a quorum is lost during a meeting, the IRB cannot take votes until a quorum is restored. Below is a list of materials made available to the committee (7) days prior to the meeting to be reviewed by all of the members present at the meeting of the IRB.

- The IRB Application
- Research Protocol/Narrative Proposal
- Proposed consent documents and all other documents noted in the IRB Application
- Grant Abstract
- The complete DHHS-approved protocol (when one exists)

Full Committee Actions

The Full Committee may act on a protocol on one of five ways:

1. It may be approved
2. It may be approved with conditions
   - The option MAY NOT BE USED when the IRB requests changes or clarifications that are directly relevant to the regulatory criteria for approval.
   - For modification and clarification that are not relevant to the regulatory criteria for approval the IRB Chair or an IRB member designated by the IRB Chair will review the modifications.
3. It may approve some components of the proposed research study and defer taking action on other components
   - The IRB may approve components of the proposed research and allow the investigator to initiate research activities only related to those approved components. In such circumstances, the IRB must ensure that the approved components of the research study are scientifically valid and satisfy all criteria required for IRB approval, even if the other components are never approved and conducted (OHRP Guidance November 10, 2010)
4. The protocol may be tabled when substantial revisions or clarification are required (such protocols will need to be re-reviewed by the full committee).
5. It may be disapproved (in this case, the study may be re-written to address all concerns and re-submitted for full committee review).

The IRB will review and determine whether the research undergoing review can be approved. The IRB Chair will read aloud, during the convened meeting, the regulatory criteria required for the protocol to
document regulatory criteria. Once the project is approved, no protocol or consent changes, amendments or addenda may be made without review and approval by the IRB.

A decision letter for the approval and a final approved version of the consent form with the approval stamp is forwarded to the researchers through IRBNet.

Approved Consent Forms

The consent form is stamped with an approval/expiration date and an approval letter is forwarded to the Principal Investigator and Faculty supervisor through IRBNet.

The expiration date on the stamped consent document is the date that the protocol has expired. (the first date that the protocol is no longer approved)

The approval date is the date of the convened meeting at which the research was approved or approved with modifications plus the approval interval, not to exceed one year. The calculation of the approval period for research is based on the date of the IRB convened meeting at which the IRB approved the protocol or approved the protocol with modifications.

Copies of all documents are stored electronically on IRBNet.

7.1.3 Continuing Review Process

Continuing review is a federally mandated requirement. All research studies approved by the IRB must be reviewed at least annually. The expiration date is stamped on each page of the consent document. As a courtesy, a notice that the continuing review report is due will be sent via IRBNet to the Principal Investigator at least sixty days prior to the study expiration date. Please note that an investigator should not depend solely on IRB notification as a prompt for submitting a request for renewal. It is the responsibility of the Principal Investigator to complete the continuing review report form and return all requested items to be reviewed at the IRB meeting in order to ensure that the review process is completed on time. The following should be submitted electronically through IRBNet to the Office of Research Integrity for continuing review:

- Human Subjects Continuing Review Form
- Research Protocol/Narrative Proposal
- Proposed consent documents
- All other documents noted in the Research Protocol/Narrative Proposal
- Currently approved consent documents

7.2 Report Findings and Actions of the IRB

Exempt/Expedited Research

If the protocol falls into one or more exemption categories and meets additional ethical criteria, it will be approved as an exempt protocol. If the protocol either (1) meets all applicability criteria for review using the expedited procedure, falls into one or more categories allowing review using the expedited procedure or (2) is a minor change to previously approved research, and in addition meets the regulatory criteria for approval it will be approved as an expedited protocol.

An email will be sent to the Principal Investigator with notice of approval. A formal approval letter along with their consent form date stamped is posted to IRBNet.
Notification of actions taken at the IRB meeting is e-mailed to the Principal Investigator after each meeting. An email will be sent to the Principal Investigator with decision notice. A formal approval letter along with their consent form date stamped is posted to IRBNet.

In cases where a study is disapproved - the IRB will provide its rationale, which includes the federal regulations and criteria, for the action taken. The investigator may request an appearance before the Committee to present arguments for reversal of the decision or propose a change in the protocol based on the advice and counsel of the Committee.

7.3 Determining Study Review Schedule

In certain circumstances, determined at the time of initial or continuing review, the Committee may stipulate that continuing reviews should take place more frequently than once a year (e.g., high risk protocols or protocols with a high risk; potential benefit ratio).

If special reporting requirements are set as a condition of approval, the investigator must submit the required information, when designated, to determine whether changes have occurred in the risk: benefit ratio.

7.4 Determining Study Verification Needs

The Committee may request additional information from sources other than the principal investigator in order to assess the completeness and accuracy of information submitted and to verify that no material changes have occurred since the last IRB review.

These situations may include the following: complex projects involving unusual levels or types of risks to subjects; projects conducted by investigators who previously have failed to comply with requirement of the federal regulations or the requirement of the ; and projects where concern about possible material changes occurring without approval have been raised, based upon information provided in continuing review reports or from other sources.

7.5 Changes in IRB Research Activities

Once the IRB has approved a project, it must be carried out exactly as planned. Any and all changes (i.e. subject population, recruitment plans, research procedures, study design, study instruments, study sites, or research personnel) must be approved by the IRB prior to implementation.

The IRB will review the following documents involving the modification using the appropriate URI IRB Reviewer Worksheet to determine whether a modification undergoing review using the expedited procedure can be approved.

- Amendment Form
- One marked copy of the document that will be revised (all changes must be highlighted or underlined)
- The IRB Application (all changes must be highlighted or underlined)
- Research Protocol/Narrative Proposal (all changes must be highlighted or underlined)
- Currently approved consent documents
- Any proposed consent documents, with all changes highlighted or underlined
- One clean copy of the amended consent document for the IRB stamp (note: the expiration date remains the same).

Minor protocol/consent changes may be approved by expedited review.

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45 CFR 46.110(b)(2) allows for minor modifications to research that required convened review and approval to be approved through expedited procedures during the period of approval.

The IRB has determined that the Chair will make the final decision of the revision is considered a "minor modification". If the Chair is not available, then all modifications will be reviewed by the full board.

The Chair will review the entire protocol and all information and assess whether the modification is considered minor. Minor changes would be defined as changes that do not adversely alter the overall risk/benefit profile of the study; would not affect the willingness of current subjects to remain in the study; and do not alter the scientific validity of the study design.

The modification will be reviewed using the URI IRB Reviewer Worksheet to determine whether research undergoing expedited review can be approved.

Those modifications that are excluded from expedited review are those that involve more than minimal risk, or do not fall into expedited categories outlined in 45 CFR 46 110(1)-(7). These modifications will be reviewed by the convened IRB and will be reviewed using the URI IRB Reviewer Form to determine whether the modifications to previously approved research undergoing can be approved.

7.6 Reporting to the IO, OHRP, FDA and DoD

7.6.1 Reportable Events

Principal Investigators or any individual involved in the research must report the following problems to the in via IRBNet within five (5) business days on an Event Reporting form.

- Allegations or findings of non-compliance. Non-compliance is defined as: failure to follow the requirements or determinations of the
- Protocol Violation: Any unapproved deviation from the protocol, or the policies is considered a Protocol Violation: whether or not it is intentional and whether or not it is under the control of the Investigator.
- Protocol Deviation: If anyone on the research team has deviated from the protocol as written and approved by the IRB:
  - Submit a Event Reporting form and follow the protocol as written, OR
  - Submit a Event Reporting form and submit a modification to the IRB, while your modification is being written, submitted, reviewed, and approved, you must follow the current, approved protocol as it is written.
- Breach of confidentiality
- Incarceration of a subject in a protocol not approved to enroll prisoners.
- Any problems involving the conduct of the study or patient participation. For example, social and behavioral interviews may deal with sensitive issues - occasionally, research subjects will become upset because of the nature of the questions, and this requires reporting.
- Any problems involving the recruitment and/or consent processes require reporting. For example, if a person who is contacted, either in writing or in person, about participating in a study becomes upset about the recruitment process, this should be reported.
- Any other problem that the investigator considers to be unanticipated and indicates that subjects or others are at increased risk of harm.
- Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.
• Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including supplemental plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
• Change in FDA labeling or withdrawal from marketing a drug, device, or biologic used in a research protocol.
• Event that requires reporting to the sponsor.
• Sponsor imposed suspension for risk.
• Events or any harm experienced by a subject or other individual regardless of whether the event meets FDA definition of “serious adverse event”, which in the opinion of the investigator are both unexpected and indicate new or increased risks to subjects
• Information that indicates a change to the risks or potential benefits of the research. For example:
  1. An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits might be different from those initially presented to the IRB
  2. A paper is published from another study that shows that the risks or potential benefits of the research might be different from those initially presented to the IRB.

All problems described above must be reported promptly. The Event Reporting form is available on the URI website and on IRBNet.

o Department of Defense Regulations regarding reporting Serious or Continuing Non-Compliance

3216.2, paragraph 4.10: Non-compliance. Issues related to non-compliance with this Directive by any DoD Component, subordinate, or supported activity should be referred initially to the next higher management echelon to take deliberate action to resolve. All findings or serious or non-compliance under this section shall be reported to the Director, Defense Research and Engineering.

Department of Navy

3900.39D Allegations of Non-compliance with Human Subject Protections. The Naval command or activity with responsibility for the research will review all allegations of non-compliance with human subject protections and take action if appropriate. Report the initiation of all investigations and report results regardless of the findings to the Navy SG and appropriate sponsors.

**7.6.1.1 Definitions**

• **Non-compliance**: Failure to follow the regulations or VHA Handbook 1200.5 and failure to follow the requirements or determinations of the IRB.
• **Allegations of non-compliance**: An unproven assertion of non-compliance.
• **Findings of non-compliance**: A proven assertion of non-compliance.
• **Serious non-compliance**: Non-compliance that affects the rights and welfare of participants.
• **Continuing non-compliance:** A repeated pattern of non-compliance likely to recur without intervention.

• **Unanticipated Problem Involving Risks to Participants or Others:** Any problem, event, occurrence or new information that is (1) unanticipated and (2) indicates that participants or others are at increased risk of harm.

• **Protocol Violation:** Any unapproved deviation from the protocol, or the IRB policies is considered a Protocol Violation: whether or not it is intentional and whether or not it is under the control of the Investigator.

• **Protocol Deviation:** If anyone on the research team has deviated from the protocol as written and approved by the IRB:
  1. Submit an Event Reporting form and follow the protocol as written, OR
  2. Submit a Event Reporting form and submit a modification to the IRB, while your modification is being written, submitted, reviewed, and approved, you must follow the current, approved protocol as it is written.

### 7.6.1.2 Review of Reports

The IRB Office staff reviews the Reportable Event Form and asks these three questions:

• Does this report involve an allegation of non-compliance?

• Does this report involve a finding of non-compliance?

• Does this report involve an unanticipated problem involving risks to participants or others?

If the answer to question 1 is yes, the report is processed as described in “Allegations of Non-compliance”.

If the answer to question 2 is yes, the report is processed as described in “Findings of Non-compliance”.

If the answer to question 3 is yes, the report is processed as described in “Unanticipated Problems Involving Risks to Participants or Others”.

If the answer to multiple questions is yes, then the multiple corresponding policies and procedures are followed.

If the answer to all questions is no, then no further action is taken.

### 7.6.1.3 Allegations of Non-compliance

IRB Office staff and the IRB chair evaluate allegations of non-compliance to determine whether it has no basis in fact or is a finding of non-compliance.

- If the basis has a basis in fact, it is handled as described in “Findings of Non-Compliance”.
- If the allegation has no basis in fact, no further action is taken under this section of the policy.
7.6.1.4 Findings of Non-compliance

IRB Office staff and the IRB chair evaluate finding of non-compliance to determine whether it is serious or continuing non-compliance.

- If the non-compliance is either serious or continuing, it is handled under the section on “Serious or Continuing Non-compliance”.
- If the non-compliance is neither serious nor continuing, it is handled under the section on “Non-serious and Non-continuing Non-compliance”.

7.6.1.5 Non-serious and Non-continuing Non-compliance

- IRB Office staff and the IRB chair work with the non-compliant parties to develop an appropriate corrective action plan.
- If the non-compliance parties do not work with the IRB in a collaborative effort to develop a corrective action plan when asked to do so, the non-compliance is handled as continuing non-compliance under the section “Serious or Continuing Non-compliance”.

7.6.1.6 Serious or Continuing Non-compliance

All serious or continuing non-compliance is handled by the convened IRB under the section on “Convened IRB Review of Problems.

7.6.1.7 Unanticipated Problems Involving Risks to Participants or Others

All unanticipated problems involving risks to participants or others are handled by the convened IRB under the section on “Convened IRB Review of Problems”

7.6.1.8 Convened IRB Review of Problems

The IRB staff will provide all IRB members with information about the problem, results of any Investigation, supporting documents, and information about the consent and protocol, when the research involves a specific protocol.

The convened IRB considers the following actions and may take no action:

- Suspension of the research.
- Termination of the research.
- Notification of participants when information about the non-compliance may affect their willingness to continue participation.
- Modification of the protocol.
- Modification of the information disclosed during the consent process.
- Providing additional information to past subjects.
- Requiring current subjects to re-consent to participate.
- Modification of the continuing review schedule.
- Monitoring of the research.
- Monitoring of the consent.
- Referral to other organizational entities.
7.7 Suspension and Termination of IRB Approval

Definitions:
Suspension: Temporarily or permanently withdrawing approval for some or all research procedures short of permanently stopping all research procedures. Suspended research must undergo continuing review.

Termination: Permanently withdrawing approval for all research procedures. Terminated research is closed and does not require continuing review.

Suspension/Terminations Conditions

The IRB can suspend or terminate approval of research that:

- Is not being conducted in accordance with the policy and requirements of
- Has been associated with unexpected serious harm to subjects

Suspension/Termination Authority

The following individuals are authorized to suspend or terminate research and who can suspend IRB approval on an urgent basis:

- President of the University
- Institutional Official
- Chair, IRB

Reporting Procedures

Individuals or bodies other than the convened IRB suspending or terminating must report that action to the convened IRB for review.

When the research is suspended or terminated, the convened IRB or the individual ordering the suspension or termination must:

- Consider actions to protect the rights and welfare of currently enrolled subjects, such as:
  - Making arrangements for medical care of a research study
  - Transfer to another investigator
  - Continuation in the research under independent monitoring
- Consider whether procedures for withdrawal of enrolled subjects considering their rights and welfare
- Consider whether subjects should be informed of the termination or suspension
- Require any adverse events or outcomes to be reported to the

The following incidents require reporting to the OHRP 45 CFR 46.103(a) and (b)(5)

- Any unanticipated problems involving risks to subjects or others;
- Any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and
- Any suspension or termination of IRB approval

Suspensions and terminations of the IRB approval are reported to the regulatory agencies and appropriate institutional officials.

These reporting requirements apply to funded research that is conducted at the University of Rhode Island.
7.8 Monitoring of the Consent Process

Situations may arise in which the IRB may consider observing the consent process as a method to protect subjects. Example:

- Inquiries into the Human Subjects Research Office on questions pertaining to the research that are addressed in the approved informed consent, for example:
  - What is the reason for this study?
  - How long am I required to participate?
  - What am I required doing?
  - Will I be compensated?
  - Will this research be anonymous?
  - Will any of my personal information be identified and shared?

The IRB Chair will appoint an individual from the IRB staff or from the IRB members. This individual will attend and observe the informed consent process between the Principal Investigator and the subject.

7.9 Review of Research Involving Drugs and Devices

Drugs:
The IRB office staff will review all documentation submitted by the Principal Investigator to determine that when an investigator proposes to conduct research that involves a drug that one of the following is true:

- The drug has an IND number and the IND number is supported by one of the following: (The Investigator Brochure may not be used for this purpose.)
  - Sponsor protocol imprinted with the IND number.
  - Written communication from the sponsor documenting the IND number.
  - Written communication from the FDA documenting the IND number. (Required if the investigator holds the IND.)
- The drug falls into one of the categories of exemption from an IND. [See 21 CFR 312.2(b)]

Control of Investigational Drugs

The IRB will review the plan for storage, control, and dispensing of the drug to evaluate whether the plan is adequate to ensure that only authorized investigators will use the drug and they will use the drug only in subjects who have provided consent.

Devices:
The IRB office staff will review all documentation submitted by the Principal Investigator to determine that when an investigator proposes to conduct research that involves evaluating the safety of effectiveness of a device that one of the following is true:

- The device has an IDE and the IDE number is supported by one of the following: (The Investigator Brochure may not be used for this purpose.)
  - Sponsor protocol imprinted with the IDE number.
  - Written communication from the sponsor documenting the IDE number.
  - Written communication from the FDA documenting the IDE number. (Required if the investigator holds the IDE.)
- The device meets the requirements for an abbreviated IDE. [See 21 CFR 812.2(b)]
• The device falls into one of the categories of exemption from an IDE. [See 21 CFR 812.2(c)]

**Control of Investigational Devices**

The IRB will review the plan for storage, control, and dispensing of the device to evaluate whether the plan is adequate to ensure that only authorized investigators will use the device and they will use the device only in subjects who have provided consent.
8.0 OPERATIONS OF THE IRB

8.1 Scheduling of meetings

The IRB Administrator informs the board members of the date and times of the scheduled meetings during the initial communication with the potential board member. The other board members are informed of the meeting schedule upon receipt of their appointment letters. The committee members at that time agree to attend the meetings, and in the event that they cannot they inform the Office of Research Integrity immediately. The IRB Administrator and Chair take into consideration the number of meetings that the board member cannot attend and a decision is made whether or not to ask the board member to recuse himself or herself for the semester.

8.2 Information Provided Prior to IRB Meeting

The University of Rhode Island’s IRB members meeting material is distributed electronically through a web-based system called IRBNet. All protocols and relevant documents are placed on (7) days prior to the scheduled meeting. The members are informed via email that the materials are available on-line and asked to review the documents and if additional information is required, please submit a request to the IRB Administrator and the Principal Investigator will be contacted for the additional information. The web posted meeting material includes:

- Meeting agenda
  - New Research
  - Modification Requests
  - Continuing Review Request
  - Listing of all approved expedited protocols
  - Listing of all administrative and exempt approved protocols
- Minutes from previous meeting
- Adverse Event/Complaint Reports
- All relevant document for protocol review
- New Business and or topics to be discussed

8.3 The Review Process

8.3.1 Documentation delivered to IRB members

Required Documentation Human Subjects from Principal Investigator for New Protocols:
The following should be submitted via IRBNet to the Office of Research Integrity for review:

- The IRB Application
- Research Protocol/Narrative Proposal
- All other documents noted in the Research Protocol
- All IRB Application Appendices as required
- Complete Grant Application (when one exists)
- Informed consent document using URI template (when one exists)

Continuing Review
The following should be submitted to the Office of Research Integrity for continuing review:

- Human Subjects Continuing Review Form
- Research Protocol/Narrative Proposal
• Proposed consent documents
• All other documents noted in the Research Protocol
• Currently approved consent documents

**Modifications**
The following should be submitted to the Office of Research Integrity for Modification requests:

• Modification Form
• All documents that will be revised (all changes must be highlighted or underlined)
• The IRB Application
• Research Protocol/Narrative Proposal
• Currently approved consent documents
• Any proposed consent documents, with all changes highlighted or underlined
• One clean copy of the amended consent document for the stamp (note: the expiration date remains the same).

**8.3.2 Criteria for approval containing all requirements of 45 CFR 46.101(b) and 110 and 21 CFR 56.110**

All protocols received by ORI will be reviewed for inclusion into the exempt or expedited category. The first assessment will be based on risk and vulnerable populations based on the following criteria: “§45 CFR 46.102(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

The protocol will then be reviewed against the exempt criteria outlined in 45 CFR 46.101(b)(1)-(b)(6). If the protocol does not fit the exempt criteria, yet is minimal risk it will be compared against the expedited criteria listed in 45 CFR 46.110 and 21 CFR 5.110.

The protocols will be reviewed using the URI IRB Reviewer Form to determine whether the research undergoing review using the expedited procedure can be approved, including:

• Initial Review
• Continuing Review
• Review of Modifications to previously approved research

**8.4 Voting Requirements**

**8.4.1 Quorum**

A quorum of more than half of the voting membership is required to conduct business. A quorum requires a majority of IRB members and at least one member whose primary concerns is in non-scientific areas to be present. It is strongly recommended that IRB members be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In this case the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions. For research to be approved, it has to receive approval of a majority of the members present at the meeting.
8.4.2 Absence or Loss of Quorum

If the quorum is not achieved or lost at a meeting due to members with conflict being excused, early departures, or a loss of a non-scientist, the meeting is terminated from further votes unless the quorum can be restored. Any absence or loss of quorum should be noted in the meeting minutes.

The secretary of the IRB will announce at the meeting, and also document in the minutes, the status of the quorum. In the event that a committee member must excuse themselves and a quorum is not met, the Secretary will announce the loss of a quorum, which will be documented in the minutes noting the time the meeting was closed due to loss of quorum.

8.4.3 Diversity Requirements of Quorum

The IRB Members consists of individuals that are sufficiently qualified to review research through their experience, expertise, and diversity, including consideration of race, gender, cultural backgrounds, and sensitivity to community issues and attitudes.

The IRB shall consist among other individuals, one member who is not affiliated with the university, one member who is a non-scientist, one member who is a scientist, and one member who is a physician, and all are to be present during the reviewing of FDA regulated studies.

The IRB Administrator may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the. These individuals may not vote with the IRB.

8.4.4 Approval Percentage

The approval of a research protocol requires a majority of votes by the IRB.

8.4.5 Voting Rights

Each IRB member has one vote. In the case where an both a member and the member’s alternate are in attendance, only the member or the alternate’s vote may be included in the vote.

8.4.6 Proxy votes

Proxy votes are not allowed, written or telephone

8.5 Further review/approval of actions by others within the institution (override of disapproval is prohibited).

By Federal regulation, institutional officials may not approve research that has not been approved by an IRB. Consequently, NIH does not have an appeal procedure if a protocol is not approved by an IRB. Principal Investigators may request an IRB to reconsider a decision regarding a human subject research activity. Investigators do not have the option to seek the reversal of an IRB decision by submitting the same protocol to another IRB.

8.6 Communication from the IRB

8.6.1 Additional Information required from the Investigator

During the initial review the IRB administrator or coordinator will compare the protocol documents received with our checklist of required documents. In the event that information is missing the investigator will be contacted via email for the documentation.
When the IRB members receive the protocol they can also contact the administrator or coordinator and request additional documentation or clarification. At this time the IRB administrator will contact the Principal Investigator via email and request the additional documentation.

8.6.2 Conveying the IRB Decision to the Investigator

Immediately after the convened meeting the IRB Administrator and IRB Chair review their notes to ensure that the committee's decisions, request for additional information or any other documentation is clearly documented.

Protocols that have been approved: The IRB staff will notify Principal Investigators that their research has been approved via IRBNet. The IRB approved stamped consent forms will be posed to IRBNet. The

Protocols that have been tabled: The IRB Administrator will outline the committee’s decision and the committee’s request or concerns regarding the study listing the Federal Guidelines that the committee considered in their decision. At this time the draft email will be forwarded to the IRB Chair for review and revision if necessary. After review, the Chair will forward the final draft to the IRB Administrator to who will post the decision letter to IRBNet and forward an email to the Principal Investigator.

Protocols that have not been approved: The IRB staff will compose a letter to the Principal Investigator noting the unfavorable decision and will include the substantial reasons for disapproval. The Chair will review and revise or authorize the letter. The IRB Administrator will post the decision letter to IRBNet and forward an email to the Principal Investigator.

8.6.3 Conveying the IRB Decision to the Institutional Official

The Institutional Official a copy of the minutes of the meeting that include the boards voting decision of all protocols.

8.7 Appeal of the IRB decision

8.7.1 Criteria for Appeal

If an IRB Application is disapproved, the reasons for disapproval will be conveyed to the investigator via IRBNet. This decision letter will include the committee’s decision and concerns regarding the study listing the Federal Guidelines that the committee considered in their decision. The investigator may request the IRB to reconsider by responding through IRBNet, and may request an opportunity to appear before the IRB.

8.7.2 Appeal of the IRB decision

All appeals of IRB decisions should be addressed to the IRB Chair through an IRBNet submission.

8.7.3 Resolving an Appeal

The IRB allows investigators various levels of appeal from the time a study receives initial review through approval or disapproval. Any and all IRB decisions are contingent upon the response of the investigator. If the Board finds that the negotiation is at an impasse, the Board may request an intramural or extramural independent consultant review.
9.0 IRB RECORD REQUIREMENTS

9.1 Membership Roster

In the fall of each year the human subject’s research review office will submit to the Institutional Official a copy of the membership roster and curriculum vitae demonstrating the qualifications of each committee member.

9.2 Procedures and Guidelines

Written procedures and guidelines are contained on the University of Rhode Island Human Subjects Research website. Hardcopies can be downloaded or obtained by contacting the Office of Research Integrity.

9.3 Meeting Minutes

The IRB Administrator is responsible for the IRB Minutes. The minutes will contain:

- Members present.
- Consultants/guests/others shown separately.
- Summary of discussions on debated issues.
- Record of IRB decisions.
- Record of voting (showing votes for, against, and abstentions).
- Separate deliberations for each action.
- When an alternate member replaces a primary member.
- The basis for requiring changes in research.
- The basis for disapproving research.
- A written summary of the discussion of controversial issues and their resolution.
- Justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
- For initial and continuing review, the approval period.
- The names of the IRB members who left the meeting because of a conflicting interest along with the fact that a conflicting interest was the reason for the absence.
- Unless documented in the IRB records, determinations required by the regulations and protocol-specific findings justifying those determinations for:
  - Waiver or alteration of the consent process.
  - Research involving pregnant women, fetuses, and neonates.
  - Research involving prisoners.
  - Research involving children.
- The rationale for significant risk/non-significant risk device determinations.

Proceedings must be written and available for review within three (3) weeks of the meeting date. Once approved by the IRB Chair, the minutes must not be altered by anyone including a higher authority. All minutes will be stored in the Office of Research Integrity through IRBNet.

9.4 Retention of Protocols Reviewed and Approved Consent Documents.

The Office of Research Integrity will retain all records required by the regulations (e.g. minutes, correspondence between the IRB office and investigators, IRB rosters, and written procedures required by regulations) for at least six years, and retains all records relating to research that has been conducted or cancelled for at least six years after completion or cancellation of research. If a protocol is cancelled without participant enrollment, the IRB records are maintained for at least three years after cancellation.
The Office of Research Integrity makes records accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner. This also includes the Department of Defense sponsored protocols, which may require submission of records to the Department of Defense for archiving.

IRB record requirements include the following in order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol:

- Protocols (including, when applicable)
  - Investigator brochure
  - Data and Safety monitoring reports
  - Unanticipated problems involving risks to participants or others
  - Documentation of non-compliance
- Recruitment materials
- Modifications to previously approved research
- Scientific evaluations
- DHHS-approved sample consent document and protocol, when they exist
- Progress reports submitted by the investigators.
- Reports of injuries to subjects
- Records of continuing review activities.
- Correspondence between the IRB and the investigator.
- Statement of significant new findings provided to participants.
- For initial and continuing review of research expedited procedure:
  - The specific permissible category
  - Description of action taken by reviewer
  - Any findings required under the regulations
- For exemption determinations, the specific category of exemption
- Unless documented the IRB minutes, determinations required by the regulations and protocol-specific findings justifying those determinations for:
  - Waiver or alteration of the consent process.
  - Research involving pregnant women, fetuses, and neonates.
  - Research involving prisoners.
  - Research involving children.

For each protocol’s initial and continuing review, the frequency for the next continuing review

9.5 Communicating with the IRB

The IRB application process is through IRBNet located on the internet at http://www.irbnet.org

All questions and/or concerns can be directed to the IRB office either by telephone (401) 874-4328 or via email at irb@etal.uri.edu

The Office of Research Integrity communicates with researchers regarding IRB decisions and requests for additional information through IRBNet, email and telephone. These communications can take the form of verbal, written or electronic. Major revisions or changes concerning IRB policy and procedures are communicated to the researchers through an IRB research listserv and the URI webpage located on the Internet at: http://www.uri.edu/research/tro/about/IRB/index.html
9.6 Records of Continuing Review

The IRB will maintain a copy of all protocols through IRBNet. Annual reviews are required for those studies that do not warrant shorter reviews. All Principal Investigators will be notified approximately (60) days prior to their expiration date, via IRBNet, and be requested to either complete the continuing review application or to complete the protocol closure form. All documentation will be retained as outlined in "Research Records".

9.7 Statements of Significant New Findings Provided to Subjects

Any and all information that is provided to the human subjects must also be provided to the Office of Research Integrity. This documentation is filed with the protocol.

9.8 Requirements for IRB Records

- Protocols
- Scientific evaluations
- DHHS-approved sample consent document and protocol, when they exist
- Reports of injuries to subjects
- For initial and continuing review of research by the expedited procedure:
  - The specific permissible category
  - Description of action taken by the reviewer
  - Any findings required under the regulations
- For exemption determinations, the specific category of exemption
- Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
  - Waiver or alteration of the consent process
  - Research involving pregnant women, fetuses, and neonates
  - Research involving prisoners
  - Research involving children
- For each protocol's initial and continuing review, the frequency for the next continuing review
10.0 INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB

10.1 Professional Qualifications

Procedures requiring special skills on the part of the investigators, licensure, accreditation, or experience in qualifying the investigator for the performance of the proposed procedures are reviewed by the IRB. In addition, the IRB will consider the facilities and equipment used to conduct the research and maintain the rights and welfare of the subjects.

The Investigators must provide proof of fulfillment of Human Subjects Research educational requirement through the Collaborative IRB Training Initiative (CITI)

- The Principal Investigator is responsible for overseeing every aspect of the research team and the project to ensure the safety of the Human Subjects.

10.2 Study Protocol that Includes/Addresses Project Proposal 22 Elements

- Provide a description of the purpose of your project in layman’s terms.
- Explain the scientific or scholarly rationale of your project, including background information and the project’s hypothesis.
- List your qualifications for conducting this research.
- Describe the risks of your project.
- Describe the benefits of your project.
- Explain whether or not the research will involve populations vulnerable to coercion or undue influence.
  - Provide a description of additional safeguards included to protect the rights and welfare of any subjects that are vulnerable to coercion or undue influence.
- Describe the methodology used for identifying and recruiting subjects.
- Describe the setting of the research, including the times, dates, places, atmosphere, etc.
- Describe the amount and schedule of all payments to the subjects.
- Provide Human Subject payment information (provide specific information, indicating the full payment amount for each subject enrolled in the study across the full term of the study).
- Describe the procedures that will be used to protect the privacy interests of subjects.
- Describe the type of analysis.
- Describe the inclusion/exclusion criteria.
- Describe how the knowledge obtained by this study will be important.
- Describe how knowledge obtained will be distributed (i.e. published, conference, etc.)
  For interviews/questionnaires/surveys a copy of all interview questions, questionnaires and surveys must be submitted.
- Describe this project’s recruitment and advertising methods. Provide a copy of all initial emails, telephone calls, Internet postings and all other forms of recruitment and advertisements.
- Provide a description of the procedures already being performed for diagnostic or treatment purposes.
- Describe provisions to monitor the project’s data, in order to ensure the safety of the subjects when research involves more than minimal risk to subjects.
- Provide a copy of the Informed Consent document (written or script). See the sample Informed Consent document here: http://www.uri.edu/research/tro/about/IRB/forms.html

  - Describe the consent process, including:
    - The person who will conduct the consent interview
    - Any waiting period between informing the prospective subject and obtaining consent
    - Steps taken to minimize the possibility of coercion or undue influence
10.3 Principal Investigators Conflicts of Interest

All Principal Investigators are required to complete the Conflict of Interest Form and submit with your research application as noted in the Expedite Full Board Review application.

The IRB will receive a copy of this form and evaluate whether the research protocol, as written, poses a conflict of interest and ensures that full disclosure is included in the consent form.

The convened IRB has the final authority to decide whether the interest and its management, if any, allow the research to be approved.

10.4 Investigation Brochure/Advertisements and Recruitment Incentives

The IRB reviews all brochures, advertisements and recruitment incentives associated with the research. The IRB considers all forms of brochures, advertisement and recruitment incentives as being directly related to the consent process and must not contain any coercion or undue influence. Advertisements will be reviewed and approved either by the Chair or designee as part of the initial review or as an amendment/change to the protocol. Payment to research subjects for participation is part of the recruitment incentive. If a subject withdraws early, payment must be prorated to reflect the time and inconvenience of the subjects participating up to that point.

**OHRP decision on recruitment incentives and Student Subject Pools**

Below are some acceptable alternative approaches for encouraging students to show up for scheduled appointments with investigators without imposing penalties on students who fail to show up. Imposing penalties is a violation of 45 CFR 46.116(a)(8). [http://www.hhs.gov/ohrp/policy/protocol/ohrp20100108.html](http://www.hhs.gov/ohrp/policy/protocol/ohrp20100108.html)

1. Students who show up for an appointment as scheduled could be awarded a credit point, or some fraction thereof.
2. Students who fail to show up for a scheduled appointment could have a decrease in the number of credits that can be earned through participation in research for a particular course, provided such students can still earn the same maximum number of credits by substituting an alternative non-research activity that involves a comparable amount of time and effort. For example, consider circumstances where students enrolled in a course can earn up to 3 extra credit points toward their final grade by participating in 3 separate studies (1 extra credit point per study). Under this option, if a student in the course fails to show up for an appointment for one study without cancelling by the specified deadline, the student is allowed to earn a maximum of 2 extra credit points by participating in two other research studies. However, the student must be able to earn a third extra credit point by completing an alternative non-research activity.

Please inform our office and the subjects, in the informed consent, which option you will incorporate in your research.

10.5 Elements of Informed Consent

10.5.1 Informed Consent

Informed consent will be sought from each prospective participant or the participant’s legally authorized representative in keeping with the criteria outlined below.

The process for obtaining consent must incorporate all of the following:
• The investigator will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative.
• Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.
• Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence.
• The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.
• The informed consent does not include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights.
• The informed consent does not release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Information that must be provided unless waived or altered

• A statement that the study involves research.
• An explanation of the purposes of the research.
• The expected duration of the participant’s participation.
• A description of the procedures to be followed.
• Identification of any procedures that are experimental.
• A description of any reasonably foreseeable risks or discomforts to the participant.
• A description of any benefits to the participant or to others that may reasonably be expected from the research.
• A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant.
• A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
• An explanation of whom to contact for answers to pertinent questions about the research.
• An explanation of whom to contact for answers to pertinent questions about the research participant’s rights.
• An explanation of whom to contact in the event of a research-related injury to the participant.
• Contact information for the research team for questions, concerns, or complaints.
• Contact information for the IRB for problems, concerns, complaints or any other questions about the research or the research participant’s rights.
• A statement that participation is voluntary.
• A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
• A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

For FDA-regulated research:

• A statement that notes the possibility that the Food and Drug Administration may inspect the records.

For Research Involving More than Minimal Risk:

• An explanation as to whether any compensation is available if injury occurs.
• If compensation is available, what it consists of, or where further information may be obtained.
• An explanation as to whether any medical treatments are available if injury occurs.
• If medical treatments are available if injury occurs, what it consists of, or where further information may be obtained.

**Additional Information to be provided when Appropriate:**

• A statement that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable.
• A statement that if the participant is or may become pregnant the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable.
• Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.
• Any additional costs to the participant that may result from participation in the research.
• The consequences of a participant's decision to withdraw from the research.
• Procedures for orderly termination of participation by the participant.
• A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.
• The approximate number of participants involved in the study.
• The amount and schedule of all payments to the participant.

### 10.5.2 Waiver or Alteration of Consent

**Most common set of conditions for a waiver or alteration**

• The research involves no more than minimal risk to the participants.
• The waiver or alteration will not adversely affect the rights and welfare of the participants.
• The research cannot practicably be carried out without the waiver or alteration.
• Whenever appropriate, the participants will be provided with additional pertinent information after participation.
• The research is not FDA-regulated.

**Less Common Set of Conditions for a Waiver or Alteration**

• 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 public benefit or service.
• Programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

### 10.5.3 Documenting the Consent Process

Informed consent will be documented.

**When the Long form of Documentation is used:**

• The consent document embodies the basic and appropriate additional elements of disclosure.
• The participant or the participant’s legally authorized representative will sign (and date for FDA-regulated research) the consent document.
• A copy of the consent document will be given to the person signing the consent document.
• The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

When the Short Form of Documentation is used:

• The consent document states that the elements of disclosure required by regulations had been presented orally to the participant or the participant’s legally authorized representative.
• A written summary embodies the basic and appropriate additional elements of disclosure.
• There will be a witness to the oral presentation.
• For participants who do not speak English, the witness is conversant in both English and the language of the participant.
• The participant or the participant’s legally authorized representative will sign (and date for FDA-regulated research) the consent document.
• The witness will sign both the short form and a copy of the summary.
• The person actually obtaining consent will sign a copy of the summary.
• A copy of the short form will be given to the participant or the representative.
• A copy of the summary will be given to the participant or the representative.

10.5.4 Waiver of Written Documentation of Consent

Condition 1

• The research presents no more than minimal risk of harm to participants.
• The research involves no procedures for which written consent is normally required outside of the research context.
• The oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.
• The IRB has determined whether the participant should be provided written information.

Condition 2

• The only record linking the participant and the research will be the consent document.
• The principal risk will be potential harm resulting from a breach of confidentiality.
• Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern.
• The research is not FDA-regulated.
• The oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.
• The IRB has determined whether the participant should be provided written information.

10.5.5 Proxy Consent

Rhode Island State Law states that surrogate consent, other than that of a parent or legal guardian is not allowable, unless there is a legal document that specifically authorizes another to act on behalf of someone for research purposes. For example, the consent of a friend would not be allowed. Those individuals allowed to give consent to a third party include:

• Persons appointed as health care agents
• Court appointed guardians
Next of kin in the following order: spouse, adult child, parent, and adult sibling when there is a legal document that specifically authorizes another to act on behalf of someone for research purposes.

**Research Conducted Outside Rhode Island**

- It is the Principal Investigators responsibility to ensure that Federal Guidelines 45.102(c) is followed: *(c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.* Therefore the Principal Investigator must provide to the IRB documentation of State Law, where the research is being conducted, concerning proxy care and these laws must be incorporated in the consent process.

**VA requirements regarding informed consent state:**

- Person must be legally able to give consent. If their legal consent is relinquished, then consent must come from their legal guardian.

**10.5.6 Research Involving Audio, Video, Photographic Recordings**

Recording the voice or image of an individual creates a type of record that requires unique handling and storage, particularly if the content may be considered sensitive. Research subjects must be informed that such recordings will occur, and be provided with information about the storage, confidentiality, and future use of the recordings.

The Human Subjects must be informed of the following:

- Type of recording that will be utilized
- Specific identifiers that will be recorded
- People who will have access to the recordings
- Confidentiality procedures of the recordings
- Indicate when the recordings will be destroyed – or – if they will be kept indefinitely
- Use of the recordings: educational; commercial; analysis by research; unspecified use

**10.5.7 Research Involving Deception**

Sometimes information must be withheld from subjects or false information provided to them. This may be for substantive reasons (e.g., to distinguish perceptual causes from other causes) or methodological reasons (e.g. to ensure natural reactions or to avoid placebo effects). These circumstances inherently involve a breach of the concept of informed consent. Consequently, several serious concerns must be met before such research can take place.

- Deception cannot be used in any study where there is risk to subjects
- The consent document should 1) never contain anything that is untrue, or be part of the deception, and 2) subjects must be provided with sufficient information for them to decide whether to participate and, as in all other human subjects research, be allowed to withdraw at any point without penalty
- No information can be withheld from subjects that could significantly affect their decision to participate (i.e. the subjects would likely participate anyway if they knew all the information)
- When the deception involves a falsehood told, no information can be provided to subjects that would have a harmful effect on them if the statement were believed
• Human Subjects need to be informed about the nature of the research in a way that does not invalidate the data
• All subjects must be debriefed regarding the true nature of the research after their participation

The debriefing should:

- Explain all truths not revealed and all falsehoods told to subjects
- Address the reasons the deceptions were necessary
- Reassure subjects that their reactions to the deceptions were normal

If having incomplete or erroneous information is not likely to be harmful to subjects, the IRB Office will consider delaying the debriefing until all subjects have completed their participation. Care should be taken in debriefing to protect the well-being of the subjects.

All debriefings must be submitted as a written document to the IRB through IRBNet. The debriefing should always be a dialogue. Those conducting the debriefing should be trained to elicit and respond to subject concerns.

Information should not be provided that might damage subjects’ self-esteem or hurt their feelings. The use of highly evaluative terms (e.g., `We tricked you" Or `We lied to you") should be avoided in explaining deceptions to the subjects.

10.6 Control of Investigational Devices

Principal Investigators (Researchers) conducting studies in which an investigational device will be used must ensure adequate control of the device. Adequate control and handling of investigational devices include all of the following:

• The investigator must ensure that the investigational device is used in accordance with the approved protocol, the Occupational Health and Safety report, the Mechanical Report, the investigational plan and applicable FDA regulations.
• The investigator must administer the investigational device only to participants under the investigator’s direct personal supervision or under the supervision of the sub-investigator directly responsible to the investigator who is listed on the Occupational Health and Safety Report as being authorized to use this equipment for the named project.
• The investigator must not supply the investigational device to any person not authorized to receive it.
• The investigator must maintain the following accurate, complete, and current records relating to their participation in the clinical investigation. Specifically, records of receipt, use or disposition of a device that relate to:
  • The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
  • The names of all persons who received, used, or disposed of each device.
  • Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

If the investigation is terminated, suspended, discontinued, or completed, the investigator must return any unused stock of the investigational device to the study sponsor, or otherwise provide for disposition of the unused stock as directed by the sponsor.
10.7 Multi-Site Study Requirements

Research that is conducted by the University of Rhode Island’s Faculty, Staff or Administrators that work in collaboration with another institution must obtain an IRB approval from the collaborating institution. If an IRB does not exist, a Letter of Agreement must be obtained from the appropriate official.

If the Principal Investigator is the lead investigator in this multi-site study the Principal Investigator must provide, on a separate document, a description of the management of information obtained in multi-site research that might be relevant to the protection of subjects, such as:

- Unanticipated problems involving risks to subjects or others.
- Interim results.
- Protocol modifications.

All modifications, revisions, continuing reviews, adverse events, unanticipated problems, complaints and any other correspondence that is received from the collaborating institution must be forwarded to the IRB.

10.8 Requests for Changes in Study after Initiation

Changes or amendments to an approved research project cannot commence until reviewed and approved by the IRB. The Principal Investigator will submit a modification form, which outlines in detail the revisions, along with any other documentation required. When a full board reviewed protocol requires a modification, these modifications will be re-reviewed by the full board. If the protocol was expedited, minor (no increase in risk) modifications may be reviewed through the expedited process. When an expedited protocol proposed change is major, then the full board must review the revisions during a convened meeting.

In rare circumstances when the change is necessary to eliminate immediate hazards to the research subject, the IRB should be informed of the changes following the implementation as soon as possible and should review the changes to determine that it is consistent with the protection of human subjects.

Revised consent forms will be re-stamped showing the date of the approved modification. This action does not change the expiration date for the yearly review.

10.9 Reports of all Unanticipated Problems/Adverse Events/Complaints

According to Federal Guidelines 45 CFR 46(103)(b)(5) written procedures are required for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

The University of Rhode Island’s Human Subjects Policy and Procedure Ensuring prompt reporting to the, appropriate institutional official, the OHRP and FDA require all incidents to be reported with five (5) business days.

Federal regulations (45 CFR Part 46, Subpart A) require written procedures and policies for ensuring reporting of "unanticipated problems" involving risk to subjects or others defined as any problem, event, or new information that is (1) unanticipated and (2) indicates that subjects or others are at an increased risk of harm. An adverse event is an occurrence or situation during the course of a research project that includes, any serious or adverse events associated with the study procedures, and /or problems involving the conduct of the study that may occur during the course of his/her own research projects.
Any problems involving the conduct of the study or patient participation must be reported. Any problems involving the recruitment or consent processes require reporting. Any deviations from the approved protocol should be reported in writing.

All adverse events must be reported promptly.

**10.9.1 Review of Reports**

The IRB Chair will review all reports with the IRB Administrator and a committee member who is knowledgeable in the area of research to determine whether it is an Unanticipated Problem involving risk to subjects or others. The review process will include the following documentation:

- Problem Form
- Review of protocol
- Review of Informed Consent
- Any and all correspondence regarding this action

All Unanticipated Problems, Adverse Events, Complaints, will be fully documented and all documentation, which includes: the complete protocol, all modifications, the informed consent and all correspondence relating to the unanticipated problem, adverse event or complaint will be placed as an information item on the agenda.

If the initial review determines that the report is NOT an Unanticipated problem involving risks to subjects or others, for example, the likelihood, severity and specificity are adequately described in the protocol, investigators’ brochure, and informed consent document, the IRB Chair reports this finding to the IRB.

If the initial review determines that the report is an Unanticipated problem involving risk to subjects or others then this may prompt requests for additional information, follow-up action, revisions of the informed consent document, a request for protocol amendment, or suspension or termination of the approval of study.

All reports determined to be unanticipated problems involving risk to subjects or others are reviewed by the convened IRB. The IRB actions may involve:

- Suspension of research
- Termination of research
- Notification of subjects when information about the non-compliance may affect their willingness to continue participation
- Modification of the protocol

Suspension or termination of approval will only occur after review and voting by the convened board unless an imminent danger to study patients warrants immediate intervention by the Chairperson. The Chair reports such action to the IRB at the next convened meeting.

The Principal Investigator will be informed of the committee decision and all documentation will be also sent to the Institutional Official. In those instances where the unanticipated problem/adverse events is deemed to pose a risk to subjects, was unanticipated in the study protocol and is judged to be causally related to the research protocol, the Institutional Official will notify the appropriate agencies.

When a non-compliance issue is reviewed by the full board, a letter will be forwarded to the Institutional Official, which will include a request that the regulatory officials are notified when the notification action is required pursuant to our Federal Wide Assurance.
The non-compliance issue will be noted in the agenda as "pending" until the regulatory official letter is processed.

When the Institutional Official letter to the regulatory officials is processed it will be presented to the Full Board for their review, announced in the agenda, and documented in the minutes. Any correspondence and/or action from the regulatory officials will be relayed to the Full Board in the same manner (i.e. announced in the agenda and noted in the minutes).

Included as part of the report to the OHRP is a description of determinations made and actions taken by the IRB in response to the event. This procedure will follow the policies outlined in the University of Rhode Island IRB Policy and Procedures.

**10.9.2 Failure to Report**

Failure to report is a breach of the conditions under which IRB approval is given, and could result in suspension or revocation of approval. Suspension or revocation of approval could result in loss of support by funding agencies and loss of right to publish.
11.0 DATA SAFETY MONITORING BOARDS (DSMB)

One of the research approval criteria is for the IRB to determine whether “risks to subjects are minimized” and “risks to subjects are reasonable in relation to anticipated benefits” 21 CFR 56.111(a)(1) and (3). Additionally, the Code of Federal Regulations stipulates that “when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects” 45 CFR 46.111 (a)(6).

Multi site research that involves a large population may require additional oversight, allowing one group to view all data and monitor any adverse events, unanticipated problem or complaints. For example, an IRB does not have the ability to review all records of participants if research is being conducted at five (5) different sites. DSMB will have the ability to review these reports:

A Data Safety Monitoring Board is defined as “a committee that is established specifically to monitor data throughout the life of a study to determine whether it is appropriate, from both scientific and ethical standpoints, to continue the study as planned” (Bankert, et al pg. 162)

The DSMB is a group of individuals who are expert in their field that are applicable to the study, individuals with statistical experience, lay representatives, and administrators. This group usually meets one to two times a year and reviews all adverse events reports from all of the study sites. The DSMB has the power to recommend termination of the study based on the evaluation of these results. There are typically three reasons a DSMB might recommend termination of the study: safety concerns, outstanding benefit, and futility.

While it is important to remember that all studies require careful monitoring, it is also important to know that not all studies require a DSMB. The following questions are designed to help make a determination as to whether or not a DSMB may be needed.

- Are there multiple study sites that involve a large subject population?
- Protocols presenting more than minimal risk to subjects. Risk assessment should include the characteristics of the subject population.
- Is the trial intended to provide definitive information about effectiveness and/or safety of an intervention?
- Would it be ethically important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed?

For more information and regarding the requirement of DSMB, please review the NIH website or contact the Office of Research Integrity at researchintegrity@ds.uri.edu

Research Monitors

When following Department of Defense regulations, the IRB considers appointment of a research monitor:

- An independent research monitor is required for studies involving greater than minimal risk, although the IRB can require this for a portion of the research or studies involving no more than minimal risk if appropriate.
- The independent research monitor is appointed by name.
- The research monitor has the authority to:
  - Stop a research study in progress
  - Remove individuals from study.
  - Take any steps to protect the safety and well being of participants until the IRB can assess.
12.0 EMERGENCY WAIVER OF CONSENT

45 CFR 46.101(i) and FDA Regulation: 21 CFR 50.24

The waiver of the applicability of the title 45 CFR part 46 (protection of human subjects) requirement for obtaining and documenting informed consent, for a strictly limited class of research involving activities which may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained. Due to special regulatory limitations relating to research involving prisoners (subpart C of 45 CFR part 46) and research involving fetuses, pregnant women, and human in vitro fertilization (subpart B of 45 CFR part 46), this waiver is inapplicable to these categories of research.

The University of Rhode Island does not have the faculty, staff or facilities to conduct research that would require a Waiver of Emergency Consent. The University of Rhode Island does not oversee the use of emergency uses of test articles in a life-threatening situation.

The complete requirements for HHS and FDA Harmonized Rule on Waiver of Consent for Emergency Research can be found at this link: http://www1.va.gov/oro/apps/compendium/Files/emergency%20waiver%201996.htm
13.0 STUDENT CLASSROOM PROJECTS

Students conducting classroom assignments which will be gathering information about people through interventions or interactions with those individuals and classroom assignments which will be gathering private identifiable information about people requires consultation with this office. The IRB Office will make a determination whether the activity is human subject research or may request a full IRB Application to be submitted through IRBNet to make this determination.

It is the faculty member’s responsibility to ensure that any activity that is “research” involving “human subjects” as defined in, conducting initial review, require IRB review and approval before the project starts. Federal regulations can be confusing, rather than risk conducting research without IRB approval, and be out-of-compliance, it is strongly suggested that you contact our office for assistance in determining if your activity involves human subjects research.

If an Internship is being conducted at an outside facility by a University of Rhode Island’s students, the student must receive IRB approval from the University of Rhode Island IRB and must obtain an IRB approval from the collaborating institution or if the collaborating institution does have an IRB, a letter of collaboration or permission must be obtained from the appropriate official.

All modifications, revisions, continuing reviews, adverse events, unanticipated problems, complaints and any other correspondence that is received from the collaborating institution must be forwarded to the University of Rhode Island IRB.
14.0 DNA/GENETIC RESEARCH

All genetic research must be reviewed by the full IRB. Genetic research is constantly evolving and more personal information is being obtained. This information can have dire consequences on the human subjects and can affect the subject’s insurability and employment opportunities. Genetic studies that generate information about subjects’ personal health risks can provoke anxiety and confusion.

The following University of Rhode Island procedures must be taken into consideration when designing a research protocol that involves the use and storage of human DNA.

- Each disclosure or redisclosure of the (human subjects identified) test results requires the express informed consent of the test subject, and no general waivers are deemed informed consent.
- While informed consent is required to allow research access to specimens; explicit re-consent is not required once linked identifiers are removed.

For the researchers convenience we provide an informed consent template that addresses all of the issues concerning genetic research.

14.1 Archived Specimen Repository and Bank Requirements

- Laboratory inspection
- Contact Safety & Risk to schedule:
  - Biosafety Committee audit

The Archive will require regular inspection (2 times per year) by Environmental Health & Safety Staff. This inspection includes the standard EH&S audit. While scheduling this, you may request that your Biosafety Committee audit is conducted at the same time. The laboratory directors will be required to forward all audit reports and compliance approvals from EH&S and the Biosafety Committee to the IRB Office.

- Laboratory security
  - Provide security measures for the archive (e.g., key-card access with time-stamped electronic recording of personnel entering lab.)

The Archive must be sufficiently secure to prevent theft, loss or destruction of valuable information. The laboratory director should be aware of all individuals with access to archive. Archive rooms should be locked and accessibly to laboratory personnel with key access. We recommend, if not already in place, that the archive be equipped with key-card access via a BU ID, so that there is an electronic time-stamped recording of personnel entering the lab.

- Data records
  - Storage report
  - Password protected and secure
  - De-identified
  - Key coded or encrypted software
  - Backed up

The protocol must include a detailed description of what type of data has been collected and how all data records are stored and kept secure. All data should be protected and backed-up (on other computers or in file cabinets, etc). All data must be kept in a secure and defined location.

- Material Transfer Agreement (MTA)
In order to function as human biological repository and specimen bank, the Archive will be required to establish an official material transfer agreement (MTA) and data use agreement (DUA) for those researchers interested in obtaining samples. The Office of Intellectual Property and Economic Development in the Division of Research and Economic Development will oversee this process. The laboratory directors will be required to forward all MTAs to the IRB Office.

- NIH Certificate of Confidentiality
  - Required if specimens are identifiable
  - Requires IRB approval. Approval can be contingent upon certificate

If the specimens in the Archive are identifiable and belong to living subjects it is a requirement to obtain a Certificate of Confidentiality before sharing information. This certificate can be obtained through the National Institutes of Health. However, if data has been de-identified this may not be required, although advisable.

Please contact the Office of Research Integrity for IRB committee review.
15.0 POTENTIALLY VULNERABLE SUBJECT GROUPS

For research including vulnerable populations as subject groups, the IRB must consider the following: recruitment inclusion and exclusion criteria; informed consent and desire and capacity to volunteer; coercion and undue influence; and confidentiality of data.

15.1 Research involving Pregnant Women, Human Fetuses and Neonates

45 CFR 46 Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research - *Non viable neonate research is not allowed at the University of Rhode Island*

§46.203 The duty of an IRB in connection with research involving pregnant women, fetuses, and neonates. In addition to other responsibilities assigned to IRBs under this part, the IRB shall review research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

1. Pregnant women or fetuses may be involved in research if all of the following conditions are met:

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- Any risk is the least possible for achieving the objectives of the research;
- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Individuals engaged in the research will have no part in determining the viability of a neonate.

2. Research Involving Neonates

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part;
part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

- Individuals engaged in the research will have no part in determining the viability of a neonate.

3. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
- Individuals engaged in the research will have no part in determining the viability of a neonate.

15.2 Research Involving Prisoners

45 CFR 46 Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

For prisoners “minimal risk” means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

45 CFR 46.305 requires additional duties for the Institutional Review Board where prisoners are involved in the research activity.

46.303(c) “Prisoner” means any individual involuntarily confined or detained in a penal institution. 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.

Epidemiologic studies must meet the following criteria:

- The sole purposes are one of the following:
  - To describe the prevalence or incidence of a disease by identifying all cases
  - The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
  - Prisoners are not a particular focus of the research

Research must fall in one or more of the following four (A-D) categories.

(A) Study of 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:

(B) 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:
(C) Research on conditions particularly affecting prisoners as a class.

- For DHHS funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.
- For DHHS funded research which require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject

- For DHHS funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.
- For DHHS funded research which require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

The following information must be supplied: (please see Appendix L - Prisoners)

- Are there any possible advantages accruing to the prisoner through his or her participation in the research, (when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison) that are of such a magnitude that his or her ability to weigh the risk of the research against the value of such advantages in the limited choice environment of the prison is impaired?
- Do the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?
- Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary Intervention by prison authorities or prisoners? Note: Unless the project director provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research project.
- Is the information presented in language understandable to the subject population?
- State how you will assure that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole? Is there adequate assurance that parole boards will not take into account a prisoner’s participation in the research in making decision regarding parole?
- Is each prisoner clearly informed in advance that participation in the research will have no effect on his/her parole? (This must be clearly stated in the consent form)
- When the research requires follow-up beyond the period of incarceration, have provisions been made for locating the individual. Please discuss these provisions below.
- Are participants informed of how follow-up will take place if such is required?
Convened meeting actions:

- The IRB must determine that the research falls into one or more categories and that the answers to questions 1-2 and 5-8 are yes.
- A majority of the IRB (exclusive of prisoner member) have no association with the prison involved, apart from their membership on the IRB.
- For DHHS funded research, the IRB Administrator, will certify to OHRP that the duties of the IRB have been fulfilled.
- Department of Defense regulations regarding research involving prisoners require:
  - Research involving Prisoners of War is prohibited
    - The IRB is aware of the definition of "prisoner of war" as defined in the DoD Dictionary of Military Terms (revised 2011) for the DoD component granting the addendum.
  - A least one IRB member is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity is present at the meeting.

A least one IRB voting member is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity is present at the meeting. (The prisoner representative may be listed as an alternative member who becomes a voting member when needed.)

- If the prisoner representative is not present; research involving prisoners cannot be reviewed or approved.
- The prisoner representative may attend the meeting by phone, videoconference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.

- The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections.
- The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer)
- The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

Minor modifications to research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.

- Modifications involving more than a minor change reviewed by the convened IRB – must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).

Continuing review – must use the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described above).

- If no participants have been enrolled, the research may receive continuing review using the expedited procedure under expedited category #8.
Expedited Review of Research Involving Prisoners

- Research involving interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
  - The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
- The prisoner representative must review the research as a reviewer, designated by the chair, or consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
- Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.
- For research that does not involve interaction with prisoners (e.g. existing data, record review) reviewed by the expedited procedure:
  - Research that does not involve interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
  - Review by a prisoner representative is not required.
  - The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.
  - Review of modifications and continuing review must use the same procedures as initial review.

Issues Related to Consent
In a closed institution such as a prison there may be extraordinary organizational and interpersonal pressures, which intrude into the decision whether or not to participate as a subject in research. This may be particularly evident in group situations and classroom environments. Wherever possible, prisoners should be given the opportunity to reflect on the decision to participate in private.

On occasion research will be situated in a prison classroom setting assuring the structured program segment for the day. A prisoner who elects not to participate in such research should be offered an alternative program for the time in question to minimize coercion.
Some prisoners may feel they will lose privileges or be punished if they choose not to participate in research; others may hope for favorable treatment or early release if they do participate. Prisoners must be assured they will be neither punished nor rewarded for their participation, and that they can discontinue their participation at any time without an institutional penalty.

Many adult prisoners are deficient readers, many have an incomplete formal education, and many speak English poorly or not at all. Investigators must use necessary measures to assure that these populations clearly understand the nature of the research and its potential risks.

Issues Related to Confidentiality
Special care should be taken to avoid requesting information in a group setting that could jeopardize the safety of individual prisoners.
In the collection of research data, special care should be taken to assure that confidential materials do not come into possession of prison administrators, guards and correctional officers, or other prisoners.

Prisoners are much more likely than other populations to be associated with sensitive data. This could include, for example, involvement in illegal activity and HIV/AIDS. Appropriate safeguards are necessary regarding the collection, storage, and destruction of such information.

Issues Related to Content
Investigators must be aware that research into certain topical areas within the institution setting can be potentially dangerous for participants. For example, the mere act of interviewing a prisoner about sensitive
topics such as gang activity, contraband, and prison prostitution may inadvertently label the respondent as an informant. Great care must be taken to balance the research against protection of the prisoner as subject.

The risk of suicide is an ever-present concern in the penal environment. The investigator must assure that debriefing is readily available to the prisoner whenever the subject is questioned about sensitive topics that could evoke self-injury once the prisoner has returned to the privacy of his or her cell. Appendix L- Prisoners form must be submitted with the IRB Application to IRBNet.

15.3 Research Involving Children

45 CFR 46. Subpart D: Additional Protections for Children Involved as Subjects in Research IRB duties.

In addition to other responsibilities assigned to an IRB under this regulation, the IRB shall review research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

The IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well being, only if the IRB finds that:

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

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- The risk represents a minor increase over minimal risk;
- The intervention or procedure presents experiences to 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 subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.
§46.407 *Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.*

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

- The IRB 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; and
- The Secretary, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
  - That the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, 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;
    - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.408 *Requirements for permission by parents or guardians and for assent by children.*

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child’s parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Research regulated by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice
of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

All research that is requesting waiver of parental permission must be reviewed by the full board. The full board must find and document the following:

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.

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information about participation.

It is further required that the parents receive notification of this research through various sources and these notifications are submitted to the full board for review.

Parental Permission cannot be waived for FDA regulated research.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

- Related to their status as wards; or
- Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

- **School Permissions**

  Schools do not have the authority to give consent for children to participate in research; only parents or guardians have that authority. Permission from the school district must be obtained before conducting research in schools within the district.

  Principals and teachers do not have the authority to grant permission for research to be conducted in a school; such permission must come from the school district. Although this permission will usually come from the superintendent, in some districts another individual or committee has been given the authority
to grant permission. Investigators should check with the district office to determine the appropriate procedure for obtaining permission.

Permission must be submitted to the IRB in writing, and whenever possible, the permission should be on school district letterhead. Provisional approval of the research project can be given by the IRB pending receipt of permission by the school district. The research cannot begin until written permission is received by the IRB.

- **Minimizing Coercion**

In conducting research on children, every attempt must be made to minimize coercion to participate. Researchers must remember that children are in a dependent relationship with adults and special care must be taken to ensure that the decision to participate as research subjects made by children is truly voluntary.

When the investigator is unfamiliar with the population to be studied, he/she should consult experts to determine the degree of coercion in the procedures to be used. Such judgments are inevitably subjective and often result in negotiation between the IRB and investigators, who should be prepared to justify questionable procedures.

- **Research Involving the Inclusion of Children or Individuals with Mental Disabilities National Institute on Disability and Rehabilitation Funded Research**

When the IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, during the convened meeting, the IRB must include at least one person primarily concerned with the welfare of these research participants.

**15.4 Research Involving Cognitively Impaired Subjects**

Cognitively impaired persons have a diminished capacity for judgment and reasoning due to psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions.

Other individuals, who may be considered decisionally impaired, with limited decision-making ability, are individuals who are also chemically dependent, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical disabilities. Decision making capacity may fluctuate.

The IRB shall consider the ethical concern of how the individuals with psychiatric, cognitive, or developmental disorders or those who are substance abusers have the capacity to understand the information presented and their ability to make a reasoned decision about participation.

Research should involve cognitively impaired subjects where:

- They compromise the only appropriate subject population
- The research question focuses on an issue unique to subjects in this population
- The research involves no more than minimal risk
- Research that involves greater than minimal risk may be acceptable where the purpose of the research is therapeutic with respect to individual subjects and where the risk is commensurate with the degree of expected benefit.
**Surrogate Permission with Subjects Judged Incompetent to Consent**

A research subject must be competent to give informed consent; otherwise, the consent of the legally authorized representative of the patient must be obtained. If competency issues are anticipated for a study, they must be acknowledged in the research proposal and the procedures used to evaluate competency must be described in detail.

**Legally Authorized Individuals, Guardians**

**DHHS Definition**

- 45 CFR 46.102(e) **Guardian**: means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
- 45 CFR 46.102(c) is followed: (c) **Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.**

**FDA Definitions**

- Title 21 Part 50.3(l) **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- Title 21 Part 50.3 (s) **Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of subpart D of this part, a guardian also means an individual who is authorized to consent on behalf of a child to participate in research.
- The FDA Regulations 21 CFR 50.55(e)(1) Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, if consistent with State law, for clinical investigations to be conducted under 50.51 or 50.52.
- Where clinical investigations are covered by 50.53 or 50.54 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if consistent with State law.

The DHHS and FDA regulations state that the definition of guardian and legally authorized representative is consistent with applicable State Law,

**Research conducted outside Rhode Island**

It is the Principle Investigators responsibility to determine which individuals are considered “children” or “guardians” outside of Rhode to ensure that Federal Guidelines 45.102(c) is followed: (c) **Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.** The FDA Regulations 21 CFR50.55(e)(1) Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, if consistent with State law, for clinical investigations to be conducted under 50.51 or 50.52.

Where clinical investigations are covered by 50.53 or 50.54 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if consistent with State law.

Therefore, the Principal Investigator must provide to the IRB documentation of State Law, where the research is being conducted, concerning proxy care and these laws must be incorporated in the consent process.
15.5 Research Involving Students, Employees and Normal Volunteers

Employees, students and normal volunteers are also considered vulnerable subjects although the federal regulations do not provide explicit protections for subjects in these categories. The IRB Guidebook, Chapter VIII: Special Classes of Subjects offers these guidelines:

- The compensation to human subjects should not be so great to constitute an undue inducement
- Students, employees and normal volunteers should be recruited through general announcement or advertisement, rather than through individual solicitations to avoid any form of undue influence.
- Confidentiality of data- sensitive subjects such as health, sexual activity, or the use of illicit drugs or alcohol, and personal health information present risk to subjects of which they should be made aware and from which they should be protected.

15.6 International Research

Research in foreign countries also presents special concerns regarding the rights and welfare of human subjects. All policies and procedures that are applied to research conducted domestically are applied to research conducted in other countries. In general, the IRB accepts the standards of the location in which the research is taking place, unless those standards grossly violate the basic principles of ethical human subjects’ research. In addition, the following issues apply to international human subjects’ research:

- The review of international research may fall under "exempt" and "expedited" review.
- All materials, including consent forms, must have English language translations included with the protocol.
- OHRP requires that IRB must have knowledge of the local research context – this can be accomplished through an outside consultant who is familiar with the region and provides the committee a summary of the risks to the human subjects in this culture.
- The IRB Administrator will solicit the assistance of the Director of the International Student & Scholar Services in locating graduate students with knowledge of local context beyond the Director:
  - When an individual has been located that is familiar with the local context and the local laws of the international research:
    - They are asked to write a summary which includes why you are able to assess the risk
    - They will be asked to sign and return to the IRB a signed confidentiality statement
  - After receipt of summary and confidentiality statement the research protocol (which includes consent documents, questionnaires, surveys, interview questions in English and the international countries language) is forwarded for the Individuals review, their responsibilities involve:
    - Review the protocol
    - Assess the risk to human subjects pursuant to the federal regulation guidelines:
    - According to federal regulations we are required to have an individual review all research who “(i) is sufficiently qualified to consider the race, gender and cultural backgrounds and sensitivity to such issues as community attitudes...”
    - The federal regulations do not provide a list of what exactly must be assessed, just that the consultant should take into consideration any harm that could come from the individual, group or society as a whole from this research.
    - An assessment as to whether the questions, interviews or the research as a whole would place these individuals at risk.
• Ensure that the research does not place the society or culture at risk which could occur through publication
• Provide the IRB their assessment of the international research a brief assessment (one to two pages)
• Forward your assessment to the Office of Research Integrity
  o Future reviews required for post approval monitoring, modifications, continuing reviews and complaints, non-compliance, and unanticipated problems will be reviewed by the full IRB and the international consultant will be retained for these reviews.

For Research that Involves no Greater than Minimal Risk to Subjects

At the discretion of the IRB Chair research that falls under the Exempt or Expedited criteria, written materials alone may suffice for a given minimal risk study (except where foreign institutional approval is also needed.

• Written materials may include, for instance, peer-reviewed research publications that provide relevant information about the local research context that would assist the IRB Chair to make their determinations.
• Written materials may include previously published peer-reviewed papers or dissertations that are judged by the IRB Chair to be applicable to the local context for the protocol being reviewed.
• Non-published, written materials provided by the investigator(s) (e.g., the protocol application itself) may not be the sole source of written material for the evaluation of the protocol by the IRB Chair.

Protocol approval by a foreign IRB (or equivalent) may be applicable for a given study when formal collaboration with a foreign institute is involved. Such approval would preclude the need for investigators to provide written materials.

Permission to Conduct Social/Behavioral Research

• If the project received federal funds and is in collaboration with a foreign institution, IRB review or some other review is required at the International site, the contact information for this international site and the review approval must be forwarded to the University of Rhode Island IRB prior to commencement of research.
• If the project is not federal funded, but is in collaboration with a foreign institution, documentation required that foreign institution reviewed and approved the protocol. The contact information for this international site and the review approval must be forwarded to the University of Rhode Island IRB prior to commencement of research.
• If the project is not funded and is not being done with a collaborating institution (but with a community for example) there is no requirement for local review.

Department of Defense Regulations

The IRB must verify the following:

• The university or researcher has permission to conduct research in that country by certification or local ethics review
• The researcher follows all local laws, regulations, customs and practices