Rhode Island College

Institutional Review Board (IRB)

Policies and Procedures Manual

This policy and application information may be obtained from RIC's IRB website: https://our.ric.edu/department-directory/office-provost-and-vice-president-academic-affairs/research-protocols/institutional-review-board

Portions of this policy are taken or adapted from the Code of Federal Regulations (45 CRF; Section 46), the revised Common Rule (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html)and the Institutional Review Boards of the State University of New York at Albany, State University of New York at Stony Brook, the Massachusetts College of Liberal Arts, Temple University, and Worcester State College.

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SECTION 1: FEDERAL DEFINITIONS

Anonymity: the identities of participants are not known.

Assent: a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Clinical trial: a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the intervention or biomedical or behavioral health-related outcomes.

Confidentiality: the information collected is not disclosed after the person has completed their participation.

Guardian: an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

Human subject: a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable private information: private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen: a biospecimen for which the identity of the subject is or may readily be ascertained by or associated with the biospecimen.

Identifying information: information that may reveal a participant's identity either directly (e.g., name, video recording) or indirectly (e.g., certain demographic information, initials, date of birth).

Informed Consent: voluntarily deciding to participate in a study after knowing the pertinent details about the study procedure, risks, and benefits.

IRB approval: the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional, federal, and state requirements.

Legally authorized representative: any individual person, judicial body or other body of individuals who are legally authorized under state and federal law to consent to research participation on behalf of a designated person. Expanded definition under Final Rule adds specific authorization to use institutional policy when there is no applicable law (state statute or regulation, case law, or opinion of a state Attorney General) that addresses this issue.

Minimal risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minors are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Parent: a child's biological or adoptive parent.

Permission: the agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Public health authority: an authority that is responsible for public health matters as part of its official mandate.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The following activities are specifically deemed not to be research (e.g., oral history, journalism, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions).

Written or in Writing: in accordance with longstanding interpretation of the current Common Rule, these terms include electronic formats.

SECTION 2: POLICY OVERVIEW

The use of human participants in research is governed by Federal and State laws. Consequently, all research involving human participants must be reviewed by an Institutional Review Board (IRB) to ensure compliance with these regulations. The Code of Federal Regulations (Title 45 CFR Part 46 Protection of Human Subjects) Subpart A was revised in a document entitled 'The Final Rule'. These revisions were intended to "modernize, strengthen, and make more effective" system of oversight that had been the federal common rule since 1991.

The Code of Federal Regulations (Title 45 CFR Part 46 Protection of Human Subjects) defines research as "*a systematic investigation, including research development, testing, and evaluation, designed to develop or to contribute to generalizable knowledge*" (*45 CFR; Part 46.102(d)*). The Final Rule (date) expands the definition of research by listing activities that are specifically deemed NOT to be research, including oral history, journalism, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions.

The major difference between research and non-research lies in the ***primary intent*** of the activity, not the methods employed in the activity. Research activities undertaken for purposes other than contributing to generalizable knowledge are exempt from this policy. Activities that meet the federal definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. This policy manual explains the implementation of the Federal regulations, which apply to all Rhode Island College (RIC) faculty, staff and students, whether their research is conducted on or off the RIC campus.

The purpose of an IRB review is to assure protection of the rights and welfare of human participants in research. The IRB review focuses on such issues as voluntary participation, risk to participants, informed consent, and confidentiality, among others. The guidelines in this policy pertain only to the use of human participants and do not address compliance with other Federally-mandated regulations, for example, those that govern animal subjects, recombinant DNA, and radioisotopes. Any investigator who wishes to employ such methods in his or her research should contact the appropriate compliance committee. Reports of violations of this policy or other complaints about a research project will be brought before the IRB at a convened meeting, and appropriate action taken (see Section 11).

Safeguarding the rights and welfare of human participants in any research activity is the responsibility of the researchers. It is the policy of Rhode Island College that no activity falling under the Federal definition of research with human participants be undertaken until those activities have been reviewed and approved according to the procedures established by RIC's IRB. The IRB may require stricter standards than those required by federal law, and it will take into account federal laws, state laws, and college policies when reviewing proposals.

According to Federal regulations the IRB cannot approve research activities that have begun or have been completed without prior IRB approval. Performing research with human participants without IRB approval is illegal, and may jeopardize federal funding to the College including student financial aid. There are penalties for any member of the RIC community (faculty, staff, student) who violates this policy (See Section 11).

SECTION 3: POLICY UPDATES

Federal and state laws may change at any time. Any revisions to this Policy and Procedures will be posted for all RIC faculty and staff to access. Investigators should check the IRB website for updates before submitting each application.

SECTION 4: DESCRIPTION OF THE INSTITUTIONAL REVIEW BOARD

A. The IRB is the only designated human participants Institutional Review Board for the RIC community. The IRB is charged with the responsibility of protecting the rights and welfare of human participants involved in research, as mandated by the Department of Health and Human Services (DHHS), the Food and Drug Administration, and the State of Rhode Island. The IRB operates under the Office of the Provost and Vice President for Academic Affairs (VPAA).

B. The makeup of the IRB membership is in accordance with Federal Policy:

   1. The IRB shall consist of at least five (5) members with varying backgrounds. In addition to possessing the professional competence necessary to review research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

   2. Membership shall include at least one person whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

   3. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

   4. The IRB may, at its discretion, invite individuals with competence in special areas (consultants) to assist in the review of issues that require expertise beyond, or in addition, to that available on the committee. Similarly, investigators may request, or be invited, to attend IRB meetings to clarify issues with the members concerning their proposed research activity. Such guests are present only to provide information and do not take part in committee deliberations or voting.

   5. No IRB member may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

C. In addition to the Federal requirements, RIC policy states that

1. Members are appointed for staggered, three-year renewable terms by the Provost and Vice President for Academic Affairs following recommendations from the IRB Chair, Deans, Department Chairs, current IRB members, or other relevant persons. Potential members may also self-nominate. All members have full voting rights; no proxy voting is permitted. Alternate members may substitute for a portion of a meeting or an entire meeting. The responsibilities of members and alternate members are to review protocols, make recommendations for revisions and/or approval of protocols, attend meetings, and vote on protocols, policies, and procedures.

2. The IRB has the authority to inspect records, and to observe (or have a third party observe) the process of any activity that it approves. Because persons who serve as members of the IRB are, in that capacity, rendering services to the State of Rhode Island, they are accorded the same immunities from personal liability for acts done as members of the IRB as State employees are generally accorded with respect to acts done in the course of their employment.

3. The Chair, who is a voting member of the committee, serves as the liaison between the research investigators and the IRB. The appointment of the Chair will be made by the Provost and Vice President for Academic Affairs, whose decision is based on prior experience with the ethics of research with human participants, as well as leadership ability. The Chair is responsible for updating IRB procedures with current and/or new relevant federal or state regulations.

4. RIC responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93, are outlined in '*Research Misconduct Policy'* on page 10. https://our.ric.edu/documents/osp-policies-and-procedures. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results). The *Research Integrity Officer (RIO)* means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) the other responsibilities described in this Policy. The RIO is appointed by the Provost of the College.

SECTION 5: MANDATORY RESEARCH ETHICS TRAINING

RIC requires that all investigators – administrators, faculty, staff, and students – complete the research ethics -training program approved by the College. Completion of training must be renewed every five years and must be documented on all applications to the IRB. Principal investigators are responsible for ensuring that project-related personnel such as co-investigators, project managers, and research assistants complete the training and renew it before expiration. Substitute training programs will not be accepted. Details regarding the approved training program are available on the IRB website (https://our.ric.edu/department-directory/office-provost-and-vice-president-academic-affairs/research-protocols/institutional-review-board).

SECTION 6: TYPES OF REVIEW

Under the Federal guidelines, the only activity that is exempt from *prior* IRB review and approval involves the *emergency use* of an investigational drug (i.e., not approved by the Food and Drug Administration). *Emergency use* is defined as the use of a test article on a human participant in a life-threatening situation in which there is no standard acceptable treatment available and in which there is not sufficient time to obtain IRB approval. Such emergency use must be reported to the IRB within 5 days. It is highly unlikely that

research conducted at RIC or by the RIC community will encounter these circumstances. In all other circumstances, prior IRB review and approval is mandatory.

There are three levels of review under the Federal guidelines: **Exempt**, **Expedited Review**, and **Full Review** (see below). The final determination of review level shall be made at the sole discretion of the IRB Chair and in accordance with all relevant Federal regulations. General guidelines for each of these categories are as follows:

6.01 Exempt

Introduction
An exemption is not the same as approval. An 'exemption' means that the research is not subject to the requirements of the Common Rule. However 'exempt' does not always mean exempt from all of the requirement of the Common Rule. Certain exempt categories now have specified requirements as a condition of exemption.
Investigators will be instructed to review the types of protocols that may be determined to be exempt as well as the specific requirements. If the investigator believes that the protocol meets the criteria for an exemption, they will be instructed to complete the exempt protocol information provided.
A protocol submitted as exempt will be initially screened to determine that it meets the criteria for an exemption and that all required information has been submitted. For projects collecting sensitive, identifiable data, a limited IRB review must be conducted to review privacy/confidentiality protections. If an exemption is issued, an annual renewal for the project does not need to be submitted.
Changes to the protocol may change exempt status; contact the IRB Chair @ric.edu for clarification as to whether resubmission is needed. If it is determined that the change potentially changes the exempt status, an amendment to the protocol should be submitted prior to implementing the changes. If the research does not qualify for an exemption, an application for a new project will need to be submitted. The IRB will then determine whether it meets the criteria for expedited review or if full IRB review is required. Please note that projects identified as greater than minimal risk always require completion of a new project application.

Types of EXEMPT research activities:

I. Exemption One: Education

Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices *that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.*
NOTE: This exemption may ONLY be used for studies about normal educational practices.
Exemption One Review Path: Complete exempt protocol application. Note, if the protocol involves use of student educational records (FERPA regulated [Family Educational Rights & Privacy Act]; *https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html*) or (Health Insurance Portability and Accountability Act; *https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html*) protected data, limited IRB review will be required; complete an exempt protocol application.

II. Exemption Two: Surveys, Interviews, Observation

Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recordings) *if at least one of the following are met*:
(a) the information obtained is recorded by the investigator in such manner that the identity of

human subjects cannot readily be ascertained, directly or through identifiers linked to subjects = INFORMATION OBTAINED IS NOT IDENTIFIABLE;
(b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, education advancement, or reputation = DISCLOSURE OUTSIDE OF THE RESEARCH WOULD NOT PUT SUBJECTS AT RISK OF HARM;
(c) or the information is recorded in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to subjects, and an IRB conducts a limited

IRB review to determine that there are adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data = INFORMATION CAN BE IDENTIFIABLE BUT A LIMITED IRB REVIEW WILL BE CONDUCTED TO DETERMINE THAT THERE ARE ADEQUATE PROVISIONS FOR PROTECTING PRIVACY AND MAINTAINING CONFIDENTIALITY.
NOTE: Research involving children is not exempt under this condition.
Exemption Two Review Path: Complete exempt protocol application.
If data are sensitive or identifiable, limited IRB review is required. Complete the exempt protocol application.

III. Exemption Three: Benign Behavioral Interventions
Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
(a) the information is recorded by the investigator in such a manner that the identify of human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects = INFORMATION OBTAINED IS NOT IDENTIFIABLE;
b) any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation = DISCLOSURE OUTSIDE OF THE RESEARCH WOULD NOT PUT SUBJECTS AT RISK OF HARM ; or
(c) the information is recorded in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to subjects, and an IRB conducts a limited IRB review to determine that there are adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data. Research involving children is not exempt under this condition = INFORMATION CAN BE IDENTIFIABLE BUT A LIMITED IRB REVIEW WILL BE CONDUCTED TO DETERMINE THAT IRB DETERMINES THERE ARE ADEQUATE PROVISIONS FOR PROTECTING PRIVACY AND MAINTAINING CONFIDENTIALITY.
NOTE: If the research involves deceiving subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware or misled regarding the nature or purposes of the research.
Exemption Three Review Path:
Exempt; complete exempt protocol application.
If sensitive or identifiable data are to be collected, a limited IRB review is required; complete the exempt protocol application.

In the event that there is undisclosed deception, a comprehensive IRB Review is required, which requires completion of a new project application.

IV. Exemption Four. Secondary Use of Identifiable Data
Secondary research are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other 'primary' or 'initial' activity.

There are four options for use of this category:
(1) Use of publicly available private information of identifiable biospecimens;
(2) Information recorded in such a way that the identity of subjects cannot be readily ascertained and the investigator will neither contact nor re-identify the subjects;
(3) Research of identifiable health information where that use is regulated by HIPPA as health care operations, research, or public health activities and purposes as those terms are defined by HIPPA. This option requires HIPPA privacy review;
(4) Analysis of data on behalf of a federal agency or department, as opposed to an investigator-initiated analysis of federally supplied data, if requirements of certain federal laws are met.
*Note: Data does not need to be existing; it can be collected prospectively under this category.
Exemption Four Review Path: this exemption may include prisoners if analysis is not seeking to examine prisoners as a population or subpopulation.
IRB determination is required; complete an exempt protocol application. HIPPA privacy review required for option 3.

V. Exemption Five. Demonstration Projects
Research and demonstration projects which are conducted by or supported (subject to the approval of department or agency heads) and which are designed to study, evaluate, or otherwise examine:
(1). Public benefit or service programs;
(2). Procedures for obtaining benefits or services under those programs;
(3). Possible changes in or alternatives to those programs or procedures; or
(4). Possible changes in methods or levels of payment for benefits or services under those programs.
*NOTE: there is a new requirement for CLARIFY agency to maintain public list of such projects and to publish the list before project is conducted.
Exemption Five Review Path:
IRB determination is required; complete an exempt protocol application.

VI. Exemption Six: Taste and Food Quality
Taste and food quality evaluation and consumer acceptance studies include:
(1). If wholesome foods without additives are consumed; or
(2). If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the DEFINE THESE FDA or approved by the EPA or Food Safety and Inspection Service of the US Department of Agriculture.
Exemption Six Review Path:
IRB determination is required; complete an exempt protocol application.

VII. Exemption Seven: Storage and Maintenance of Identifiable Information or Biospecimens
Storage or maintenance of identifiable biospecimens and identifiable private information for secondary research collected under broad consent. Storage and maintenance may be exempt if the

IRB determines there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality and if broad consent* is obtained. *Broad consent is an alternative consent process with required elements.
BROAD CONSENT WILL NOT BE IMPLEMENTED BY THE RIC IRB AT THIS TIME.

Exemption Seven Review Path:
Limited IRB review is required to assess the terms of broad consent complete an exempt protocol application.

VIII. Exemption Eight: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
(a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; BROAD CONSENT WILL NOT BE IMPLEMENTED BY THE RIC IRB AT THIS TIME.
(b) Documentation of informed consent or waiver of documentation was obtained;
(c) An IRB conducts a limited IRB review and makes the determination that adequate provisions are in place to protect the privacy of subjects and maintain the confidentiality of data;
(d) The investigator does not include returning individual research results to subjects as part of the study plan. However, this provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
Exemption Eight Review Path:
Limited IRB review is required; complete an exempt protocol application.

Note: Continuing review is NOT required for research reviewed under exempt or limited IRB review.

If limited IRB review is required, the IRB will use an expedited review procedure. The review may be carried out by the IRB Chair or by one or more experienced reviewed designated by the IRB chair from among IRB members. In a limited IRB review, an IRB must conduct a review and make certain determinations as a condition of exemption. For example, that "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data" (46.111(a)(7).

6.02 Expedited Review

Introduction
The IRB may use the expedited review procedure for new applications that involve *no more than minimal risk* to the participants. Minimal risk is defined as circumstances in which "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" (*45 CFR; Part 46.102(i)*).

Types of Expedited Projects (45 CFR 46.110.)
A new project application should be completed, anticipating an expedited review, if:

(a) The Determination of Exempt Review instructions were reviewed and it was determined that the project did not meet the criteria for exemption; or

(b) The proposed research meets one of the expedited categories on the HHS Secretary's list (1998) and the researcher determines, and reviewer agrees, that the study is minimal risk.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

    b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an

invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(c) The proposed project involves no more than minimal risk.

Expedited Review Process

Under an expedited review procedure, federal regulations allow for such minimal risk studies to be reviewed only by the IRB Chair or by one or more experienced IRB members designated by the Chair. If an expedited reviewer determines that a study involves greater than minimal risk, the reviewer can override the presumption but must document the rationale.

In reviewing the research, the reviewer(s) may exercise all of the authorities of the full IRB except that the reviewers may not disapprove the research (disapproval may only be decided at a meeting of the full committee) (46.110(b) (2). Once the review has been completed, the investigator will receive written notification indicating whether the application was fully approved, required modifications and/or clarifications in order to secure approval, or was deferred for full committee review.
Each IRB using an expedited review procedure shall continue to adopt a method for keeping all members advised of research proposals that have been approved using the procedure (46.110(c)).

Continuing review is not required for research under limited IRB review or approved by expedited review (minimal risk studies), unless the reviewer explicitly justifies that it would enhance protection of subjects. The expedited reviewer must document the rationale of greater than minimal risk determination.

Research initially approved by a convened IRB that has progressed to the point of (a) data analysis, including analysis of identifiable private information or identifiable biospecimens, or (b) accessing

follow-up clinical data from procedures that subjects would undergo as part of clinical , do not require continuing review.

Even when continuing review is not required for a project, the investigators still have the obligation to: submit amendments for project changes; report adverse events, such as unanticipated problems; terminate the project once it ends or when the personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.

6.03 Full Review

A full board review is required for research that is not eligible for exempt or expedited review. Research that is judged to involve more than minimal risk, or involves protected populations such as children, prisoners, or disabled individuals, may be required to undergo a full board review. Other full board research includes: projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants; projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal); international research.

Research designated for full board review will be reviewed by the full IRB at one of its convened meetings. In general, protocols that require full review are those that pose greater than minimal risk to participants, that involve vulnerable populations (see Section 9), that wish to waive or alter informed consent (see Section 8), or that risk violating participants' anonymity and/or confidentiality.

SECTION 7: RESEARCH PROJECTS & THE REVIEW PROCESS

All research involving human participants conducted at RIC, by any RIC community member, or via any campus-related organization, must be reviewed by the IRB prior to commencement of the research activity. Approval can never be given retroactively. Most submissions require revision; consequently, investigators should start their application well before the submission deadline to allow time for these revisions. Meetings dates and submission deadlines are posted on the IRB website.

7.01 Pilot Studies

All pilot research projects are held to the same standards as full research projects. Pilot studies require IRB review prior to the commencement of any research activities.

7.02 New Applications

The current application process is specified on the IRB website (https://our.ric.edu/department-directory/office-provost-and-vice-president-academic-affairs/research-protocols/institutional-review-board). Materials required for review must include a completed application, recruitment materials, consent/permission/assent materials,

copies of all data collection materials, debriefing, and any other relevant documents. The Chair of the IRB will notify investigators in writing of the outcome of the IRB's review. Communication regarding student projects will be sent to the faculty advisor.

7.03 Changes to Approved Protocols

Any revisions to the approved research activity, including the omission or cessation of any previously approved activity, must be submitted to the IRB for review prior to implementing the change. The current application process is specified on the IRB website (https://our.ric.edu/department-directory/office-provost-and-vice-president-academic-affairs/research-protocols/institutional-review-board). When submitting an amendment, the investigator must include copies of any new or revised materials. In the case of revised consent/permission/assent forms, the revised version can only be used to admit new participants for enrollment in the study. Participants who are already enrolled in the study must be notified of and consent to any changes in the study if those changes impact their on-going participation

7.04 Renewal of Approval

IRB approval periods are granted on the basis of degree of risk associated with the particular protocol, but no greater than 1 year. Note that continuing IRB review will not be required: for exempt research, even if it received limited IRB review; research reviewed by expedited review; research that has progressed so that it only involves one or both of the following: (1) data analysis, including analysis of identifiable private information or identifiable biospecimens; or (2) access to follow-up clinical data from standard clinical care procedures.

Projects are automatically inactivated at the end of the approval period if a request for renewal is not received within 30 days before the approval expires. If the approval expires, all activities involving human participants must be stopped immediately. Activities may resume only upon approval by the IRB. Consult the IRB Chair to determine how to obtain approval for expired projects. A new application may be required. The current application process is specified on the IRB website (https://our.ric.edu/department-directory/office-provost-and-vice-president-academic-affairs/research-protocols/institutional-review-board). Even when continuing review is not required, the PI must still terminate the project once it ends, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.

7.05 Complaints, Problems, and Adverse Events

Investigators who experience any complaints, unanticipated problems, or adverse events must report this information promptly (typically, within 48 hours) to the IRB for evaluation. The current application process is specified on the IRB website (https://our.ric.edu/department-directory/office-provost-and-vice-president-academic-affairs/research-protocols/institutional-review-board).

RIC responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93, are outlined in are outlined in '*Research Misconduct Policy'* on page 10. https://our.ric.edu/documents/osp-policies-and-procedures.

This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results). The *Research Integrity Officer (RIO)* means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that

potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) the other responsibilities described in this Policy. The RIO is appointed by the Provost and Vice President for Academic Affairs of the College

7.06 Obtaining Other Approvals

Principal Investigators are responsible for knowing about and securing other internal or external approvals that are required to conduct the research. Examples include RIC or non-RIC administrative offices, school principals or superintendents, business owners or managers, or IRBs at other institutions.

7.07 URI/RIC Joint Ph.D. in Education Program

Students in the URI/RIC joint Ph.D. in Education program may be required to undergo IRB review at one or both campuses. If the student's major advisor is at RIC, review by the RIC IRB will be required. If the major advisor is at URI and any research activities will occur at RIC, the student is required to consult with the RIC IRB chair to determine whether review is required by the RIC IRB. Review by the RIC IRB is not required if the major advisor is at URI and no recruitment, data collection or other research activities will occur at RIC. Students should consult independently with the URI IRB to determine which projects require review at URI.

7.08 Students Conducting Research

Course-based student research activities designed solely to demonstrate the learning of course material are not considered research under the Federal definition and do not require IRB review.

Research projects conducted by students that are ***intended to demonstrate scholarly contributions to the discipline by contributing to generalizable knowledge*** must be reviewed by the IRB. Such projects include undergraduate honors projects, independent or directed research projects, graduate theses or dissertations, or any other form of independent or directed study regardless of whether the student receives course credit. Research projects on which students serve as paid or unpaid research assistants to faculty advisors require IRB review. Student research is held to the same standards as faculty/staff research.

The RIC IRB requires that student research using human participants be supervised by a RIC faculty or staff member who serves as the responsible investigator for the project. Communication about student projects will be sent to the faculty/staff advisor.

7.09 Participant Pool

Any department that wishes to implement a participant pool must submit its participant pool policy for IRB approval. The main issue to address when developing a participant pool is minimizing the chances for students to feel coerced to participate in research by ensuring that: (a) credit given towards a course grade is not so excessive as to be coercive, (b) reasonable alternative assignments are offered that require similar time and effort from the students, and (c) instructors of courses offering credit do not know whether students participated in research or in alternative assignments.

7.10 RIC Students as Research Participants

Although research is an integral part of academic life, research activities should not interfere with students' learning of course material. The use of class time for research activities must be justified on the IRB application as being directly relevant to the course.

7.11 Research at Non-RIC Sites / Collaborative Review

RIC requires that applications for data collection at a non-RIC site include a letter of permission from a person at that site with the authority to grant that permission. The letter must be on the site's letterhead, signed, scanned into a PDF file, and sent with the IRB application.

When conducting research at a non-RIC site, a RIC-affiliated investigator may need to obtain approval from multiple IRB's. The PI is responsible for acquiring and maintaining approvals from any IRB or other approval entity external to RIC. The RIC IRB cannot approve a project simply because another IRB approval exists.

For multi-site projects, the RIC IRB will consider requests for Collaborative Review in which an institution other than RIC is deemed responsible for the IRB review. The RIC IRB retains all rights to decline such a request or to require modifications to the research protocol. The RIC IRB will consider requests for Collaborative Review if all of the following conditions are met:

- The Principal Investigator (PI) is employed by a U.S. college, university, or research institution other than RIC
- The PI's institution has an approved federal assurance on file for their IRB.
- IRB approval from the PI's institution is currently active.
- The RIC employee/affiliate requests Collaborative Review. RIC Investigators should consult with the IRB chair to determine how to complete the RIC application. A copy of official documentation from the PI's institution indicating that its IRB approval is current and active is required.

The RIC employee/affiliate must adhere to all regulations in this policy and must provide all official documentation to the RIC IRB. The RIC IRB retains the right to withdraw its approval of Collaborative Review at any point in time and for any reason, if it determines that sufficient cause exists to do so.

7.12 Non-RIC Investigators Recruiting Participants from RIC

On occasion, researchers who are not affiliated with RIC want to recruit RIC faculty, staff, or students to participate in a study. The researcher should complete the *Determination of RIC Engagement in Research for External Projects form*, provided to the researcher by the IRB Chair. The researcher should be instructed to return the form to the IRB Chair, who will determine if RIC is 'engaged' in the proposed research. If no RIC administrator, faculty, student, staff members serve as investigators, consultants, or otherwise collaborate on the research project, then the RIC IRB does not review the proposal and provides no official sanction of the research project. Non-RIC investigators may use means of communication that are available to the general public (e.g., purchasing an ad in the student newspaper) to advertise their study, but are not permitted to use official RIC means of communication including the use of RIC letterhead, campus mail, or email. Those researchers not affiliated with RIC who do not need IRB review still should contact the Office of Institutional Research to gain approval for conducting survey research on campus https://ric.qualtrics.com/jfe/form/SV_bOUgDOW3TKWiGvX.

7.13 Use of Photographs or Video/Audio Recording

The RIC IRB requires that researchers collecting photographs or video/audio recordings have a specific statement on the consent form to which the participants can agree or not agree to participate in those procedures. Because voice and image are clearly identifiable, researchers must discuss on their IRB

application how the identities of their participants will be protected. When groups are photographed or recorded, such as in a classroom, the investigator must explain how the wishes of those people who do not wish to be recorded will be respected. Suggestions for how to accomplish this include: Having participants sit in the same area and placing recording devices so that they do not include non-participants; Blurring images of non-participants so that they cannot be recognized; Erasing non-participants' voices; or other similar methods that a PI may wish to propose.

7.14 Use of Compensation or Incentives

Compensation and incentives, if offered, must be described in the application. *Compensation* refers to reimbursement for expenses laid out by the participant (e.g., bus fare; parking fees). An *incentive* refers to something given in exchange for the participant's time in the study (e.g., money, gift cards). Compensation and incentives are NOT benefits to participating in the study. Neither compensation nor incentives should be so large as to constitute coercion to participate in the study. Incentives may be prorated for partial completion of the study, but the prorated amount must be explained in the application and in the consent materials.

7.15 Use of Non-English Materials

All non-English materials must be approved by the IRB. Materials submitted for review must include the original material and the non-English translation by a person qualified in the language (i.e., can speak, read and write). **For minimal risk studies** that are eligible for expedited review, the IRB will accept documents translated by an individual fluent (i.e., can speak, read and write) in a given language. The qualifications of the individual performing the translation will be assessed by the IRB. The qualifications of the person conducting the translations must be described on the application. **For greater than minimal risk studies**, two options for translation are possible: (a) translation by a certified translator or (b) back translation into English completed by someone other than the original translator. For a certified translation, a copy of the certification from the translator or translation service should be attached to the application. For back translation, the credentials of the people conducting the translations must be described on the application (e.g., native Spanish-speaker). **When submitting an application, investigators may wait to translate materials until the final wording is approved by the IRB.**

7.16 Administering Surveys

Survey research.

When conducting a survey of students, faculty, staff, or other RIC constituencies for which an individual or group does not have direct responsibility, it is necessary to seek approval through the college's survey research policy. Examples of situations in which the survey research policy would apply include faculty members who wish to survey students outside of their classes or department, managers who want to survey faculty or staff outside their units, or a party external to RIC who seeks to survey *any* RIC constituency. If in doubt about whether a particular project is subject to the policy, please consult the Office of Institutional Research & Planning."

Online or via Email Surveys

Online surveys and those administered via email may violate the principle of anonymity of participants' responses. In the case of email, the email address is clearly identifiable. In the case of online surveys, IP

addresses may be identified which makes the participants potentially identifiable. Researchers who want to administer surveys via email or online must address this issue in the application. The application must specify how participants will be protected from any potential harm from their identity being discerned. Typically, researchers should indicate that neither IP nor email addresses will be collected or should justify the need to collect the identifying information.

7.17 International Research Projects

When collecting data at an international site, the following information is required for the IRB application:

- Identify the countries other than the U.S. involved in the project and the location(s) within each country where the research will be conducted (e.g., village name, university name).

- Identify a contact person for each who can provide information about local laws/regulations regarding research compliance.

- Whether any of the locations named above have their own IRB. For each one, indicate which rules of research compliance are followed by the institution (e.g., the Common Rule; the Declaration of Helsinki). This information would be available from their research compliance office.

- How any collaborating institutions are engaged in the research project.. Specifically indicate whether any of the following activities are involved: recruiting participants, securing consent from participants, conducting research procedures, or receiving or sharing private identifiable information about participants.

- How the "local context" (e.g., local customs or conditions) affects participants' ability to provide informed consent (e.g., differences in age of consent; illiteracy). Also, discuss the ability of women to provide consent within the local context; i.e., is she allowed to consent on her own, or does she need a family member to consent on her behalf.

- How the "local context" (e.g., local customs or conditions) affects participants' perceptions about the topics being studied or the questions being asked in the study.

7.18 Determination of Exempt Status and Approval

Actions taken may include determination of an exempt status, approval, a request for clarifications and/or modifications, a deferral for full review (in the case of expedited reviews), or disapproval. Protocols must be referred to as "under review" until an exempt determination, approval or disapproval notice is issued. In order to approve a research activity, reviewers must determine that all of the following requirements are satisfied:

- Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to physical or psychological risk, and, whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable, in relation to the purposes of the research and the setting in which the research will be conducted.
- Informed consent, permission, and/or assent are obtained in compliance with this policy.

- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- Where some or all of the participants are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, persons with cognitive limitations, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these participants.

If these conditions are satisfied, IRB approval is are granted on the basis of degree of risk associated with the particular protocol. Protocols that are referred by the full board may be approved for no more than 1 year. If an investigator wants to renew the approval, s/he must apply for a renewal of approval no later than 30 days before the end of the approval period. Note that continuing IRB review will not be required: for exempt research, even it received limited IRB review; research reviewed by expedited review; research that has progressed so that it only involves one or both of the following: (1) data analysis, including analysis of identifiable private information or identifiable biospecimens, or (2) access to follow-up clinical data from standard clinical care procedures.

Disapproval of an activity may be determined only during meetings at which a majority of the IRB membership is present. Typically, the circumstances under which disapproval would be given include those when the committee determines that the risk to participants outweighs the benefit of the information that would be obtained, or if the investigator repeatedly fails to provide requested information or revisions to a protocol.

7.19 Appealing IRB Decisions

A principal investigator has the right to appeal IRB decisions either in writing or in person at an IRB meeting. The final decision rests with the IRB Committee and has no higher avenue of appeal. If the appeal is denied, the investigator may request re-review by IRB only after significant changes are made to the research protocol that adequately address the committee's prior concerns. The college administration may not override IRB disapproval

SECTION 8: INFORMED CONSENT

8.01 Types of Informed Consent

A fundamental ethical principle of research with human participants is that each person has the right to choose whether to be in a study. No person can be coerced to participate in research, and there can be no negative consequences of declining participation or withdrawing from a study. The consent document provides participants with a description of the study, its risks and benefits to the participants, and explains their rights as a research participant. The consent document should provide sufficient information for the person to make an informed decision about whether to participate. Depending on the targeted population, different documents may be needed:

- *Consent Document*: For adults who are legally capable of providing consent on their own behalf. Adults who are incapable of providing legal consent in any way due to medical, psychological,

developmental, or cognitive limitations or conditions require the permission of a legal guardian in order to be a research participant.

- *Permission Document*: For legal guardians of adults incapable of giving legal consent or for minors (under the age of consent). The age of consent may vary depending on the local customs of where the data is collected. 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. A waiver of permission may be granted if the research involves a population for which parental or guardian permission is not a reasonable requirement in order to protect the participants (for example, neglected or abused children), provided an appropriate mechanism for protecting the children who participate in the research is substituted, and provided that the waiver is not inconsistent with federal, state, or local law.

- *Assent Document*: For minor participants (7-17 years of age). Children below the age of 7 are given a verbal description of the activities and asked whether they would like to participate in the activity. Parents or legal guardians must give permission before asking the child for assent. A waiver of assent may be granted if the capability of some or all of the children is so limited that they cannot reasonably be consulted or if 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. See Section 9.03 for more information regarding research with minors.

8.02 Documentation of Informed Consent

Informed consent should be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative prior to participating in the study. A copy must be given to the person signing the form. However, in some cases, the investigator may request waiver of consent or of the signature aspect of consent (see 8.03 and 8.04). In this case, the standard approved consent form should be used with the signature line removed.

Consent materials must avoid the use of technical language or jargon and must be written at a language level appropriate for the average layperson (e.g., the RIC IRB recommends a high school reading level for the general adult population; lower reading levels may be required for other populations).

Consent documents must avoid either subtly or overtly coercive language. For example, the document should refer to the person "deciding" rather than "agreeing" to be in the study to help emphasize the right to choose.

- As per Federal Law, consent documents must include all of the information listed below. Consistent with the changes to the Final Rule, revisions were mandated that require key information essential to decision-making receive priority by being presented at the beginning of the consent document. See the IRB website for templates on preparing consent documents. The opening statement should clearly state that consent is being sought for research and that participation is voluntary. Indicate the anticipated time period of involvement in the study.

- *Purpose of the study*: The purpose of the research must be described in language suitable for a person who is not a professional in the field. This section should be phrased as an invitation to participate in a study and should end with "Before deciding whether to be in this study, please read this entire document and ask any questions that you may have.

- *The name of the investigator*: Must appear on the first page of the document; e.g., "John Doe, a faculty (student) at Rhode Island College, is conducting this study.

- *Number of intended participants:* The number of participants you plan to include in the study should be stated in the consent form. We recommend doing this in the first paragraph.

- *Procedures*: The consent form must describe all procedures that participants will experience. It must also provide an estimate of the time it will take to complete the study (e.g., 30 minutes; four 1-hour sessions scheduled every two months).

- *Risks of Being in the Study*: Describe reasonable risks whether physical, emotional, or to the person's reputation. Do not say that there are "no" risks, but you could say that "the risks are considered minimal, meaning that they are about the same as what you would experience in your normal daily activities." Also, provide instructions for what the person should do if they experience those risks.

- *Benefits*: Describe only direct, tangible benefits that the person will receive (e.g., medical care free of charge). Otherwise, indicate that there are no direct benefits to the person. Indirect or uncertain benefits (e.g., "You may learn more about yourself") or benefits to others (e.g., "You may help us to learn more about this topic") are not allowed.

- *Appropriate alternatives, if any, that might be advantageous*: Treatment studies must describe what treatments are available other than the experimental one being tested. Non-treatment studies will omit this section.

- Compensation and incentives must be listed in the Procedure section, if they are provided. Compensation refers to reimbursement for expenses laid out by the participant (e.g., bus fare; parking fees). An incentive refers to something given in exchange for the participant's time in the study (e.g., money, gift cards).

- *Voluntary Participation*: Explain that the person's participation is voluntary and is not required by their job, school, or any other such appropriate entity. Also indicate that the person can change his/her mind about participating at any time with no negative consequences.

- *Confidentiality*: Indicate that the records of this research will be kept private and who will have access to the records. Indicate where data will be stored and that it will be stored for a minimum of three years after completion of the study, after which it will be destroyed. Finally, include a statement that says "Data from this study may be seen by the RIC Institutional Review Board and by government agencies responsible for protecting human participants in research."

- *Contacts and Questions*: Provide the contact information for the Principal Investigator and the research coordinator, if one exists. Include the following statement: "If you think you were treated unfairly or have any complaints or concerns about your rights or safety as a research participant, please contact Chair of the Institutional Review Board at IRB@ric.edu." Check the IRB website for the current contact information.

- *Documentation of consent*: A statement of consent, signature line, and date is required unless a waiver of consent is requested and validated. If the participant's voice or image is being collected (photographs, audio-recording, video-recording), then a statement must appear for the participant to indicate whether they agree to these procedures. In addition, there must be a space for the person(s) obtaining consent to record their names. See the sample on the IRB website for how to phrase the consent statement and provide signature lines.

- If the consent form is longer than one page, the bottom of each page must have a place to initial in order to indicate their understanding of the information on that page.

- All consent, permission, and assent documents will be stamped with the IRB approval number and expiration date following approval. Only documents with the approval stamp may be used with participants. For those studies for which consent is collected online the participants must be able to download a stamped copy of the consent. You will find this consent in your application saved as a pdf.

8.03 Requesting an Alteration or Waiver of Consent

An investigator may request approval for an alteration or waiver of the consent process described above. The investigator must make a sufficient case that all of the following conditions are met:

- The research involves no more than minimal risk to participants.
- The waiver or alteration will not adversely affect the rights and welfare of participants.
- The research could not practicably be carried out without the waiver or alteration. Requests will only be granted if a sufficient case is made that the research cannot take place without the alteration or waiver. Convenience for the researcher is not sufficient justification for waiving or altering the consent process.

8.04 Requesting a Waiver of the Documentation of Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form if:

- The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he or she wants documentation linking the participant with the research, and the participant's wishes will govern;

  OR

- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Convenience for the researcher is not sufficient justification for waiving the documentation of consent. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

SECTION 9: SPECIAL CONSIDERATIONS FOR VULNERABLE POPULATIONS

9.01 Pregnant Women or Fetuses

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb

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

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

2. 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;

3. Any risk is the least possible for achieving the objectives of the research;

4. The pregnant woman's consent is required if the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means ***AND*** if one of the following conditions is met: (i) the research holds out the prospect of direct benefit to the pregnant woman, (ii) the prospect of a direct benefit both to the pregnant woman and the fetus, or (iii) no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal;

5. The pregnant woman's and biological father's consent is required if the research holds out the prospect of direct benefit solely to the fetus. 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.

6. Each individual providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

7. For minor children who are pregnant, permission from the minor's parent/guardian and assent from the minor are required.

8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

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

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

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

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

C. Until it has been ascertained whether a neonate is viable, a neonate may not be involved in research unless the following additional conditions have been met:

1. The IRB determines that: (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, **OR** (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research;

2. 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. The consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

D. After delivery, nonviable neonates may not be involved in research unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;

2. The research will not terminate the heartbeat or respiration of the neonate;

3. There will be no added risk to the neonate resulting from the research;

4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means;

5. The legally effective informed consent of both parents of the neonate is obtained. Consent from legally authorized representatives of either parent of a nonviable neonate is not permitted. Waivers or alterations in informed consent are not permitted. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest.

E. A neonate, *after delivery, that has been determined to be viable* may be included in research only to the extent permitted by and in accord with the requirements of this policy.

F. Research involving, *after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus*, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities. If information associated with this material is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all pertinent parts of this policy are applicable.

G. Contact the IRB Chair for information regarding research on pregnant women or fetuses not covered in this section.

9.02 Prisoners

A. Because prisoners have limits in their ability to make voluntary decisions regarding their environment and activities, additional safeguards are required to protect prisoners involved in research activities. The federal law defines a prisoner as “any individual involuntarily confined or detained in a penal institution” (**§46.303)**. 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.

B. Approval for research with prisoners will be granted only if the proposed research solely involves one the following:

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of prisoners.

C. Review of protocols that include prisoners as research participants will include review by an IRB member who serves as a prisoner advocate. Prisoner advocates are appointed by the IRB. Investigators are responsible for obtaining any required reviews and approvals from the prison and must submit a letter stating such approval before RIC's IRB will grant approval.

D. Applications for research with prisoners must meet the following standards:

- 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, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

- The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

- Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

- The information is presented in language which is understandable to the subject population;

- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole;

- When there is a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

- Under Exemption Four, as specified in the Final Rule, related to secondary use of identifiable data, this exemption may include prisoners if analysis is not seeking to examine prisoners as a population or subpopulation.

9.03 **Research with Minors (less than 18 years old)**

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-407-review-process/index.html

A. *Research on minors that involves minimal risk* must obtain permission from the parents and assent from the children. For research that is not greater than minimal risk, 45 CFR 46.404 is the applicable category

B. *Research on minors involving greater than minimal risk but presenting the prospect of direct benefit* to the individual subjects may be approved if

1. The risk is justified by the anticipated benefit to the participants;

2. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches; and

3. Adequate provisions are made for soliciting the permission of the parents/guardians and assent of the children

C. *Research on minors 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 may be approved if

1. The risk represents a minor increase over minimal risk;

2. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

3. The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and

4. Adequate provisions are made for soliciting permission of the parents/guardians and assent of the children.

D. *Children who are wards of the state or any other agency, institution, or entity* can be included in research only if the research is (a) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards, OR (b) Related to their status as wards. In this case, 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 with the research, the investigator(s) or the guardian organization in any way except in the role as advocate or member of the IRB.

SECTION 10: RESPONSIBILITIES OF INVESTIGATORS

Once a project is approved by the IRB, the investigator must adhere to **all** of the following:

- Conduct all aspects of the project as approved by IRB. Neither the addition nor elimination of materials or procedures is permitted without IRB approval. Qualitative research projects with evolving purpose or methods must remain within the approved scope of the protocol.

- Promptly report any revisions or amendments for review and approval *prior to* implementing the revisions.

- Report within 48 hours days any unanticipated problems or adverse events involving risks to participants or others.

- Assume full responsibility for selecting participants in strict accordance with the inclusion/exclusion criteria outlined in the application materials.

- Where consent/permission/assent form(s) have been approved for the research activity, only IRB-approved, stamped forms may be used in the consent process.

- Requests for renewal of approval must be received within 30 days before the approval expiration date.

The IRB has the authority to suspend, terminate, or place restrictions on any study in which the investigator has not met the above requirements, or in the event that information is disclosed to the IRB, which indicates that this policy is being violated in any way or that the rights and/or welfare of human participants are at risk.

SECTION 11: VIOLATIONS OF IRB POLICY

Complaints or reports of violations of this policy will be brought to the IRB for discussion. The IRB will make a determination regarding the need for additional information or further investigation. While investigating a report of a violation of this policy, the IRB may take any of the following forms of action:

- Requiring immediate cessation of all research activities
- Reviewing any research records associated with the protocol as deemed appropriate by the IRB
- Temporarily confiscating data associated with the research protocol
- Talking to participants about the study

RIC responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93, are outlined in '*Research Misconduct Policy'* on page 10. https://our.ric.edu/documents/osp-policies-and-procedures. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results). The *Research Integrity Officer (RIO)* means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) the other responsibilities described in this Policy. The RIO is appointed by the Provost of the College.

FOR ADDITIONAL INFORMATION

- DHHS: Code of Federal Regulations, Title 45 Part 46: Protection of Human Subjects

- FDA: Code of Federal Regulations, Title 21 Parts 50 (Informed Consent), 56 (IRB's), 312 (Investigational New Drugs), 812 (Investigational Device Exemptions)
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
- State of Rhode Island Public Health Law