Rhodes State College
Office of Institutional Effectiveness Planning

Institutional Review Board (IRB)

Charter and Operational Procedures

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Charter & Standard Operating Procedures

TABLE OF TABLE OF CONTENTS

Institutional Review Board (IRB)

Charter & Standard Operating Procedures

INTRODUCTION

Rhodes State College (RSC) places emphasis on teaching, research, and public service in a manner relative to its institutional Mission and purpose. Although research is not an expectation, the College encourages and supports the scholarly endeavors of its students, faculty, and staff. The Office of Institutional Effectiveness Planning has oversight of what is commonly termed "institutional research" which primarily involves gathering data (i.e., enrollment, retention, persistence, student outcomes statistics, etc.) for the purpose of data-driven decision making. In response to the expansion of grant projects, studies and requests to conduct research related to the impacts of teaching, learning and support services on student success, RSC established an Institutional Research Board (IRB).

OVERVIEW

No research on human subjects by any participant in any of our programs at whatever level may be conducted without prior IRB review and approval. Some research projects involving human subjects are exempt from IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the subjects are not identified; and surveys or interviews in which the subjects volunteer and are not personally identified.

The IRB for Human Subjects Research at RSC has oversight for carrying out the RSC's commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications, or disapprove research activities conducted by any internal or external researcher using human subjects.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project for compliance with ethical standards with regard to issues such as informed consent, confidentiality, and potential risk participants.

Institutional Review Board (IRB)
Charter & Standard Operating Procedures

I. INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures establishes and empowers the RSC committee for human subjects protection. Currently RSC has one committee, registered with the federal Office for Human Research Protections (OHRP) as an Institutional Review Board (IORG0007235). This committee is hereinafter referred to as the "IRB". The IRB also abides by the Statement of Ethical Principals outlined by the Association of Institutional Research (AIR).

In accordance with the terms of the Federal Wide Assurance (FWA00018814), RSC adopts the following reporting procedure:

All Principal Investigators (INVESTIGATOR / RESEARCHER) and RSC employees are required to report to the IRB Chair any of the following upon knowledge of:

1. Unanticipated problems involving risks to subjects or others; and
2. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the RSC IRB, the President, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and the OHRP.

II. PURPOSE

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

III. BASIC PRINCIPLES

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained Belmont Report, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979 [Belmont Report].

B. Therefore, the following principles apply to all research, including student projects, involving human subjects at RSC to ensure that adequate safeguards are provided:

1. Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.

5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

7. All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review ***prior*** to their initiation or ***prior*** to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

IV. DEFINITIONS

In making determinations about research proposals, the IRB uses definitions in line with the Federal code.

The explanations below are how we define these important terms:

A. Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

B. Human subject means 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.

C. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

D. Interaction includes communication or interpersonal contact between investigator and subject.

E. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

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

G. An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

H. **IRB** means an institutional review board established in accord with and for the purposes expressed in this policy.

I. **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

J. **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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

K. **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.

L. **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this 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. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public

health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

5. Primary research is defined as research conducted to gather first-hand information (raw data) by the researcher him/herself.

6. Secondary research is defined as research that involves the use of information that is analyzed and interpreted as part of the research project but gathered originally as primary research by someone else.

M. Principal Investigator (INVESTIGATOR/RESEARCHER) is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

N. Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

V. PROTECTED POPULATIONS

Federal guidelines have additional protections built in for research using specific populations of people. These guidelines are meant to protect groups of people who may be more vulnerable to coercion or undue influence than are other groups. Groups that are specified in the federal code are as follows:

A. Children. If humans under the legal age of consent (generally age 18) are to participate in research, two levels of consent must be obtained. First, parents or legal guardians of the child must sign a consent form. Second, children must give verbal assent that they agree to participate. A child's absence of refusal cannot be taken as assent.

B. Prisoners. Research involving prison populations undergoes more rigorous review because prisoners may not have the same ability to make decisions in the absence of coercion. For these research proposals, a member of a prison population must be involved in the determination of approval and the majority of the rest of the IRB cannot be associated with the prison from where the population will be sampled.

C. Individuals with impaired decision-making capacity. This category may include individuals with Alzheimer's disease, those who have had a stroke or traumatic brain injury, those with developmental disabilities affecting cognition, or others. In general, research using members of these groups requires the consent of a legally authorized representative and the consent/assent of the participant, if consent/assent is able to be given in the context of the research.

D. Economically or educationally disadvantaged persons. Members of these groups may be more susceptible to coercion than other groups. Thus, care should be taken by the researcher to make sure that no element of coercion is present in the research.

The use of any of these populations for research, unless otherwise exempted from review, requires a Full Review by the IRB. Researchers wishing to use any of these populations are encouraged to read the subparts of the federal code which address the population of interest and/or meet with the convener of the IRB.

VI. GUIDELINES FOR GRANTING IRB REVIEW

In making its decision to conduct an IRB review of submitted proposals, the IRB's first priority must be a focus on factors promoting RSC's mission. Any submitted proposal must meet the minimum standard of having the likelihood of providing knowledge that contributes to the long-term success of RSC's faculty, staff, and students. Accordingly, applicants not affiliated with RSC must obtain an approval letter from academic (department Chair or above) or administrative leadership.

In reaching its conclusions concerning the granting of an IRB review, the IRB will consider the following factors:

A. Has the researcher made a strong and compelling case that the research will provide insight into learning and student success factors and is the research aligned with RSC's mission?

B. Has the proposal clearly articulated how findings will be communicated to the RSC?

C. Have all costs which will be incurred by RSC been fully considered; do the benefits outweigh the costs, and has provision been made to reimburse RSC for any unusual data collection expenses?

D. Has the research been determined to be in compliance with FERPA requirements?

E. In the opinion of the IRB, is the research design sufficiently rigorous to lead to meaningful insights?

F. Has the researcher identified a RSC full-time faculty or staff member who is willing to serve as the internal sponsor for the research? Has the individual acknowledged acceptance of this

role and has the individual identified the value of the research findings to his/her area of responsibility?

G. In the opinion of the IRB, have the individuals making up the research sample been overly burdened with requests to serve as research subjects?

H. Is the researcher a RSC full-time faculty or staff member conducting research for an advanced degree?

VII. THE AUTHORITY OF THE IRB.

A. RSC holds a Federal Wide Assurance (FWA) through OHRP. As part of this Assurance, RSC agrees to consider ***all*** research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution (unless the research is conducted at another institution with which RSC has an "IRB Authorization Agreement" as specified in RSC's FWA), or

2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which RSC has an "IRB Authorization Agreement" as specified in RSC's FWA), or

3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or

4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

   In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval. If the instructor has any doubt concerning the classification of these activities, they are required to complete an Exempt Protocol Summary Form for approval and submit it along with the protocol and any accompanying consent form(s), cover letter(s), and/or questionnaire(s) in order to obtain the guidance of the IRB regarding such activities.

B. The IRB reviews all projects and programs involving human subjects in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, and grant funding entity's policies and guidelines.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

D. The IRB has approval authority of human subject protocols, and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Institutional Research Coordinator. However, the Institutional Research Coordinator may not approve the non-exempt research if it has not been approved by the IRB.

E. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

F. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

G. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.

H. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

VIII. THE IRB'S FUNCTIONAL RELATIONSHIPS

A. The IRB functions administratively as part of the Office of Institutional Effectiveness Planning with oversite by Institutional Research. This structure provides for administrative coordination for the IRB with the various academic and administrative offices of RSC.

B. The IRB advises and makes recommendations to the President and Cabinet and to any other RSC administrative or academic office on matters related to the use of human subjects in research.

IX. THE MEMBERSHIP OF THE IRB

A. The IRB is composed of at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. Recommendations for IRB membership are brought forward by the office of IEP, approved by the President, and once confirmed reported to OHRP.

B. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of RSC policy, relevant law and regulations, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

C. The IRB must include at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific, and at least one member who is not otherwise affiliated (either directly or through immediate family) with RSC.

D. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

X. MANAGEMENT OF THE IRB.

A. The IRB Chair is designated as the Institutional Research (IR) Coordinator. The Chair has authority to sign all IRB action items. In the event that the IR Coordinator position becomes vacant, the IRB Vice Chair shall assume responsibilities as Interim IRB Chair until the IR vacancy is filled.

B. The IRB Vice Chair (Executive Director of IEP) is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair has authority to sign all IRB action items in the absence of the IRB Chair.

C. Members of the IRB shall be appointed in consultation with the President for a tenure of three (3) years. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that they are unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

D. All IRB members are required to undergo formal training no later than 30 days after the time of their initial appointment. Training that satisfies this requirement includes but is not limited to the following: RSC specific IRB Training, and/or training provided by the Office of Human Research Protection (OHRP). The IRB Chair will maintain a log of training completion dates. Continuing education of IRB members is accomplished through scheduled meetings and/or the IRB Chair providing online education/training materials for review and completion.

IRB members submit certificate(s) of training and a signed Training Verification Form as part of documentation of IRB training. IRB member must complete training and provide verification every three (3) years.

E. IRB members do not receive compensation for their service.

F. Liability coverage for IRB members is provided through RSC's liability insurance coverage, whether or not the IRB member is an employee of RSC.

G. Consultants with competence in special areas may be used when deemed appropriate.

H. Conflict of interest policy and procedure

1. Project Investigators shall not be involved in the selection of IRB members.

2. Investigators will be asked in RSC's Conflict of Interest form, "The Report Form for Financial Disclosure" whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.

3. Investigators and IRB members who are RSC employees and who apply for federal grants and contracts are subject to the RSC Conflict of Interest Policy.

4. The RSC Office of the President will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human subjects.

5. Other conflict of interest guidelines specifically for IRB members are found in Section XVII of this Charter and Standard Operating Procedures.

XI. TYPES OF IRB REVIEW

A. Exempt Review

Under the auspices of the IRB, the IRB Chair will review Exempt Protocol Summary Forms eligible for "exempt" (see below), expedited review, or if significant risk is inherent in the study; petition to the IRB for full board review.

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency has determined otherwise. Exempt types of research include:

Research that has no risk to the participants and does not include vulnerable populations may be exempt from IRB review. However, individual investigators are not allowed to make this

determination, so this form "RSC IRB Exemption Form 2022," (*Appendix A*) must be used for any research that may be exempt should be submitted to the IRB.

In order to be considered exempt from IRB review, every part of the research project must fall under one of the Exemption types of research. [NOTE: Some types of approved Exempted research may still require informed consent from participants (e.g., anonymous surveys using online participant pools); in such cases, researchers should submit a consent document to the IRB].

Based on the federal guidelines for research exempted from Full IRB Review, investigators may apply for an Exemption if:

1. The project involves investigating normal educational practices, such as a comparison of curricula or classroom management methods in an established educational setting.

2. The project uses observational, survey, interview (oral history), or educational (cognitive, diagnostic, aptitude, achievement) testing procedures, if one of the following is true:

    a. Participant identities are anonymous or cannot be easily determined through description or linked identifiers.

    b. Any disclosure of identity would not lead to criminal liability or damage to participants' employment, financial standing, education, or reputation.

    c. The IRB approves the disclosure of participant identities.

3. You are doing research using benign behavioral interventions paired with data collection, if one of the following is true:

    a. Participant identities are anonymous or cannot be easily determined through description or linked identifiers.

    b. Any disclosure of identity would not lead to criminal liability or damage to participants' employment, financial standing, education, or reputation.

    c. The IRB approves the disclosure of participant identities.

4. The project is secondary research that involves studying existing data, recordings, or other documents, if any of the following are true:

    a. Participant identities and specimens are publicly available.

    b. Identities are stripped and not labeled in a way that can lead to identification.

    c. Research focuses on federally mandated analysis of health data.

5. The project is supported by the federal government/agency and focuses on evaluation of public benefit programs and is approved by the organization being studied, if relevant.

6. The project is on customer perception of taste and food quality using only FDA approved wholesome foods or includes products at or below levels found safe by various federal agencies (e.g., FDA).

7. Storage of identifiable data/biospecimens for secondary research when broad consent was obtained from participants.

8. Secondary research on stored identifiable data/biospecimens, if ALL of the following are true:

    a. Broad consent was given by participants at the time of data collection.

    b. There is documentation of informed consent.

    c. The IRB does a minimal review to ensure participant identities are secure.

    Research projects and protocols that are exempted from full IRB review do not need to be re-approved unless there are changes which are going to occur (e.g. changes in population, research methods, questions, etc.). Any changes to the project will need to be submitted to the IRB using a "RSC Research Change / Continuation Request Form 2022" (*Appendix D*).

    The IRB Chair, not the investigator, shall make the determination as to whether a project is, or is not exempt. To obtain an exemption, an investigator must Petition the IRB with an exemption request citing the specific exemption category and providing justification for the exemption.

B. Expedited Review

Research projects that present minimal or no risk to human participants, which covers most of the research conducted on the RSC campus, may be submitted to the IRB for an Expedited Review. An Expedited Review does not need to be deliberated on at a convened meeting of the IRB. Instead, approval will involve the IRB Chair and two members of the IRB committee. It is up to the discretion of the IRB if Expedited Review proposals have an expiration date.

Research submitted for an Expedited Review cannot be used for research where subjects could be harmed if identified, unless reasonable protections are in place to prevent participant identification. In addition, all informed consent requirements are in place for research approved via Expedited Review.

In order to submit a project for Expedited Review, **all** research procedures must fit within the federally approved categories below:

1. Collecting blood samples by finger, heel, or ear stick from healthy, non- pregnant adults weighting at least 110 pounds or from other adults and children as long as the following requirements are met: no more than 2 blood collections per week over a period of not more than 8 weeks, where blood drawn is less than 50 ml per kg of body weight in adults or less than 3 ml per kg of body weight in children.

2. Collecting biological specimens for research in a non-invasive way, such as non-disfiguring hair or nail clippings, sweat collection, saliva collections of unstimulated or stimulated forms (e.g., by chewing gum base), skin cells collected via buccal scraping, or other similar non-invasive ways.

3. Collecting data using non-invasive, regularly employed clinical means, such as external sensors, sensory acuity testing, strength-testing, or other means, but excluding x-rays or microwaves.

4. Engaged in research on materials that were not collected solely for research purposes, such as medical treatments. (Some of this research may be exempt from IRB review, see below.)

5. Collecting data from a preexisting recording made for research purposes, including voice, video, digital, or image recordings.

6. Collecting data on individual or group behaviors/characteristics, such as research about perception, attitudes, identity, language, etc., using surveys, interviews, focus groups, or other methodologies. (Some of this research may be exempt from IRB review, see below.)

   All research submitted for Expedited review must be of minimal or no risk. Even research falling within the aforementioned categories is subject to a Full Review. Investigators should complete the form titled "RSC IRB Expedited Review Form" (*Appendix B*). In addition to this form, an informed consent document and other relevant materials must be submitted for IRB review.

   The IRB Chair may recommend a protocol to the IRB for: (1) expedited review; (2) expedited review pending recommended changes/clarifications; or (3) for review by the full board. The IRB Chair cannot "disapprove" of a protocol but may table action pending further information/clarifications. The IRB Chair will inform the INVESTIGATOR / RESEARCHER of its actions. Any disagreement between the INVESTIGATOR / RESEARCHER and the IRB Chair must be resolved by the IRB.

   The INVESTIGATOR / RESEARCHER will be notified of the IRB decision by the Chair.

If it is determined that one of these protocols require IRB review, it will be returned to the INVESTIGATOR / RESEARCHER, with comments, for revision and submission to the full board. Upon receipt of the material from the INVESTIGATOR/ RESEARCHER, the IRB Chair will distribute copies to each IRB member.

C. Full Review

Protocols for full-board (IRB) review must be submitted to the IRB Chair as soon as possible. The prospective INVESTIGATOR / RESEARCHER will submit to the IRB Chair one (1) original and the required number of copies of the "Full IRB Review Protocol Summary Form" (*Appendix C*). In the request, the investigator assures the IRB that they will follow the principles, procedures and guidelines established and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with these procedures.

The INVESTIGATOR / RESEARCHER must be available to discuss the protocol and/or consent forms at the discretion of the IRB.

There are historic examples of research conducted in the United States wherein harm was done to human participants. In order to minimize "harm," federal guidelines stipulate what types of research related activities require a review by the entire IRB. Research projects requiring Full Review contain one or more of the following characteristics:

1. Study of vulnerable groups. This includes all of the groups listed under "Protected Populations" above and/or anyone who might lack the capacity for full, free, informed consent or refusal.

2. Exposure or potential exposure of the identities of participants.

3. Demonstrable or potential risk to the physical health and safety of participants greater than minimal (e.g., certain exercise protocols, ingestion of substances not proven to be wholesome, encroachment on a subject's bodily boundaries).

4. Risk of emotional distress (e.g., invasive questioning on sensitive issues).
5. Potential loss of livelihood (e.g., interviewing a subject regarding their work environment).

6. Use of deception (e.g., giving participant's false feedback about their scores on a personality test).

7. Research going beyond strictly classroom pedagogical purposes that will be presented to the wider public (e.g., at a conference or in a publication) that might expose participants' identities, regardless of whether they have consented to the risk of identity exposure.

8. Risk of criminal or legal liability for the subject (e.g., asking questions about stealing).

9. Research conducted in non-US locations (e.g., research conducted while on a study abroad program).

If **any** of the above conditions are met, a full review must be conducted. Please complete the form titled "RSC IRB Full Review Form 2022" (*Appendix C*). In addition to this form, the ALL research-related documents/materials must be included for IRB review.

When conducting research outside of the United States, the guidelines of the U.S. and the country in which the research will occur must be followed (in the event the project is approved, investigators/researchers will be affiliated with RSC) and the RSC IRB reviews and approves research even when it is conducted internationally. Additional information may be needed (e.g. additional research guidelines for the specific location where the research will take place) so the IRB should refer to the Office of Health and Human Services International Compilation of Human Research Standards for additional guidance.

Research projects and protocols approved by Full Review are approved for one (1) year from the date of the approval. If the research is anticipated to extend past one (1) year, a Change/Continuation form (see below) must be submitted and/or another IRB review may be required prior to the expiration date of the original approval.

Finally, research projects approved by Full Review that are considered by the IRB to have a high degree of risk will be visited randomly by an IRB Member in order to verify that no material changes have been made since IRB approval.

D. Continuing Review

The IRB may conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Principal Investigators will be informed of the annual review by receipt of a Continuing Review Questionnaire. This Continuing Review Questionnaire is to be completed and returned to the Chair of the IRB along with the informed consent document currently in use with the project being reviewed. The INVESTIGATOR / RESEARCHER will be notified of the action taken (e.g., Approved, Approved Subject to Restrictions, etc.).

When a Continuing Review request is submitted, the IRB Chair shall consider the following: changes to the research, protocol deviations and violations, since the last scheduled review; adverse event reports; reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports; and investigator compliance.

If the protocol and/or other documents used in the project have been amended within the past five years, the INVESTIGATOR / RESEARCHER will be requested to submit a new protocol incorporating these amendments if such have not previously been submitted.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the IRB approval, the protocol will be considered closed and enrollment of new subjects cannot occur nor can any data collected be used for research purposes.

E. Procedures Pertaining to Both Initial and Continuing Review

1. The IRB shall have authority to determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review, particularly: (i) complex projects involving unusual levels or types of risk to subjects; (ii) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and (iii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

2. INVESTIGATOR / RESEARCHER shall be informed at the time of protocol approval (both initial and continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects;

3. INVESTIGATOR / RESEARCHER shall be informed at the time of protocol approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.

4. Serious or continuing noncompliance by an investigator, or any suspension or termination of activities, is to be reported promptly to the office of Institutional Effectiveness Planning (IEP) so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

F. Adverse Event Reporting Guidance

1. The Office of Human Research Protections (OHRP) recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

2. Principal Investigator(s) and any RSC employee will report to the Chair of the IRB Committee any of the following upon knowledge of such:

    a. Unanticipated problems involving risks to subjects or others; and

    b. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

XII. ACTIONS OF THE IRB

A. The IRB may take one of the following four actions concerning the proposed protocol and consent form: Approved, Approved Subject to Restrictions, Tabled, or Disapproved.

Approved
When a protocol has been approved, the Chair completes the "Action of the IRB" form, signs and dates it, and distributes one copy of the form to the principal investigator, the IRB files, and, if appropriate, the performance site.

Approval of the protocol will be based on the following:

1. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.

2. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.
3. Assurances of acceptable debriefing, if appropriate.

    It is the responsibility of the INVESTIGATOR / RESEARCHER to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time.

    There is an exception to this delay: In those cases, in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

4. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.

5. Anticipated benefits, if any.

6. The personal risk to the subject in relation to expected benefits.

7. The adequacy of procedures for securing informed consent from the subject.

8. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.

9. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

Approved Subject to Restrictions
If the protocol is approved subject to restrictions, then the Chair completes the appropriate form, signs and dates it, and sends the form with a memo to the INVESTIGATOR / RESEARCHER outlining the restrictions. The INVESTIGATOR / RESEARCHER then must respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the protocol is then processed as an approved protocol and distributed as described above.

Tabled
Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the INVESTIGATOR / RESEARCHER is notified by the Chair of the IRB and the additional information necessary for completion of the IRB review is requested. In the case of a tabled protocol, the INVESTIGATOR / RESEARCHER may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

Disapproved
If the protocol is disapproved, the INVESTIGATOR / RESEARCHER will be informed in writing of the reasons for disapproval. The INVESTIGATOR / RESEARCHER may revise and resubmit his/her protocol for another review.

XIII. OPERATIONS OF THE IRB

A. IRB meetings are scheduled as needed but typically the committee will not meet more than once per term.

B. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

C. The IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new protocol, who receive the complete study documentation for review. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned based on their expertise, lead the discussion of that protocol. Other IRB members review summary information only, but have access to complete study

documentation upon request. If external reviewers are also assigned, they must be subject to the same conflict of interest policies as IRB members.

D. Voting Requirements

1. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.

3. Principal Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

E. Appeals

The INVESTIGATOR / RESEARCHER may appeal the decision of the IRB when a protocol has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the INVESTIGATOR / RESEARCHER, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the INVESTIGATOR / RESEARCHER and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The INVESTIGATOR / RESEARCHER will be promptly notified of actions of the *ad-hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

F. Amendments - Change to or Continuation of Previously Approved Research

In cases where small changes need to be made to an approved research protocol, researchers must complete and submit a RSC Research Change/Continuation Form (*Appendix D*). In all cases, it is possible that the IRB convener will request a new review based on any proposed changes.

Research Proposals **with** an Expiration Date

- Only one Change/Continuation form may be submitted per approved research protocol. Afterwards, a new proposal must be submitted.

- A Change/Continuation form must be submitted before the expiration date of the initial approval has passed. If the expiration date has passed, a new proposal will be required.

- Approval of a Change/Continuation will change the expiration date of the original approval to one year after the approval of the Change/Continuation.

Research Proposals **without** an Expiration Date

- Only two Change/Continuation forms may be submitted per approved research protocol. Afterwards, a new proposal must be submitted.

- Approval of a Change/Continuation may or may not lead to an expiration date for the updated research. If an expiration date is added, that expiration date applies to the entire research protocol, not simply the changed elements.

Below are the types of adjustments that may be submitted via a Change/Continuation form.

1. Minor changes to research protocols that were previously approved. Submitting this type of change means that data collection must be stopped until the changes are approved or may continue only under the previously approved protocol. Some examples include:

    a. The addition or removal of questions asked of participants;

    b. The addition or removal of questions asked of participants;

    c. Recruiting/data collection from a new population source; and/or,

    d. Increasing the number of participants to be involved.

    e. Addition or deletion of study team members;

    f. Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;

    g. Removal of research procedures that would thereby reduce the risk to subjects;

    h. Addition of non-sensitive questions to invalidated survey or interview procedures;

    i. Addition of or revisions to recruitment materials or strategies;

    j. Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

2. Continuation of research previously approved. This type of change request will be most common for research proposals with an expiration date. Some examples of research continuation include:

a. No changes are being requested aside from an extension of an expiration date for an approved research protocol; and/or,

b. Research is closed to new participants and all enrolled participants have completed research-related activities, but long-term follow-up with existing participants is desired.

Other types of changes may also be considered.

Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of significant changes to a study may include, but are not limited to, the following:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
- Addition of research procedures that involve greater than minimal risk to subjects;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed, either by the screening committee or by the full IRB. However, if an amendment by the screening committee is determined to increase the level of risk beyond minimal risk, the screening committee will refer the amendment to the full IRB.

3. Sponsor Agency Modifications

Modifications can be made only to IRB approved studies. A sponsor agency may modify the research protocol before the study has received final approval from the IRB. If this occurs, it is recommended that investigators await receipt of the IRB approval letter before making changes to the research protocol.

Sponsor agency generated modifications (or addenda) require review and approval by the IRB or Screening Committee, as appropriate. The investigator should provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants.

G. Grievances

The IRB shall be informed of all grievances (e.g., of a research subject against an INVESTIGATOR / RESEARCHER) and, if requested, the board will act in an advisory capacity.

H. Cooperative Activities

Cooperative activities relating to human subjects are those which involve RSC and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

1. Both institutions have Federal Wide Assurances (FWAs) approved by OHRP;

2. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and

3. The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

   In the absence of these conditions, the INVESTIGATOR / RESEARCHER must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved FWAs.

XIV. RECORD REQUIREMENTS

A. The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.

3. Detailed minutes of IRB meetings, showing:

   a. Members present (any consultants/guests/others shown separately).

   b. Results of discussions on debated issues and record of IRB decisions.

   c. Record of voting (showing votes for, against and abstentions).

4. Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.

5. Copies of all correspondence between IRB and the investigators.

6. Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.

7. Adverse reactions, reports and documentation that the IRB reviews such reports.

8. Emergency use reports.

9. General project information provided to subjects (e.g., fact sheets, brochures).

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB, and self-assessments.

B. All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the INVESTIGATOR / RESEARCHER leave RSC, signed consent forms are to be transferred to the IRB Chair.

XV. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB

A. Professional qualifications to do the research (including a description of necessary support services and facilities);

B. Proof that those involved in the research have completed the Responsible Conduct of Research (RCR) training as described in Section XIV "For Researchers".

C. Appropriate RSC review form including protocol summary.

D. Complete study protocol which includes/addresses:

1. Title of the study and summary of the research to be conducted,

2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),

3. Sponsor of the study,

4. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),

5. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners, or handicapped, economically/educationally disadvantaged, or mentally disabled persons),

6. Study design (including, as needed, a discussion of the appropriateness of research methods),

7. Description of procedures to be performed,

8. Provisions for managing adverse reactions,

9. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations,

10. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ('minor' is defined in Ohio as an individual under the age of 18), using legally authorized representatives (see XII.B.&C.), witnesses, translators and document storage,

11. Remuneration to subjects for their participation,

12. Any compensation for injured research subjects,

13. Provisions for protection of subject's privacy,

14. Extra costs to subjects for their participation in the study,

15. Inclusion/exclusion of women, minorities, and/or children;

E. Investigator's brochure (when one exists);

F. The case report form (when one exists);

G. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s); or request for waiver of the requirement to obtain informed consent;

H. Copies of advertisements and surveys, questionnaires, or other materials provided to subjects;

I. Copies of relevant grant applications (if any);

J. Requests for changes in study after initiation including changes to consent forms;

K. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports;

L. Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XVI. PRINCIPLES OF INFORMED CONSENT

Federal guidelines specify that ethical practices for research involving human participants include informed consent by either the participant or the participant's legally authorized representative.

RSC has an example of an informed consent document that is available upon request to the IRB Chair. In most cases, participants (or legal representative) will sign a consent form verifying that they have been informed of their rights and consent to participate. For research conducted exclusively online, signing a document may not be practical. In these cases, alternative wording must be provided in an informed consent document (e.g., that providing responses indicates consent).

The necessary elements of an informed consent document are also stipulated by Federal guidelines. This information is necessary in order for participants to make a fully informed decision about their participation in any research. For the majority of research projects, all of the following information must be included in an informed consent document.

A. Researchers must provide participants with the information that a reasonable person would want to have to make an informed decision about whether to participate (e.g., procedures, duration, etc.). Additionally, researchers should answer questions about other aspects of the research if participants inquire.

1. For research that is medical in nature, any experimental procedures must be identified and any available alternative treatments must be explained.

B. Researchers must inform participants about any possible physical, mental, or emotional discomfort that could arise as part of participation in the specified project. Researchers must do their best to minimize any distress.

C. Researchers must inform participants about any possible benefits, either to participants, society, or the academic discipline. This should include a statement about any compensation (or lack thereof).

D. Researchers must inform participants about their rights regarding the specified research. These include the right to discontinue participation at any time or in any way without negative external consequences, the right to receive a summary of the results, and the right to have a copy of the informed consent document. These rights must be respected by the researcher. For research conducted online, participants should be told to print a copy for their records or contact the investigator for a mailed copy.

E. Researchers must inform participants about what will be done with the data collected and how it will be kept. This includes information about confidentiality or anonymity (if applicable), data storage procedures, and possible publication.

F. Researchers must provide contact information for those who can provide information about the research (generally the researcher) and who can provide information about participant rights (generally the IRB convener).

G. For research involving more than minimal risk, researchers must provide an explanation as to whether any compensation or medical treatments are available if injury occurs.

H. When using research with identifiable data/biospecimens, researchers must include a statement that:

1. The participant's data/biospecimens will not be used for future research; or

2. The participant's data/biospecimens might be used for future research without soliciting further informed consent provided identifiers are removed.

Additional elements may be required dependent on the type of research (e.g., for some clinical trials or research with biological specimens not used completely during analysis). The IRB will advise in such cases. Some examples of these new elements are below:

1. Whether remaining biospecimens will be used for commercial profit;

2. Whether results from a clinical trial will be disclosed to participants; and/or,

3. Whether the project might include sequencing of the whole human genome.

Broad Consent
Broad consent, rather than informed consent may be sought in limited cases, which are rare at RSC. This includes storage, maintenance, and secondary research use of identifiable data/biospecimens.

Waiver of Consent
In some research scenarios, obtaining informed consent may be impossible or doing so may undermine the research. In these cases, it is possible for informed consent to be waived. Federal guidelines indicate that informed consent may be waived when **all** of the following conditions are met.

1. The research presents no more than minimal risk of harm;

2. Removal or alteration of informed consent will not affect the rights or welfare of the participants in a negative way;

3. The research could not be carried out without some alteration or waiver of informed consent, whether involving identifiable or non-identifiable private data/biospecimens; and,

4. When appropriate, participants will receive information pertinent to their participation after the study.

In these situations, a case must be made to the IRB that standard informed consent is not practical or feasible. Research without informed consent may only occur with IRB approval.

Debriefing

Related to the principle of informed consent is the idea of debriefing. Debriefing is a thorough explanation of the research being conducted, which may include procedures, hypotheses, variables/methods used, etc. Often, this information can be included in the informed consent document. However, there are many times when some or all of this information cannot be included in the informed consent document. For example, participants may not be told that a person they interact with during the study is a confederate (not another participant). This information should then be included in a debriefing document or statement provided at the end of a study.

The IRB **requires** a debriefing document for all studies where deception or incomplete disclosure occurs. Otherwise, debriefing statements are optional according to the IRB, but may still be required by your program, a collaborating partner's institution, or other constituent.

In general, debriefing should occur after every study in which it is possible. Debriefing statements can be written or oral or both, and should provide full clarification about the study, including an explanation of any deception or withholding of information used in the research. Participants should be given opportunities to ask questions following presentation of debriefing information.

There are examples of an oral and a written debriefing document available on the IRB's SharePoint, but this format will be most helpful for those engaged in experimental or correlational research. The IRB can help other researchers with debriefing statements if desired.

Recordings of Research

Many researchers want to make some type of recording as part of their research project. If any type of video, audio, or visual recording occurs during the research, participants should be given an opportunity to consent to the specific type of recording. As always, participants should not experience negative repercussions if they choose not to participate in research that will be recorded. Consent for recordings may happen in any of the following ways.

1. Consent for recording can be included in the language of a larger informed consent document. This is likely to happen when engaging in the project without recording would serve no purpose (e.g., studying how people present themselves on camera). If the research is not possible without recording, participants must be made aware that recording is necessary prior to giving informed consent.

2. Consent for recording can be a separate document for participants to sign. This option would be best for research programs wherein research participation is possible without being recorded (e.g., an audio recording is preferred, but written notes are acceptable for the purpose of the research). As with the general informed consent documents, alternative wording for this document is acceptable.

3. In rare instances, the IRB may approve research protocols where recording occurs without participant knowledge. In these cases, the fact that recording occurred during a research project **must** be divulged to research participants at the end of their involvement in the research. At that point, participants must also be given the option to have the recording of their participation destroyed immediately. At no point can any data be used from a recording without participant consent to record.

XVII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS

A. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

1. Is an investigator or sub-investigator on the protocol;

2. Has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest (see the RSC Conflict of Interest Policy for the definition of "significant financial interest");

3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or

4. Has identified him or herself for any other reason as having a conflicting interest.

B. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.

C. Typically, there are three (3) distinct phases of an IRB's consideration of a matter: discussion, deliberation and actions (including vote). In general, IRB member(s) who have a real, or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair, during the discussion of the matter, in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

D. Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

XVIII. FOR RESEARCHERS

A. Important Information

1. Only the exact procedure and materials approved by the IRB should be used in an approved research study. Any changes to an approved protocol **must** be submitted to and approved by the IRB before they can be implemented in a research study.

2. The expiration date of IRB approval for research proposals varies based on the type of proposal. Full Review proposals are approved for one year from the date of notification of approval. Expedited and exempt proposals do not expire unless the IRB determines that an expiration date is necessary for a specific proposal. For example, a longitudinal research program of minimal risk may have an expiration date of two (2) or three (3) years, although such a proposal could be renewed.

3. For all research, all communication and data should be kept for at least three (3) years after publication.

B. Required Training – Online Research Ethics Course

The Online Research Ethics Course is critical for excellence, as well as public trust, in science and engineering. The National Science Foundation (NSF) encourages training of faculty in the responsible and ethical conduct of research. Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act requires that ‘‘each institution that applies for financial assistance from the (National Science) Foundation for science and engineering research or education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project.”

Therefore, in order to ensure full compliance, all RSC faculty, staff, and students participating in a NSF-funded project must complete the Responsible Conduct of Research (RCR) training found at: Online Research Ethics Course

This course is divided into six sections that cover the major topics in research ethics. As

research at RSC will not involve animals, completing Section V on animals in research is not mandatory. Each section includes an introduction that identifies learning goals, major issues for discussion, at least one case study, external links, and an examination on the concepts covered. The case studies are intended to be explored through an investigation of all the offered choices. Each of the six sections may be examined independently. Each section, not counting explorations into external links, will take between 30 and 45 minutes to complete. The six sections are:

1. **Ethical Issues in Research: A Framework**
   Compliance and Ethics
   Compliance Concepts
   Ethics Concepts
2. **Interpersonal Responsibility**
   Mentor/Trainee Responsibilities
   Determining Publication Practices and Responsible Authorship
   Collaborative Science/Competitive Science
3. **Institutional Responsibility**
   The Institutional Process Regarding Allegations
   Conflicts of Interest and Conflicts of Commitment
   IRB/IACUC
4. **Professional Responsibility**
   Proposing Research
   Dissemination of Findings
   Peer Review
5. **Animals in Research** (Not Required)
6. **Human Participation in Research**

In addition, understanding the ethics behind research with human subjects is important for academic scholarship and the protection of research subjects. A violation of these ethical principles is a violation of Academic Integrity. Once you have successfully completed the Section Assessment, you may print out a certificate of completion for the section.

C. Researcher Rights

Individual researchers (or research groups) also have rights related to research and the IRB approval process.

1. If a research project has been terminated or not approved by the IRB, the researcher has the right to appeal the decision to the IRB during a convened meeting. This is unlikely to occur, as most research not approved upon first submission is generally approved after clarification and communication between the IRB and researcher(s).

2. If there are questions concerning possible violations of ethical guidelines (either on the part of the researcher(s) or on the part of the IRB), the researcher(s) and IRB committee are responsible for meeting to discuss these concerns and attempting to achieve a mutually agreeable solution.

3. None of the information above should be construed to prohibit non-experimental research in field settings. If possible, permission for such research should be obtained for those in authority over the research setting. Impracticality of informed consent by those being observed and providing full clarification of the study should not rule out this type of research. Proposals of such research should still come through the IRB.

History

	Date:	**Reason:**
Original:	November 2006	Original Draft Charter
Issued:	January 2013	Final Charter and Standard Operating Procedures
Revised:	May 2022	Reviewed/Updated based on Revised Common Rule

REFERENCES

2018 Requirements (2018 Common Rule)

RSC Institutional Research Web Page

Online Research Ethics Course

Office for Human Research Protections (OHRP) Database for Registered IORGs & IRBs

APPENDICES

Appendix A - IRB Exemption Form

Appendix B - Research Change-Continuation Request Form

Appendix C - IRB Expedited Review Form

Appendix D - IRB Full Review Form