



**POLICIES AND PROCEDURES  
FOR  
PROTECTING HUMAN SUBJECTS  
FROM RESEARCH RISKS**



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## INTRODUCTION

### 1.0 Purpose and Scope of this Manual

The Institutional Review Board (IRB) documents its written procedures, according to [45 CFR 46 §115\(a\)\(6\)](#), [45 CFR 46 §103\(b\)\(4\)](#) and [45 CFR 46 §103\(b\)\(5\)](#). This manual contains current policies and procedures and will be regularly updated to reflect new standards, regulations and Radford University policy. The policies set forth in this manual are applicable to all faculty, staff, employees and students at Radford University who propose to use humans as subjects in research and development. The Radford University IRB does not review research involving the use of investigational drugs or devices with human research subjects. Radford University policy mandates that all proposed research involving human subjects must receive Institutional Review Board (IRB) approval prior to initiating the research. This includes review of human subjects research (see definition of human subjects research in Section 1.3) done as part of a course. Failure to have human subjects research reviewed by the IRB is a violation of University policy.

The purpose of this document is to assist the Radford University IRB in the review of research proposals submitted for review by faculty, staff, employees and students at Radford University. The review procedures of the IRB are designed to assist the investigator in the protection of the safety and privacy of the individual subject. Additionally, the review should assure that the potential subject can make an informed judgment that the likely results of participation in the study justify the possible risks, stresses, or violations of privacy of the subject.

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### 1.1 The Radford University Commitment

Radford University research policies adhere, as closely as possible, to the federal regulations set forth in Title 45 Code of Federal Regulations Part 46 Subpart A ([45 CFR 46 §101](#)), also known as "[The Revised Common Rule](#)." This set of federal policies is developed to implement the basic ethical principles endorsed in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Title 45 contains three subparts (B, C, and D) which contain regulations pertaining to research with Pregnant Women & Human Fetuses, Prisoners, and Children, respectively. In addition, Radford University research policies adhere to the Belmont Report and the Commonwealth of Virginia regulations governing human research as promulgated in Title 32.1 [Chapter 5.1 of the Code of Virginia Chapter 5.1 of the Code of Virginia](#) ([§32.1-162.16](#) through [§32.1-162.20](#)).

Further information may be obtained from the [IRB web site](#) or by visiting the Research Compliance Office. Please see the Radford IRB website for the current location, or by calling (540) 831-5290. The IRB Administrator is available to respond to questions or concerns.

### 1.2 Administration of Research Ethics (Federal)

The [Office of Human Research and Protections \(OHRP\)](#) provides leadership on human research subject protections and implements a program of compliance oversight for the Department of Health and Human Services' (DHHS) regulations for the protection of human subjects – Title 45, Part 46 of the Code of Federal Regulations ([45 CFR Part 46](#)).



OHRP works to support and strengthen the nation's system for protecting those who volunteer to participate in research that is conducted or supported by agencies of the DHHS. To carry out its mission, OHRP has formal agreements with more than 10,000 federally funded universities, hospitals, and other medical and behavioral research institutions in the United States and abroad wherein they agree to abide by the human subject protection regulations found in the Code of Federal Regulations (45 CFR 46).

OHRP evaluates all written substantive allegations or indications of noncompliance with DHHS regulations. In cases where allegations or indications of noncompliance are identified, the relevant institution is notified of the allegation by OHRP and asked to investigate the basis for the complaint. The institution then provides a written report of their investigation, along with relevant institutional IRB and research records, to OHRP which determines what, if any, regulatory action needs to be taken.

OHRP provides guidance to IRB members and staff, as well as scientists and research administrators on the complex ethical and regulatory issues relating to human subjects protections in medical and behavioral research. The office conducts national educational workshops in partnership with other related federal agencies and organizations. OHRP also provides on-site technical assistance to institutions conducting DHHS-sponsored research. In addition, OHRP helps institutions assess and improve their systematic protections for human subjects through quality improvement programs.

OHRP provides quality improvement consultation and research ethics training to domestic and foreign institutions involved in international biomedical and behavioral research to help ensure that recognized ethical protections are afforded to persons participating in research conducted in countries outside the United States. OHRP prepares policies and guidance documents as well as interpretations thereof on human subject protections and disseminates this information to the research community. In addition, every institution engaged in human subjects research conducted or supported by DHHS must obtain an assurance of compliance approved by the OHRP.

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1101 Wootton Parkway, Suite 200  
Rockville, MD 20852  
Toll-Free Telephone within the U.S. 866.447.4777  
Telephone 240.453.6900  
Email: [OHRP@HHS.gov](mailto:OHRP@HHS.gov)  
<https://www.hhs.gov/>

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### **1.3 Applicable Commonwealth of Virginia Laws**

#### **Reporting Requirement**

[Section 63.2-1509](#) of the *Code of Virginia* provides that persons who, in their profession or official capacity, have reason to suspect that a child is an abused or neglected child, shall report the matter immediately to the local department of the county or city wherein the child resides or wherein the abuse or neglect is believed to have occurred or to the Department's toll-free child abuse and neglect hotline.



[Section 32.1-162.16](#) defines the following terms:

Legally authorized representative means, in the following specified order of priority, (i) the parent or parents having custody of a prospective subject who is a minor, (ii) the agent appointed under an advance directive, as defined in [§54.1-2982](#), executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research, (iii) the legal guardian of a prospective subject, (iv) the spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final, (v) an adult child of the prospective subject, (vi) a parent of the prospective subject when the subject is an adult, (vii) an adult brother or sister of the prospective subject or (viii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research shall include an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision.

The attorney in fact shall not be employed by the person, institution, or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Nontherapeutic research means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

DHHS regulations define research as "a systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. To be considered research, the activity must be characterized by systematic investigation AND the primary goal is to contribute to generalizable knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to [45 CFR 46 §101\(b\)](#).

As described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn..." Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective." Thus, Research can encompass a wide variety of activities, including experiments, observational studies, surveys, tests, and recordings.

Studies assigned an Investigational New Drug (IND) number or an Investigational Device Exemption (IDE) by the FDA are by definition, research that requires IRB review. ([21 CFR 56.103](#)) "Research" generally does not include such operational activities as: defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring in public health); studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, or marketing studies. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is clear advance intent to contribute to generalizable knowledge with a scientific protocol. Intent to publish is one possible indication of intent to contribute to generalizable knowledge.



Human subject: "A living individual about whom an investigator (whether a professional or student) conducting research obtains **(1)** information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or **(2)** uses studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention: Includes both physical procedures by which data are gathered (for example, a venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes." [45 CFR 46 §102\(f\)\(1\) and \(2\)](#).

Informed consent means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent shall include:

1. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected.
2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the person.
3. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to them.
4. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third-party reimbursement for the proposed procedures or protocols; and
5. An offer to answer and answers to any inquiries by the person concerning the procedures and protocols.

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#### **1.4 Additional [ORHP Definitions](#)**

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

Activities deemed not to be research: (1) Scholarly and journalistic activities, (2) Government functions with separately mandated protections.

Benign behavioral intervention: Interactions which are brief harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

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

Child: A person who has not attained the legal age for consent, or is not an emancipated minor, to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.

Guardian: An individual who is authorized under applicable state or local law to give consent on behalf of a child for general medical care and to give permission for the child to take part in research.



Intervention: Includes physical procedures, manipulations of the subject or manipulations of the subject's environment for research purposes. Interaction includes communication between the investigator and the subject. This includes face-to-face, mail and phone interaction as well as any other mode of communication.

Parent: A child's biological or adoptive mother or father. A pregnant woman is not a parent until she gives birth to a living child.

Privilege: a special benefit, exemption from a duty, or immunity from penalty, given to a particular person, a group or a class of people.

Private information: 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., medical record).

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 the investigator or associated with the biospecimen.

Vulnerable subjects: Persons vulnerable to coercion/undue influence.

Ward of the State: A person who is housed by and receives protection and necessities from the government (e.g., when a governmental agency has custody of a minor or a mentally incompetent person for his or her protection and care).

## **1.5 Administration of Research Compliance - Radford University / Institutional Official (IO)**

Federal regulations require that there be a point of responsibility within an institution for the oversight of research and IRB functions. This point should be an official of the institution who has the legal authority to act and speak for the institution and should be someone who can ensure that the institution will effectively fulfill its research oversight function.

The institution's president shall appoint or delegate the appointment of the individual. The President of Radford University has delegated this authority to the Associate Provost for Research, Faculty Success, and Strategic Initiatives.

The Associate Provost also serves as the Institutional Official (IO) and has the authority to legally commit Radford University to meet federal regulatory requirements. The Institutional Official is responsible for appointing the members. As Institutional Official, the Associate Provost for Research, Faculty Success, and Strategic Initiatives signs Radford University's Federalwide Assurance (FWA), The Institutional Review Board reports to the I.O.



For questions please contact:

IRB Office, located within the Research Compliance Office is located in the Office of Sponsored Programs and Grants Management, 540.831.5290 / [irb-iacuc@radford.edu](mailto:irb-iacuc@radford.edu)

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## **1.6 The Radford University Institutional Review Board (IRB)**

The IRB was established pursuant to Title 45 Code of Federal Regulations Part 46 including Subparts A, B, C, and D, and Title 21 Code of Federal Regulations Part 56. The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB is able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB therefore includes persons knowledgeable in these areas. IRBs that regularly review research involving a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, shall include one or more individuals knowledgeable about and experienced in working with these populations.

The Institutional Review Board (hereinafter IRB) for the Review of Human Subjects Research is composed of five or more individuals. The IRB must include a faculty member with scientific expertise, a faculty member with non-scientific expertise, a community member who is not affiliated with Radford University, a member of the student body (graduate or undergraduate), and one faculty or staff member familiar with student psychological adjustment issues.

The IRB meets throughout the calendar year on approximately a monthly basis. Members serve staggered three-year terms except for student members, who will only serve for one academic year (specifically, the first day of classes for the Fall semester through the last day of classes of the Spring semester).

A chair is elected in July for a two-year term. A vice-chair will also be elected for a two-year term to serve as Chair-Elect where possible. The University's IRB is appointed by and responsible to the Institutional Official.

## **1.7 Research Compliance Office (RCO)**

The Research Compliance Office provides administrative support to the Institutional Review Board. The Research Compliance Office reports to the Associate Provost for Research, Faculty Success, and Strategic Initiatives / Institutional Official and through the IO to the Office of the President of Radford University. While the IO may attend all meetings of the IRB, it is the responsibility of the Research Compliance Office to keep the IO informed of IRB activities by providing meeting minutes and by frequent interaction and consultation.

The University's Federalwide Assurance and Registration are maintained by the Research Compliance Office.



The Research Compliance Office supports facilitates ethical conduct of research through advanced and continuing protocol review; monitoring and reporting; convening regular meetings for review of proposed and continuing research; and providing educational programs for faculty, staff, and students.

The Research Compliance Office oversees the development and implementation of policies, procedures, and educational programs which satisfy the many regulations governing the conduct of such research.

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## THE INSTITUTIONAL REVIEW BOARD

### 2.0 General IRB Policies

The Radford University IRB policies are governed by [45 CFR Part 46](#). The Radford University IRB Registration Number is IRB00003066 and the Radford University Federalwide Assurance Number is FWA00004850.

In addition, the Radford University IRB and Carilion Health Systems IRB have a reciprocity agreement registered under IRB00001142 and IRB00001190.

#### 2.0.1 Functions and Responsibilities

1. The IRB will conduct official business meetings only if (a) a quorum (one-half plus one of members and/or alternates, the Chair and/or Vice-Chair or designee, and the non-scientist member is present. Failure to fulfill both requirements will suspend official action until quorum requirements are fulfilled. Only IRB members, alternates, and the Chair may vote on official IRB business.
2. The IRB will review and have the authority to approve, require modifications in, or disapprove all research activities involving human subjects, including any proposed changes in previously approved human subjects research protocols.
3. IRB members will independently review and evaluate applications prior to the IRB meeting, and will vote to approve, disapprove, require modifications, or table protocols. If a member feels that they cannot provide an unbiased evaluation of a protocol under review, they will inform the IRB Chair and not participate in decisions involving that protocol.
4. The IRB may invite primary investigators (PIs) to attend the Board meeting to further explain or discuss protocols. PIs will be required to leave before any deliberation by the IRB takes place.
5. The IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals will not be voting members of the IRB and must sign a non-disclosure agreement prior to the initiation of the Board meeting unless the PI waives the right to confidentiality.
6. The primary focus of the IRB is to reduce or eliminate proposed risks in human subjects research. The IRB may request modifications to research design or methodology if such modifications will reduce the risks contained within the proposed human subjects research.



7. The IRB, Chair, or designated reviewer will review and approve all potential subject recruiting advertisements.
  8. The IRB reserves the right to observe and review the consent process or any other part of research involving human subjects. The IRB will ensure that legally effective informed consent documents are obtained and documented for each subject or their legally authorized representative.
  9. The IRB will ensure that adequate measures are in place to protect the privacy of research subjects and maintain confidentiality of data.
  10. The IRB will determine when additional protections are required for children, pregnant women and fetuses, prisoners, mentally impaired persons, non-English speaking subjects, and other vulnerable subject populations. For research involving prisoners as subjects, a prisoner advocate or prisoner representative must be added to the IRB as a voting member. OHRP will be promptly notified when IRB membership is modified to satisfy this federal requirement.
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### **2.0.2 Confidentiality of the Review Process**

Materials provided to the Institutional Review Board will be considered privileged information and the IRB shall assure the confidentiality of the data contained therein. Individuals providing consultation to the IRB agree to sign a confidentiality agreement prior to the receipt and review of submission documents.

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### **2.0.3 Suspension and Termination Policy**

In any instance in which IRB requirements are not being followed, the IRB Chair or designee will inform (within five (5) calendar days) the PI and the Radford University Research Compliance Manager, the latter of whom will be asked to enforce the requirements. If the PI does not comply with these additional measures, the Institutional Official will terminate the research. Such action will be accompanied by a letter to the principal investigator stating the reason for the action.

If unanticipated risks to the subjects, researcher noncompliance, or research project termination by the Institutional Official occur, those federally funded projects will be reported to the Secretary of the Department of Health and Human Services and appropriate funding agencies by the Institutional Official within seven (7) calendar days of the letter of termination to the principal investigator.

If the study is funded by a non-federal agency, the funding agency will be contacted and informed of the situation within the timeframe described above.

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## **2.1 IRB Review Process**

All human subjects research under the auspices of the University must meet the criteria for one of the following methods for determination/review:

- Exempt review (“exempt” or “exempt review”).
- Expedited review (“expedited” or “expedited review”); or
- Full review by a convened IRB (“convened IRB review” or “convened IRB”).

### **2.11 Electronic Submission**

Radford University utilizes an electronic submission system for the administration and management of the IRB. The system offers management of protocols and documents; with on-line submissions; web-based protocol sharing and collaboration; automatic notifications; event tracking; and other important electronic features to facilitate the oversight of human subjects protections at the University. All protocols must be submitted electronically, and all review decisions will be delivered electronically.

### **2.12 Human Subjects Research Determination**

The responsibility for an initial assessment as to whether an activity constitutes human subjects research rests with the PI. The PI should make this assessment based on the definitions of human subject and research contained in Section 1.3. The IRB will make a final determination as to the correct review category of all protocols submitted.

### **2.13 IRB Preliminary Review**

The Research Compliance Office (RCO) staff will perform a screening of all protocol materials submitted to the IRB for determination of completeness and accuracy. Only complete submissions will be referred for further consideration (i.e., expedited or convened IRB review). The investigator will be informed of missing materials and to resubmit corrections before further review can take place. The PI is responsible to provide the RCO with an active e-mail address and current contact information. The Research Compliance Office will identify any main issues with the IRB reviewer when the application is sent for review.

### **2.14 Reviewers**

After it has been determined that the protocol submission is complete, the RCO staff sends the IRB application for review to the designated IRB member reviewer or to the full Board for review.

For applications submitted to the IRB for convened IRB review, the Chair will lead the review discussion. For applications submitted to the IRB qualifying for expedited and exempt review, one reviewing member is assigned as reviewer and conducts the review.



When the IRB is presented with a protocol which, in the opinion of the IRB Chair, may be outside of the knowledge base or representative capacity of all of the IRB members, an outside consultant will be sought. Proposals for which appropriate expertise cannot be obtained for a given meeting will be deferred to another meeting when appropriate expertise can be achieved.

Reviewers are responsible for:

- Having a thorough knowledge of all details of the proposed research;
- Performing an in-depth review of the proposed research and supporting documents;
- Discussing the proposed research at the convened meeting, presenting both positive and negative aspects of the research, and going through the regulatory criteria for approval; and
- Making suggestions for changes to the proposed research, where applicable.

For convened IRB review all IRB members have access to all information available and are expected to review all IRB proposals.

IRB Amendments submitted for the addition of personnel only, may be reviewed and administratively approved by the Research Compliance Office following confirmation of completion of required CITI training.

## **2.2 Meetings**

The Radford University IRB meets on a regular basis throughout the year. The schedule for the IRB may vary due to holidays or lack of quorum. The deadline for submission of research protocols requiring full IRB review and approval is approximately fifteen (15) calendar days before the scheduled meeting. Materials submitted for review after the submission deadline will not be considered for review by the IRB until the next scheduled meeting, with exceptions to be considered on a case-by-case basis.

Special meetings may be called from time-to-time throughout the year by the IRB Chair/Vice-Chair.

Meeting dates and submission deadlines will be published on the official [Radford University IRB website](#).

## **2.3 IRB Meeting Minutes**

The minutes for each IRB meeting are recorded in writing per [45 CFR 46 §115\(a\)\(2\)](#). The IRB approves the previous month's minutes at the next IRB meeting. The final version of the approved meeting minutes is kept on file at the Research Compliance Office.

The meeting minutes must include:

1. Attendance, including designation of advocates for vulnerable populations that are present and visitors.



2. A list of all full IRB board studies with the following information
  - (a) Actions taken and decisions made by the Board, including disapprovals
  - (b) Vote on these actions (numbers for, against and abstaining)
  - (c) Basis for requiring modifications to the research protocol proposal or informed consent documents or for disapproving protocols
  - (d) Summary of any controversial issue discussions and their resolution(s)
  - (e) Summary of discussions pertaining to the protocol
  - (f) Documentation of determinations required by regulations along with project-specific findings that justify each determination. These determinations include:
    - (i) Waiver or alteration of consent
    - (ii) Waiver of consent documentation
    - (iii) Research involving pregnant women and fetuses
    - (iv) Prisoners
    - (v) Children

Minutes will include separate deliberations, actions, and votes for each protocol undergoing consideration by the convened IRB. The minutes will also reflect any potential conflict of interest that a member of the IRB may have with a particular protocol. Meeting minutes are retained for at least three years after closure of all protocols cited therein.

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## 2.4 Approval Timeframes

Full review studies are approved for a maximum period of one year from the approval date, and expedited review studies are approved for a maximum period of three years from the approval date. If the project will no longer be continued with no new data collection, a study closure form is due **ten (10) calendar days before the study's expiration date**.

Protocols that are to be continued must have a request for continuation filed at least ten (10) calendar days PRIOR to the original submission approval date. A compelling reason must be provided for requests for continuation filed after the expiration date, and a plan to avoid future delays must also be provided.

The original anniversary date is retained for all re-approvals.

Pursuant to OHRP's Guidance on IRB Continuing Review of Research (2010), original (or fixed) anniversary dates of expirations may only be utilized when submissions are approved within the 30 days prior to the effective approval date.



The effective approval date of either an Expedited or Full Board submission is defined as the date of the last review by an IRB Member (e.g., if a staff member from the IRB office is not a member of the IRB, the approval date will be based on the date of final, albeit conditional, approval of the protocol by an IRB Member Reviewer.) The actual date of the last review by an IRB Member will be used for other approvals as per the above referenced policy.

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## 2.5 Principal Investigators

Only full-time or Emeritus faculty employed by Radford University may be the Principal Investigator on an IRB application. Exceptions will be reviewed on a case-by-case basis, with considerations given to credentials and employment status of the applicant; in some cases, a full-time Radford University co-PI may be required.

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## 2.6 Student Research with Human Subjects

Student research with human subjects generally falls into two categories, (1) Classroom Exercises and (2) independent or directed human subjects research projects.

### A. Classroom Exercises

Course projects usually do not lead to generalizable knowledge and are often not undertaken with specific research goals in mind. These projects do not need Radford University IRB approval **UNLESS** they:

1. Will be presented in any form outside of the immediate Radford University Community (e.g., the Radford University Undergraduate/Graduate Research Forum, Waldron College Symposium, and the Masters of Social Work Poster Presentation).
2. Involve the questioning of children or other vulnerable populations as stipulated in 45 CFR 46;
3. Ask about illegal activities (e.g., underage drinking) that can be subpoenaed by a court of law;
4. Involve socially stigmatizing and/or stigmatized behavior and/or attitudes;
5. Involve the use of subject matter which could cause emotional distress
6. Involve the use of videotaping and/or audio taping

It is the responsibility of the faculty advisors to ensure that course projects are conducted according to the standards of their relevant discipline. See applicable policy prior to implementing a project that may qualify as a Classroom Exercise project.

### B. Independent or Directed Research Projects

Anything not falling under Section 2.6 A., §2.3.1 of this document must be reviewed and approved by the Radford University IRB, the IRB Chair, or the Chair's designee.



This includes:

1. Honors theses
2. Independent undergraduate research projects
3. Master's theses and doctoral dissertations
4. Non-thesis graduate research projects (e.g. a pilot project or a research project with a faculty member)

The faculty advisor is responsible for determining whether an undergraduate project should be subject to IRB review, and when a student project is not classified as a course project, the faculty member is responsible for assisting the students in preparation of review materials for the IRB. The IRB Administrator is available for assistance, but it is the primary responsibility of the faculty member to direct the preparation of these documents.

## **2.7 Continuing Review Notices**

PIs are sent courtesy e-mail expiration notices approximately sixty (60), thirty (30), and seven (7) days prior to the study's expiration date for all expedited and full review studies via the IRB online software system. Additional notices may be sent as needed. One email notice will also be sent on or about the actual date of expiration. One (1) past due email may be sent to PIs, who will have (10) calendar days to comply with submission of closure documentation. It is important to note, however, that it is the Principal Investigator's responsibility to know when a protocol is due to expire. Any notices sent by the Research Compliance Office are courtesy notices only.

Requests for continuation documentation for Expedited submissions must be submitted prior to the expiration date. Protocols that are to be continued must have a request for continuation filed at least ten (10) calendar days PRIOR to the approval date. A compelling reason must be provided for requests for continuation filed after the expiration date, and a plan to avoid future delays must also be provided.

Requests for continuation documentation for Full Board submissions must be submitted by the deadline of the meeting scheduled prior to the expiration date of the protocol. Investigators should note that meeting dates are subject to change when a quorum cannot be established and are advised to contact the IRB office in order to confirm meeting dates, particularly when regular academic semesters are not in session.

Please note that Full Board submissions that are no longer recruiting participants (analysis on identifiable data only) may request continuation via the Expedited method, and thus not be submitted for Full Board review.

Submissions that are no longer recruiting subjects and all data collection is complete (the analysis of only de-identified data) do not need to be continued.

Please contact the IRB Office for current regulatory guidance if you have any questions or concerns. Such submissions must be sent to the IRB Office at least 10 calendar days prior to the expiration date of the protocol.

No activity may continue on a protocol, including data analysis of identifiable data, if the continuation is not approved prior to the expiration date, regardless of the date of submission of the request for continuation.

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## **2.8 Research Protocol Files**

Any paper-based protocol files are maintained in locked offices in the Research Compliance Office, which houses IRB records. Electronic files are maintained on either or both password-protected Radford University share-drive data servers, email servers, and online protocol management system. Records are retained per [45 CFR 46 §115\(b\)](#). Individual protocol records are retained for at least three years after a protocol has been closed. All records must be accessible for inspection and copying by authorized representatives of the Federal department or agency supporting or conducting the research at reasonable times and in a reasonable manner. Such records must also be accessible to federal auditors.

Each protocol file may contain the following:

1. A copy of the Initial Application for IRB review
2. Supplemental materials, which may include consent documents, questionnaires, recruitment materials, training documents, etc.
3. Any correspondence with the IRB, both formal and informal, related to the research protocol.
4. Official notification of IRB action
5. Any IRB-requested changes to original proposal
6. A copy of the approved informed consent form
7. Application for continuation of the research study, if applicable
8. Any application to amend previously approved protocols
9. Reports of unanticipated problems and related IRB review or action
10. Final report for any completed studies
11. Investigator agreement form for researchers not affiliated with Radford University.

## **2.9 Complaints, feedback, concerns and issues**

All complaints, feedback, concerns, or related issues about IRB procedures should be directed to the IRB Administrator, who will bring the complaints to the next IRB meeting. Complaints will be formally documented, and appropriate resolutions annotated in protocol files.



Any concerns about implemented research, research compliance, or research misconduct should be directed to the IRB Administrator or Institutional Official.

## GENERAL RESEARCH PROCEDURES

### 3.0 Confidentiality

Any promise to research participants that their responses and data will be confidential requires implementation of protocols that will prevent the accidental and/or intentional breach of confidentiality. All measures used to assure confidentiality should be understood by research staff before research is initiated and implemented throughout the course of the research. All confidentiality procedures must be approved by the Radford University IRB.

Any research that will address sensitive, stigmatizing, or illegal subjects must explicitly outline the steps taken to ensure that any information linking participants to the study will be maintained in confidence. If there is any reasonable risk that data or participant identities might be sought by law enforcement agencies or subpoenaed by a court of law, the researcher(s) should obtain a [Certificate of Confidentiality](#).

Certificates of Confidentiality provide protection against compelled disclosure of identifying information about subjects enrolled in sensitive biomedical, behavioral, clinical, or other research. This protection is not limited to federally supported research. For more information, please see the [NIH Policy & Compliance](#) website.

### 3.1 Data Collection Over the Internet

While the internet is generally considered a public domain, the expectation of privacy on the internet is relative and largely dependent upon the purpose of users.

Participants in a casual online chat room may have little expectation of privacy, while members of virtual communities for vulnerable populations, such as HIV patients or substance abusers, correctly or incorrectly, assume some privacy within that community. The online community's purpose and level of accessibility are central to any discussion about informed consent in this environment. Therefore, researchers must be sensitive to how internet users define their online activities.

For more information, please see the information found on this OHRP [webpage](#).

Data Collection: Any personally identifiable data collected from human subjects over computer networks must be transmitted in secure format (e.g. https).

If the content of the responses would pose a risk to the respondents if the information were shared, the highest level of encryption must be used, within the limits of feasibility and availability. This may require that study subjects use a specific type or version of browser software.

In circumstances that require respondent tracking, a separate webpage should be used at the completion of the survey that will allow the respondent to enter tracking information that will not be linked to the completed survey. The use of a unique participant identification code within the study's welcome webpage is highly recommended by the IRB.



Server Administration: It is recommended that online data be collected by a professionally administered survey server, as secure as needed based on the sensitivity of the data collected, or that the server be administered by a professionally trained person with expertise in computer and internet security.

Access to the server should be limited to key project personnel and be configured with firewalls to minimize the possibility of external access to the server data.

Data Storage and Disposal: If a server is used for data storage, personal identifying information and IP addresses should be deleted from the data after data collection is completed, and such data should be stored in a password-protected environment. Data backups, if any, should be stored in a password-protected environment. If data include information that could put subjects at risk of harm if unauthorized access should occur, the data files should be saved as encrypted files.

Data destruction services or methods should be employed to ensure that no data can be recovered from discarded electronic media.

For projects with minimal risk, if these data safeguards cannot be implemented, then language in the informed consent should be added indicating that complete confidentiality cannot be guaranteed. It is recommended that encryption should be used for highly sensitive data.

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### **3.2 Conflict of Interest**

A conflict of interest arises when an employee is involved in a particular matter as part of their official duties within an outside organization in which they also have a financial interest, or one which is imputed to him/her, i.e., the employee's spouse, minor children, an organization in which the employee serves as officer, director, trustee, partner, or employee, or a person or organization with which the employee is negotiating for prospective or has an arrangement for prospective employment.

A PI or IRB member is said to have a conflict of interest whenever the PI or IRB member, his or her spouse, or dependent child falls under any of the following conditions:

1. The IRB member is an investigator or co-investigator on the protocol;
2. Has entered into financial arrangements with the sponsor or agent of the sponsor;
3. Acts as an officer, director or agent of the sponsor;
4. Has an equity interest in the sponsor exceeding \$5,000 or 3% of the equity of the sponsor;
5. Has received payments or other incentives from the sponsor that are in excess of \$5,000 total.
6. Has identified him or herself for any other reason as having a conflict of interest.

All investigators are required to disclose any conflicts of interest on the IRB Initial Review of Research Protocol Form.



### 3.3 Record Retention Requirements

Regulations require each investigator to retain research data not only while the research is being conducted, but also after the research is completed. There is more than one set of regulations governing retention of research records, each with different requirements. As a result, researchers must comply with the longest applicable standard according to current institutional policies.

- **OHRP Requirements:** [45 CFR 46§ 115](#) requires research records to be retained for at least 3 years after closure of the research.
- **HIPAA Requirements:** Any research that involved collecting identifiable health information is subject to HIPAA requirements. [45 CFR § 164.316](#) stipulates that records must be retained for a minimum of 6 years after each subject signed an authorization.
- **FDA Requirements:** Any research that involved drugs, devices, or biologics being tested in humans must have records retained for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. *Please note – this length of time can be much greater than 2 years. You should receive written confirmation from the sponsor and/or FDA granting permission to destroy the records.* ([21 CFR § 312.62.c](#))
- **Sponsor Requirements – contract:** If your study is sponsored you must ensure that you comply with any terms for record retention detailed in the contract with the sponsor. For example, a sponsor may require you to retain your research related documents for 20 years. Prior to agreeing to a contract that specifies how long records will be maintained you should ensure you will receive adequate funding to pay for the storage.
- **Questions of Data Validity:** If there are questions or allegations about the validity of the data or appropriate conduct of the research, all of the original research data must be maintained until such questions or allegations have been completely resolved.

All records collected, prepared, and/or maintained by the IRB are open for inspection and copying by the authorized representatives of OHRP, DHHS, Sponsors, and Radford University officials during normal business hours and in such a manner as defined in [45 CFR 46 §115\(b\)](#).

Research protocol files, as defined per section [2.8](#) of this manual, shall be retained or archived a minimum of three (3) years after the research is closed with the IRB. After that time, files will be destroyed. As per section [2.3](#) of this manual, the minutes of each IRB meeting will be retained by the office of the IRB Coordinator and are kept for a period of three (3) years, at which point they may be destroyed.

(Look up data security about the confidentiality and retention of the PI's data.)

### **3.4 Guidelines on Compensation for Research Subjects**

Compensation of research subjects must not be large enough to be considered coercive. The researcher and the IRB must consider the socioeconomic status of the subject pool while reviewing protocols involving payment for research participation. Considerations for compensation will be made on a per study basis by the IRB.

The IRB will consider the following issues regarding compensation during review of the research:

1. Amount of payment (monetary, extra credit, gift certificates, etc.)
2. Method of payment
3. The inclusion of compensation within the study advertisement
4. Prorating compensation during long-term studies (i.e., study completion incentive) or prorating when compensation exceeds nominal amounts
5. Contingencies. Payment will not be contingent on the participant completing the study procedures. If a subject decides to withdraw from the study, they must be compensated, at least partially, based on what study procedures have been completed.
6. Socioeconomics of the subject pool

The use of a lottery method is allowed, but the following must be addressed in the informed consent documentation.

1. Potential odds and the nature of prizes that that can be won
2. Individual responsible for drawing the winner
3. Individual responsible for observing the drawing, to ensure the results are not biased.

For those faculty providing opportunities for extra credit via participation in research projects, alternative means of earning extra credit must be made available to the students who choose not to participate in the research activity.

### **3.5 Equitable Subject Recruitment**

The IRB will evaluate all research applications to determine if reasonable efforts are proposed recruit a diverse subject pool. The proposed sampling protocols will be evaluated to ensure that some classes of individuals are not favored for participant selection because of ease of selection, compromised positions, or manipulability.

The IRB will require researchers to make reasonable efforts to include women and members of minority groups in subject pools, if appropriate.



### **3.6 Funded/Sponsored Research**

The Office of Sponsored Programs and Grants Management will not release funds from federally funded non-exempt studies until the IRB Chair or the Chair's designee, has had the opportunity to compare the Office of Sponsored Programs/Grant Management (OSPGM) proposal to the IRB application. It is the responsibility of the principal investigator to upload a copy of the research proposal associated with the research described in the grant proposal.

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### **3.7 Scientific Merit**

It is not the responsibility of the IRB to comment or debate the scientific merit of proposals submitted for review.

The merit of research is the responsibility of the principal investigator and the appropriate personnel within each department. The exception to this is when the scientific merit, or lack thereof, increases the risks to the research subjects or the research burden upon any subjects, such that risks deriving from participating as a subject in the research cannot be justified by potential benefits resulting from the research.

### **3.8 Cooperative Research/Research Collaborations / IRB Reliance Agreements**

[§46.114](#) (a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.

The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

Occasionally, non-Radford University personnel or other entities will collect data from faculty, staff, and/or students on campus. The determination as to whether the Radford IRB needs to review the proposed activity depends on whether Radford is *engaged* in the research.

#### **A. Situations in Which Radford University is *Engaged* in Research**

If Radford University is engaged in the study, IRB review is required. Radford University is considered *engaged* [as defined in [§45 CFR 46.101](#) in non-exempt human subjects research when the involvement of its employees or agents in that project includes any of the following:

- Receipt of an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e., awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.



- Intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures. Examples include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.
- Intervene for research purposes with any human subject of the research by manipulating the environment. Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.
- Interact for research purposes with any human subject of the research. Examples of interacting include engaging in protocol-dictated communication or interpersonal contact, asking someone to provide a specimen by voiding or spitting into a specimen container, and conducting research interviews or administering questionnaires.
- Obtain the informed consent of human subjects for the research.
- Obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research.
- Data are collected from Radford University students, faculty members, or staff members.

It is important to note that, in general, Radford University employees or agents who obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the University's employees or agents do not directly interact or intervene with human subjects.

In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to observing or recording private behavior; using, studying, or analyzing *for research purposes* identifiable private information or identifiable specimens provided by another institution/university; and using, studying, or analyzing *for research purposes* identifiable private information or identifiable specimens already in the possession of the investigators.

In general, private information or specimens are considered individually identifiable [as defined in [§45 CFR 46.102\(e\)](#)] when they can be linked to specific individuals by the investigator either directly or indirectly through coding systems.

## **B. Situations in Which Radford University is *Not Engaged* in Research**

In cases where Radford University is not engaged in the research, review by the Radford IRB is not required. For example, marketing research firms may send email to Radford University students, inquiring about their vacation preferences.

If the email addresses are not provided by any Radford University office, and if there are no Radford-associated research personnel, the IRB will not review the study.



In cases where Radford University faculty, staff, or students are conducting human subjects research at Radford *strictly in their capacity as students at another institution/university*, they must obtain IRB approval from the institution/university where they have matriculated, but the Radford University IRB will not review the study.

### **C. IRB Reliance Agreements**

A reliance agreement (i.e., IAA's, IIA, etc.) is an agreement between two or more institutions/universities that allows an institution's IRB to rely on another, unrelated institution's IRB for review of human subjects' research. A reliance agreement comes in multiple formats, with the most common being Institutional Authorization Agreements (IAA), Memorandum of Understanding (MOU), and Master Reliance Agreement (MRA). An Investigator working at multiple institutions, each having their own IRB, may decide to have one IRB serve as the IRB of record for some or all participating sites. This practice is commonly referred to as ceded review, reliance agreements, or deferral of IRB oversight.

In this scenario, the Radford University IRB will either serve as the reviewing IRB (IRB of Record) or will cede oversight (rely) of the research activity to another equally qualified institution's IRB. Each individual IRB will indicate which agreement format is appropriate for a specific study.

**Note: Effective January 25, 2018, the National Institutes of Health mandated the use of single IRBs as a contingency for funding of multi-center studies.**

### **D. Agreement Types**

#### **IRB Authorization Agreement (IAA)**

An IRB Authorization Agreement (IAA) is an agreement between Radford University and another institution/university that holds a Federal Wide Assurance (FWA) with the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS).

Any institution (e.g., university, medical centers, Non-governmental organizations (NGOs), community organizations, survey research organizations that receives funds from HHS must have an FWA.

Entities use this agreement type to establish which institution will serve as the IRB –of Record. Each institution's Institutional Official or designee signs the IAA.

#### **Master Reliance Agreement**

A Master Reliance Agreement (MRA) is utilized when multiple studies cede review to a specific external IRB. Master Agreements may be reciprocal in that signatory institutions can act as the site providing IRB review and oversight or the site relying. Master Reliance Agreements may be for a single protocol or a number of protocols that are negotiated on a case by case basis.

#### **Memorandum of Understanding**

Radford may draft a Memorandum of Understanding (MOU) to acknowledge an ongoing and strategic relationship between institutions. An MOU is intended to be a long-term agreement and/or to support a specific research study. The agreement generally describes a very broad concept of mutual understanding, goals, and plans shared by the parties. It may also list areas of possible joint activities, without creating financial obligations or committing resources.



Radford University will cede authority for IRB review under a Master Agreement with Carilion Clinic (CC), effective Fall 2020. Students with IRB projects involving students and/or patients at Carilion Clinic will undergo CC's IRB review process with a CC faculty member as PI for the project. Following approval of the IRB protocol, a copy of the IRB approved protocol, approval letter, and corresponding documents shall be sent to Radford's Research Compliance Office for documentation purposes.

## INFORMED CONSENT

### 4.0 Informed Consent

The principle of respect for persons, as set forth in the [Belmont Report](#), states that the consent process must address three elements: information, comprehension, and voluntariness.

Sufficient and complete information about the study must be provided in language comprehensible to the participant. The investigator must clearly convey to participants what they are agreeing to do and ensure that they understand (comprehend).

Participants' agreement must be given voluntarily (freely) and without undue influence. This communication occurs in the consent process and is generally documented in the written consent form.

A participant may generally not be enrolled in research unless the investigator has obtained his or her informed consent or that of the participant's legally authorized representative.

See Section 4.2.2, below, Informed Consent, C. Exception to the Requirement for Documenting Informed Consent 1), 2), and 3) for a discussion of consent waivers and studies involving deception or concealment.

The process of obtaining and documenting informed consent must comply with the requirements of DHHS regulations at [§45 CFR 46.116](#) and [§45 CFR 46.117](#) and the FDA consent requirements provided in [§21 CFR 50.20-27](#) and [§21 CFR 56.109](#).

The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

Except in situations described in §4.3 and §4.4 of this manual, see below, a researcher cannot enroll any human subject into a research project without first obtaining a legally effective, written informed consent from either the subject or a legally authorized representative of the subject prior to enrollment in the research study. The Radford University IRB is responsible for reviewing all informed consent documents.

The information contained in the informed consent must be presented in language that is clear and understandable to the subject. The informed consent cannot contain any exculpatory language through which subjects waive any legal rights or releases, or appears to release, the researcher, sponsor or Radford University from liability for negligence.

The consent process must provide sufficient opportunity to withdraw from the research project. Institutional pressures must be addressed in the research design and will be further explained in §4.5 of this manual. It is the responsibility of the principal investigator to avoid the use of any coercive language and to minimize other influences.



The Radford University IRB will examine all informed consents to ensure that all research protocols protect research subjects from undue influence to participate. A copy of the approved, stamped copy of the consent form must be used for all study participants. A copy of this approved, stamped form will also be included in the research protocol file in the office of the IRB Administrator.

Exempt submissions may or may not utilize informed consent documents. Internet-based survey research must utilize the Radford University [Cover Letter for Internet Research](#) (including Exempt, Expedited and Full Board surveys), to be located at the start of the survey or in (or attached to) recruitment material. Research that involves audio or video-recordings requires informed consent. If the investigator chooses to use informed consent documents for non-survey research, they must use all elements of informed consent, as per Expedited and Full Board submissions. The Exempt Informed Consent document(s) will be stamped by the IRB Office and a copy of the stamped form must be used with all study participants. Any language used in consent forms communicated to participants must be identical to the approved and stamped language."

Language and readability must be appropriate for the subjects. Think of the consent document as a teaching tool, not as a legal instrument. It is not a contract between participant and researcher! The consent document should be written in second person; i.e., "If you agree to be in this study, you will be asked to..."

Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute a coercive influence over a subject.

Use of scientific jargon and legalese is not appropriate. The average person reads at the 8th grade level, and consent forms intended for that population should be written at that reading level.

Investigators are encouraged to use computer software applications or other techniques to assess reading level of the finished document; use a larger font size; use short, simple sentences, and avoid technical language; define all abbreviations and acronyms when they first appear in text. Before submitting a consent form for IRB review, the reading level should be checked.

#### **4.1 Essential Elements of Informed Consent**

The federal regulations require that certain information must be provided to each subject.

"Informed Consent" means an agreement between investigator and freely participating subjects that informs them of their role, the procedures, and potential hazards or risks and describes all activity features that might reasonably be expected to influence willingness to participate.

The following items are required in the informed consent per 45CFR 46.116 and [§32.1-162.18 of the Code of Virginia](#):

##### **1. Research acknowledgement**

- Use this section to explain to the participant that the study is for research purposes. Consent forms must disclose that participants are being asked to be a volunteer in a research study. The word "research" must be used in the explanation. Protocols that pose greater than minimal risk to participants, such as experimental medical treatments, must include language substantively similar to the following two sentences:

"You are encouraged to take your time in making your decision. Discuss this study with your friends and family."

## 2. **Purpose of the project**

- Explain why the research is being done and why you are asking the subject to participate.

## 3. **Procedures**

- This section should give detailed descriptions of what the subject will be asked to do, using language that the participant can easily comprehend. Include a description of all research procedures; the frequency, scheduling and time commitment of each procedure and visit; and the total time commitment. Any audio or video recording should be addressed in this section in addition to specific language that details the activities, including the length of time the recording will be kept by the researcher.

If participants are being randomly assigned to different groups, this should be disclosed with a statement such as "You will be randomly (by chance, like flipping a coin) assigned to one of...."

## 4. **Number of subjects in the study**

- The number of subjects or approximate number should be stated here, or it may be contained within one of the sections described above.

## 5. **Risks**

- Clearly explain the psychological, physical, social, legal, and/or financial risks involved in this research. This section should also outline how likely it is that any of these risks will occur and what will be done if they do occur. Access to support services should be specified in this section, if applicable.
- For research involving more than minimal risk, provide an explanation as to whether any compensation will be provided and an explanation as to whether any treatments are available if injury occurs and, if so, what they consist of and where further information may be obtained.
- It cannot be said that research has no risk. All research has some risk, though it may be minimal or no more than daily life.

## 6. **Benefits**

- Clearly outline any potential direct benefits to the subject and/or society. Explain clearly how likely it is that these benefits will occur and outline what the benefits may be.

## 7. **Alternatives**

- If extra credit is being offered to students in exchange for their participation as a research subject but a student does not want to serve as a research subject, alternative means of securing an equivalent amount of extra credit must be available (e.g., writing a paper). The alternative must require a reasonable equivalent of time and effort of the subject.

## 8. **Extent of confidentiality or anonymity**

- Explain how any collected information or participation status will be kept confidential. This section should outline who will know or need to know the information pertaining to this study. This statement should also include where and how the data will be stored.
- In some studies, the greatest risk to participants is that of inadvertent disclosure of personal information that could reasonably place participants at risk of criminal or civil liability or be damaging to subjects' financial standing, employability, or reputation. For other good reasons, researchers must securely store research data.
- Web-based research has its own special set of privacy concerns. State whether the connection to the server uses a secure (encrypted) https protocol, of the kind typically used to handle credit card transactions. What information will be stored on the server, for how long, and who has access to it?
- There are some situations in which confidentiality may be breached. Personal information may be given out if required by law, such as pursuant to a court order. There are circumstances where investigators are required to break confidentiality and share information with local authorities. These include having a reason to believe that a child, an elder, or a disabled individual is being abused or neglected, or becoming aware of serious threats of subjects harming themselves or others.

## 9. **Compensation**

- For studies that have greater than minimal risk, explain that Radford University will not cover any medical costs if a subject becomes injured.
- For studies that have payments or reimbursement, this section should state the nature of compensation, the amount of compensation, and the schedule for receipt of compensation. For studies that have multiple payment disbursements, this section should also explain the payment consequences of early withdrawal from the study.
- Information provided about compensation should make it clear that amounts of compensation do not constitute an inappropriate inducement to participate as a research subject.

## 10. **Freedom to withdraw**

- Participants must be free to withdraw at any time during the course of the study without penalty. They will be compensated for the portion of the study completed (if financial compensation is involved).
- The consent form should state that 1) participation is voluntary, 2) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and 3) the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- Studies using students need to clearly state that withdrawal from the study will not result in a reduction in points or grade in the course. Subjects are free to decline to answer any questions or to decline to respond to situations that they choose without penalty.

## 11. Subject responsibilities

- This section should have a statement that clearly outlines the subject's responsibilities as it applies to his/her participation in the study.

## 12. Contact information

- Use this section to list the contacts for any pertinent questions about the research, conduct of the study, subject's rights and whom to contact in the event of injury, if applicable.
- Contact information for the Principal Investigator, research advisor (if a student is performing the research), and the Radford University Institutional Official must be included. Students' personal phone numbers or other personal contact information, beyond their Radford University email address, may not be included in informed consent documents or any other documents the subject will see without obtaining approval to do this from the IRB.

## 13. Subject permission

- This section should contain the following information: "I have read the Consent Form and conditions of this project. I have had all questions answered, and I hereby acknowledge the above and give my voluntary consent."

It may be necessary to include a statement addressing unforeseeable risks and any additional costs that the participant may incur. Language may be included in the consent form that allows the PI to terminate the participation of a subject without regard to the subject's consent. A copy of the consent form should be available to the subject.

**\*\*\*Consent forms are not valid unless an unexpired, dated validation stamp from the Radford University IRB Office is present\*\*\***

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## 4.2 Additional Consent Information

In some cases, the informed consent document will need additional information. Studies that involve the use of sensitive items, deception, audio and video recordings, students and extra credit, and children have specific additional requirements.

### 4.2.1 Additional Considerations for Studies that Involve Sensitive Items

#### Risks Section:

1. Be specific regarding the potential risks (psychological, social, legal, economic, dignity and/or physical).
2. Be aware of potential emotional distress during the completion of surveys.
3. Provide a detailed explanation of the study's efforts to reduce potential risks.
4. State that contact information for professional counselors within the area will be made available.

5. Use clear language which states that any use of paid counselors by the subject will be at the subject's expense.
6. Inform the subject that any information provided that is indicative of potential harm to themselves or others must be reported to the appropriate authorities per legal mandate.
7. Provide a thorough explanation of how the study will ensure the confidentiality of this sensitive information.

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## **4.2.2 Studies that Involve Deception**

Deception in a study occurs when participants are intentionally told something untrue about the study, such as its real purpose. By its very nature, deception in research violates the principles of voluntary and informed consent to participate in research. Therefore, deception is an extraordinary measure that is not normally permitted in human subjects' research.

Deception poses special challenges and must be adequately justified. Deception occurs, for example, when researchers "lurk" in a chat room, giving false identities and purpose for their participation while observing and perhaps recording interactions among other chat room members.

When the researchers' true purpose and identities are revealed, chat room members may react with anger, feel that their privacy and trust have been assaulted, and suffer anxiety.

Federal regulations permit deception only when a waiver of informed consent is approved by the IRB which affirms that risks to subjects are no greater than minimal; the rights and welfare of subjects will not be adversely affected by the waiver; deception is essential in order for the investigator to carry out the research; and at the earliest possible time, subjects must be informed of the nature of the deception and given a reasonable opportunity to withdraw from participation and to have their data excluded. Whenever possible, a full debriefing will be provided. A decision not to provide a debriefing must be approved by the IRB.

Deception should be employed only when there are no alternative procedures available. In the situations where deception is a necessary part of the experiment, the Radford University IRB generally requires that preliminary consent be obtained, when possible. The subject should be fully debriefed at the conclusion of the experiment.

The IRB recognizes that there are situations where fully informed consent cannot be obtained, or a debriefing provided; however, the researcher should make reasonable attempts to obtain fully informed consent after the deception has taken place.

The IRB will make the decision as to when the use of deception is acceptable, to what extent it is unavoidable in order to perform the research, and whether the benefits derived from the use of deception outweigh the risks.



The use of major deception (e.g. leading a subject to believe that he has committed a crime or has a disease) will need to be clearly justified by the investigator, and the benefits of the research must outweigh the risk to the subject.

### **Consent Criteria When Deception is Used**

Deception can only be allowed when a waiver of informed consent is justified in accordance with [§45 CFR 46.116\(f\)](#). When proposed, the deception must meet all the following criteria:

- Risks to subjects are no greater than minimal.
- The rights and welfare of subjects must not be adversely affected.
- Deception is essential in order for the investigator to carry out the research.
- At the earliest possible time, subjects must be informed of the nature of the deception and be given a reasonable opportunity to withdraw from participation and to have their data excluded.

If deception is proposed in internet research, see "[Data Collection Over the Internet](#)" in these Policies & Procedures.

### **Studies that Involve Concealment**

Sometimes, particularly in social/behavioral research, investigators plan to withhold information about the real purpose of the research or even to give subjects false information about some aspect of the research.

Concealment is often a less serious form of deception. Concealment occurs when the researcher intentionally withholds some of the research details from participants, and this may elicit less heightened concern on the part of the IRB.

### **Debriefing**

The IRB requires debriefing of all deceived subjects involved in studies that use unavoidable deception.

The purpose of debriefing is multifaceted: (1) to repair the breach of informed consent inherent in deception studies, (2) to remove any confusion and defuse any tensions that may be generated by the use of deception, (3) to make clear to all subjects, especially children, that deception is permissible only in exceptional circumstances, and (4) to repair the breach of trust (to the maximum extent possible) that has occurred between the investigator and the subject, and the potential breach of trust between all researchers and all subjects.

The written debriefing statement should 1) express regret for the necessity of deceiving the subject(s), should explain the nature of the deception and why it was necessary, 2) offer the subjects a chance to ask questions, 3) provide any additional pertinent information ([§ 45 CFR 46.116.d.4](#)) and offer information about sources of support or further counseling (in cases of significant risk of negative reactions). When students are involved in deception studies, it is also important to clearly present the material in a way that introduces the subjects to the broader conceptual and research issues involved.

## The Debriefing Form

The debriefing form is a separate document from the consent form and must include the following sections:

1. Apology for using deception
2. Explanation of why deception was necessary
3. Offer the subjects a chance to ask questions or work through any confusion that has resulted from the use of deception
4. Clearly describe the extent to which the researcher is able to ensure confidentiality of data gained from the deception
5. If the nature of deception or concealment could reasonably impact the decision of the subject to initially participate in the study, subjects should be given an opportunity to have their data removed from the study.
6. The IRB requires that in studies where the nature of deception or concealment could reasonably impact the decision of the subject to initially participate in the study, the researcher must gain affirmative consent from the subject to include their data.

### 4.2.3 Studies Involving Audio or Video Recordings

Subjects must provide full consent before any audio or video recording can take place. Researchers must ensure that the study participants are comfortable with the recording during the consent process and during the course of the study.

Participants must be informed that they can stop the recording at any time and that they have the right to have those records destroyed. In cases where written documentation of informed consent is impractical, consent to participate in the research and consent is to be included on the video or audiotape.

When a signed consent form is used, a separate space must be left on the consent form for the study participant to initial that specifically provides consent for the audio and/or video recording.

The use of audio or video recordings in deception studies is a very sensitive issue, and the Radford University IRB will carefully weigh the options and alternatives for these studies. The use of the *Audio/Video Use in Deception Studies* Form must be given to and signed by each participant. The use of audio and video recording in deception studies should only be used if there are no other reasonable alternatives.

Additional information to provide in the informed consent documents:

Procedures section:

1. Inform subjects that the study will involve audio and/or video recording.



2. Inform subjects whether or not these recordings are required to participate in the study procedures.
3. Space at the end of the consent document allowing the study participant to initial their consent specifically for the audio/video recording.

Confidentiality Section:

1. How the study will ensure the security of the recording(s).
2. Who will be transcribing the recordings.
3. Who will have access to the recordings.
4. When and how the recordings will be destroyed.

#### **4.2.4 Studies Involving Students and Extra Credit**

Additional language must be added to the compensation section that clearly outlines the following:

1. Extra credit given for completion of each study session and for total completion of the study.
2. The impact this extra credit will have on the student's grade will be determined by the student's instructor.

Please note: For those faculty (including but not limited to those faculty recruiting subjects from one or more of their own classes) providing opportunities for extra credit via participation in research projects, alternative means of earning extra credit must be made available to the students who chose not to participate in the research activity. Alternative extra credit activities should be comparable in terms of the amount of time and effort.

#### **4.2.5 Child Assent and Parental Permission**

The use of children or minors (< **18 years of age**) as research subjects requires additional safeguards to be in place. Federal regulations require the assent of the child and parental or guardian permission in the place of the consent of subjects. If guardianship is shared by two individuals, both persons must give their permission for the child to participate in a greater than minimal risk research study ([Code of Virginia §32.1-162.18\(a\)](#)). Although children are legally incapable of giving informed consent, they do possess the ability to assent or dissent from participation. Children should be asked whether or not they wish to participate in the research, particularly if the research is encompassed in the following:

1. Does not involve an intervention.
2. Children can comprehend and appreciate what it means to volunteer for the benefit of others.

The IRB will determine, based upon the proposed protocol, whether all children are capable of assenting to participation, based upon the age, status, and condition of the proposed subjects.



An explanation of the proposed research procedures should be given in a language that is appropriate to the child's age, experience, maturity, and condition. This explanation should include discussion of any discomforts and inconveniences that the child may experience if he or she agrees to participate.

Child assent and parental permission must be obtained for each participating minor, and a witness must be present during the presentation of child assent materials. The witness can be any adult present during the time of the assent/consent process, but researchers actively involved in the assent process cannot serve as a witness. Child assent and parental permission templates are available on the Radford University IRB website.

The child assent form should be written as simply as possible and should cover the following points:

1. What the study is about
2. Why he/she was selected for the study
3. Taking part in the study is voluntary
4. The procedures that will be done
5. Potential benefits of the study
6. Potential risks of the study
7. Assurance that he/she will be treated the same whether or not he/she agrees to join the study
8. An invitation to ask questions about the study
9. Assurance that he/she may withdraw from the study after discussing it with his/her parents

**For children less than 5 years of age,** a simple oral explanation of the study should be given to each child before any study-related procedures are conducted. This explanation is in addition to parental permission. A form should be available for the witness of the assent process to sign.

**Children 5 to 12 years of age:** Informed voluntary verbal assent should be obtained without pressure from parents or investigators. The "Initial Application for IRB Review" form should include an example of the explanation to be offered to the child. A sample child assent form is available.

The child's assent should be solicited and recorded in the presence of a parent, and the signed parental permission form should include the following statement: *"This study has been explained to my child in my presence, in language he/she can understand. He/she has been encouraged to ask questions both now, and in the future, about the research study."*

**Children 13-17 years of age:** Investigators may choose to handle the consent/assent requirements for this group in one of two ways.



They may either submit a combined child assent/parental permission form that is written at a level simple enough for both parent and child to read and understand, (i.e., about a 6<sup>th</sup> grade reading level), or they may choose to submit a permission form for parents and a separate assent form for the child to read and sign. If a single form is designed for both parent and child, it should be signed by each after the study has been explained.

#### **4.2.6 Research Conducted in Public Elementary and Secondary Schools**

Investigators must determine the locally applicable requirements for review and approval of research that will be conducted in public elementary or secondary schools.

When conducting research in public elementary and secondary schools, investigators are responsible for ensuring that the school has confirmed in writing that it is in compliance with the [Family Educational Rights and Privacy Act \(FERPA\)](#) and the [Protection of Pupil Rights Amendment \(PPRA\)](#). FERPA controls access to and disclosure of personal identifiable student information and records; PPRA controls the development and administration of surveys that involve protected information in local educational agencies and schools.

Under FERPA, with certain exceptions, the permission of parents or guardians must be obtained before disclosing a student's record or personally identifiable information. Likewise, under PPRA, the permission of parents or guardians must be obtained (or in some cases the parents must be allowed to exclude their children from the survey) if an investigator develops or administers a survey to students that covers one of the following areas of protected information:

1. Political affiliations or beliefs of the student or the student's parents;
2. Mental or psychological problems of the student or the student's family;
3. Sexual behavior or attitudes;
4. Illegal, anti-social, self-incriminating or demeaning behavior;
5. Critical appraisals of other individuals with whom respondents have close family relationships;
6. Legally recognized privileged or analogous relationships, such as those with lawyers, physicians, or ministers;
7. Religious practices, affiliations, or beliefs of the student or the student's parents; or,
8. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program.)

Investigators must provide a letter of support from the school to the IRB with their application when conducting research within the school system. The letter should include a statement that the school will comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA), and a statement that the school supports the research. Research applications that do not provide such a statement will be reviewed but cannot be approved by the IRB.



#### 4.2.7 Wards of the State

Children who are wards of the state or any other agency may be included in the allowable categories of research if the research is:

1. Related to their status as wards, or
2. Conducted in settings in which a majority of children who are subjects are not wards.

If the research involves:

- a. Greater than minimal risk and has no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition ([45 CFR 46 §406](#)),  
**or**
- b. The research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children ([45 CFR 46 §407](#)).
- c. Investigators must make provisions for a child advocate for each child who is a ward of the state ([45 CFR 46 §409](#); *Code of Virginia §31-8* and [§31-14.1](#)). The advocate must 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 in any way, except as a member of the Radford University IRB. One person may serve as advocate for more than one child.
- d. The advocate may not be a child's guardian or a person acting *in loco parentis*. The PI's research explanation must either provide for this requirement or state that wards of the state will be excluded from participation.

#### 4.2.8 Emancipated Minors

Emancipated minors are deemed emancipated and treated as adults for all purposes. Definitions of emancipated minors include those who are: (1) self-supporting and/or not living at home, (2) married, (3) pregnant or a parent, (4) in the military, or (5) declared to be emancipated by a court. Many states give decision making authority (i.e. without the need for parental involvement) to some minors who are otherwise unemancipated or who have decision-making capacity ("mature minors") or those minors who are seeking treatment for certain medical conditions, such as sexually transmitted diseases, pregnancy, and drug or alcohol abuse.

Because the situations in which minors are deemed partially or totally emancipated vary from state to state, the Radford University IRB has determined that all persons under the age of 18 are not emancipated minors for the purposes of participating as subjects in research. However, if a researcher wishes to use emancipated minors, the burden of legal proof as promulgated by the *Code of Virginia* will be assumed by the principal investigator.

Otherwise, anyone under the age of 18 (including enrolled Radford University students) may not be used as a participant in human subjects research without first obtaining parental permission (unless waived) and the student's assent.



### **4.3 Documentation of the Informed Consent**

Federal regulations require the written documentation of informed consent when human subjects are used in research, unless the research meets the criteria for waiver of documentation of consent per §4.4 of this document.

Informed consent at Radford University will be documented in the following manner:

1. All consent documents will, at a minimum, contain the elements stated in §4.1 of this document. Consent form templates are available on the [IRB website and current IRB submission software, as appropriate](#).
2. Language contained in the informed consent will be at the appropriate reading level of the target subjects. Keep in mind that the average adult has an 8<sup>th</sup> grade reading level.
3. The consent forms will contain no grammatical or typographic errors.
4. The consent document will be submitted to the IRB office at the time of the protocol submission and the approved document will have a dated stamp that will have the (a) date of approval, (b) date of expiration, and (c) initials of the IRB Administrator or designee.
5. There will be no exculpatory language contained in the consent form through which the subject is made to waive or appear to waive any rights.
6. For non-English speaking participants, the consent form must be written in a language understandable to the subject.
7. The IRB approval stamp should be clearly visible on all copies of consent forms that are given to subjects.
8. A witness must be present when obtaining informed consent from children, prisoners, cognitively impaired individuals, non-English speaking persons, or any subjects to whom the consent form must be read. The witness is verifying that the subject was fully informed and that the subject voluntarily agreed to participate in the study. For non-English speakers, the witness must be fluent in both English and the language of the subject.
9. All informed consent documents submitted to subjects will have an official Radford University logo and letterhead.

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### **4.4 Waiver of Informed Consent**

The Radford University IRB may waive the requirements ([45 CFR 46 §116\(c\)](#); [Code of Virginia §32.1-162.18](#)) for obtaining informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed in § 4.1, provided that:



1. The research is of minimal risk
2. The research could not be practically carried out without the waiver
3. The waiver will not adversely affect the rights and welfare of the subjects
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation
5. The research is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate or otherwise examine:
  - a. Public benefit or service programs
  - b. Procedures for obtaining benefits or services under those programs
  - c. Possible changes in or alternatives to those programs or procedures
  - d. Possible changes in methods or levels of payment for benefits or services under those programs

#### **4.5 Waiver of Informed Consent Documentation**

In accordance with [45 CFR 46 §117](#) and the [Code of Virginia §32-162.18\(e\)](#), the Radford University IRB may waive the requirement for the documentation of informed consent for some or all subjects if it finds per [45 CFR 46 §117](#) subsection (c):

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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

#### **4.6 Broad Consent**

Broad consent is permitted under the Revised Common Rule and may be obtained in lieu of informed consent in accordance with the basic and additional elements of consent, but only with respect to the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes). This is not a waiver, but rather an alternative.



The procedures and documentation are in addition to what would be required if there were no intention to use data in the future. Broad consent and Exempt research – under Category 7 §45 CFR 46.104(d)(7) and Category 8 §45 CFR 46.104(d)(8). See [§45 CFR 46.116\(d\)](#) for highlights of requirements of Broad Consent.

Further information about broad consent, including a template for developing a broad consent form for subjects, is [provided on the HHS website](#).

## TRAINING IN THE PROTECTION OF HUMAN SUBJECTS

### 5.0 Required Training for Researchers

The Radford University IRB and federal regulations require that all persons conducting research involving human subjects receive education in the responsible conduct of such research. All prospective Radford University researchers whose research requires interacting with human subjects must complete the currently required Radford University Human Subjects Training, or an equivalent, approved, human subjects research training course. Please refer to the Radford University [IRB website](#) for more information about training requirements.

The researcher is responsible for submitting the certification form and/or the course description to the IRB Administrator in situations where the IRB Administrator is unable to view the training record via the training service's database.

Certification must be confirmed before any protocol requiring IRB review will be approved. Completion of required training will be confirmed by the IRB. Certification is valid for three years.

After three (3) years, training must be renewed. Researchers who believe they have completed education comparable to the online course should contact the IRB Administrator.

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### 5.1 Training for IRB Members

IRB members, alternates, and the prisoner advocate should be familiar with and have completed the following training:

1. Policies and Procedures of the IRB
2. The Radford University [IRB website](#)
3. CITI Program (or equivalent) IRB Member Course module(s)
4. CITI Program (or equivalent) Social & Behavioral Research Course module(s)



## 5.2 Training for IRB Staff Members

The following is list of educational resources that all IRB staff are required to review and be knowledgeable within three (3) months of employment:

1. Policies and Procedures of the IRB
2. The Radford University [IRB website](#)
3. CITI Program (or equivalent) Social & Behavioral Research Course module(s)

Attendance at regional and national meetings, such as [PRIM&R](#), is encouraged and supported for staff members.

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## INITIAL IRB REVIEW OF HUMAN SUBJECT RESEARCH PROTOCOLS

### 6.0 Initial Review Requirements

Radford University utilizes online software for submission of human subject research applications. Please refer to the Radford University IRB website for the link to the system.

The Radford University IRB reviews all human subject research conducted by faculty, staff, and students, regardless of the location of the research activity (on or off campus), source of funding, and whether the research is exempt under the Code of Federal Regulations for Protection of Human Subjects ([45 CFR 46](#)).

Research involving human research participants will fall into one of three review categories: exempt, expedited, or full board. Each category is defined and discussed below. The IRB will make a final determination as to the correct review category of all protocols submitted.

#### **The following are required for all IRB submissions:**

1. An appropriately completed Initial Application for IRB Review via online protocol submission software.
2. Consent documents to be included as applicable. In addition to the informed consent form for adults, there are special circumstances that could require additional documents. These could include:
  - (a) If minors are involved, submit a copy of the proposed Parental Permission Form and Child Assent form(s)
  - (b) PIs may request a Waiver of Informed Consent Documentation
  - (c) Exempt studies will require the use of an information sheet that contains all the information of a consent document, without a signature line and without any IRB approval language.



3. CV for all Principal Investigators.
  4. Training verification is required only if the training was completed through a system wherein the Radford University IRB Office is unable to verify the training status electronically.
  5. An appropriately completed copy of the Investigator Agreement Form for all non-Radford University researchers. The Radford University Investigator agreement is contained within the online IRB application.
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## 6.1 Submission Schedule Requirements

The IRB generally meets once a month or as often as necessary during the normal academic year.

The deadline for submission of any full board review packets is 15 calendar days (3 weeks) prior to the meeting date. Any full board protocols received after the submission deadline may not be reviewed until the next scheduled IRB meeting, except on a case-by-case basis. See the IRB website for meeting dates and submission deadlines. If the study is eligible for Expedited or Exempt review, it will be processed in the order received.

The IRB Administrator receives all research applications and evaluates the protocol to confirm the correct level of review: Exempt, Expedited or Full Board. Any questions about the appropriate review level, applicability of the definition of human participants, jurisdiction of the IRB, or any other matter relating to the necessity of protocol review should be directed to the IRB Administrator and/or the IRB Chair. IRB staff and the IRB Chair review the agenda and ensure that the IRB includes at its convened meeting, persons knowledgeable about or experienced in working with vulnerable populations when protocols involving these populations are reviewed.

## 6.2 Exempt Review

Many social, behavioral and educational studies involve little or no risk to participants. According to [45 CFR 46 §102\(i\)](#), *minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Research of existing data, medical records, and pathological specimens also usually present little risk to subjects, particularly if identifiers are removed from the data. While subjects' rights and welfare must still be protected, the federal regulations permit less detailed scrutiny by the Institutional Review Board in most studies of these kinds.

Research in this category is considered *exempt from further committee review, requiring no continuing review*. However, federal regulations require a determination of exemption be made *not by the Principal Investigator* but by someone authorized and appointed by the Institution.

Therefore, the Radford University IRB requires that such activities be on file with the Research Compliance Office (RCO) and that they be reviewed and determined to be *exempt* by a voting member of the IRB.

### 1. Special Considerations

Certain populations have special protections, as outlined in Subparts B, C, and D of §45 CFR 46. *Please see a description of the populations and how the Exempt categories apply to each population.*



See §45CFR46, *Subpart B*: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research; *Subpart C*: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, and *Subpart D*: Additional Protections for Children Involved as Subjects in Research.

**a. Pregnant Women, Fetuses, and In Vitro Fertilization ([Subpart B](#))**

Research that involves pregnant women, fetuses, and in vitro fertilization ([Subpart B](#)) may be eligible for exemption from further committee review if the conditions of the exemption are met.

**b. Prisoner Research ([Subpart C](#))**

The exemptions in this section do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners. Any research involving prisoners may not be granted exemption, regardless of the risk level.

**c. Children ([Subpart D](#))**

The exemptions at paragraphs (d)(1), (4), (5), and (6) of this section may be applied to research involving children if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

**2. Exempt Review Categories**

Research activities in which the only involvement of human subjects will be in one or more of the following categories meet the requirement for approval as *Exempt from Further IRB Review*:

1. 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.

This includes most research on regular and special education instructional strategies, as well as research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) 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, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

3. **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 obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - (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, educational advancement, or reputation; or
  - (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§46.111\(a\)\(7\)](#).
- (i) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
- Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- (ii) If the research involves deceiving the 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 of or misled regarding the nature or purposes of the research.
4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
- (i) The identifiable private information or identifiable biospecimens are publicly available;
  - (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
  - (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at [45 CFR 164.501](#) or for "public health activities and purposes" as described under [45 CFR 164.512\(b\)](#); or



(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

### **Secondary Research Requiring Broad Consent**

Exempt categories seven (7) & eight (8) always require limited IRB review and are only available when broad consent will be (or has been) obtained. Refer to Section 4.6 for information about broad consent, and section 6.5 for information about limited IRB review.

## **7. Storage or Maintenance of Identifiable Data or Biospecimens for Secondary Research.**

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes a determination required by [§46.111\(a\)\(8\)](#):

- (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1) – (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
- (ii) Broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with §46.117 (See Sections 8.6 and 8.7); and
- (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

## **8. Secondary Research Using Identifiable Data or Biospecimens.**

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117 (See Sections 8.6 and 8.7);
- (iii) An IRB conducts a limited IRB review and makes the determination required by [§46.111\(a\)\(7\)](#): “When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data” and makes the determination that the research to be conducted is within the scope of the broad consent referenced in 8.i above; and
- (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Once a determination of exemption has been made, the investigator will be notified. The full IRB is to be informed of all protocols reviewed and approved under the expedited review process. The responsibility for this communication lies with the Research Compliance Office.

Although not regulated by federal regulations, the Radford University IRB does not allow exemption of research that involves interventions or interactions with individuals confined to behavioral health facilities, nursing homes, or other facilities where the individual’s freedom of movement is restricted.

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### 6.2.1 Exempt Educational Research

Three areas of exempt research are most pertinent to educational research:

1. Research conducted in educational settings, involving normal educational practices.
2. Research using educational tests, surveys, interviews, or observations of public behavior.
3. Secondary use of **EXISTING** data (data collected [by anyone] before your study for some other purpose (e.g., prior test scores)).

Additionally, signed consent forms are not required for exempt research, Protocols not meeting the above criteria are referred for expedited or full board review.

However, please note that the footnote located at the end of 45 CFR 46.101 clearly states "The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, **does not apply to research with children**, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed."

### 6.2.2 Passive (Opt-Out) Parental Consent

In limited cases, the IRB may allow an opt-out consent process, where a parent or guardian's consent is assumed unless they communicate otherwise. This is limited to cases where all of the following are true: (1) the study poses no risk; (2) the research cannot practicably be carried out otherwise; and (3) the IRB agrees that opt-out consent is appropriate under the circumstances.

If research is conducted in a school setting, the school must agree that an opt-out model is consistent with their internal policies. Additional considerations:

- a. Justify waiver of active consent: Since active consent is expected, you must justify your use of opt-out consent as necessary and ethically appropriate. The IRB will want to know: if the research is part of regular classroom activities; the expected duration of the children's participation; whether the research could pose any risk, such as sensitive questions that may upset or embarrass; and whether identifying information will be collected.
- b. Document school approval: For research in schools, include in your IRB application a letter of support for using opt-out consent, signed by the principal or another senior administrator.
- c. Develop a robust plan for informing parents: Inform parents/guardians about the study and give them an opportunity to state that they do not want their child to participate. Ensuring that information is actually received can be a challenge -- a flyer sent home may never make it there. Therefore, use more than one method to contact parents/guardians, if possible.
- d. Make it easy to opt out: Similarly, the IRB recommends providing multiple ways for a parent/guardian to inform the researcher that they do not want their child to participate.

- e. Build in sufficient time: Make sure to give sufficient time for parents/guardians to review the information and act (at least a week), and include a due date for responses.
- f. Set the right tone: Be helpful and respectful in your communications. Describe the study activities clearly and in detail. A sample opt-out information sheet is provided on the next page.
- g. Have a plan to address concerns: If a parent/guardian expresses a concern you should address it immediately, beginning by informing the IRB office.
- h. Consider non-English speakers: In situations where the researcher expects that a substantial number of parents/guardians are illiterate or do not read English, offer an appropriate alternative method of communicating information about the study.

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### 6.3 Expedited Review Process

The Department of Health and Human Services and the Food and Drug Administration regulations governing protection of human subjects recognize that full Institutional Review Board review is not necessary for every protocol. Hence, certain types of research may be reviewed and approved under an *expedited* procedure. When allowable, expedited approvals may be granted by the Institutional Review Board Chair or any other IRB members designated by the Chair. Reviewers may exercise all authority of the IRB, except that no individual member, including the Chair, may disapprove a research protocol.

Any proposed disapproval is to be referred to the full board for review and disposition. If the PI is ultimately unwilling to make changes requested by the reviewer, then the expedited study will be reviewed by the full board.

In order to qualify for expedited review, research activities must present no more than minimal risk to human subjects and involve only procedures listed in one or more of the nine categories listed below.

The categories in this list apply regardless of the age of subjects, except as noted. The expedited review procedure is not permitted when identification of the subjects and/or their responses would reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Categories one (1) through seven (7) below pertain to both initial and continuing IRB review, while categories eight (8) and nine (9) apply in certain cases to research already approved by the full board.

Research must meet all of the following criteria, including the list of categories of research that may be reviewed by the IRB through an expedited review procedure, in order to be reviewed by the IRB through an expedited review procedure. [§45 CFR 110](#).

- Be of minimal risk to the subjects
- Must not involve prisoners or mentally impaired persons

- Must be in one or more of the following categories:
  1. Clinical studies of drugs and medical devices only when the following conditions are met:
    - (a). Research on drugs for which an investigational new drug application 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.) AND
    - (b). Research on medical devices for which an investigational device exemption is not required, OR the medical device is cleared/approved for marketing and 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). 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 (persons under 18 years old) 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 non-disfiguring 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 gum base 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 sub gingival 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 non-research purposes (such as medical treatment or diagnosis).

(Note: See section 6.2 for similar research that may fall into the exempt category. 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: See section I.A. for similar research that may fall into the exempt category. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the full committee as follows:

- (a). Where:
  - (i). the research is permanently closed to the enrollment of new subjects;
  - (ii). all subjects have completed all research-related interventions; and
  - (iii). the research remains active only for long-term follow-up of subjects; or
- (b). Where no subjects have been enrolled and no additional risks have been identified; or
- (c). Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the University's IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Once an expedited review has been completed, the investigator will be notified regarding the status of the application. This written notification will indicate whether the application was fully approved, required modifications/clarifications in order to secure approval, or deferred for full committee review. The full



Institutional Review Board is to be informed of all protocols reviewed and approved under the expedited review process. The responsibility for this communication lies with the Research Compliance Office staff.

All completed (e.g., approved) Expedited items (i.e., new protocol review applications, amendments to previously approved protocols, continuation requests, unanticipated problems, study closures and/or terminations) are listed in a monthly agenda and the corresponding minutes as a method of informing IRB members of their review outside of Full Board review since the last convened meeting.

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#### **6.4 Greater than Minimal Risk Protocols**

All protocols determined by the IRB staff to be more than minimal risk (i.e. failing to meet the requirements of [§6.2](#) or [§6.3](#) of this document) are required by federal and state regulation to be reviewed and approved by a fully convened IRB.

The Radford University Institutional Review Board adheres to the following process to facilitate the thorough review of each protocol according to Federal ([45 CFR 46 §111](#)) and State of Virginia (*Code of Virginia* [§32.1-162.19](#)) regulations:

1. The IRB Administrator and/or designee specifically review the protocol submission for completeness and request changes to the protocol as necessary. This review and request for changes is accomplished prior to distributing protocol submission materials to Board members.
2. A complete set of documents is available in IRBManager to the IRB member who is asked to review the IRB application and supporting documents in detail. These documents are available to all Board members and alternates, regardless of their intention to attend the meeting.
3. Prior to the full IRB meeting, Board members may correspond with the PI(s) and/or IRB staff to resolve any questions. Furthermore, any Board member may contact the PI, co-PI, other IRB members, or outside sources as necessary to ensure a thorough investigation of risks and benefits of the proposed research.
4. All submissions undergoing review (i.e., new protocols, continuation requests, amendment requests, etc.) are discussed individually by the IRB at the convened IRB Meeting, except for continuations per the current OHRP Guidance (specifically referring to Full Board continuations that are no longer enrolling participants).
5. Researchers are invited to be available during the meeting, either by phone or in person, to respond to any questions the Board may have. **\*\*\*Note:** Researchers are only present during discussion and are dismissed prior to final deliberations and determinations.
6. After complete and individual discussions, each protocol is voted upon for one of four possible dispositions ([45 CFR 46.109](#)):
  - a. **Approved**- The IRB accepts and endorses without reservations “approved” studies.

- b. **Require Modifications (to secure approval)**- The IRB votes to approve the study pending modification of the protocol as specified by the IRB membership. S This is accomplished in one of two ways:
- 1) where clearly specified changes are requested and documented, the final review may be conducted by a reviewer or group of reviewers as designated by the Chair, or,
  - 2) in the case of non-specific changes or extensive changes, the protocol is re-submitted to the Full Board for further consideration.
- c. **Tabled**- A study may be tabled if the Board did not have sufficient time, expertise, or appropriate personnel present (e.g., prisoner advocate) to vote on the study, or because the Board requires substantive clarification or modifications regarding the protocol or study documents to determine whether to approve or disapprove the study.
- d. **Disapproved**- A protocol that is disapproved is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in major areas.

The PI will be advised of the decisions and the reasons for the disapproval in writing. A PI has the right to appeal the disapproval to the Board and ask to have the decision reconsidered.

Following the presentation and discussion of protocols receiving either initial or continuing review, a listing of protocols reviewed and administratively approved for continuation, a listing of protocol modifications, a listing of unanticipated problems and a listing of those protocols approved through expedited review procedures and other information relating to ongoing research activities are reported to the IRB and are included in the IRB agenda.

Protocols requesting significant modifications or of special interest to the IRB are discussed in detail and voted upon by the convened IRB. The PI is notified of the status of the submitted protocol, typically within three (3) days of the IRB meeting.

There may be times when the risks associated with a protocol are such that continuing review should take place more frequently than annually. In these cases, the IRB will specify that the PI report to the IRB either at a shorter time interval or after a specified number of subjects are enrolled. The PI's report must describe the observed effects of the research activities and/or how the subject(s) responded to the research interventions. The determination will be recorded in the IRB minutes and reports forwarded to the IRB by the IRB office, when they are submitted.

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## 6.5 Limited IRB Review

Limited IRB review is a process that is required only for certain exemptions, and does not require an IRB to consider all of the IRB approval criteria in [§46.111](#). In limited IRB review, the IRB must determine that certain conditions which are specified in the regulations are met. Limited IRB review may be done via the expedited review mechanism, by the Chair or an experienced IRB member designated by the Chair

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(although it may also be conducted by the full IRB). Continuing review is not required. [45 CFR §46.109\(a\) and §46.109\(f\)\(1\)\(ii\)](#)

## 6.6 Non-compliance with IRB Policies and Decisions

Human subjects research that deviates from the policies, procedures, stipulations, decisions, state, or federal law is non-compliant and subject to further inquiry by the IRB, Radford University, and the Office of Human Research Protections (OHRP). All reports and complaints of non-compliance should be directed to the Radford University IRB Administrator via email, telephone, or in person. The IRB Chair and/or a subcommittee of IRB Members and/or other qualified personnel will immediately investigate all allegations of non-compliance.

If necessary, the IRB Administrator will send the investigator(s) in question a notice requesting the immediate suspension of all specified research activities while the issue of non-compliance is reviewed. This is consistent with Federal Mandate [45 CFR 46 §113](#). This initial notice will also include a statement detailing the rationale for the IRB's action. There are three categories of non-compliance: general, serious, and continuing.

1. **General Non-compliance:** Any study deviating from the Radford University IRB policies and procedures, federal regulations, and/or state law is in "general non-compliance." All non-compliance studies will undergo an evaluation by the IRB Chair. The IRB Chair will review the nature of the non-compliance and make a recommendation based upon each specific case.

The IRB Chair issues recommendations to the IRB for a vote. If the IRB rejects the IRB Chair's recommendations, then the IRB must propose conditions for successful resolution of the situation (see "Possible Outcomes" below). Any PI with outstanding study closure documentation will not have any further IRB review privileges until all reports have been submitted.

2. **Serious Non-compliance:** All non-compliance substantially affecting the participants' rights and/or welfare, or impacting upon the risks or benefits is "serious non-compliance." The IRB will assess and vote upon all serious non-compliance determinations.
3. **Continuing Non-compliance:** In the event that the IRB finds reasonable evidence that restrictions, procedures, stipulations, or decisions of the IRB have been systematically or habitually overlooked, the individuals in question may be monitored to ensure that the quality of human subjects protection is being upheld to the satisfaction of the IRB and in compliance with the federal regulations promulgated in [45 CFR 46](#) and Commonwealth of Virginia regulations set forth in [§32.1-162.16](#) through [§32.1-162.20](#) of the *Code of Virginia*.

**Possible Outcomes:** It is within the purview of the IRB to recommend the termination of research activities given evidence that the person or persons who would direct or have directed the scientific and technical aspects of an activity have failed to discharge responsibility for the protection of the rights and welfare of human subjects ([45 CFR 46 §113](#)). The IRB reserves the right to request additional consultation and expertise to resolve non-compliance.



### **6.6.1 Subject Population Sample Size**

Radford University requires that applications for human subjects research specify a number of participants to be enrolled in a research study. The Radford IRB requires the submission of a modification or amendment to increase the approved sample size of the proposal.

An amendment submitted for IRB review must state the number of participants to be enrolled. When approval is issued, approval is granted to enroll only the number of participants listed in the application.

This number is defined as the number of participants who sign the informed consent document, are enrolled using an oral consent process, or are enrolled with a waiver of consent. If this number is reached, enrollment must cease. Enrollment of participants beyond the initial approved number is considered non-compliance with the terms of the project approval. In order to increase the sample size above the number approved, a modification must be submitted to the IRB for review. Enrollment may not continue above the approved sample size until the IRB approves the change in research. A modification concerning sample size may be eligible for an expedited review by the Radford University IRB.

### **6.7 Health Insurance Portability and Accountability Act (HIPAA) for Protected Health Information**

*Personal health information that is not obtained from a covered entity, that is self-disclosed by research participants, and that is kept only in the researcher's records is not subject to HIPAA but is regulated by other human subjects protection regulations.*

The Department of Health and Human Services' National Standards to Protect the Privacy of Personal Health Information are promulgated in the [Health Insurance Portability and Accountability Act \(HIPAA\) of 1996](#), commonly referred to as the "Privacy Act."

This Act specifies requirements for protection of individually identifiable health information (IIHI) or "protected health information" (PHI). PHI is individually identifiable health information (IIHI) such as name, address, social security number, email address, telephone number, etc., that is created, received or maintained by a Covered Entity (CE).

A CE is a Health Care Provider that performs one of the standard electronic transactions identified in the HIPAA Privacy Rule; a Health Plan; or a Health Care Clearinghouse. Virtually all doctors, hospitals, and other health care facilities are Covered Entities.

#### **A. Definitions**

For the purposes of this discussion, it is important to understand certain definitions within the context of HIPAA:

##### **1. Covered Entity**

Covered entities are health care providers (if they transmit any information in an electronic form in connection with a transaction for which HHS has adopted a standard), health plans, health care clearinghouses, and their business associates.



## **2. Hybrid Entity**

A hybrid entity under HIPAA is a single legal entity that is a covered entity whose business activities include both covered and non-covered functions and that designates certain units as health care components. To break that down, a covered entity means a company that offers some health care-related services and some non-health care-related services.

A covered function means anything that would render the performer a health plan, health care provider, or health care clearing house (for more information on these terms, see <https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>).

Some institutions are a hybrid entity, with only portions of the University subject to HIPAA.

As a hybrid entity, any individually identifiable health information maintained by other components of the university (i.e., outside of the health care component), such as a law enforcement unit, or a research department, would not be subject to the HIPAA Privacy Rule, notwithstanding that these components of the institution might maintain records that are not "education records" or treatment records under FERPA. For an institution to consider itself as a hybrid entity, it must assess which of the components or business units comprising your entity could be considered health care components, documenting the designation in writing by adopting a hybrid entity policy.

## **3. Authorization (Consent)**

(Patient) authorization is the HIPAA equivalent of consent to use and disclose (patient) data.

## **4. Protected Health Information (PHI)**

Protected health information includes all individually identifiable health information transmitted or maintained by an organization covered by the HIPAA regulations (a "covered entity"), regardless of form. Specifically, if it is Individually Identifiable Health Information (IIHI) that is:

- created or received by a health care provider, health plan, employer, or health care clearinghouse; AND
- personal health information that relates to:
  - the past, present, or future physical or mental condition,
  - the past, present, or future provision of care to an individual, or
  - the past, present or future payment for provision of health care to an individual, and
  - identifies the individual (or there is a reasonable basis to believe that the information can be used to identify the individual).

Health-related information is PHI if:

- The researcher obtains the information from a healthcare provider, health plan, health clearinghouse, business associate, or employer (other than records solely relating to employment status);  
**OR**
- The records were created by a healthcare provider, health plan, health clearinghouse, or employer, AND the researcher obtains the records from an intermediate source which is not a school or employer record related solely to employment status;  
**OR**



- The researcher obtains the records directly from the study subject in the course of providing treatment to him. Health-related information is not considered PHI if the researcher obtains it from:
  - Student records maintained by a school;  
**OR**
  - Employee records maintained by the employer for employment status;  
**OR**
- The research subject directly, if the research does not involve treatment.

## **B. What Research Is Subject to the HIPAA Regulations?**

Any research conducted under the auspices of Radford University that creates, uses, or discloses protected health information obtained from a covered entity is subject to the [Health Insurance Portability and Accountability Act](#) (HIPAA).

## **C. Types of Health Information**

There are three categories of health information. The requirements for use are different for each.

### **1. Individually Identifiable Health Information (IIHI)**

IIHI includes any subset of health information, including demographic information collected from an individual, that:

- i. Identifies the individual (or there is a reasonable basis to believe that the information can be used to identify the individual.)
- ii. The general rule is that an authorization signed by the research subject is required for the disclosure of individually identifiable health information. An IRB may waive this requirement.

### **2. De-Identified Data Sets**

Health information is considered de-identified when it does not identify an individual and the covered entity has no reasonable basis to believe that the information can be used to identify an individual. Information is considered de-identified if 18 identifiers are removed from the health information and if the remaining health information could not be used alone, or in combination, to identify a subject of the information.

An IRB may waive authorization for the use of de-identified data.

The 18 identifiers that may not be included in de-identified data sets are:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census:
  - The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people;



- and
  - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
  4. Phone numbers;
  5. Fax numbers;
  6. Electronic mail addresses;
  7. Social Security numbers;
  8. Medical record numbers;
  9. Health plan beneficiary numbers;
  10. Account numbers;
  11. Certificate/license numbers;
  12. Vehicle identifiers and serial numbers, including license plate numbers;
  13. Device identifiers and serial numbers;
  14. Web Universal Resource Locators (URLs);
  15. Internet Protocol (IP) address numbers;
  16. Biometric identifiers, including finger and voice prints;
  17. Full face photographic images and any comparable images; and
  18. Any other unique identifying number, characteristic, or code (This does not refer to the unique code assigned by the investigator to code the data).

### **3. Limited Data Sets**

*A limited data set is information disclosed by a covered entity to a researcher who has no relationship with the individual whose information is being disclosed. The covered entity is permitted to disclose PHI, with direct identifiers removed, subject to obtaining a data use agreement from the researcher receiving the limited data set.*



The PHI in a limited data set may not be used to contact subjects. The IRB may waive authorization for use of limited data sets in research.

Direct identifiers that must be removed from the information for a limited data set are:

1. Name,
2. Address information (other than city, State, and zip code),
3. Telephone and fax numbers,
4. E-mail address,
5. Social Security number,
6. Certificate/license number,
7. Vehicle identifiers and serial numbers,
8. URLs and IP addresses,
9. Full face photos and other comparable images,
10. Medical record numbers, health plan beneficiary numbers, and other account numbers,
11. Device identifiers and serial numbers,
12. Biometric identifiers including finger and voice prints.

Identifiers that are allowed in the limited data set are:

1. Admission, discharge and service dates,
2. Birth date,
3. Date of death,
4. Age (including age 90 or over),
5. Geographical subdivisions such as state, county, city, precinct and five-digit zip code.

#### **D. Authorization (Consent) Requirements**

HIPAA regulations use the term "authorization" to describe the process through which a patient consents for researchers to access protected health information.



Blanket authorizations for research to be conducted in the future are not permitted. Each new use requires a specific authorization.

The authorization for disclosure and uses of protected health information may be combined with the consent form that a research subject signs before agreeing to be in a study. It may also be a separate form.

In either case, the information must include:

**1. Elements of Required Authorization**

- a. A description of the information to be used for research purposes;
- b. Who may use or disclose the information
- c. Who may receive the information
- d. Purpose of the use or disclosure
- e. Expiration date of authorization
- f. How long the data will be retained with identifiers
- g. Individual's signature and date
- h. Right to revoke authorization
- i. Right to refuse to sign authorization (if this happens, the individual may be excluded from the research and any treatment associated with the research)
- j. If relevant, that the research subject's access rights are to be suspended *while the clinical trial is in progress*, and that the right to access PHI will be reinstated at the conclusion of the clinical trial.
- k. That information disclosed to another entity in accord with an authorization may no longer be protected by the rule.

**2. Waiver of Authorization for Research**

The Institutional Review Board uses the following criteria in approving requests for a waiver of authorization for research:

The use or disclosure of protected health information must involve no more than minimal risk to the privacy, safety, and welfare of the individual;

- a. The research could not practicably be conducted without the waiver or alteration; and



- b. The research could not practicably be conducted without access to the protected health information.

The Institutional Review Board must also consider if the researcher has provided:

- c. an adequate plan to protect the identifiers from improper use or disclosure;
- d. an adequate plan to destroy the identifiers at the earliest opportunity, unless retention of identifiers is required by law or is justified by research or health issues; and
- e. adequate written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization signed by the research subject.

#### **E. Information Needed for Review by the IRB**

Detailed information is needed about the types of information investigators will use in their research, how it will be used, who will have access to it, and when it will be destroyed. Specifically, researchers should address:

- What risks are posed by the use of the data and how have they been minimized?
- What is the justification for access to the data and why are they necessary to conduct the research?
- What plan does the researcher have to protect identifiers from improper use or disclosure?
- What is the researcher's plan to destroy the identifiers? If it is not possible to destroy the identifiers, what is the health, legal, or scientific justification?
- Has the researcher provided adequate written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization signed by the research subject?

Researchers requesting waivers of authorization will need to explain that the use or disclosure poses no more than minimal risk to the subject; that the research could not practicably be conducted without the waiver; and that the research could not practicably be conducted without access to the protected health information.



The researcher must explain:

- how the use of PHI involves no more than minimal risk to individual
- why such a waiver will not adversely affect privacy rights or welfare of individuals in the study
- why the study could not practicably be conducted without a waiver
- why it is necessary to access and use protected health information to conduct this research
- how the risks to privacy posed by use of PHI in this research are reasonable in relation to the anticipated benefits
- the plan to protect identifiers from re-disclosure
- the plan to destroy identifiers. Provide a date by which this will take place. If identifiers must be retained, provide the reason (scientific, health, or other) why this is necessary.
- and confirm that the PHI will not be reused or disclosed to anyone else.

## **F. Human Subjects' Rights**

### **1. Right to an Accounting**

When a research subject signs an authorization to disclose PHI, the covered entity is not required to account for the authorized disclosure. An accounting is not required when the disclosed PHI was contained in a limited data set or is released to the researcher as de-identified data.

However, an accounting is required for research disclosures of identifiable information obtained under a waiver or exception of authorization. Research subjects may request an accounting of disclosures going back for up to six years.

### **2. Right to Revoke Authorization**

A research subject has the right to revoke his or her authorization unless the researcher has already acted in reliance on the original authorization.

Under the authorization revocation provision, covered entities may continue to use or disclose PHI collected prior to the revocation as necessary to maintain the integrity of the research study.



Examples of permitted disclosures include submissions of marketing applications to the FDA, reporting of adverse events, accounting of the subject's withdrawal from the study and investigation of scientific misconduct.

### **3. Subject Recruitment**

#### **1. Recruitment is Subject to the General Authorization Requirements**

The Privacy Rule classifies recruitment as "research" rather than as health care operations or marketing. Because development or use of research databases falls within the definition of "research," a covered entity may disclose PHI in a database to sponsors for subject recruitment only after an authorization from the research subject or a waiver from the Institutional Review Board has been obtained.

#### **2. Requirements to Disclose PHI Contained in a Limited Data Set or as De-Identified Data**

It is easier to create databases of potential subjects' limited data sets to verify feasibility to conduct a clinical trial or to perform epidemiological research.

#### **3. Limitations on Use of PHI in a Limited Data Set for Subject Recruitment**

The PHI may not be used to contact subjects, and, because telephone numbers, internet provider addresses, and email addresses are not part of a limited data set, this information may not be collected by researchers from prospective subjects.

#### **4. Recruiting Subjects Identified using their PHI**

When researchers want to approach potential subjects to participate in a study who they have identified using PHI under a waiver of authorization, they must use an approach method that has been approved in advance by the IRB.

Examples include using an intermediary such as the patient's primary care provider or a member of the medical staff actually caring for that patient, or sending the potential subject a letter signed by the patient's provider.

### **G. Requirements for Security of Protected Health Information under the Health Insurance Portability and Accountability Act (HIPAA)**



All investigators performing human subject research that involves access to Protected Health Information (PHI) are required to comply with both the Privacy Rule and Security Rule of the Health Insurance Portability and Accountability Act (HIPAA).

The Research Compliance Office and Information Technology Services have partnered to ensure that researchers utilizing PHI are able to adequately safeguard those data. All researchers needing access to PHI shall complete the CITI [HIPAA Privacy Rule](#) training beforehand.

Therefore, investigators who create, use or otherwise obtain individually identifiable health information are asked to: Complete the HIPAA Privacy Rule training module by logging in or creating an account in CITI and adding a course.

With these provisions in mind, the Radford IRB requires that investigators who create, use or otherwise obtain PHI provide more detailed information about data storage, security, planned re-disclosure, and destruction; and provide more information to research subjects in the consent and authorization process about their PHI will be used.

It is a violation of this policy for any person performing work with PHI for Radford University as an employee or independent contractor to fail to comply with any Privacy and/or Security Rule obligation for which they are responsible, regardless of whether such failure is intentional or not.

## **1. [HITECH Act of 2009](#)**

On April 17, 2009, the Department of Health and Human Services (HHS) issued guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals, as required by the Health Information Technology for Economic and Clinical Health (HITECH) Act passed as part of the American Recovery and Reinvestment Act of 2009 (ARRA).

This guidance was developed through a joint effort by the Office of Civil Rights, the Office of the National Coordinator for Health Information Technology, and the Centers for Medicare and Medicaid Services.

There are two breach notification regulations, one issued by HHS for covered entities and their business associates under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Sec. 13402 of HITECH), and the other issued by the Federal Trade Commission (FTC) for vendors of personal health records and other non-HIPAA covered entities (Sec. 13407 of HITECH).

## **2. Strengthened Enforcement Measures**

Perhaps the most significant feature of the HITECH Act is the strengthening of HIPAA enforcement measures.



Whereas the Office of Civil Rights (OCR) and the Department of Justice were the only HIPAA enforcement authorities previously, the Act authorizes state Attorneys General to enforce HIPAA violations in federal court.

Should the Department of Justice not pursue criminal penalties for a violation that constitutes criminal behavior, the Office of Civil Rights is now authorized to pursue civil penalties for the same violation.

The Act includes new civil and criminal penalties for employees, with monetary fines being returned to OCR for future enforcement purposes and, eventually, to compensate victims. Civil monetary penalties for willful neglect violations were previously maxed at \$25,000; the Act tiers civil monetary penalties with a maximum of \$1.5 million.

## POST-APPROVAL DOCUMENTATION OF APPROVED RESEARCH

### 7.0 Procedure for Continuation of Approved Protocols

Continuing review of research must be substantive and meaningful. In accordance with HHS regulations at [45 CFR 46.108\(b\)](#) and at [46.115\(a\)\(2\)](#), continuing review by the convened IRB is required unless the research is otherwise appropriate for expedited review as described in OHRP Guidance on Categories of Research That May Be Reviewed by the IRB Through an Expedited Review Procedure.

Therefore, if research was initially approved by the convened Board, continuing review will normally be reviewed by the convened Board.

The Radford University IRB is responsible for conducting continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected and to review the progress of the entire study.

Protocols must continue to have ongoing IRB approval as long as the research continues to involve human subjects, even when research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and only long-term follow-up is being conducted or the only remaining activity is limited to data analysis of personally identifiable information.

At the time of initial approval and then with subsequent continuing review, the IRB determines the frequency and extent of continuing review for each study appropriate to the degree of risk, but not less than once per year. Most protocols undergo continuing review annually, but the IRB has discretion to require protocols to undergo continuing review more frequently as warranted by such factors as:

1. The nature of the study
2. The degree of risk involved
3. The vulnerability of the study subject population.
4. The PI has a history of non-compliance with IRB policy



In specifying an approval period for studies of less than 12 months, i.e., those deemed by the IRB to pose higher risk to subjects or those PIs that historically disregard IRB policies and procedures, the IRB may, at its discretion, define the continuing review period with either a time interval (e.g. 3 or 6 months), or a maximum number of subjects (e.g. after 3 subjects). If a continuing review period is defined by a maximum number of subjects the IRB must also list a maximum time interval. The minutes and/or comment sheets for such projects should reflect these determinations regarding risk and approval period.

Continuing to conduct research after expiration of IRB approval is a violation of the Federal Regulations. If IRB approval expires, research activities must stop. These activities include:

1. the collection, use, or reporting of any data
2. the performance of any study interventions, unless the IRB finds that it is in the best interests of individual subjects to continue participating in research interventions or interactions;
3. the enrollment or screening of any new subjects; and/or
4. receipt of any study funding.

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## **7.1 Continuation Procedures**

The Continuation Request is submitted via IRBManager by Investigators and considered by the IRB. It provides a status report on the progress of the research and is required by federal law.

The IRB may, at its discretion, require verification from sources other than the investigator that no material changes have occurred in the research since the previous IRB review. Protocols that may require verification include, but are not limited to, those projects conducted by investigators who previously have failed to comply with the requirements or determinations of the IRB or Federal regulations and 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. The investigator may be required to submit additional information as determined by the IRB.

Under the revised Common Rule, [§45 CFR 46.109](#), [46.110](#), and [46.115\(a\)\(8\)](#), continuing review is not required for:

- Research that is eligible for expedited review
- Exempt research conditioned on limited IRB review
- Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable
- Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures



Importantly, the IRB can override this default and still choose to require continuing review, as long as the IRB documents the decision and the rationale for this decision. All non-exempt protocols approved by the IRB are subject to continuing review. When a protocol is first approved, the IRB determines the appropriate approval period based on the information available and the perceived risk to the subject.

The approval period can be no more than 12 months for protocols approved by the full IRB and no more than 36 months for protocols approved through the expedited process.

Protocols reviewed by a convened meeting of the IRB unless it qualifies for Expedited review under [Expedited Category 8](#), which states:

8. Continuing review of research previously approved by the convened IRB as follows:
  1. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
  2. where no subjects have been enrolled and no additional risks have been identified; or
  3. where the remaining research activities are limited to data analysis.

**Investigator Responsibilities:** Investigators must complete the Continuation Request/Study Closure xForm in IRBManager, and the most recent copy of approved informed consent documents and any other documents that were stamped and will now expire (if new subject enrollment continues).

Any revisions (e.g., amendments or modifications to the study) must be submitted according to the amendment guidelines below. Failure to submit a continuation request sufficiently prior to the expiration date of the protocol will be considered general non-compliance.

**Research Compliance Office Responsibilities:** Continuing Review submissions received by the IRB Administrator or designee are reviewed for completeness (which includes the inclusion of all required paperwork, including stamped materials) and accuracy. Investigators or their designee are contacted as appropriate to provide clarification and/or documentation prior to any applicable Board Review.

Only submissions fulfilling all Radford University IRB administrative requirements will be scheduled for the next available convened meeting, or, if eligible for Expedited review, distributed to the next appropriate and available reviewer.

**Reviewer Responsibilities:** If the protocol is to be reviewed during a convened meeting by virtue of failing to qualify for Expedited processing under Expedited Category 8(c), the following applies, otherwise it is reviewed as any other Expedited submission:

During the week prior to the meeting (whenever possible), all board members will receive a link to the electronic documents in IRBManager for their review.

A designated primary reviewer may be assigned as a "champion" for the Continuation. The designated reviewer will receive an electronic copy of all supporting documents in addition to the link for access through IRBManager.



The reviewer is responsible for considering and evaluating the responses provided by the Investigator on the Continuing Review Form, for ensuring that answers are complete and not in conflict with information provided previously, and for presenting this information to the convened Board.

Additionally, the reviewer should ensure that the currently approved or proposed consent document is accurate and complete. Investigators may be contacted as appropriate to provide clarification and/or documentation prior to Board Review. Copies of e-mail correspondence with Investigators should be submitted to the Research Compliance Office with continuing review paperwork for maintenance in the IRB file.

The reviewer should present a brief review of the protocol and information provided in the Continuing Review Report to the Board and should make a recommendation regarding the acceptability of granting the renewal. In this assessment, the reviewer should ensure that the criteria for approval continue to be satisfied including consideration of the risks and benefits and current safeguards for human subjects and determine whether any new information has emerged that might affect the risk/benefit ratio.

Whether or not a reviewer has been directly assigned to the submission, the IRB should ensure that new information or findings, which may relate to the subjects' willingness to continue participation, is provided to study subjects.

The discussion of the continuing review application is led by the designated assigned reviewers, if any, and directed by the Chair. The entire membership is expected to participate in the review of all protocols, not just the protocols assigned to them.

At the end of the discussion, based on the information reviewed, presented and discussed, the primary reviewer and/or Chair make a recommendation for action, risk level and approval period (continuing review interval based upon risk to subjects). A vote is taken on each action and recorded in the database.

## **7.2 Closure Procedures**

The Study Closure documentation submitted via IRBManager by Investigators and considered by the IRB provides a status report on the progress and termination of the research.

The IRB may, at its discretion, require verification from sources other than the investigator that no material changes have occurred in the research since the previous IRB review.

Protocols that may require verification include, but are not limited to, those projects conducted by investigators who previously have failed to comply with the requirements or determinations of the IRB or Federal regulations and 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. The investigator may be required to submit additional information as determined by the IRB.

**Investigator Responsibilities:** Investigators must complete and submit the appropriate Study Closure documentation on or before the expiration date of the protocol. Any revisions must be submitted according to the revision guidelines. Failure to respond to properly close an IRB protocol prior to the expiration date may be considered general non-compliance.



**Office Responsibilities:** Study closures are usually reviewed administratively within the IRB Office or by the IRB Chair. The IRB Office is expected to process and document that closure documentation appropriately and in a timely fashion. If an adverse event or unanticipated problem is described on the closure documentation, or other anomalies exist therein, the IRB Office shall promptly take it to the IRB Chair for consideration and instructions for further review either by the Chair or via presentation to the IRB at a convened meeting, if any.

### **7.3 Amending Approved Protocols**

Investigators are responsible for prompt reporting of proposed changes in research activity to the IRB, and for ensuring that changes in IRB approved research are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. Minor changes in previously approved research may be reviewed utilizing an expedited process.

Determination of what constitutes a minor change will ultimately be made by the IRB Chair or designee. The IRB must review and approve all changes to previously approved research, no matter how minor, before they are implemented. Proposed changes may affect, but are not limited to, the protocol, informed consent form, changes in study population, and the collection of data from additional subjects.

Investigators are responsible for submitting proposed changes in research activity to the IRB, and for ensuring that changes in IRB-approved research are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

If changes to the protocol must be implemented for the safety of the subject prior to IRB review and approval, such changes must be reported to the IRB as soon as possible, with any supporting documentation necessary for the IRB to determine the change was consistent with ensuring the subjects' continued welfare. Information relating to protocol changes will be provided to subjects when such information may relate to the subjects' willingness to continue to take part in the research.

Amendments for protocols reviewed by the Expedited process may usually be reviewed by the Expedited process unless the requested change(s) may or actually elevate the risk level of the project to that of Full Board review. The Chair or designee makes the ultimate decision as to the level of a review for a protocol that is unclear as to the new review category.

MAJOR revisions to existing Full Board protocols involve changes that represent significant changes to the protocol, particularly concerning those areas of the study that are considered to be of greater than minimal risk, and include, but are not limited to, a change in PI for Full Board protocols and/or anything that would increase potential risk or decrease potential benefits to subjects.

Major revisions are reviewed by the Full Board and will be scheduled for an IRB meeting according to the IRB meeting deadlines and guidelines. These revisions are placed on the IRB agenda and may be assigned to a designated reviewer to present to the full Board for action. The request must be reviewed with the same criteria for concern for human subjects as used in the review of a new protocol.



MINOR revisions to existing Full Board protocols may, at the discretion of the Chair, be reviewed via Expedited procedures, pursuant to [45 CFR 46.110\(b\)\(2\)](#), which states:

Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in [§46.108\(b\)](#).

Amendments to approved protocols adding only personnel, may be reviewed and approved by the Research Compliance Office after confirming completion of required CITI courses for human subject research.

**Investigator Responsibilities:** Investigators must submit a completed Request for Modification xForm using IRBManager, and, if necessary, uploading a revised Informed Consent Form(s) and/or other forms, needed for IRB review of the proposed amendment. In addition, "clean" copies of affected documents to be stamped at the time of approval must be submitted if revisions were made.

**Research Compliance Office Responsibilities:** Revisions received by the IRB Administrator are reviewed for completeness (which includes the inclusion of all required paperwork). Once complete, the submission, including all of the supporting documents provided by the PI including a project history, the last IRB-approved informed consent, and the current protocol, are either forwarded on for inclusion on the applicable meeting agenda and determination of review status or are distributed to the next applicable Expedited reviewer, if applicable.

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## 7.4 Unanticipated Problems and Adverse Events: Identifying and Reporting

Federal Regulations ([45 CFR 46 §103\(b\)\(5\)](#)) require that adverse events and unanticipated problems involving risk to subjects or others be promptly reported to the IRB, appropriate institutional officials, and any supporting department or agency head and OHRP, where applicable (e.g., when federal funding is associated with the project). Although the regulations do not define unanticipated problems, OHRP (2007) published guidance on unanticipated problems and adverse events.

### Definitions

Unanticipated problems (UPs): any incident, experience, or outcome that meets **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;



2. Related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Events that do not cause detectable harm or adverse effects to subjects or others may still represent unanticipated problems.

Adverse Events (AEs): The HHS regulations at 45 CFR part 46 do not define or use the term adverse event, nor is there a common definition of this term across government and non-government entities.

In this guidance document, the term adverse event in general is used very broadly and includes any event meeting the following definition:

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

Both **risks to subjects** and **risks to other individuals** (e.g., research personnel, subjects' family members) are included in the concept of AEs and UPs. Risks may reflect any type of potential harm (e.g., physical, psychological, social, economic) and may include events related to data security which result or may result in breaches of confidentiality or other harm related to data provided by participants

Any major problems involving human subjects should be reported to the IRB immediately. In addition, the PI shall refer any subjects exhibiting signs or symptoms of the unanticipated problem should be referred to the appropriate medical or psychological resources for assistance. Minor problems involving the conduct of the study or subject participation (including recruitment, consent, screening and termination) should be reported during the continuing review process.

**Investigator Responsibilities:** The Principal Investigator is responsible for knowing which unanticipated problems and/or adverse events require expedited reporting and for completing the applicable reporting forms (available at the IRB website) and for submitting the reporting form and any other supporting documentation to the IRB Administrator promptly after discovery.

Investigators are encouraged to review OHRP's [Unanticipated Problems Involving Risks & Adverse Events Guidance \(2007\)](#) to assist them in their determination. Investigators are strongly encouraged to err on the side of caution and report a finding if any doubt exists as to whether it is an AE or UP.

If an event, incident, experience, or outcome is life-threatening or fatal, the IRB Administrator must be notified immediately or early the next business day if the discovery is made outside of office hours.



At minimum, the investigator's report is to include:

1. Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
2. A detailed description of the adverse event, incident, experience, or outcome;
3. An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and
4. A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

**Research Compliance Office Responsibilities:** Reportable events (serious and unexpected adverse events and/or unanticipated problems) are documented by the PI by uploading the Adverse Event Reporting Form to IRBManager. The IRB Office reviews for completeness the documentation of the adverse event provided and promptly forwards the report to the Chair.

**Chair Responsibilities:** The IRB Chair will review any reports to determine if the research has been associated with unexpected serious harm to subjects and/or if there is any immediate risk to subjects participating in the protocol. In such a case, the Chair may immediately suspend the study or enrollment in the study and refer the issue to the next full board meeting for discussion. The Chair or designee will notify the Investigator and appropriate Institutional officials of the suspension (see [§1.4](#)). Deaths that are unexpected and related or possibly related to study interventions, or where a relationship cannot be ruled out, will be referred from the Chair to the full Board for review and may require the additional oversight of the Institutional Official, Provost, and/or the Radford University President.

If no immediate risk to human subjects exists, and in the opinion of the Chair the event(s), incident(s), experience(s), or outcome(s) could result in an increase in perceived participant risk, the Chair will address the event in a memo and request the event be added to the agenda for the next applicable full board meeting. If the event is clearly not unexpected, does not suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) and/or is not serious and is not related to or possibly related to participation in the study than was previously known or recognized, the Chair may determine that no further action is needed.

At the discretion of the Chair, any event, incident, experience, or outcome can be forwarded to the Board for consideration and determination.

The IRB Administrator will include the submission on the next applicable agenda and notify the investigator in writing that the submission has been forwarded to the Full Board for review.

If a finding is made that a UAP may have occurred and the project is federally funded, prompt reporting will be made to OHRP per their current guidance. If a finding is made that a UAP has occurred, regardless of funding source, remediation plans will be made and required to be implemented by the PI.

**Reporting Timeframe:** The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting to OHRP where appropriate, except "promptly." For a more serious incident, this may mean reporting to OHRP within days.



For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow by the earlier of:

- a specific date; or
- when an investigation has been completed or a corrective action plan has been implemented.

#### **Reference Policies:**

[Guidance on Reporting Incidents to OHRP \(2011\)](#)

[Unanticipated Problems Involving Risks & Adverse Events Guidance \(2007\)](#)

[Guidance on IRB Continuing Review of Research \(2010\)](#)

[Guidance on Written IRB Procedures \(2011\)](#)

## **RESEARCH INVOLVING VULNERABLE POPULATIONS**

### **8.0 Requirements for Research Involving Vulnerable Populations**

Federal regulations acknowledge the challenges of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The Radford University IRB also considers terminally ill patients and institutional residents as potentially vulnerable.

When investigators propose the inclusion of some or all subjects, including Radford University Students and Radford University staff, who are likely to be vulnerable to coercion or undue influence, the Investigator and IRB will consider additional safeguards, as necessary, to protect the rights and welfare of these subjects.

Investigators wishing to include potentially vulnerable populations as either the "targeted" population or in the demographics of the potential subject pool must provide information relevant to their inclusion in the applicable paperwork for consideration by the IRB. Information including but not limited to subject selection, recruitment and consenting procedures, and justification for the inclusion of vulnerable subjects and any additional safeguards should be included. IRB forms and form instructions have been designed to elicit information that the IRB needs to review, consider, and evaluate in order to make the determinations required under regulation and approve research.

When reviewing projects involving vulnerable or potentially vulnerable subjects, the IRB follows Full Board or Expedited Review Procedures (§6.3 and §6.4 of this document) as applicable and will be sufficiently qualified to review such projects either through representation of individuals knowledgeable on the Board or will rely on consultants to provide additional expertise as needed.



In its review, the IRB will consider information provided by the PI and may request additional information or clarification as needed before approving the research.

The IRB systematically evaluates research and the protocol submission and considers the inclusion of vulnerable subjects on a protocol-by-protocol basis including the justification for the inclusion of vulnerable subjects or populations in the study and any additional safeguards that may be needed to protect the rights and welfare of these subjects and minimize risks. Additional safeguards may include, but are not limited to:

1. Using an adult third party not involved in the research to witness informed consent
2. The inclusion of a consent monitor or subject advocate
3. A waiting period between initial contact, consent discussion and enrollment to allow time for family discussion and questions; **and/or**
4. Provisions for additional consent protections such as obtaining consent from a legally authorized representative (LAR) and/or assent from subjects with limited autonomy.

In addition to the regulatory criteria set forth for the approval of research, in the absence of additional codified protections, when reviewing projects that may involve vulnerable populations, the IRB may consider approving research that involves vulnerable subjects if at least one of the following conditions is met:

1. The research does not involve more than minimal risk to the subject
2. The research is likely to benefit the subject directly, even if the risks are considered to be more than minimal; or
3. The research involves greater than minimal risk with no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.

For all research involving vulnerable or potentially vulnerable subjects, IRB records, including but not limited to, documents submitted by the PI and reviewed and approved by the IRB or Chair's designated reviewer, minutes and/or reviewer comment sheets (for projects undergoing full board or expedited review) will document the inclusion of vulnerable subjects, and protocol specific findings, additional safeguards and determinations of the IRB for research involving pregnant women, human fetuses, neonates, prisoners, children, and/or other vulnerable populations.

The IRB must approve a protocol for the enrollment of potentially vulnerable subjects prior to their inclusion in the protocol. If the IRB does not approve a project for the inclusion of vulnerable subjects, the Investigator must revise the project prior to the inclusion of any individual or class of individuals deemed vulnerable or potentially vulnerable.



If a member of a vulnerable population is enrolled whose population has not been approved for the project, the IRB must be notified as soon as possible.

### **8.1 Inclusion of Pregnant Women, Fetuses and Neonates in Research**

Definitions:

Pregnancy: Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the presumptive signs of pregnancy, such as missed menses, until the results of pregnancy testing are negative, or until delivery.

Fetus: The product of conception from implantation until delivery.

Neonate: A newborn.

Pregnant women or fetuses may be involved in research if all of the following conditions are met ([45 CFR 46 §204](#)):

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. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

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7. For children (as defined in [§4.5.8](#) of this document) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
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.

Neonates of uncertain viability and nonviable neonates may be involved in research if all the following conditions are met ([45 CFR 46 §205\(a\)](#)):

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 under paragraph (b)(2) or (c)(5) of this section 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.
4. The requirements of paragraph (b) or (c) of this section have been met as applicable.

According to [45 CFR 46 §205\(c\)](#), if the neonate is nonviable after delivery, all of the following additional conditions must be 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; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of [45 CFR 46 §116\(c\)](#) and (d) do not apply.

However, 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 to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).



According to [45 CFR 46 §207\(b\)](#), research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates will be sent to the Secretary of the Department of Health and Human Services for review. The Secretary will determine the approvability of the research based on the conditions stated in [45 CFR 46 §207\(b\)](#).

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## **8.2 Inclusion of Prisoners in Research**

Definition:

Prisoner: any person involuntarily confined or detained in a penal institution. The term also includes persons detained in other facilities (e.g., group homes, work release centers) by statute or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, as well as persons detained pending arraignment, trial, or sentencing.

[45 CFR 46 Subpart C](#) is applicable to all biomedical and behavioral research involving prisoners as subjects.

The use of prisoners as subjects is severely limited since such subjects' ability to voluntarily consent is limited by the "coercive nature of the environment." All research involving prisoners will require full committee review. If a subject in an ongoing research study subsequently becomes a prisoner, the researcher must report this to the IRB immediately so that the IRB can review the protocol again with a prisoner representative present, to adequately assess the special conditions that the prisoner will face with respect to continued participation in the study while incarcerated.

DHHS funded research involving prisoners must be approved by both the local IRB and the federal funding department/agency head.

The research must be limited to 'minimal risk' studies of criminal behavior and incarceration, penal institutions and prisoners as a social class; research on conditions affecting prisoners--including social and psychological problems--only if approved by the department/agency head after expert consultation; and therapeutic research, with control groups also requiring the department/agency head's approval. Unfunded and non-HHS supported research does not require approval by the federal agency.

A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB. At least one member of the IRB must be either a prisoner or a prisoner representative/advocate with appropriate background and experience to serve in that capacity. The IRB can approve research involving prisoners only if it finds that:

1. The research under review represents one of the categories of research permissible under [45 CFR 46 §306\(a\)\(2\)](#); **AND**
2. 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; **AND**
3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers; **AND**
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project; **AND**
5. The information is presented in language which is understandable to the subject population; **AND**
6. Adequate assurance exists that parole boards will not consider 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; **AND**
7. Where the IRB finds there may be 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, considering the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

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### 8.3 Inclusion of Children in Research

Definitions:

Children: persons who have not attained the legal age for consent, or not classified as an emancipated minor, to treatments or procedures involved in research or clinical investigations, under the applicable laws of the jurisdiction in which the research or clinical investigations will occur.

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

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

Parent: the child's biological or adoptive parent

Guardian: an individual who is authorized under state or local law to consent on behalf of a child to general medical care when general medical care includes participation in research.



Children are recognized as vulnerable under the federal regulations and as such have additional protections codified under [Subpart D to 45 CFR 46](#). For studies involving children, the IRB may approve only the categories of research listed below provided all applicable criteria are met:

1. **Research not involving greater than minimal risk** ([45 CFR 46 §404](#)), if the IRB finds that no greater than minimal risk to children is presented, the approval may be given only if adequate provisions are made for soliciting the assent of the children and the permission of at least one (1) parent/guardian.

Please see [Section 6.2.2](#) of this manual for policies regarding passive "Opt-out" parental consent.

Minimal risk means *"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 activities or during the performance of routine physical or psychological examinations or tests."* [45 CFR 46 §102\(i\)](#)

2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects** ([45 CFR 46 §405](#)), if the IRB finds that more than minimal risk to children has been presented by the intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, **approval may be given only if the IRB finds:**
  - A. The risk is justified by the anticipated benefit to the subjects, **AND**
  - B. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches **AND**
  - C. Adequate provisions are made for soliciting the assent of the children and at least one (1) parent/guardian.
3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subject's, but likely to yield generalizable knowledge about the subject's disorder or condition** ([45 CFR 46 §406](#)), if the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, **approval may be given only if the IRB finds that:**
  - A. The risk represents a minor increase over minimal risk, **AND**
  - B. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, **AND**
  - C. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, **AND**



- D. Adequate provisions are made for soliciting assent of the children and permission of BOTH parents/guardians.
4. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children** ([45 CFR 46 §407](#)), if the IRB does not believe the research meets the requirement of [§404](#), [§405](#) or [§406](#), **approval may be given if:**
- A. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
  - B. The Secretary of the Department of Health and Human Services, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
  - C. That the research in fact satisfies the conditions of [§404](#), [§405](#), and/or [§406](#) as applicable, **or**
  - D. The following:
    - i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
    - ii. The research will be conducted in accordance with sound ethical principles;
    - iii. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

### **8.3.1 Requirements for Consent and Assent Involving Children**

In addition to the determinations required under other applicable sections of [45 CFR 46 Subpart D](#), the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall consider the ages, maturity, and psychological state of the children involved.

This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accordance with [45 CFR 46 §116\(d\)](#):



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

In addition to the minor's assent, researchers are also responsible for obtaining the permission of the child's parent or guardian as set forth in the *Code of Virginia*, [§32.1-162.18](#), [45 CFR 46 §116](#) and any additional elements the Radford University IRB deems necessary.

One parent's signature is sufficient for research that is minimal risk or greater than minimal risk with prospect for direct benefit to the participants ([§8.3](#), Radford IRB Manual, [45 CFR 46 §404-405](#)).

For research conducted under [45 CFR 46 §406 and §407](#), consent is required from both parents/guardians unless:

1. One parent is deceased, unknown, incompetent, or not reasonably available **OR**
2. Only one parent/guardian has legal responsibility for the care and custody of the child.

Parental consent must be documented according to [45 CFR 46 §117](#).

Minors who are wards of the state as defined in [§4.5.7](#) of this document, require the addition of a participant advocate to the IRB. One individual may act as an advocate for more than one minor.

The Radford University IRB requires the advocate to disclose any conflicts of interest. Only those persons without conflicts of interest can be appointed as advocates.

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#### **8.4 Inclusion of Adults Who Lack Decision Making Capability**

Special procedures for IRB review and approval are necessary for research projects involving incapacitated adults. The term incapacitated refers to diminished or absent decision-making capabilities. Impaired capacity is not limited to individuals with neurological, psychiatric, or under the influence of a substance diagnoses. Conversely, individuals with these problems should not be presumed to be cognitively impaired.

Generally, cognitively impaired potential or actual research subjects may not understand the difference between research and treatment or the dual role of the researcher. Therefore, when appropriate, it is essential that the assent process clearly indicate the differences between individualized treatment (e.g., special education in the classroom setting) and research. PIs may want to consider using an independent expert to assess the participant's capacity to consent or assent.



Commonwealth of Virginia law requires the presence of a legally authorized representative **and** an adult witness during the consent process of any adult that has been judged to have a diminished decision-making capability.

The Radford University IRB will only approve research involving adults that cannot consent provided the following criteria are met:

1. The research question cannot be answered by using adults able to consent, **AND**
2. The research is of minimal risk or more than minimal risk with the prospect of direct benefit to each individual participant, **AND**
3. The assent of the adult will be a requirement for participation, unless the adult is incapable of providing assent, **AND**
4. When assent is obtained, the PI will document the assent by noting on the consent or assent form that the subject assented to participate in the research

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## **8.5 Inclusion of Radford University Employees and Students in Research**

In addition to pregnant women, children, prisoners and incapacitated adults, the Radford University IRB considers, in some circumstances, students and employees a population requiring special consideration. For example, students and employees may be in subordinate or collegial relationships with researchers that make it difficult to consent freely, without undue influence, to participate in research.

Therefore, the Radford University IRB follows special procedures designed to safeguard these subjects.

The IRB will approve research that includes Radford University employees and students provided all of the following conditions exist:

1. The research must not bestow upon participating Radford University subjects any competitive academic or occupational advantage over other Radford University students or employees who do not choose to participate. If an advantage is offered, an alternative shall be provided for non-participants, **AND**,
2. No penalty can be levied against any student or employee who does not volunteer, **AND**,
3. Any participating RU employees or students should not be treated differently from non-affiliated study participants.

The Radford University IRB will review all Exempt, Expedited and Full Board studies involving the participation of Radford University students and employees.

### **8.5.1 Research Involving Students as Research Subjects**



Subject pools are defined as students enrolled in particular departmental courses encouraging participation in one or more research projects.

The following items must be observed when considering research involving students:

1. All student participation in subject pool research must be completely voluntary.
2. Reimbursement for participation must not jeopardize the student's confidentiality or anonymity.
3. Alternatives must be provided for classes that offer research participation, and these alternatives should be of equal time burden.
4. It is up to the student to decide whether to participate in a particular study; instructors cannot require or mandate student participation.
5. Instructors are strongly discouraged from recruiting subjects they directly supervise or selecting subjects on such basis.

### **8.6 Older Adults, Cognitively Impaired or Institutionalized Subject Populations**

It is generally agreed that the elderly is, as a group, heterogeneous and not usually in need of special protections, except in two circumstances: cognitive impairment and institutionalization. Under those conditions, the same considerations are applicable as with any other nonelderly subject in the same circumstances.

In the past, persons in nursing homes or other institutions historically have been selected as subjects because of their easy accessibility. It is now recognized, however, that conditions in institutional settings increase the chances for coercion and undue influence because of the lack of freedom inherent in such situations. Research in these settings should therefore be avoided, unless the involvement of the institutional population is necessary to the conduct of the research.

Points to consider:

1. Does the proposed consent process provide mechanisms for determining the adequacy of prospective subjects' comprehension and recall?
2. How will subjects' capacity to consent be determined?
3. Will the research take place in an institutional setting? Has the possibility of coercion and undue influence been sufficiently minimized?