Radford University Institutional Review Board

Policies and Procedures

POLICIES AND PROCEDURES FOR

PROTECTING HUMAN SUBJECTS FROM RESEARCH RISKS

RADFORD UNIVERSITY INSTITUTIONAL REVIEW BOARD

Approved August 2007

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INTRODUCTION

1.0 Purpose and Scope of this Manual

The Institutional Review Board documents its written procedures, according to 45 CFR 46 §115(a)(6), 45 CFR 46 §103(b)(4) and 45
This manual contains current policies and procedures and will be regularly updated to reflect new standards, regulations and Radford University (RU) policy. The policies set forth in this manual are applicable to all faculty, staff, employees and students at RU 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 and 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 research done as part of a class or as a class requirement. 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 of 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 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 State of Virginia regulations governing human research as promulgated in Title 32.1 Chapter 5.1 of the Code of Virginia (§32.1-162.16 through §32.1-162.20).

Further information and additional forms may be obtained from the IRB website, the IRB office at 201 Walker Hall, or by calling (540) 831-5290. The IRB Administrator is available to respond to questions or concerns.

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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 Part 46).
OHRP evaluates all written substantive allegations or indications of noncompliance with DHHS regulations. The relevant institution is notified of the allegation and is 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.

Office of Human Research Protection
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Toll-Free Telephone within the U.S. (866) 447-4777
Telephone (301) 496-7005
Fax: (301) 402-0527
Email: ohrp@osophs.dhhs.gov
http://www.hhs.gov/ohrp

1.3 Applicable State 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: 800-552-7096.
Section 32.1-162.16 defines the following:

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.

Human research means any systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to 45 CFR 46 §101(b).

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 him;

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.

1.4 Administration of Research Compliance- Radford University
The Vice Provost for Academic Administration and Institutional Effectiveness, Dr. Ricky Slavings, Ph.D., is responsible for the administration and oversight of research compliance at Radford University. He oversees the functioning of the Institutional Review Board (IRB).

For questions please contact:

Laura Noll
(540) 831-5290
irb-iacuc@radford.edu

1.5 The Radford University Institutional Review Board (IRB)

The Institutional Review Board for the Review of Human Subjects Research (hereinafter IRB) is composed of five or more individuals. The IRB must include a faculty member with scientific expertise and faculty member with non-scientific expertise, a non-university affiliated community member, a member of the student body (graduate or undergraduate) and one faculty member familiar with student psychological adjustment issues. The IRB meets throughout the calendar year on at least a monthly basis. Members serve staggered three-year terms except for student members, who will only serve for one academic year. A Chair will be elected every other year to a two-year term. A Vice Chair will also be elected for a two-year term with the intent to become Chair at the end of that term. This will allow the Vice Chair to become familiar with IRB issues and procedures prior to becoming Chair. The University's IRB is appointed by and responsible to the Vice Provost for Academic Administration and Institutional Effectiveness, who for purposes of federal registration is also designated the Institutional Official.

2.0 General IRB Policies

The RU IRB policies are governed by 45 CFR Part 46. The Radford University IRB Registration Number is IRB00003066 and the RU 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 and the Chair) and (b) 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 an unbiased evaluation is not feasible, they will inform the IRB Chair and not participate in an event 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 subject’s 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. OHRP will be promptly notified when IRB membership is modified to satisfy this federal requirement.

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.

2.0.3 Suspension and Termination Policy

In any instance in which IRB requirements are not being followed, the IRB will inform (within five (5) working days) the PI and the Radford University IRB Administrator, who will be asked to enforce the requirements. In the event that the PI does not comply with these additional measures, the Vice President for Research and Planning 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 Vice Provost for Academic Administration and Institutional Effectiveness occur, these will be reported to the Secretary of the Department of Health and Human Services and appropriate funding agencies by the Vice Provost for Academic Administration and Institutional Effectiveness within seven (7) working 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.

2.1 Meetings

The Radford University IRB holds regular meetings usually on the third Monday of each month from 3-5 PM. The deadline for submission of research protocols requiring full IRB review and approval is fifteen (15) working days before the schedule meeting. Materials submitted for review after the submission deadline will not be considered for review by the IRB until the next scheduled meeting. Graduate students must submit protocols requiring full IRB review within ten (10) working days of the scheduled meeting.

2.2 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 are signed by the IRB chair and kept on file at the office of the IRB Administrator.

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.

2.3 Approval Timeframes

Exempt, expedited, and full review studies are approved for a maximum period of one year from the approval date. Expedited and full review studies must be re-approved within ten (10) days of the study’s expiration date, and the original anniversary date is retained for all re-approvals.

2.3.1 Student Research with Human Subjects

Student research with human subjects generally falls into two categories, (1) course projects and (2) independent or directed research projects.
A. Course Projects

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 RU IRB approval unless they:

1. Involve the questioning of children;
2. Ask about illegal activities (e.g. underage drinking) that can be subpoenaed by a court of law;
3. Involve socially stigmatizing behavior and/or attitudes;
4. Involve the use of emotionally charged subject matter
5. Involve the use of videotaping and/or audio taping

B. Independent or Directed Research Projects

Anything not falling under §2.3.1(a) of this document must be reviewed and approved by the RU IRB, the IRB Chair, or the Chair’s designee. This includes:

1. Honors theses
2. Independent undergraduate research projects
3. Master’s theses
4. Non-thesis graduate research projects

It is the responsibility of the faculty advisors to ensure that course projects are conducted according to the standards of their relevant discipline.

The faculty advisor is responsible for determining whether an undergraduate program is exempt from 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.

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2.4 Continuing Review Notices
The IRB office will send PIs e-mail notices sixty (60) days prior to the study expiration date, and mail notices thirty (30) days prior to the study’s expiration date for all expedited and full review studies. One (1) past due letter will be mailed to PIs, who will have (10) working days to comply, before research termination procedures are implemented (§2.0.3 of this document).

2.5 Research Protocol Files

Protocol files are maintained in locked offices in the IRB Office. Records are retained per 45 CFR 46 §115(b).

Each protocol file contains the following:

1. A copy of the IRB review form
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 faculty and students)

2.6 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 academic misconduct should be directed to the IRB Administrator.

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 once research is initiated. All confidentiality procedures must be brought before the RU IRB. Any research that will address sensitive, stigmatizing, or illegal subjects must explicitly outline the steps they will take 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, a Certificate of Confidentiality should be obtained.

3.1 Data Collection over the Internet

Data Collection: Any data collected from human subjects over computer networks must be transmitted in encrypted format. 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.

Data collected using online survey instruments must not contain requests for identifying information of subjects (this includes name, address, email address, SSN and student ID number). 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 study code within the invitation document is highly recommended by the IRB.

Server Administration: It is recommended that online data be collected by a professionally administered survey server 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. There will be documented, regularly scheduled security audits or security scans of the server that should be provided to the IRB Administrator for inclusion in the research protocol file. It is the responsibility of the principal investigator to ensure that any servers utilized adhere to these statutes.

Data Storage and Disposal: If a server is used for data storage, personal identifying information and IP addresses should be kept separate from the data, and such data should be stored in an encrypted format. Data backups should be stored in a secured location that is environmentally controlled and has limited access. Data destruction services 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 and/or that encryption of responses is not provided.

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 $10,000 or 3% of the equity of the sponsor;
5. Has received payments or other incentives from the sponsor that are in excess of $10,000 total;
6. Has identified him or her self 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

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 promulgated by 45 CFR 46 §115(b).

Research protocol files, as defined per §2.5 of this manual, shall be retained or archived for three (3) years after study closure. At that time, the files will be destroyed. As per §2.2 of this manual, the minutes of each IRB meeting will be retained by the office of the IRB Administrator and are kept for a period of five (5) years, at which point they can be destroyed.

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
5. 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:

1. Potential odds and amount of winning
2. Individual responsible for drawing the winner
3. Individual responsible for observing the drawing, to ensure the results are not biased.

3.5 Equitable Subject Recruitment

The IRB will evaluate all research applications to determine that every effort has been made to 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 every effort 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 the opportunity to compare the OPSGM proposal to the IRB application. It is the responsibility of the principal investigator to apprise the IRB of the appropriate proposal number.

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.
4.0 Informed Consent

Except in situations described in §4.3 and §4.4 of this manual, 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 RU 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 the 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. It is the responsibility of the principal investigator to remove any coercive language and to minimize other influences. The RU IRB will examine all informed consents to ensure that all research protocols protect research subjects from undue influence to participate. An 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.

4.1 Essential Elements of Informed Consent

"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 45 CFR 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. The word research must be used in the explanation.

2. **Purpose of the project**
   Explain why the research is being done and why you are asking the subject to participate.

3. **Procedures**
   Describe what happens to the subject, what the subject needs to do as part of the research and what the expected duration of the experiment will be. This section should give detailed descriptions of what will be performed in a language that the participant can easily comprehend.

4. **Risks**
   Clearly explain the psychological, physical, and/or social 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.

5. **Benefits**
   Clearly outline any potential direct benefits to the subject. Explain clearly how likely it is that these benefits will occur and outline what the indirect benefits may be. If no benefits are known at the time of the research, state, “There are no known direct benefits.”
6. **Alternatives**
   Use this section to clearly explain what will happen if the subject decides not to participate in the study, whether the subject can get or do the same thing without participating and what else is available if they decide not to participate.

7. **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. Where and how the data will be stored should also be included in this statement.

8. **Compensation**
   For studies that have greater than minimal risk, explain who will pay if the subject becomes injured. For studies that have payments or reimbursement, this section should be used to explain how much will be paid, what kind of reward it will be, and what the schedule of payment will be. For studies that have multiple payment disbursements, this section should also explain the payment consequences of early withdrawal from the study.

9. **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). 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 refuse to answer any questions or to decline to respond to situations that they choose without penalty.

10. **Subject responsibilities**
    This section should have a statement that clearly outlines the subject responsibilities or the study director can have the subject write the items in to confirm understanding of subject responsibilities.

11. **Subject permission**
    This section should contain the following statement: “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.”

12. **Number of subjects in the study**
    The number of subjects or approximate number should be stated here, or may be contained within one of the sections described above.

13. **Contact information**
    Use this section to list the contacts for any pertinent questions about the research, conduct or subject’s rights and/or whom to contact in the event of injury. The investigator, faculty advisor (if student is performing the research), and the RU Institutional Officer contact information should be included.
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 signed consent form should be given to the subject.

***Consent forms are not valid unless an unexpired validation stamp from the RU IRB is present***

4.2 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 promulgated in §4.1 of this document. Consent form templates are available on the IRB website.

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 8th 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 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.

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 must 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, 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 consents submitted to subjects will have an official Radford
4.3 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:
   i. Public benefit or service programs
   ii. Procedures for obtaining benefits or services under those programs
   iii. Possible changes in or alternatives to those programs or procedures
   iv. Possible changes in methods or levels of payment for benefits or services under those programs

4.4 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:

1. The research presents no more than minimal risk of harm to subjects and involves procedures that do not require written consent when performed outside of a research setting, or
2. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality.

4.5 Additional Consent Information

In some cases, the informed consent document will need additional information. In particular, studies that involve the use of
4.5.1 Studies that Involve Sensitive Questions

Risks Section:

1. Be specific regarding the potential risks (psychological, social, legal, economic, dignity and/or physical). Be aware of potential emotional distress during the completion of surveys.
2. Provide a detailed explanation of the study’s efforts to reduce potential risks.

Confidentiality Section:

1. Provide subject with contact information of professional counselors within the area that are available for his/her use.
2. Use clear language that indicates any use of the counselors by the subject will be at the subject’s expense.
3. 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.
4. Provide a thorough explanation of how the study will ensure the confidentiality of this sensitive information.

4.5.2 Studies that Involve Deception

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 RU 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 instances in which no consent can be obtained or debriefing done, but the researcher should make reasonable attempts to obtain 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 deception research 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 merit of the research must counterbalance the risk to the subject.

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 express regret for the necessity of deceiving the subject(s), should explain what the deception was and why it was necessary, it should offer the subjects a chance to ask questions and should 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 the study can ensure confidentiality of data gained from the deception
5. Inform the subject that they have the right to have data obtained from the research destroyed instead of used for data analysis

The IRB requires that the study have subjects sign the debriefing form to provide written consent for the use of the data during data analysis.

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### 4.5.3 Studies Involving Audio or Video Recordings

Studies involving the use of audio and/or video recording of human subjects do not qualify for exempt status. Subjects must provide full consent before any 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 experiment. Participants can stop the recording at anytime and have the right to have those records destroyed. 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. Optional recording should have an additional space at the end of the consent document that allows 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 tape(s).
2. Who will be transcribing the recordings.
3. Who will have access to the recordings.
4. When and how the tapes will be erased/destroyed.

4.5.4 Studies Involving Students and Extra Credit

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

1. The amount of 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.

4.5.5 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.

The child should be given an explanation of the proposed research procedures 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 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. That 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 “Request for Initial Review of Research Protocol” 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 6th 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.

4.5.6 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 not yet approved by the IRB.

4.5.7 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

1. 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
2. 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),

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 RU IRB. One person may serve as advocate for more than one child. 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.

4.5.8 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. Since 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 RU students) may not be used as a participant in human subjects research without first obtaining parental permission (unless waived) and the student’s assent.

Definitions

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

**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.

**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.

**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).
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 CITI Human Subjects Training. The researcher is responsible for submitting the certification form to the IRB Administrator. Certification must be received before any protocol requiring IRB review will be approved. Proof of education will be retained by the IRB and need not be submitted except with an initial protocol. Certification is valid for three years. After three years, it must be renewed. Researchers who believe they have completed education comparable to the online course should contact the IRB Administrator.

5.1 Training for IRB Members

IRB members, alternates, and the prisoner advocate are provided with training that provides information and copies of the following information:

1. Policies and Procedures of the IRB
2. Public website for the IRB
3. Quarterly education segments distributed with the meeting agenda

5.2 Training for IRB Staff Members

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

1. Policies and Procedures of the IRB
2. Public website of the IRB

Attendance at regional and national meetings, such as PRIM&R, is encouraged and supported for staff members.
6.0 Initial Review Requirements

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). All forms can be downloaded from the Radford University IRB webpage. All forms can be electronically submitted, although any documents that require an original signature must have the signature page printed, signed, and submitted to the IRB Administrator. See Section 2.3 for the approval timeline for IRB submissions.

The following are required for all IRB submissions:

1. A completed, signed copy of the Investigator Agreement Form.
2. The Request for Initial Review of Research Protocol Form with an original signature. The Request form and documents can be electronically submitted, but IRB review and approval will not occur until the original signature page(s) have been submitted.
3. Consent document templates
   (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 of the information of a consent document, without a signature line and without any IRB approval language.
4. Bio-sketch or CV for all investigators
5. Training verification- the NIH certificate must be submitted to the IRB Administrator.

6.1 Submission Schedule Requirements

There is usually one IRB meeting per month. Meetings are usually held on the third Monday of each month, except for the month of December, when special dates are assigned. The deadline for submission of any full board review packets is 15 working days (3 weeks) prior to the meeting date. Any full board protocols received after the submission deadline will not be reviewed until the next scheduled IRB meeting. See the IRB website for meeting dates and submission deadlines. If the study is eligible for Expedited or Exempt review, it will be reviewed in the order received.

The IRB Administrator receives all research applications and evaluates the protocol to determine 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 the IRB Chair. IRB staff and/or the IRB Chair review the agenda for protocols involving vulnerable populations and ensure that the IRB includes persons knowledgeable about or experienced in working with these participants or obtains consultation.
6.2 Exempt Review

Exempt research must be of minimal risk. 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. If the protocol meets all requirements for Exempt Review, it is reviewed by the IRB Administrator, who will correspond with the PI via phone or email until the study is acceptable. The study is then available for review by the IRB Chair or the Chair’s designee. All administratively approved protocol titles and PIs will be reported in the appropriate agenda and minutes to the IRB at the next monthly meeting.

Listed below are the six categories of human subjects research that the federal government considers to be exempt. Research must be of minimal risk. Any research involving prisoners may not be granted exemption, regardless of the risk level. 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. Research with children (under age 18) is eligible for exempt review under Category 2 of 45 CFR 46, §101(b)(2) only if the research involves surveys of children, interviews of children, or observation of public behavior where the investigator(s) do not participate in the activities being observed. Although not regulated by federal regulations, the RU IRB does not allow exemption for any studies involving videotaping or audio taping.

Exempt research must fall into one of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. research on regular and special education instructional strategies, or
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
   c. the research is not FDA regulated

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
   c. the research involves surveys of children, interviews of children, or observation of public behavior of children where the investigator(s) participate in the activities being observed.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   a. the human subjects are elected or appointed public officials or candidates for public office; or
   b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens,
if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (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.

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 be required for exempt research, provided that the elements of consent are clearly stated on the questionnaire themselves or on a cover letter. Protocols not meeting the above criteria are referred for expedited or full board review.

6.3 Expedited Review Process

Protocols determined to be minimal risk, but not falling into any exempt category, may be considered for expedited review. The IRB Administrator and the IRB Chair review the protocols fulfilling the requirements for expedited review to ensure completeness and will correspond accordingly with the PI(s) by phone or email until the packet is complete. A reviewer then completes the Expedited review checklist. The protocol is then available for review by the IRB, the IRB Chair, or the Chair’s designee. Expedited protocols cannot be disapproved by the IRB Administrator or the IRB Chair/Chair’s designee. If the PI is ultimately unwilling to make these changes, then the expedited study will be upgraded to the full board review category. All 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.

Research must meet all of the following criteria in order to be reviewed by the IRB through an expedited review procedure (45 CFR 46 §110):

1. Be of minimal risk to the subjects
2. Must not involve prisoners or mentally impaired persons

3. Must be in one or more of the following categories:

   A. Clinical studies of:

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

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

   B. 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, 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.

   C. Prospective collection of biological specimens for research purposes by noninvasive means.

      Examples:

      (a) hair and nail clippings in a nondisfiguring manner;

      (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

      (c) permanent teeth if routine patient care indicates a need for extraction;

      (d) excreta and external secretions (including sweat);

      (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing 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 subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

      (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

      (j) sputum collected after saline mist nebulization.

   D. 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 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
amounts of energy into the subject or an invasion of the subjects privacy; 
(b) weighing or testing sensory acuity; 
(c) magnetic resonance imaging;
(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, 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.

E. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

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

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

6.3.1 Online research may be restricted based on the probability of research subjects’ adverse reactions and will be considered on a case-by-case basis. Minimal risk research will be reviewed by a member of the Exempt Sub-committee who has the option to recommend further review by the Expedited Sub-committee; more than minimal risk research will be reviewed by a member of the Expedited Sub-committee who has the option to recommend a FULL BOARD review.

6.3.2 Researchers must insure that the storage of data of more than minimal risk is in an adequately encrypted format if the data are digital.

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 Chair and the IRB Administrator 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. The IRB Administrator provides a complete set of documents to each IRB member, who is asked to review the protocol(s) and supporting documents in detail. These documents are mailed to all Board members, 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 insure 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.
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. For initial review applications, all Board members are provided with a Review Checklist (A or B) to complete. Each member is responsible for completing the checklist and returning it to the IRB Administrator.
7. After complete and individual discussions, each protocol is voted upon for one of four possible dispositions: approve, disapprove, table, or provide contingent approval.
   a. **Approved**- The IRB accepts and endorses without reservations “approved” studies.
   b. **Approved with Contingencies**- Studies approved with contingencies, the IRB accepts and endorses provided the PI concurs with the requested changes and recommendations.
   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 needed 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 several major areas. 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. 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 within 3 days of the IRB meeting. Letters are sent to the PI through campus mail.

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 reports to the IRB either at a shorter time interval or after a specified number of subjects are enrolled. The PI’s reports 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.

6.5 **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 RU IRB Administrator 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 RU 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 must propose conditions for successful resolution of the situation (see “Possible Outcomes” below). Any PI with outstanding study closure reports 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 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 Appeals Process**

If the IRB FULL COMMITTEE decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond orally or in writing. The details of this opportunity should indicate that the PI has a right to appeal in person at the next scheduled meeting of the IRB FULL COMMITTEE that reviewed the research or to respond in writing to the IRB. After an in-meeting appeal or the receipt of a written appeal, the IRB FULL COMMITTEE will vote again. The second vote of the IRB FULL COMMITTEE will be final.
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 (http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm). Therefore, if research was initially approved by the convened Board, continuing review will normally be considered by the convened Board.

The RU 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.

The Continuation Request/Study Closure Report submitted by Investigators and considered by the IRB provides a status report on the progress 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.

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. The approval period can be no more than 12 months and is based on the information available and the perceived risk to the subject.
Investigator Responsibilities: Investigators must submit typed answers to the Continuation Request/Study Closure Report, and the most recent copy of approved informed consent (if new subject enrollment continues). Any revisions must be submitted according to the revision guidelines. Failure to respond to either the 60 day, 30 day or past due notices within the specified time period will be considered general non-compliance.

Office Responsibilities: Continuing Review submissions received by the IRB Administrator are entered into the database and reviewed for completeness (which includes the use of current forms and inclusion of all required paperwork) 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 RU IRB administrative requirements will be scheduled for the meeting.

Reviewer Responsibilities: During the week prior to the meeting (whenever possible), all board members will receive an electronic copy of all documents as described above.

A designated reviewer is assigned; and the designated reviewer will receive a hard copy of all supporting documents in addition to the electronic copy. The reviewer is responsible for considering and evaluating the responses provided by the Investigator on the Continuing Review/Study Closure Report, 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 Administrative 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. The IRB should ensure that new information or findings, which may relate to the subjects’ willingness to continue participation is provided to study subjects. Applicable Reviewer Comment Sheets are provided and should be completed and submitted as described in Review of Research. The discussion of the continuing review application is led by the designated assigned reviewers 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.

7.1 Amending Approved Protocols

Investigators are responsible for reporting 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. When a proposed change in an approved research study is not minor; that is, the revision involves greater than minimal risk to subjects, the revision must be reviewed at a convened meeting of the IRB before the change can be implemented. Minor changes in previously approved research may be reviewed utilizing an expedited process (See Expedited Review Process: Revisions).

The IRB must consider 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, and changes in study population. 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 are implemented for the safety of the subject prior to IRB review and approval, such changes must be reported to the IRB within 5 days, with any supporting documentation necessary for the IRB to make a determination that 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.

**MAJOR revisions** involve changes that may increase the risk to subjects 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. These revisions are placed on the IRB agenda and are assigned to two designated reviewers 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.

**Investigator Responsibilities:** The preliminary determination of revision type is the responsibility of the investigator. Investigators must submit a completed Request for Modification Form and, if necessary, a cover letter, explaining the revisions, protocol, Informed Consent Form and/or other forms, and any information to be provided to the subject to the IRB Office. Changes to the protocol, consent, IRB forms, or other documents must be indicated in the track modifications tool in Microsoft word. See the Request for Modification form on the IRB website for more information. In addition, “clean” copies of affected documents must be submitted if revisions were made.

**Office Responsibilities:** Major revisions received by the IRB Administrator are entered into the database and reviewed for completeness (which includes the use of current forms and inclusion of all required paperwork). Once complete, the submission, including all of the supporting documents provided by the PI and those provided by the IRB Administrator including a project history, the last IRB-approved informed consent, and the current protocol, is forwarded on for inclusion on the applicable meeting agenda and determination of review status. Reviewer Comment Sheets are attached to each hard copy.

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### 7.2 Unanticipated Problems: Identifying and Reporting

Federal Regulations (45 CFR 46 §103(b)(5)) require that 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. Although the regulations do not define unanticipated problems, OHRP (2007) published guidance on unanticipated problems.

**Definitions**

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

a. 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;

b. 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

c. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, social harm) than was previously known or recognized. Events that do not cause detectable harm or adverse effects to or others may still represent unanticipated problems.

Both **risks to subjects** and **risks to other individuals** (e.g., research personnel, subjects’ family members) are included in the concept of UPRs. Risks may reflect any type of potential harm (e.g., physical, psychological, social, economic).
Any major problems involving human subjects should be reported to the IRB immediately. In addition, any subjects exhibiting signs or symptoms of the unanticipated problem should be referred to the IRB Chair for assistance. Any 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 within 5 working days of discovery. If an event, incident, experience, or outcome is life-threatening or fatal, the IRB must be notified by phone within 24 hours.

**Office Responsibilities:** Reportable events (serious and unexpected adverse events and/or unanticipated problems) received by the IRB Administrator are entered into the database and reviewed for completeness (which includes the use of current forms and inclusion of all required paperwork).

**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.

**RESEARCH INVOLVING VULNERABLE POPULATIONS**

**8.0 Requirements for Research Involving Vulnerable Populations**

Federal regulations acknowledge the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The IRB also considers terminally ill patients and institutional residents as potentially vulnerable. When investigators propose the inclusion of some or all subjects, including RU Students and RU 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 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. Any subject who may be considered vulnerable enrolled in a project without prior IRB approval should be reported in writing to the IRB within 5 business days of discovery.

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;
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).

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 take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; 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, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

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.
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. 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, 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:
1. That the research in fact satisfies the conditions of §404, §405, and/or §406 as applicable, or
2. 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 take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in 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. State 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 RU 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

8.5 Inclusion of Radford University Staff and Students in Research

In addition to pregnant women, children, prisoners and incapacitated adults, the RU IRB considers students and staff a vulnerable population. Students and staff are likely to be in subordinate or collegial relationships with researchers that make it difficult to consent freely, without undue influence, to participate in research. Therefore, the RU IRB follows special procedures designed to safeguard these subjects. The IRB will approve research that includes RU staff and students provided all of the following conditions exist:

1. The research must not bestow upon participating RU subjects any competitive academic or occupational advantage over other RU students or staff who do not volunteer
2. No penalty can be levied against any student or staff member who do not volunteer, AND
3. Any participating RU staff or students should not be treated differently from other non-affiliated study participants

Due to the potential for perceived or real coercion to participate, RU students and staff who desire to participate in the research must not be under the direct supervision of the PI or listed as research collaborators except as necessitated by scientific merit or overwhelming benefit to subjects unless approved by the IRB.

The RU IRB will review all studies involving the participation of RU students and staff (exempt, expedited and full board). The IRB may waive any and/or all of the above conditions provided the study demonstrates either of the following:

1. Overwhelming benefit to the subject, OR
2. Reasonable scientific merit

8.6 Student Subject Pools

Subject pools are undergraduate students enrolled in particular departmental courses encouraging participation in one or more research projects. All student participation in subject pool research must be completely voluntary. Reimbursement for participation must not jeopardize the student’s confidentiality or anonymity. Alternatives must be provided for classes that require research participation, and these alternatives should be of equal time burden. It is up to the student to decide whether to participate in a particular study; instructors cannot require or mandate student participation. Instructors are strongly discouraged from recruiting subjects they directly supervise or selecting subjects on such basis.

8.7 Elderly and Aged Individuals

It is generally agreed that the elderly are, 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 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?