REGENT UNIVERSITY

RESEARCH AND SPONSORED PROGRAMS HANDBOOK

A Guide for Research Involving Human Subjects

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1. Introduction

Regent University has always placed a high priority on the pursuit of knowledge that aligns with ethical, legal, and Christian standards. In a time marked by rapid research advancements and global collaboration, it becomes imperative to document policies guiding the way we conduct research at our institution. Central to this commitment is our Institutional Review Board (IRB), an interdisciplinary team ensuring that all human subject research not only meets federal ethical standards but also embodies Regent's unique mission and vision. Our mission, "to provide excellent education through a biblical perspective and global context, equipping leaders to change the world," is linked with our research philosophy. Hence, the Regent IRB's review processes exemplify this mission statement by ensuring that our research process is not only academically robust but also ethically grounded and globally relevant, thereby supporting leaders with the knowledge and integrity to drive meaningful change.

While federal regulations such as the Revised Common Rule primarily govern federally-supported research, Regent University aspires to meet and transcend these benchmarks. We apply the principles and procedures relevant to federally-funded research across all research proposals, reflecting our motto, "Christian leadership to change the world." Researchers will find references to specific federal codes and regulations throughout this handbook, as we highlight the relevance of each code to our IRB's processes.

Beyond the IRB's role, this handbook clarifies the broader ethical guidelines that underpin our research, including Biblical foundations, federal and Virginia state regulations, and the rights of research participants. It outlines the informed consent process, with particular attention to minors and vulnerable populations, and addresses research misconduct. The operational aspects of the IRB, such as submission procedures, types of review, review approval timelines, and guidelines for researchers seeking IRB approval, are thoroughly detailed in this handbook.

The handbook also includes some relevant policy and guidance on aspects of our University organizational life pertinent to research but it is not a contract. Policies are subject to revision and are offered alongside related policies found in other documents such as the Faculty and Academic Policy Handbook, Employee Handbook, etc. For instance, it contains the policy on Specially Recognized University Centers (SRUC), defining their role, classification, and operational principles. It explains the nuances of various types of research, including human subjects or participants, vulnerable populations, and international research. This handbook is an essential resource for Regent researchers, covering risk management, compliance, training, mandatory certifications, and vital aspects of record-keeping, documentation, and maintaining confidentiality in research.

Collaborations with external entities, including inter-institutional agreements and guidelines for collaborative research, are also addressed. Procedures for reporting problems, handling complaints, and appeal processes are outlined in this document in order to foster a responsive and responsible research culture.

This research handbook is not just a directive but a resource, offering templates, checklists, additional readings, and resources to support our researchers. Our goal is to align the pursuit of transformative knowledge with a steadfast commitment to ethically sound research practices, deeply rooted in Regent values. This document will guide and support our researchers in projects that not only meet ethical, legal, and Christian benchmarks but also contribute significantly to our vision: "to be the most influential Christian, transformational university in the world."

1.1 Purpose of the IRB

Research involving human subjects has the responsibility to protect their rights, welfare, and privacy. The IRB at Regent University is a multi-disciplinary, cross-departmental committee, constituted in accordance with the federal mandate (45 CFR 46.107).

The IRB's primary objective, as mandated by the Revised Common Rule (45 CFR 46), is to review, assess, and oversee research involving human subjects. This review ensures that every research activity aligns with established federal standards, safeguarding participants from potential harm while also ensuring their informed consent, and preserving their dignity.

A. Primary Functions

I. ***Review of Potential Risks.*** The IRB is dedicated to critically evaluating the potential risks associated with proposed studies. It also examines the measures proposed by the research team to protect participants from these risks (45 CFR 46.108, 46.109, 46.111).

II. ***Research Design Consideration***. While the main goal of the IRB is not to critique the research design, 45 CFR 46.111(a)(1) highlights the importance of ensuring that participant risks are minimized through sound research design. Thus, the IRB might offer feedback on design, especially when it directly impacts participant risks and benefits or unnecessarily exposes them to such risks.

III. ***Protection and Assurance.*** An approval from the IRB does not equate to a research endorsement but rather serves as an assurance. It signifies that, if conducted as per the approved protocol, the research upholds the dignity, rights, and welfare of its participants. This assurance can offer some measure of protection to researchers from potential research-related liabilities.

B. Commitment to the Common Rule

In 1991, multiple federal departments[1] established the Federal Policy for the Protection of Human Subjects, popularly known as the 'Common Rule'. It underwent revisions that

[1] United States Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency, Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs;

became effective in January 2019 (details available at HHS site www.hhs.gov/ohrp; 45 CFR 46). While this rule is binding for institutions receiving federal research funds, Regent University has chosen to extend the Common Rule principles (see below) to all human subject research, irrespective of the funding source. This decision underscores our unwavering commitment to the highest ethical standards.

C. Guiding Ethical Principles

Our regulations are influenced by the internationally recognized ethical tenets discussed in the Belmont Report (1979). These are:

I. ***Respect for Persons.*** This principle recognizes the worth of all individuals, granting them autonomy and protecting those with diminished autonomy. Before participation, human subjects must be fully informed about the research and voluntarily consent to participation. For example, if a researcher from the School of Education is conducting research on the lived experiences of students, he or she must ensure that human subjects are fully aware of the nature, purpose, and potential impacts of the research. Special considerations are in place to safeguard the rights of populations who might be vulnerable to coercion or undue influence. Extra precautions should also be undertaken when involving minors or individuals with cognitive impairments to protect their autonomy and well-being.

II. ***Beneficence.*** This principle mandates that researchers should have the welfare of the human subject as a goal. In other words, Regent University researchers must do no harm by maximizing possible benefits and minimizing potential risks. Prior to initiating research, a preliminary analysis is conducted to weigh the potential benefits against the risks involved. This can be done by intentionally formulating a research design that maximizes positive outcomes while reducing risks. Throughout the research, continual monitoring is essential to ensure the participants' safety and well-being. Regent researchers must conduct regular reviews and adjustments based on real-time data and feedback to continually uphold the principle of beneficence.

III. ***Justice.*** This principle emphasizes that the benefits and burdens of research should be distributed fairly. It necessitates that the selection of research subjects is equitable and just, thus ensuring that the selection process for human subjects is fair and does not unduly involve groups who may be susceptible to higher risk or fewer benefits. As an illustration, a research project from the Robertson School of Government aiming to study societal trends based on data from human subjects should ensure, when pertinent to the research focus, the diverse representation of participants from various socio-economic backgrounds to uphold the principle of justice. We acknowledge that sometimes diversity is not possible given the subject matter of the research (e.g., a project focusing on college enrollment in a minority community). Regardless, all

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Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; Department of Transportation.

participants are entitled to fair treatment during the research process, such as establishing mechanisms to prevent bias and prejudice in research processes and ensuring a fair and respectful treatment of all participants.

For a more in depth understanding of these ethical principles, we recommend referring to the Belmont Report.

1.2 Regent Christian Commitments

Regent University is committed to fostering a research environment that is firmly grounded in Biblical principles, drawing on the rich heritage of scriptural teachings. This defines and gives context to our particular research culture. As we commit ourselves to 'changing the world' through research innovation and excellence, it is imperative to integrate the following considerations based on our values as a Christian institution:

A. ***Respect for the 'Imago Dei' in Every Individual.*** All research activities uphold the dignity, worth, and uniqueness of each individual as made in God's image (see Genesis 1:27). This perspective highlights the importance of upholding the ethical principles discussed in 1.1.c. And thus, in accordance with federal policy for the protection of human participants (see Revised Common Rule), researchers are expected to prioritize the welfare, rights, and safety of participants, making sure they are not put at an unreasonable physical, mental, or emotional risk.

B. ***Love and Beneficence.*** The goal of research at Regent University should be to promote the welfare of individuals and society as a whole, imitating the love of Christ (see 2 Corinthians 5:14–15). Potential harms should be kept to a minimum while potential benefits should be maximized (see 1.1(c)). This is in line with upholding the principle of justice, striving for a selection of participants that is not tainted by invidious discrimination, mirroring the biblical call to "act justly" as found in Micah 6:8. This emphasizes our duty as stewards of God's love and care for humanity (1 Peter 4:10).

C. ***Christian Integrity and Honesty.*** All research processes and findings should be communicated truthfully, free from deception or manipulation (see Psalm 51:6; John 8:32). Researchers are expected to conduct their studies with honesty, avoiding falsification or manipulation of data, which resonates with the commitment to truthfulness expressed in the commandment against bearing false witness (Exodus 20:16). We promote openness, integrity, and reliability in our research as a reflection of the character of God. In rare cases, and only with sufficient justification in the face of the potential costs to subjects, the use of deception is determined to be the only feasible way to investigate a specific research question. For instance, this may be necessary if subject responses are likely to be substantially distorted if the subjects are aware of all of the details of the question.

Case Example: Imagine a study on the effects of performance pressure. If participants knew the true objective was to measure their stress levels under observation, they might behave differently, trying to appear less stressed, thus skewing the results. Therefore, researchers might tell participants that the study is about something else to preserve the integrity of the data. This is a form of deception that could be justified if the research could not be conducted in any other way without influencing the subjects' genuine reactions.

In other words, full disclosure to subjects might not be possible because it could significantly alter the responses or outcomes, leading to unreliable data. This is common in psychological studies where knowing the true nature of the study might affect participants' behavior. As Boynton, Portnoy, and Johnson (2013) have noted, deception *may* only be approved when stringent conditions have been met, such as

- The absence of any alternative way to do the study that would not use deception;
- the compelling potential contribution of scientific knowledge that would result;
- a determination that there would be no "significant harm or severe emotional distress" to the participants caused by the deception;
- a debriefing to the subjects occurs as soon as possible explaining the deception that has occurred, its purpose and offering appropriate support for any psychological consequences.

D. ***Pursuit of Wisdom and Knowledge.*** In keeping with Proverbs 2:6, "For the Lord gives wisdom; from his mouth come knowledge and understanding," research should be a sincere pursuit of God's truth (see Psalm 51:6), with the goal of positively contributing to the academic community and society at large.

E. ***Stewardship.*** As custodians of God's creation, we should manage our resources, participants, and data with utmost care and responsibility (see Genesis 1:26-28). The biblical principle of stewardship encourages researchers to utilize resources responsibly and to contribute constructively to the community and the world. This involves ensuring the sustainability of our research methods, protecting human subjects' data, and making judicious use of research funds. Researchers are encouraged to work towards the betterment of society, embodying the stewardship principle outlined in 1 Peter 4:10: "Each of you should use whatever gift you have received to serve others, as faithful stewards of God's grace in its various forms."

F. ***Compassion***. In line with the Christian call to compassionate living in Colossians 3:12, the principle of compassion can be implemented in a research project by a shared dedication of the research team to understand and alleviate human suffering. Research aimed at understanding and alleviating human suffering should be designed with empathy and a genuine desire to help, reflecting the values mentioned in Colossians 3:12: "...clothe yourselves with compassion, kindness, humility, gentleness, and patience."

G. ***Community and Collaboration.*** In line with the Christian ethos of community/*koinonia*, research at Regent encourages interdisciplinary collaboration. By collaborating through research, we reflect the diverse 'body of Christ,' combining our strengths to achieve research excellence.

H. ***Commitment to Regent's Christian Values.*** All research undertakings should align with our Christian commitments as articulated in our key policies such as Regent's Statement of Faith, the core tenets of our Christian goals or the Statement of Christian Community and Mission. This means that research topics and methodologies should not contravene the foundational principles upheld by the University. For instance, no activities may occur in university facilities that are inconsistent with its Christian mission.

I. ***Academic Freedom and Christian Mission.*** Regent's Academic Freedom policy is found in the Faculty and Academic Policies Handbook. It states that a "…faculty member may choose topics, may pursue any line of approach or inquiry, and may disseminate his/her opinions and conclusions in whatever form and forum he/she chooses" in a manner consistent with Regent's Christian commitments. Regent's Christian commitments reflect the explicitly affirmed, common convictions of those who voluntarily come to work at Regent. Thus, our scholarship is informed by this common adherence as its starting point. Regent does not understand this as a barrier to academic freedom but as an instance of it, since the Regent community are jointly pursuing research guided by its shared worldview. This provides a multiple millennial long tradition of scholarly inquiry spanning many cultures, historical epochs, and academic contexts. Regent's Christian commitments are compatible with a broad range of scholarly paradigms that operate in the disciplines active at Regent.

J. ***Engaging the World with Christian Perspective.*** While research at Regent is deeply rooted in Christian beliefs, it should also aim to dialogue with wider academic and societal discourses. Engaging secular perspectives with respect, humility, and conviction allows for a richer understanding and contribution to global knowledge.

K. ***Continuous Reflection and Prayer.*** Every research project should be accompanied by continuous reflection and prayer, seeking God's guidance, wisdom, and discernment in every phase.

This Christian commitment provides motivation for Regent's community of scholars to aspire to academic excellence in a way that also exemplifies serving as a beacon of Christ's love, wisdom, and truth in the world.

2. Ethical Principles

To maintain the integrity and quality of scholarly endeavours, research must be founded on ethical principles. In this section, we explain the fundamental ethical principles that guide research at Regent University, placing special emphasis on how federal and state regulations shape these principles.

2.1 Federal and Virginia State Regulations

In line with the biblical foundations that guide research ethics at our institution, adherence to federal and Virginia state regulations is imperative to maintain the integrity and lawful conduct of research activities. These regulations function as a structural framework within which the research progresses, ensuring that it meets the established norms and safeguards for the well-being of participants and the community at large. Here, we summarize the key regulations that govern research ethics at our institution.

2.1.1 Federal Regulations

Regent University strictly adheres to the U.S. Department of Health and Human Services' regulations for the protection of human research subjects, outlined in Title 45, Part 46 of the Code of Federal Regulations. These regulations provide a framework for ensuring the rights, welfare, and well-being of research participants.

A. ***The Revised Common Rule*** (45 CFR 46; also see 1.1(b) above). This federal policy, revised in 2018, delineates the principles for the protection of human subjects involved in research. The rule prescribes that the selection of participants should be equitable and that safeguards should be instituted to protect the privacy of participants and maintain the confidentiality of data. When designing research, researchers are expected to adhere strictly to these guidelines, ensuring the transparent and ethical treatment of participants, with due respect for their privacy and well-being. We will elaborate on some of these guidelines in subsequent pages of this handbook.
B. ***The Belmont Report*** (1979). A cornerstone document that outlines the basic ethical principles and guidelines to address ethical issues arising from the conduct of research with human participants. It emphasizes respect for persons, beneficence, and justice (see 1.1(c) above). Researchers must ensure that their studies uphold the principles outlined in the Belmont Report.
C. ***Conflict of Interest*** (45 CFR 94). This federal regulation prescribes that researchers should disclose any conflicting interests that might potentially bias the research. The aim is to prevent financial or other interests from compromising the objectivity and integrity of the research. All potential conflicts of interest should be transparently disclosed to the IRB.

2.1.2 Code of Virginia

Regent University's location in the state of Virginia means its research practices are not only influenced by federal guidelines but also must comply with specific state regulations. Virginia has established a series of codes and regulations that address research practices and the protection of human subjects in order to ensure the rights and welfare of all participants. Here are the relevant sections of the state of Virginia Code and regulations that Regent adheres to (most of which are similar to the federal regulations):

A. ***Informed Consent*** (Va. Code § 32.1-162.18). Virginia's Code mandates that researchers obtain informed consent from all participants. The process must be thorough, ensuring participants understand the nature of the research, its risks, and benefits. Written documentation of this consent is also necessary (see 2.3).

B. ***Human Research Review Committee*** (Va. Code § 32.1-162.19). Virginia requires research institutions to have an established human research review committee that reviews and oversees any research involving human subjects (see 3.1 to 3.3). The establishment of an IRB is also in alignment with federal guidelines.

C. ***Confidentiality*** (Va. Code § 54.1-2400.2). This section of the Code emphasizes the importance of maintaining confidentiality in research. Regent ensures that all personal data, records, and findings remain confidential unless explicit permission is granted.

D. ***Virginia's Data Protection Act*** (Va. Code § 18.2-186.6). Research involving the collection of personal data must adhere to this Act: the need for security measures to protect against unauthorized access, use, or disclosure of personal information of human subjects.

E. ***Use of Animals in Research*** (Va. Code § 3.2-6500 to 3.2-6590). While these sections primarily relate to animal welfare, they are critical for any institution in Virginia involved in research with animals. They mandate proper care, housing, and ethical treatment (also see 5.8).

F. ***Protection of Minors*** (Va. Code § 40.1-100 to 40.1-103.4). When research involves minors, Virginia State regulations mandate specific protections (e.g., Informed Consent, Risk Assessment, Confidentiality, Regular Oversight, Benefit Assessment, Special Provisions for Sensitive Topics), ensuring that the rights and welfare of minors are prioritized.

G. Va. Code § 32.1-162.16 to 32.1-162.23 has specific regulations addressing research's ethical considerations, which ensures that all such projects adhere to the highest standards of ethics and responsibility. We will cover some of these regulations in subsequent pages.

2.2 Rights of A Research Participant

The following rights are presented to ensure clarity, respect, and protection for individuals participating in human subjects' research approved by the Regent IRB.

A. Participants have the right to be informed about the nature and purpose of the research they are participating in.
B. A clear description of any potential discomforts or risks that might reasonably be expected from participation should be provided.
C. Participants should be provided with a signed (except in situation where a waiver is applied, see 2.3.5.1 and 2.3.5.2) and dated copy of their written consent form, detailing all the aspects of the research. The written consent form is the default means of documenting the informed consent (see 45 CFR §46.117).
D. If applicable, participants should be given an explanation of any benefits they might reasonably expect from their participation.
E. Information on any suitable alternative procedures, drugs, or devices that might be beneficial, and a comparison of their risks and benefits, should be provided.
F. Participants should receive a thorough explanation of all research procedures, including any drugs or devices that will be used.
G. At any point during the research, participants should know that they have the right to withdraw their consent and discontinue participation without facing any repercussions.
H. Participants must be informed of any available medical treatment options should complications arise during and post-research.
I. Participants have the right to ask any questions about the research or associated procedures and expect clear answers.
J. If an aspect of the research protocol is against the religious beliefs or core values of a potential participant, informed consent should not be sought, even through a legally authorized representative (e.g., someone who has the legal authority to make decisions on behalf of a participant who cannot consent for themselves). This could be due to various reasons such as the participant being a child, having cognitive impairments, or being incapacitated.
K. The decision to participate or not should be entirely the participant's, and free from any form of force, deceit, coercion, or undue influence.
L. Specific populations, such as foster care children and youth, are safeguarded from participating in research where there could be a potential conflict of interest, especially when governmental bodies are involved.

These rights ensure that the dignity, rights, and well-being of research participants are at the forefront of every research project. Upholding these rights is not just a legal mandate but a moral and ethical responsibility for Regent University researchers.

2.3 Informed Consent

Informed consent is an important process in research involving human subjects. It ensures that participants voluntarily agree to partake in a study after fully understanding its implications. For research connected to Regent University, it is imperative that all human

participants, or their legal guardians (in cases where the participant is a minor), provide this consent. While minors offer assent, legal guardians are responsible for giving consent.

In certain exceptions, there might be a waiver for documented consent or the entire informed consent process. Additional details and clarifications can be found at the official Regent IRB webpage.

While the informed consent document serves as a vital legal instrument, the Principal Investigator (PI) bears the responsibility of effectively communicating its contents to participants. Please note that the PI is the individual who has been formally designated by Regent to have the appropriate level of authority and responsibility to direct a research project or program. This person would oversee all scientific, ethical, regulatory, and administrative aspects of the research. The selection of a PI at Regent would typically follow the respective Regent College or School's policies, often involving approval from departmental heads or committees or the Regent IRB.

It is paramount that participants' agreement to be involved is acquired freely, without any external pressures. Therefore, the content of the document should be transparent, devoid of technical jargon, and should use language tailored to the participant's age and comprehension levels in order to ensure that they grasp all essential details before deciding to participate.

The updated regulations in the Revised Common Rule introduce an enhancement in the informed consent document (refer to 45 CFR 46.116(a)(5)), which emphasizes the upfront presentation of crucial details essential for the decision-making process. This involves:

A. Explicit mention that the research seeks consent, and that participation is discretionary.
B. Objectives of the research, expected duration, and the procedures involved.
C. Foreseeable risks or potential discomforts.
D. Anticipated benefits, either to the participant or to others.
E. Alternatives to the proposed procedures, if any, that might be beneficial to the participant.
F. The IRB evaluating the Informed Consent information in addition to the research proposal. The aim is to ensure that all important details a "reasonable person" would desire to know before participating have been articulated clearly in order to make an informed decision (as per 45 CFR 46.116(a)(4)).

Beyond the aforementioned key details, there are nine foundational elements of consent that need to be considered, though contingent on their relevance to specific types of studies (see below).

2.3.1 Foundational Elements of Informed Consent (45 CFR 46.116(b)(1-9))

Here is a clear breakdown of what you should expect to see in a standard informed consent form. If an element is not pertinent to the research at hand, it is not obligatory to include it in the informed consent.

A. ***Study Introduction.*** Clearly state that the project is research-based, explain the objectives of the research, the anticipated duration of the participant's involvement, detail the steps involved, and highlight any experimental elements. It is also recommended that the researcher clarify their association with Regent University within this section.

B. ***Potential Risks.*** The Informed Consent must mention any foreseeable risks or discomforts the participant might encounter during the research.

C. ***Anticipated Benefits.*** Describe any benefits that might accrue to the participant or others from the research. Note that remuneration for participation is not considered a benefit.

D. ***Alternative Procedures.*** If applicable, discuss any alternative procedures or treatment routes that might be more beneficial to the participant. If participants are being recruited from a specific course or for extra credit, the consent form must clearly mention this and provide details about alternative assignments or tasks available.

E. ***Confidentiality.*** Detail the measures taken to ensure the confidentiality of records that identify the participant, though confidentiality may be breached if the participant expresses intent to harm themselves or others, as the researcher has a duty to report such risks to prevent harm.

F. ***Compensation and Medical Treatment.*** For any kind of research, mention if there is any compensation available, and if there are medical treatments in place in case of any injury during the research (especially when it entails more than minimal risk).

G. ***Contact Information.*** Provide details on whom participants can reach out to for queries about the research, their rights as a participant, or any research-related injuries. This section should ideally include the contact details of the Principal Investigator and the faculty advisor, if relevant. In addition, a brief description of the IRB and its role can be beneficial.

H. ***Voluntary Participation.*** Highlight that the participant's involvement is voluntary, they can decline without any repercussions, and they can withdraw at any stage without facing any penalties.

I. ***Data Handling in Future Research.*** For research collecting identifiable information or biospecimens, include one of the following:
    I. Indicate that identifiable data might be anonymized and potentially used for future research without needing further consent.
    II. State explicitly that the data or biospecimens gathered will not be used for future research, even if anonymized. PIs should also disclose if they plan on using the same data for further research.

As much as possible, ensure that your informed consent document is concise, preferably confined to a single page, but still comprehensive. The format of the document can vary based on what best conveys the information, such as a letter or a Q&A format. Sample consent forms are available on the Regent IRB webpage for reference.

2.3.2 Guidelines for Drafting an Informed Consent Document

A. Start by outlining important details for a prospective participant's decision-making regarding their involvement in the research.
B. Adopt a legible font such as Times New Roman or Arial at 12-point size.
C. Maintain consistent spacing, especially after bolded headings, and establish 1-inch margins throughout.
D. Try to confine the content to a single page without omitting vital information.
E. Engage prospective participants by employing direct pronouns like “you” and “your”.
F. Write with clarity and simplicity, targeting an 8th-grade comprehension level.
G. Abstain from using specialized or scientific terminology and avoid unnecessarily long or convoluted sentences.
H. Instead of the term ‘research subject’, use ‘participant’ to honor and emphasize the autonomy of those involved.
I. Disclose your identity at the outset. If conducting research as a student, it is prudent to also mention your supervising faculty advisor.
J. Explicitly state the reasons for inviting a specific participant, such as specific criteria or qualifications they meet.
K. Emphasize that all research, irrespective of its perceived magnitude, entails inherent risks.
L. If the research is being conducted on Regent University's campus, ensure that participants are equipped with the contact details of the Regent Counseling Services or our Psychological Services Center. This provision ensures they have accessible support channels should any unforeseen risks or concerns surface during the duration of the study.

2.3.3 Additional Elements for Informed Consent (45 CFR 46.116(c)(1-9)

When appropriate and relevant to the research project, the following supplementary elements should be incorporated into the informed consent process:

A. ***Unforeseeable Risks.*** Participants should be informed of potential risks, including unforeseeable ones (e.g., the potential for unknown long-term side effects from a new intervention or treatment being tested).
B. ***Termination of Participation.*** Details of any conditions under which the researcher might end a participant's involvement without their consent.
C. ***Potential Additional Costs.*** Any potential costs that may arise for the participant as a result of their participation should be outlined.
D. ***Withdrawal Consequences.*** Explanation of the outcomes should a participant decide to withdraw, including the steps for orderly exit. If participants receive course or extra credit for participation, this should be addressed.
E. ***Communication of New Findings.*** Assurance that any significant discoveries made during the research that could influence a participant's decision to continue will be communicated.
F. ***Participant Count.*** Declare the approximate number of participants in the study.
G. ***Commercial Use of Biospecimens.*** Notification if the participant's biospecimens might be used for commercial gain and whether they will share in any profits.
H. ***Disclosure of Research Results.*** Clarity on if and when clinically relevant research results will be shared with participants.
I. ***Whole Genome Sequencing.*** For research involving biospecimens, inform participants if the study might include whole genome sequencing.

If researchers plan to share de-identified data (e.g., via the Open Science Framework or in a research database), the de-identification and sharing procedures should be clarified to participants with informed consent.

2.3.4 Documentation for Informed Consent

Consent should be documented with an IRB-approved written form signed by the participant or their legally authorized representative (see detailed guidelines on storage of research documents in Section 9 of this handbook). This includes digital signatures as per 21 CFR 11.1(a). A copy (either physical or digital) should be provided to the signatory.

The consent form can either:

A. Be a comprehensive document that adheres to the requirements of 45 CFR 46.116.
B. Be a concise form indicating that required consent elements were orally presented, with a written summary of the presentation. For this, the IRB must approve the written summary, and a witness should be present during the oral presentation.

When consent is procured in a non-English language, additional criteria may be needed, such as evidence of accurate translation. For further details, consult the Regent IRB.

While federal guidelines allow certain research categories to deviate from these standards, the Regent IRB mandates that even exempt research must have comprehensive informed consent documents. If any alterations or omissions are requested for an exempt research application, they must be justified in the IRB application.

2.3.5 Waiver of Informed Consent

2.3.5.1 Waiving the Requirement for a Signed Consent Form (45 CFR 46.117(c))

The IRB may, under specific conditions, grant a waiver of the requirement for a Principal Investigator to obtain a signed informed consent form from participants. The waiver can be granted if the IRB determines:

A. ***Confidentiality Concerns.*** The sole record associating the participant with the research is the informed consent form, and the main risk is potential harm from a confidentiality breach. Participants or their legally authorized representatives will decide if they desire a record connecting them with the research.

Case Example: Regent researchers are investigating the efficacy of a new rehabilitation technique for post-stroke patients. Participants' progress, both medical and therapeutic, is closely monitored. The only document that links a patient to this research is the informed consent form. If there is a confidentiality breach, participants could face potential bias from insurers or employers due to their medical history. To avoid this risk, some participants, or their legally authorized representatives, opt not to keep any records associating them with the study. However, alternatives are possible, such as assigning each participant a unique number and separating out the name in a separate file to associate it with the number.

B. ***Minimal Risk.*** The research poses minimal harm to the participants and does not involve procedures that usually necessitate written consent outside the research setting.

Case Example: Researchers at Regent University are conducting research on the study habits of university students. Participants are observed in the university library during normal study hours, and the researchers record general non-identifiable data such as the frequency of study breaks and the use of digital versus print materials. Since the observation occurs in a public setting and does not involve interaction with the students or disruption of their study behavior, and because the data collected does not include personal identifiers, the risk to participants is deemed minimal. Thus, the IRB may not require written consent for this study.

C. ***Cultural Considerations.*** For participants or their legally authorized representatives from distinct cultural groups or communities where form signing is not customary, the research should present minimal harm risk. There should also be a suitable alternative method to document that informed consent was secured.

Case Example: Researchers at Regent University are conducting a study on traditional storytelling practices within a remote indigenous tribe. Within this tribe, written documentation is not customary, and form signing is viewed with suspicion, as it is seen as a form of binding agreement that they are unfamiliar with. Given the cultural sensitivities, Regent researchers may decide to use a voice recorder, with the tribe's permission, to orally document informed consent. In this audio format, tribal elders and participants verbally express their understanding of the study and give their approval. The research itself is non-invasive, merely involves listening to stories, and poses minimal harm risk to the participants.

Note: *Even if the requirement for a signed informed consent document is waived, researchers must still record that the informed consent process occurred. They should also provide participants or their legally authorized representatives with a written summary of the research in the subject's native language. This written summary might need prior review and approval by the IRB.*

2.3.5.2 Waiver or Alteration of Informed Consent (45 CFR 46.116(e-j))

When conducting research, there may be circumstances under which obtaining informed consent in its standard form is either not feasible or not in the best interest of the research objectives. Under these circumstances, the Regent IRB may grant a waiver or alteration of informed consent. No waiver of obtaining informed consent is permissible without Regent IRB approval.

Definitions:
Waiver of Informed Consent (45 CFR 46.116(f)(1)). The IRB waives the need to obtain informed consent for specific research that would typically require it.

Alteration of Informed Consent (45 CFR 46.116(f)(2)). The IRB approves a consent form that lacks some of the standard elements of informed consent. However, the general requirements for informed consent, including the provision of key information (i.e., 45 CFR 46.116(a)), remain intact.

Conditions for Waiver or Alteration:
Research may qualify for a waiver or alteration of informed consent if:

A. The study poses minimal risk to participants.
B. The study could not feasibly be conducted without the waiver or alteration.
C. If the research uses identifiable private data or biospecimens, it cannot practically proceed without accessing the data or biospecimens in an identifiable format.
D. The waiver or alteration will not negatively impact participants' rights or welfare.
E. When suitable, participants will receive relevant additional information after their participation.

Additional Circumstances for Waiver:
Research might be considered for a waiver or alteration if:

A. It is overseen or approved by state or local government officials and aims to:
   i. Assess public service or benefit programs.
   ii. Examine procedures to obtain benefits or services.
   iii. Evaluate potential modifications to those programs or methods.
   iv. Analyze potential changes in payment methods or levels for those services.

B. The study would not be feasible without the waiver or alteration.

In certain cases, the IRB may also approve research involving screening, recruiting, or determining participation eligibility without standard informed consent procedures. Such instances include when the researcher:

A. Obtains information through direct communication with potential participants or their authorized representatives.
B. Accesses identifiable private data or biospecimens from records or stored sources.

Legal Considerations:
Informed consent requirements do not override any federal, state, or local laws that demand additional information for valid consent. They also do not limit a physician's authority to offer emergency care as allowed by law.

For clinical trials, there are unique considerations regarding informed consent processes. Refer to 45 CFR 46.116(h) for more information. For example, for every clinical trial sponsored by a federal entity, one IRB-approved consent form used for enrollment must be displayed on a designated federal website. The supporting federal department can allow or mandate redactions if some information should not be public (e.g., confidential business details). The consent form should be uploaded after recruitment ends, but within 60 days following the protocol's last study visit by any participant.

2.4 Assent for Minors in Research

When minors (e.g., individuals under 18 years old in the state of Virginia or equivalent in other states and countries) are involved in research, it is essential to secure both parental or legal guardian consent and the assent of the minor. While the legally authorized representative (usually the parent or guardian) provides formal consent, the minor's assent ensures that they are willing to participate.

Definitions:

A. ***Consent.*** Formal approval by the parent or guardian for the minor to participate in the research.

B. ***Assent.*** Verbal or written affirmation from the minor indicating their willingness to participate.

Note: "Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR 46.402(b)). This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way."

Procedure:

A. ***Parental Consent.*** Before seeking assent from the minor, written consent must be obtained from their parent or guardian.
B. ***Verbal Assent.*** After securing parental consent, the researcher should obtain verbal assent from the minor. The language used should be age-appropriate and convey the key elements of informed consent.
C. ***Written Assent.*** For older minors, obtaining written assent (in additional to parental consent) might be more suitable. The document should be clear, concise, and use language the minor can easily understand.

Regulations:
Refer to 45 CFR 46.408(a) for detailed guidelines on assent requirements for minors and the provisions for waiving this requirement.

Key Elements for Assent:
While the assent process is simpler than full informed consent, it should still cover the basics:

A. Introduction of the researcher.
B. A brief explanation of the purpose of the study.
C. Outline what participation involves.
D. Assurance that participation is voluntary and that they can opt out at any point.

2.5 Research Misconduct

To uphold the integrity of research conducted under the aegis of Regent University, this policy outlines the definition of research misconduct, the responsibilities of individual researchers, and the procedure for reporting and addressing allegations of misconduct.

Definition of Research Misconduct:

According to the Code of Federal Regulations (42 CFR 93.103), research misconduct refers to any act that involves fabrication, falsification, or plagiarism in the proposal, execution, review, or reporting of research results.

A. ***Fabrication.*** Generating data or results and then recording or reporting them without actual basis.

B. ***Falsification.*** Manipulating research materials, tools, processes, or altering or omitting data or results, resulting in an inaccurate representation of the research.

C. ***Plagiarism.*** Using another individual's ideas, processes, results, or writings without proper acknowledgment.

For an action to qualify as research misconduct, it must:

A. ***Deviate significantly from accepted research norms and practices.*** This includes actions that fall far outside the boundaries of ethical research conduct, such as fabricating data or plagiarizing work. If a researcher invents data for a clinical trial, this would be a clear deviation from the norms of conducting and reporting research.
B. ***Be committed intentionally, knowingly, or recklessly.*** Misconduct must result from a researcher's deliberate intent, a conscious disregard for the truth, or a reckless neglect of research standards. An example is if a researcher knowingly uses another's work without citation, which demonstrates intent and awareness of the misconduct.
C. ***Be supported by substantial evidence.*** There must be a strong and convincing body of evidence to support claims of misconduct, which usually requires a thorough investigation. If multiple witnesses and documentation can confirm that a researcher manipulated research data, this would constitute substantial evidence that could lead to a majority agreement on the misconduct.

Responsibilities of Individual Researchers:

A. Regent researchers must maintain the highest standards of honesty and integrity in all research work.
B. Researchers should promptly report any observed, suspected, or apparent research misconduct to the appropriate university authorities (e.g., Office of Research and Sponsored Programs).
C. Researchers must ensure their research is free from any form of misconduct, including but not limited to fabrication, falsification, and plagiarism.

Procedure for Reporting and Addressing Misconduct:

A. ***Submission of Allegations.*** Any individual who suspects or observes an instance of research misconduct should promptly submit a detailed written report, accompanied by supporting evidence, to Regent's Director of the Office of Research and Sponsored Programs (orsp@regent.edu).

B. ***Review.*** Upon receipt of the allegation, the allegation of misconduct shall be reviewed by a small panel, including the Director of the ORSP, the EVPAA (or designee), and the Chair of the IRB to assess the validity of the claim.
C. ***Further Action.*** If the inquiry suggests a potential case of research misconduct, a thorough investigation will be carried out to determine the facts of the case and decide on appropriate action. The EVPAA will make the final decision on the cause of action.

3. IRB Membership

The Institutional Review Board (IRB) at Regent University is comprised of a diverse group of faculty members as well as non-academic and community members (refer to 45 CFR 46.107(c)). They act as the gatekeepers of ethical, policy, and compliance concerns in human-subject research. To ensure we have a multi-disciplinary IRB committee, faculty members were selected by the Office of Academic Affairs in collaboration with deans from across Regent colleges and schools, including:

- College of Arts and Sciences
- College of Health and Behavioral Sciences
- School of Business and Leadership
- School of Communication and the Arts
- School of Divinity
- School of Education
- Robertson School of Government
- School of Law

This integrative approach ensures that the IRB benefits from a wide range of disciplinary (scientific and non-scientific) perspectives and expertise that fosters a rich environment for ethical decision-making. The collective knowledge base allows for a holistic review of research proposals in order to enhance the board's ability to safeguard the interests of human subjects involved in research conducted at Regent University.

3.1 Composition and Responsibilities

3.1.1 Composition

The Regent IRB includes a mix of core faculty members and non-faculty members (see the IRB webpage for the full list). This integrative approach is carefully adopted to align with federal and Virginia state regulations that govern research ethics and procedures. The composition of the Regent IRB strictly adheres to guidelines stipulated in the federal policy delineated in 45 CFR 46.107, which necessitates the inclusion of at least five members reflecting a diverse representation of gender and cultural backgrounds. The IRB committee includes at least one scientist and one non-scientist, complemented by an individual who neither affiliates with Regent nor is a direct family member of anyone affiliated with it, as mandated by 45 CFR 46.107(c). This specific composition ensures a balanced and unbiased review of research proposals, reminiscent of the ethical principles outlined in the landmark Belmont Report (1979).

Regent IRB operates with a deep commitment to uphold the Federal Policy for the Protection of Human Participants, also known as the Revised Common Rule. Each member, upon appointment, undergoes extensive internal and external training (e.g., mastery of Regent

research policies and research administration software; the Collaborative Institutional Training Initiative (CITI) online tutorial), an important step in fostering an environment of safety and respect for human participants. This proactive approach helps to nurture a board that is well-versed and updated in safeguarding the welfare and rights of human participants in congruence with Regent's mission and operations. A roster of our current IRB membership can be accessed on the official IRB webpage, ensuring transparency and accessibility.

3.1.2 Responsibilities

The responsibilities vested in the IRB are of paramount importance, centered primarily on the protection of human participants involved in research activities conducted at Regent. These responsibilities are multifaceted and involve various components, from proposal review to conflict resolution, each carried out with the utmost diligence and expertise.

A. ***Proposal Review.*** The Regent IRB undertakes the pivotal role of scrutinizing each research proposal, ensuring adherence to ethical standards and federal policies. This process is amplified by the expertise pooled from different schools and colleges, which helps foster a collaborative atmosphere where diverse insights come into play. For instance, a proposal focusing on societal behavior would benefit from the collective insights of IRB members from the School of Communication and the Arts and the Robertson School of Government, ensuring a thorough and balanced evaluation.

B. ***Risk Assessment.*** At the heart of the Regent IRB's function is the assessment of risks associated with research proposals. The board collaborates to conduct a comprehensive risk-benefit analysis to ensure that the potential gains of the research significantly outweigh any potential risks to participants. This is in sync with the federal guidelines that underscore the importance of safeguarding participants from unreasonable physical, mental, or emotional risks (see 45 CFR 46.109(e)).

C. ***Monitoring Research.*** The IRB holds the mantle of overseeing the progress of ongoing research and ensuring stringent adherence to ethical guidelines and federal policies. It applies the principles of the Revised Common Rule, which focus on the continuous monitoring of data and safety provisions for participants, thus fulfilling criteria outlined in sections 45 CFR 46.109(f)(1)(i) and 45 CFR 46.109(f)(1)(iii).

D. ***Conflict Resolution***. The IRB also functions as an adept mediator, stepping in to resolve any conflicts that might arise during the research process. This involves utilizing the diverse expertise of its members to find balanced solutions and maintain the integrity of the research process.

E. ***Regulatory Compliance and Approval.*** Acting in accordance with the federal guidelines specified in 45 CFR 46.109(a), the IRB holds the authority to approve,

mandate modifications, or disapprove research activities involving human participants conducted at or affiliated with our institution. This process is carefully designed to be in line with the Federal Policy for the Protection of Human Participants in order to ensure a responsible and ethical approach to research. In cases where proposals are disapproved, the IRB offers feedback and facilitates an opportunity for researchers to address the noted issues (refer to 45 CFR 46.109(d)).

3.2 Selection and Term of Members

Below, we elaborate on the procedures and criteria for selection of Regent IRB members and the defined terms for members (see 45 CFR 46.107).

3.2.1 Selection Criteria

The selection process is guided by a strict set of criteria based on guidelines outlined in 45 CFR 46.107. The primary aim is to create a body that reflects a wide range of backgrounds, expertise, and perspectives that promote a holistic approach to research evaluation. Here, we detail the various criteria considered during the selection process:

A. ***Expertise and Background***. Members are selected based on their expertise in their respective fields, ensuring a well-rounded understanding and evaluation of research proposals. For example, a faculty member from the School of Divinity might be selected for their understanding of ethical considerations in religious issues.

B. ***Diversity in Race and Gender.*** A conscious effort is made to achieve representation across race and gender, with the hope of fostering a body that can address various perspectives and nuances.

C. ***Community Representation***. In accordance with 45 CFR 46.107(c), at least one member should be unaffiliated with the institution and not part of the immediate family of a person affiliated with the institution so as to provide a community perspective and minimize institutional bias.

3.2.2 Term of Members and Procedures

To ensure dynamism and freshness of perspective, members serve a predefined term, after which a rotation policy facilitates the introduction of new members. The terms are defined as follows:

A. ***Term Duration.*** Regent IRB members are appointed by the Office of Academic Affairs for a period of three years, renewable based on the evaluation of their

contributions and the needs of the IRB. This stipulation helps to prevent stagnation and promotes ongoing growth and adaptation to emerging trends and standards.

B. ***Training and Development***. Newly appointed members are required to complete a comprehensive training program, such as the CITI online tutorials/training, to equip them with the necessary knowledge and skills to protect human participants effectively. On the other hand, new members joining an existing board will undergo one-on-one onboarding sessions with the IRB chair, including training on current ethical standards, procedural protocols, and other relevant areas to equip them adequately for their role.

C. ***Feedback and Evaluation.*** Exiting members will be encouraged to provide feedback on their tenure to glean insights and foster continual improvement. A formal evaluation process might be implemented to assess the contributions of outgoing members and identify potential areas of improvement.

D. ***Rotation Schedule.*** A predetermined rotation schedule (usually at the beginning of the Fall semester through Summer) will be maintained where a portion of the board (e.g., one-third) rotates off at regular intervals, making room for new members to join. This schedule will be publicly available and regularly updated to track the rotation timeline effectively.

E. ***Vacancy Filling Procedure.*** In the event of unforeseen vacancies arising due to resignations, retirements, or other circumstances, the IRB shall initiate a swift procedure to identify and integrate suitable replacements within a designated time frame (e.g., within 60 days of the vacancy arising), thereby ensuring uninterrupted operations.

F. ***Quorum.*** For the purposes of the IRB at Regent University, 'quorum' is defined as a simple majority of the IRB's voting members. This majority must constitute over half of the voting members, specifically at least 51%, and the quorum must include at least one member whose expertise is in non-scientific areas. Each member who is present at an IRB meeting has the same right to vote. It is imperative that a quorum is both achieved and maintained for the duration of the meeting to ensure the legitimacy of the proceedings. If a member has a conflict of interest, they are excluded from the quorum count. For research that falls under the purview of the Food and Drug Administration, the presence of a licensed physician is mandatory for the discussions, deliberations, and voting process, in compliance with the requirements set out in Title 21 of the Code of Federal Regulations, section 56.108(c).

3.3 OHRP Registration and Membership Roster

It is the duty of the Director of Research and Sponsored Programs or an appointed representative to handle the administration of the Office for Human Research Protections (OHRP) registration documentation to ensure it aligns with federal regulations and is up to date. The Director is also tasked with keeping records of the IRB membership list, which is essential for establishing quorum during official meetings. The IRB Membership Roster is required to include specific details for each member:

- Full name of the member
- Degrees obtained
- Classification as a scientist or non-scientist
- Areas of expertise or specialization
- Association status with the institution (either affiliated or non-affiliated)
- Information regarding the voting alternate, if the member has one.

3.4 Conflict of Interest Policy

In order to safeguard the credibility of research processes, it is imperative to have a stringent conflict of interest policy embedded in the operations of the IRB. Adhering to both federal and Virginia state regulations, this policy is designed to forestall any potential biases and ensure an objective review process. The following are the critical components of this policy: disclosure, recusal, transparency, and monitoring.

A. ***Disclosure.*** At the outset of any research proposal review, members of the IRB are required to disclose any potential conflicts of interest that might skew or influence their judgment or the review process. This stipulation is in line with the federal emphasis on maintaining the ethical rigor of research, ensuring that personal or financial interests do not compromise the evaluation process. For example, if an IRB member from the School of Business and Leadership is involved in a startup that stands to benefit from the research under review, it becomes that member's duty to disclose this potential conflict, hence preserving the integrity of the review process.

B. ***Recusal.*** In cases where a conflict of interest is identified, the involved IRB member is expected to recuse themselves voluntarily from the deliberations and review process of that specific proposal. This step is not just about eliminating potential bias; it stands as a testament to the ethical standards upheld by our IRB.

C. ***Transparency.*** Our IRB practices and models stand as a bastion of transparency, with the aim of ensuring that every decision taken is free from undue influence and is grounded in objective analysis. This commitment to transparency extends to clear communication channels and documentation that allows for scrutiny and accountability. Meeting minutes and decision-making processes are documented and

thus offer a clear trail of the rationale behind each decision, making it accessible for necessary scrutiny and fostering an environment of trust and clarity.

D. ***Monitoring.*** To uphold the highest ethical standards in research, continuous monitoring of potential conflicts is essential. The Regent IRB fosters a culture of honesty and openness, wherein members are encouraged to remain vigilant and proactive in identifying and reporting potential conflicts, a practice that aligns well with the regulatory expectations. Regular training and workshops are organized by the Office of Research and Sponsored Programs to keep the members abreast of the nuances of identifying and mitigating potential conflicts in order to foster a proactive approach to maintaining the ethical pedestal upon which the IRB operates.

The conflict of interest policy ensures a fair and objective review of each proposal, such that it helps the IRB to safeguard the interests of both the research community and the participants involved.

4. Research Review Process

The research review process safeguards the principles of ethical research at Regent. It is structured to ensure that respect for persons, beneficence, and justice (see the Belmont Report) are upheld in all research projects undertaken at Regent University. In this section, we outline what the review process entails, starting with the types of reviews (4.1), submission procedures (4.2), and review approval timeline (4.3).

4.1 Types of Review

The types of reviews are integral in ensuring that research conducted within our institution maintains a high standard of ethical integrity. Depending on the nature and scope of the research, it could undergo one of the following types of reviews:

4.1.1 Exempt Review

Research classified under this category is generally perceived to have minimal risk. It involves standardized procedures where the potential for harm or distress is low. Research activities involving human subjects that fall within the specified categories (see below) in 45 CFR 46.104(d) are exempt from full IRB review. However, they must still adhere to the specific requirements and stipulations within each category.

The Final Rule provides eight exempt research categories, but **Regent IRB only approves six of them (i.e., A - F below)** outlined in 45 CFR 46.104(d)(1-6). Categories G and H, associated with broad consent (see 45 CFR 46.116(d)) and conditional exemption based on limited IRB review (45 CFR 46.104(d)(7) and 45 CFR 46.104(d)(8)(iii)) are not recognized categories at Regent.

4.1.1.1 Exemption Categories—45 CFR 46.104(d):

A. ***Educational Settings and Practices.*** Research conducted in recognized learning settings involving typical educational practices. This generally includes studies on both regular and specialized education strategies, as well as research analyzing the efficacy of different instructional techniques, curricula, or classroom management methods.
B. ***Interactions Involving Educational Tests.*** Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior.

Exemption Criteria:

I. Information is recorded in a way that subjects cannot be easily identified.

II. Disclosing subjects' responses would not harm their reputation, finances, job prospects, or education.
III. Information is recorded such that subjects can be identified, but an IRB conducts a limited review as required by 45 CFR 46.111(a)(7).

C. ***Benign Behavioral Interventions.*** Research involving harmless behavioral interventions with adult subjects providing verbal/written responses or being audio-visually recorded.

Criteria:

I. Information is recorded without revealing subject identities.
II. Disclosed responses will not harm the subjects in any way.
III. Identifiable information is used, but an IRB conducts a limited review.

D. ***Secondary Research without Required Consent.*** Uses identifiable private information or biospecimens under certain conditions:

I. Publicly available information.
II. Information recorded without revealing identities and without contacting or re-identifying subjects.
III. Research involves only information collection and analysis in line with 45 CFR parts 160 and 164.
IV. Research carried out by or for a federal department or agency, using data sourced or collected by the government for non-research purposes, is permissible if:
    1. The research produces identifiable private data.
    2. This data is or will be stored on IT systems that adhere to section 208(b) of the E-Government Act of 2002 (44 U.S.C. 3501 note).
    3. All identifiable private data gathered, used, or generated is retained in record systems compliant with the Privacy Act of 1974 (5 U.S.C. 552a).
    4. If relevant, the data for the research was originally collected in line with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

E. ***Public Benefit or Service Program Research.*** Research or projects supported by a federal agency to evaluate public benefit or service programs. Federal agencies must list these projects on a public website or other platforms before starting the human subjects research.

F. ***Food Quality and Taste Evaluation.*** Research involves:

I. Consuming wholesome foods without additives.
II. Consuming food with safe levels of ingredients, agricultural chemicals, or environmental contaminants, as determined by relevant federal agencies (e.g., Food and Drug Administration, the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture).

4.1.1.2 Exemption Submission Procedure

The process for determining if a study qualifies for an exemption from certain IRB requirements typically involves the following steps:

A. ***Initial Assessment by the PI.*** The PI assesses the study against the established exemption categories above (A to F) as defined in **45 CFR 46.104(d).**
B. ***Submission to the IRB.*** The PI submits an application for exemption through Regent's designated research administration software, e.g., Cayuse. Within the submission portal, the PI must detail the justification for exemption, aligning the study with specific federal exemption criteria.
C. ***IRB Review.*** An IRB Analyst or the IRB Chair reviews the submission to verify that the study indeed fits an exempt category. This review is to ensure that, despite the exemption, the study still adheres to ethical standards and federal regulations.
D. ***Decision.*** The IRB Chair makes the final decision on whether the exemption is granted. If the IRB Chair determines that the study meets the criteria for exemption, it will approve the request. However, the IRB Chair or Committee may also require additional information or modifications, or it may determine that the study does not qualify for exemption and requires a full review.

Note: The PI does not have the authority to exempt the study independently; they can only request an exemption by selecting "Exempt Research" in the application. The IRB has the responsibility to decide on the exemption status, ensuring the research complies with all regulatory requirements and ethical standards. Exempt reviews are typically processed more swiftly compared to other types.

4.1.2 Expedited Review

This type of review is reserved for research projects that present no more than minimal risk to participants, involving procedures that are clearly listed in the federal guidelines for expedited review categories (45 CFR 46.110 and 21 CFR 56.110). A 'minimal risk' scenario implies that any anticipated harm or discomfort due to the research is not greater than what is generally encountered in daily routines or during standard physical or psychological assessments (45 CFR 46.102(j)). Even though the research activities mentioned are designed to be minimal risk, exceptions can arise. If the IRB assesses an activity as potentially exceeding this risk threshold, it is imperative to document the rationale for not considering expedited review, and if applicable, reasons for the continuation of the review (45 CFR 46.115(a)). Please note that the term 'expedited' does not infer a 'rushed' review.

Expedited review allows for a more streamlined approval process while still maintaining a focus on the safety and welfare of the participants. Research projects under this category might include studies where data is collected through non-invasive procedures, or

investigations into individual or group characteristics or behavior, where the parameters of the study are well-defined, and risk mitigation strategies are in place.

4.1.2.1 Categories Eligible for Expedited Review

There are nine specific categories of research considered to hold minimal risk as outlined by the Office for Human Research Protections.

A. **Clinical Studies Involving Drugs and Medical Devices.**
   I. Research activities that involve drugs not necessitating an investigational new drug application (21 CFR Part 312).
   II. Research on medical devices which either do not require an investigational device exemption application (21 CFR Part 812) or have received marketing clearance/approval.

B. **Collection of Blood Samples.**
   I. Blood samples drawn from healthy, nonpregnant adults weighing at least 110 pounds, adhering to specific volume and frequency limitations (e.g., < 550 ml in an eight-week period).
   II. Blood sample drawn from other adults and children, taking into account various factors including age, weight, and health, with defined restrictions on volume and frequency (e.g., < 50 ml or 3 ml per kg in an eight-week period).

C. **Noninvasive Biological Specimen Collection for Research.** When gathering biological specimens for research, it is required to utilize noninvasive methods. Here are examples of such specimen collections:

   I. Hair and nail clippings, taken in a manner that avoids the participant being disfigured.
   II. Deciduous teeth collected either when they naturally fall out or, in cases where routine patient care calls for extraction.
   III. Permanent teeth, but only if standard patient care deems extraction necessary.
   IV. Bodily waste materials and external secretions, including sweat.
   V. Saliva that is not obtained through cannulation. This can be either unstimulated or induced by chewing gum base, wax, or by applying a diluted citric solution to the tongue.
   VI. The placenta, after it has been removed during childbirth.
   VII. Amniotic fluid, harvested at the time the membrane ruptures, either prior to or during labor.
   VIII. Dental plaque and calculus from both above and below the gumline, ensuring the collection is not more invasive than a regular teeth cleaning and adhering to standard prophylactic techniques.

IX. Cells from the mucosal lining and skin, gathered via methods like buccal scraping, skin swabbing, or mouth rinsing.
X. Sputum, especially when collected after the individual has inhaled a saline mist.

D. **Noninvasive Procedures for Data Collection**. Data acquisition through noninvasive means, explicitly excluding X-rays or microwaves, with devices that have received marketing clearance or approval. Examples of eligible procedures include:

I. The use of physical sensors that are attached to the body's surface or placed at some distance, without transmitting significant energy to the participant or breaching their privacy.
II. Techniques to measure or test body weight and sensory perception.
III. Imaging methods such as magnetic resonance imaging.
IV. Diagnostic procedures like electrocardiography, electroencephalography, thermography, natural radioactivity detection, electroretinography, ultrasound, infrared diagnostic imaging, doppler blood flow assessment, and echocardiography.
V. Activities such as moderate exercises and tests to gauge muscular strength, body composition, and flexibility, considering the participant's age, weight, and overall health.

E. **Use of Data or Specimens for Non-research Purposes.** Engaging in research that employs materials such as data, documents, or specimens acquired solely for non-research activities (e.g., medical treatment or diagnosis).

Note. Some research activities within this category might qualify for exemptions from the regulations set by the Department of Health and Human Services (HHS) concerning the protection of human subjects (see 45 CFR 46.101(b)(4)). However, this particular listing specifically addresses research activities that are not granted such exemptions.

F. **Voice, Video, Digital, or Image Recordings.** Data derived from voice, video, digital, or image recordings, specifically designed for research purposes.

G. **Behavioral or Group Characteristic Research.** Research focusing on individual or group traits, behaviors (e.g., perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social attitudes), or employing certain methodologies including surveys, interviews, and human factors evaluations. Some studies within this category might also qualify for exemptions (see 45 CFR 46.101(b)(2) and (3).

H. **Ongoing Review of Research Previously Approved by the IRB.** For research that has previously received approval from the convened IRB, the following criteria apply for ongoing or continuing review:

I) The research is no longer open for the recruitment of new participants; all participants have undergone all the research-related procedures; the only active component of the research is the long-term tracking or follow-up of the participants; or
II) Circumstances where no participants have been enrolled, and there are no newly identified risks associated with the research; or
III) Instances where all remaining activities in the research are solely focused on analyzing data.

If your research falls under the "III" category and has advanced to a phase where only data analysis remains, it is eligible for a shift to a status that does not necessitate ongoing review. To initiate this transition, you should complete and submit the '*Continuing Review Release Request Form*' via Cayuse. This form will undergo a streamlined, expedited review process.

I. **Continuous Review of Minimal Risk Research.** Continuous review of research not tied to an investigational new drug application or investigational device exemption, where categories 2 through 8 are not applicable but the IRB has determined the research is of minimal risk.

Expedited application IRB approvals generally do not come with an expiration date. It is the responsibility of the Principal Investigator to submit a conclusive '*Study Closure Report Form*' upon the culmination of the research.

Please note that an expedited review still demands a thorough evaluation process, albeit usually quicker than a full board review. Some subject matters, even if they fall under expedited categories, due to their sensitive nature, may warrant a full board review.

4.1.3 Full Board Review

Research proposals characterized by higher than minimal risk that do not qualify for exempt or expedited reviews are subject to a full board review. This process involves a detailed scrutiny by the IRB to ensure the utmost adherence to ethical principles and regulatory requirements. The full review involves an in-depth analysis of potential risks and benefits, with a focus on safeguarding the rights and well-being of participants. Projects in this category often involve vulnerable populations, complex interventions, or potential for significant risk, and require a full board evaluation and a multi-layered approach to risk management. For instance, a study aiming to explore the experiences of trauma survivors would necessitate a full board review given the sensitive nature of the topic and potential emotional risks to participants.

Special Attention to Vulnerable Groups:
Research that involves vulnerable groups, such as pregnant women, unborn babies, prisoners, or individuals potentially lacking full capacity to give informed consent, must be thoroughly reviewed by the convened IRB. This includes adherence to regulations listed in 45 CFR 46.201 - 207 for pregnant women; 46.300-306 for prisoners; and 46.401 - 409 for children and minors, barring exceptions in exempt and expedited categories.

Examples of Sensitive Topics Warranting Full Board Review:

I. Research on sexual orientation, gender identity, attitudes, practices, or preferences.
II. Activities that are illicit or could lead to legal ramifications, including consumption of alcohol, drugs, or other addictive substances.
III. Information that, if disclosed, might jeopardize an individual's financial stability, job prospects, or reputation.
IV. Data, often from medical records, that if revealed, could result in societal stigmatization or bias.
V. Traumatic events, involving physical, emotional, or sexual abuse, and wartime/veteran experiences.
VI. Topics addressing religious freedom, religious discrimination, or religious practices.
VII. Issues related to race, racial discrimination, or racial identity.

This review necessitates a convening of the entire board, where members scrutinize every aspect of the proposal, from the study design to the measures put in place for participant protection. Researchers should be prepared to provide detailed documentation and potentially adjust research protocols based on feedback from the board.

Rationale for Highlighting Sensitive Topics:
Beyond the standard federally protected groups, the Regent Academic Affairs' Office of Research and Sponsored Program deems that research exploring sensitive topics requires a full review in order to ensure protection for potential participants involved.

Researchers uncertain about whether their proposed study touches upon any of the sensitive areas mentioned above should consult the IRB for initial advice before submitting their application by contacting irb@regent.edu. Once the Full Board Review application is greenlit by the IRB, such an approval **typically lasts for a year,** unless specified otherwise in the approval email.

Should the research extend beyond a year, the Principal Investigator (PI) must present a '*Continuing Research Renewal Request*', ensuring there is ample time for the review and subsequent approval of this request. At the conclusion of the research, it is mandatory for the PI to complete and submit a '*Study Closure Report Form*'. For additional details, refer to the "4.2.4 Post-Review Process" section below.

4.2 Submission Procedures

The start of the research review process hinges on a systematic and structured submission procedure. This is designed to guide researchers through the necessary steps required to ensure a transparent and efficient progression from the conceptual phase to the initiation of the research project. Here, we outline each stage in detail:

4.2.1 Pre-Review Preparation

Before the research proposal reaches the IRB, a significant amount of preparatory work is involved. This includes the formulation of the research proposal with a well-defined objective, methodology, and risk-benefit analysis.

Initial Steps:

A. Ascertain if your project meets the criteria for research (refer to *5.5 What is Considered Research?*).
B. Assess if your project involves human subjects (see *5.1. Human Subjects Defined*).
C. Undertake or update CITI Certifications or other type of Certification required as part of the submission process. For instance, a provisional/departmental approval (*Awaiting Certification* on Cayuse) from the sponsor (department chair or dean) or Principal Investigator (faculty sponsor) at the IRB stage may be essential to initiate the review process. The IRB might consider an equivalent additional certification upon its discretion.
D. Develop a thorough research proposal. For Regent doctoral students this process typically involves completing the dissertation proposal defense first. The IRB application necessitates an evaluation of the entire research protocol from start to finish. The IRB does not endorse vague research concepts.

Operational Guidelines:

A. Determine the type of application relevant to your research. This could be categorized as exempt, expedited, or full board review (For detailed information please refer to *4.1 Types of Review*).
B. Register your credentials on Cayuse via the Office of Research and Sponsored Programs or the IRB webpage (https://regent.edu/irb). Ensure that every section of the application is completed.
C. Gather all required documents in accordance with the guidelines provided on the Cayuse portal. Please be advised that applications that are incomplete, incorrect, or improperly formatted will be returned to the Principal Investigator for rectification.
D. Applications are accepted exclusively via the Cayuse Regent portal. Upon submission on the Regent research administration portal, you can expect an acknowledgment of receipt automatically.
E. The IRB conducts reviews based on the category of the research submitted (e.g., exempt, expedited, full board). It is important to note that the category does not

dictate the review duration. Generally, reviews take approximately 2-4 weeks. However, projects with a higher degree of risk may require an extended review period. Also, please be aware that the IRB may not be operational during certain University holidays. After the review, one of the following will be communicated to the researcher:

i. The submission does not qualify as human subjects research.
ii. The research is approved as submitted.
iii. The research requires modifications for approval, overseen by the IRB Chair or a designated representative.
iv. Significant revisions are needed. In such cases, the applicant will be asked to amend and resubmit. The revised application will be reviewed either by the original panel or the full board, as determined by the IRB.
v. The research is not approved. This decision is made after thorough IRB review. Should the IRB deny approval for your research, as the principal investigator, you have the option to petition this decision. You can do so by writing a formal letter to the IRB (irb@regent.edu), noting your request for a re-consideration. At the discretion of the IRB chair, you may present your appeal either in writing or in person to the board. An appeal of the disapproved project must be deliberated upon at a subsequent full board meeting.

F. If modifications are requested, researchers have a four-week period to make and submit these changes. If the revised application is not received within this timeframe, the application will be closed. To continue, the Principal Investigator must begin a new application process.

Using the Research Administration Software (e.g., Cayuse):

A. ***Project Detail.*** Researchers should input all pertinent details about the project into the Cayuse administrative portal (see *13.3 Checklist and Guidance Documents*), including its title, objectives, methods, and projected impacts.
B. ***Collaborative Working.*** The Cayuse platform supports real-time collaboration, and enables the research team members to consolidate their inputs into a unified, cohesive proposal.
C. ***Budget Outline.*** If applicable, researchers are encouraged to use the Cayuse's budget planning tool to outline the financial blueprint of the project, including projected costs and financial allocations.

Available Submission Types:

Each type of submission serves a specific purpose in the lifecycle of a study. Below are the various submission types available in the Cayuse system:

A. ***Initial Submission.*** This is the primary submission made when a new study is entered into the system. It details the intended research and methodology and must be approved before any research activities can begin.

B. ***Modification.*** Used for proposing changes to an already approved study. Includes details of the proposed modifications. Approval is necessary before implementing any changes.
C. ***Renewal.*** Necessary when a study is nearing its expiration date and needs to continue. It includes justification and details for continuing the research and must be approved for the study to continue beyond its original timeframe.
D. ***Incident Reporting.*** Used to report any adverse incidents associated with the study. It includes content such as the details of the incident, its impact, and any corrective actions taken. Can be submitted any time after approval, including post-closure of the study. Multiple reports can be submitted for a single study.
E. ***Withdrawal.*** This type of submission is used to inform the Office of Research and Sponsored Programs of your decision to retract your initial submission and discontinue the study. Once a study is withdrawn, it is marked as finalized, meaning no further modifications can be made to it. Regent researchers have the option to submit a withdrawal at any stage after the initial submission has been made but before it receives approval. In cases where the initial submission has already been approved and you decide not to pursue the research, a closure submission must be made to officially close the study.
F. ***Closure.*** Signifies the completion of the research study. Form includes summary of the study outcomes and confirmation of its completion and marks the study as finalized, preventing further modifications.
G. ***Legacy.*** This is for studies imported from previous systems. It replaces the initial submission for imported studies. Additional submissions (modifications, renewals, etc.) are possible post-finalization of the legacy submission.

4.2.2 Submission to IRB

After putting together the research proposal, the next step is to gather and submit all necessary documents in order to help facilitate the review process.

Procedure:

A. ***Structured Compilation.*** Researchers are tasked with assembling all necessary documents in an organized manner to facilitate a smooth and streamlined submission process.
B. ***Document Upload***. Necessary documents such as research protocols, informed consent forms, and data collection tools should be uploaded as per the stipulated guidelines.
C. ***Submission Tracking.*** The Cayuse platform via the Regent IRB portal (which can be found in my.regent.edu) offers tracking features that keep researchers abreast of their submission status, and thus fostering open communication channels throughout the process.

4.2.3 IRB Review

Once the submission phase is completed, the IRB committee embarks on a preliminary review. This step is necessary to verify the completeness of the submitted documents and assess their readiness for review, while also considering the necessary ethical considerations and potential repercussions of the research. The IRB utilizes the diverse multidisciplinary expertise of its members from various Regent colleges and schools to perform a review of the proposal.

Procedure:

A. ***Automated Notifications.*** The Cayuse system supports automated notifications to keep researchers informed about the progress of the initial review, including any feedback or additional information requests. Researchers must monitor their emails.
B. ***Feedback Integration.*** If any gaps or shortcomings are identified during the initial review, the Cayuse research administration software enables smooth feedback integration in order to help researchers make the required adjustments expediently.
C. ***Efficient Review Transition.*** Leveraging the Cayuse software, the IRB Chair can quickly transition from initial exempt or expedited review submission to a full review (if he or she sees fit) in order to ensure a swift and smooth progression through the review phases and in compliance with ethical guidelines.

Please note that adherence to informed consent guidelines is essential to uphold the ethical integrity of the research at the review phase (please see the guidelines for Informed Consent above in 2.3).

4.2.4 Post-Review Process

After the review, the IRB communicates its decision to the researchers. This post-review phase also includes ongoing monitoring and offers a platform for dialogue between the IRB and the researchers.

Procedure:

A. ***Feedback and Modifications.*** Post the initial review; researchers may receive feedback and a request for modifications, if necessary, which needs to be addressed promptly.
B. ***Approval.*** Once the IRB is satisfied with the proposal, approval is granted, thus authorizing the commencement of the research. When making decisions on submissions, the IRB can choose from a variety of options, each leading to different outcomes and statuses for the study. The available decisions vary depending on the type of review being conducted.

Decision Types in Human Ethics:

1. ***Approved.*** The study has received IRB approval. Approved, with no further edits allowed to the submission. **APPROVED**

2. ***No Engagement in Research***. The submission is deemed as not constituting research (see Section 5.1.3**)**, thus does not require IRB approval. **APPROVED**
3. ***No Human Subjects Research.*** The study does not involve human subjects research and does not require IRB approval. **APPROVED**
4. ***Noted.*** The IRB has acknowledged the incident report. **APPROVED**
5. ***Rely on External IRB or NCI-CIRB.*** Approval by an external IRB or NCI-CIRB is acknowledged and recorded. **APPROVED**
6. ***Exempt.*** The study falls into a category that qualifies for exemption. In other words, the study is exempt, with no further edits to the submission. **EXEMPT**
7. ***Suspended.*** The IRB suspends the study, necessitating changes before it can proceed. Submission is returned to the PI and cannot be edited. Please also note that suspension can be lifted through an approved modification after appropriate review. **SUSPENDED**
8. ***Closed.*** Used when research is complete, and the study can be closed. This also means that no further research is permitted. **CLOSED**
9. ***Withdrawn.*** Indicates retraction of the initial submission by the research team before its approval. **WITHDRAWN**
10. ***Not Approved.*** Major issues lead to non-approval of the study or submission. A not approved status means that submission and study are non-editable and archived if initial. **NOT APPROVED**
11. ***Deferred.*** Major issues identified; corrections required for approval. Submission is returned to PI for editing.
12. ***Minor Stipulations.*** Minor issues to be addressed before approval. In other words, the study requires changes; submission is returned to PI for editing. **REQUIRES CHANGES**
13. ***Return to PI.*** The submission is returned for changes, not approvable in current form. This means that submission is returned for editing. **REQUIRES CHANGES**
14. ***Not Expedited/Not Exempt.*** Incorrect review type assigned; needs reassignment. This is returned to the Regent Cayuse Analyst or IRB Chair for correct review type assignment. **N/A**
15. ***Not Reviewed.*** Submission not discussed at the meeting; pending future review. This is returned to Analyst for assignment to a new meeting. **N/A**
16. ***Voided.*** Request withdrawn or changes no longer needed. This means that the study is not approved, and changes requested are discharged. **NOT APPROVED**

Note: The above decisions apply to all studies except legacy studies, which retain their original status regardless of the decision made. Certain decisions (like "Suspended," "Withdrawn," "Not Approved," etc.) lead to specific actions or status changes for a study, impacting its progress and the ability to conduct further research.

C. ***Ongoing Monitoring.*** The IRB may engage in periodic internal assessment to monitor the progress and ethical adherence of the research projects under its supervision.

4.3 Review Approval Timeline

The following outlines the general sequence and the expected duration for each review phase, keeping in mind that complex research projects might necessitate a more extended period for thorough evaluation.

4.3.1 Pre-Review Phase

These are the preliminary activities before officially submitting the IRB application, including developing the proposal and gathering all necessary documents.

> ***Expected Duration.*** Depending on the complexity of the research project and departmental requirements, this phase can range from a couple of weeks to several months/years.

4.3.2 Initial Review

This step involves the initial scrutiny by the IRB, in which they check for the completeness and readiness of the documentation submitted before assigning the submission for a more detailed review.

> ***Expected Duration.*** Typically, the initial review is conducted within 2-4 weeks of submission. This period allows the IRB to examine the documents and offer preliminary feedback, if any.

4.3.3 Detailed Review

If the proposal passes the initial review, it progresses to a detailed review where each aspect of the research is examined critically based on established ethical considerations, methodology, and potential impacts.

> ***Expected Duration.*** This phase is generally completed within 4-6 weeks, although it might extend if the proposal necessitates modifications or additional details.

4.3.4 Final Approval

This final phase signifies the completion of the review process, where the IRB grants approval for the research to commence. It may involve a few iterations or revisions based on the feedback received during the initial or/and detailed review phase.

> ***Expected Duration.*** Once the detailed review is complete and all requisite modifications have been incorporated, final approval is usually granted within 2-4 weeks.

Regent researchers should expect a period of 4 to 10 weeks for IRB approval, pending feedback at the initial or detailed review, the complexity of the research proposal, the type of review, and other specific ethical considerations relevant to the application.

Researchers are encouraged to factor in this timeline while planning their projects, allowing sufficient time for each phase to meet their project deadlines.

5. Specific Types of Research

5.1 Human Subjects or Participants

According to the Code of Federal Regulations, a 'human subject' is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information" (see 45 CFR 46.102(e)(1)).

5.1.1 Defining Components

A. ***Intervention.*** This refers to procedures by which data are collected and 'manipulations' of the subject or the subject's environment for research purposes. In behavioral science research, an example of intervention could be exposing participants to specific visual or auditory stimuli to observe and measure their cognitive or emotional responses.

B. ***Interaction.*** This includes communication or interpersonal contact between the investigator and the subject (e.g., through interviews, focus groups). It could be direct or through electronic/digital means.

C. ***Identifiable private information.*** Information is considered identifiable when the identity of the subject/participant is or may readily be ascertained by the investigator or associated with the information. This could include names, addresses, or any data points that can single out an individual.

5.1.2 Common Scenarios Involving Human Subjects/Participants

Examples of research involving human subjects include clinical trials, behavioral experiments, interviews, surveys, and some observational studies. Please note that the mere use of human tissue or data does not always constitute human subjects research; the data or tissue source's identifiability and the manner of its acquisition are key factors (refer to *4.1 Types of Review*).

5.1.3 Scholarly Activities that Do Not Require an IRB Approval

Though the definition of what constitutes 'research' under HHS regulations (45 CFR Part 46) has been clarified above (see 5.1), certain scholarly and journalistic activities focusing directly on specific individuals about whom information is collected are excluded from this definition. **Activities excluded from this definition, and thereby not regarded as research for the purposes of this policy, include oral history, journalism, biography, literary**

criticism, legal research, and historical scholarship (see the HHS guidance on this matter, consistent with the 2018 Requirements of the Revised Common Rule**).**

Implications for Conduct and Oversight:

A. ***Ethical and Regulatory Framework.*** These activities (see above) do not fall under the purview of the human subject protection regulations outlined in 45 CFR part 46. Thus, the standard requirements for minimizing risks to subjects, informed consent, and IRB review and approval do not apply.
B. ***Intent and Purpose.*** The primary intent of these activities is not to develop **generalizable knowledge** but to provide a factual, evidence-based portrayal of the individuals involved.
C. ***Field and Methodology.*** The activities may span various fields and methodological traditions in the arts and humanities field. They should, however, be focused on the specific individuals of interest rather than intending to generalize findings to broader populations.

Exceptions and Clarifications:

H. If the scholarly activity extends beyond the portrayal of specific individuals and aims to generalize findings, it may no longer fit within this exclusion category and could be subject to standard research regulations.
I. Given the diverse nature of scholarly and journalistic activities, it is important to assess each case individually to determine whether it falls within the scope of this exclusion.

Seeking Guidance:
Investigators and relevant officials must exercise due diligence in interpreting and applying these guidelines. When in doubt, seek clarification from the IRB or directly from Regent University's Office of Research and Sponsored Programs.

Note. **Regent IRB only reviews human subjects research.**

5.2 Vulnerable Populations

Vulnerable populations include individuals who might be at a greater risk of harm or wrongful treatment due to their limited capacity to provide informed consent or their susceptibility to coercion or undue influence. Below are some the primary vulnerable populations identified in the Common Rule, along with specific considerations for how Regent researchers should approach these different groups:

A. ***Children/Minors (Subpart D).*** Under the Code of Federal Regulations (CFR), children are persons who have not attained the legal age for consent to treatments or procedures involved in the research (usually < 18 years in most US states).

Considerations (see 45 CFR 46, subpart D)**:**

I. Before involving minors in research, the Regent IRB must determine that the research falls into one of several permissible categories based on the risk and benefit profile.
II. Parental or guardian permission is generally required, and assent of the child might also be required, depending on their age and comprehension (see 2.4).

B. ***Prisoners (Subpart C).*** A prisoner is any individual involuntarily confined in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute and individuals detained pending arraignment, trial, or sentencing.

Considerations (see 45 CFR 46, subpart C)**:**

I. There are additional protections due to the concerns about the diminished capacity of prisoners to provide truly voluntary and uncoerced consent.
II. The nature and purpose of the research must be relevant to the prisoner population, and risks need to be especially justified.

C. ***Pregnant Women, Human Fetuses, and Neonates (Subpart B).*** Pregnant women are expectant mothers, human fetuses refer to unborn babies at conception from implantation until birth, while neonates are newborns.

Considerations:

I. The potential benefits of the research must substantially outweigh the risks, especially when it concerns the human fetus.
II. If research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is required, with some exceptions.

D. ***Individuals with Intellectual or Cognitive Disabilities.*** This group can be considered vulnerable because they may have diminished capacity to understand the nature and implications of the research being carried out, thus making the process of informed consent challenging for them.

E. ***Economically or Educationally Disadvantaged Persons.*** These individuals might be vulnerable to coercion or undue influence, especially if they perceive participation in research as their only option to access healthcare or other services.

F. ***Elderly or Aging Populations.*** Those with cognitive impairments, may require special considerations regarding the informed consent process and potential risks.

5.2.1 General Considerations for Research Involving Vulnerable Populations

A. Ensure that participation is truly voluntary, free from coercion or undue influence.

B. Tailor the informed consent process to the cognitive and emotional capacity of the participants, and ensure that they fully understand the implications of their participation.
C. Ensure that the potential benefits of the research to the participants, or the population they represent, outweigh the potential risks.
D. Involve community advocates or family guardians in the research consent process when appropriate.
E. Regent's IRB should always be informed about the specific needs and vulnerabilities of these groups in order to provide additional protections as needed.

5.3 International Research

When Regent University researchers are involved in human participants research outside the U.S., understanding and navigating the ethical and regulatory complexities becomes even more crucial. In such scenarios, both the local regulations of the host country and U.S. regulations, such as the Common Rule, may apply. Hence, engaging in international research demands a multifaceted approach, especially given the intricacies of differing geographical, cultural, and legislative landscapes.

Here are some considerations and steps for conducting international research involving human subjects at Regent University:

A. ***Cultural Considerations***
    I. Familiarize yourself with local laws, regulations, and guidelines governing human participants research in the host country.
    II. Understand the local customs, traditions, and cultural norms related to research participation, informed consent, and respect for human subjects. For example, some populations might be considered vulnerable in some cultures due to religious, social, or political reasons. Researchers should be aware of these nuances and ensure additional protections for such groups.

B. Local Ethics Clearance
    I. In some cases, it is required to obtain approval from a local ethics review board or its equivalent in the host country.
    II. This local ethics review/clearance ensures that the research is culturally sensitive and adheres to local standards and regulations.
    III. Seek approval from Regent IRB in addition to the local review. The local ethics clearance should not replace our IRB.

C. Informed Consent
    I. The process of informed consent might need modifications based on language, culture, and local understanding.

II. Translations of consent forms should be accurate and provided in the local language, and Regent researchers should ensure that the participant truly understands the implications of participating.

D. Collaboration with Local Researchers

I. Regent researchers are encouraged to collaborate with local researchers and institutions when conducting international research.

II. Local researchers can provide invaluable insights into cultural norms, and can help the project team to navigate local regulations and facilitate community engagement.

E. Data Handling and Privacy

I. ***GDPR Compliance.*** Our policy mandates a thorough understanding of the General Data Protection Regulation (GDPR). Research activities must align with the principles outlined in Articles 5 and 6 regarding the lawfulness and transparency of data processing. Security measures set forth in Article 32 will be rigorously implemented to ensure the integrity and confidentiality of personal data.

II. ***International Data Transfer Protocol.*** In compliance with GDPR Articles 44 through 50, Regent researchers will adhere to the regulations governing the transfer of data outside the United States and the European Union. This ensures that the level of protection afforded to personal data is not undermined.

III. ***U.S. Data Protection Standard Alignment.*** Regent research protocols will also align with U.S. data protection standards in order to ensure the protection of personal data throughout our operations. Regular reviews and updates to our compliance processes will be conducted to maintain this alignment.

F. Training and Capacity Building

I. Often, international collaborations include components of training and capacity building. We encourage Regent researchers to consider this additional component in their international research projects. Such commitments can help ensure long-term sustainability of research efforts and improve local research standards.

II. Consider any post-study obligations, such as providing feedback to the community, ensuring access to interventions if proven effective, or other forms of benefit-sharing.

5.4 Animal Research

While Regent University respects the principles of ethical animal research, such as the 3Rs of Reduction, Refinement, and Replacement, we currently do not have an Institutional Animal Care and Use Committee (IACUC). However, for guidance and approval on animal research

projects, please consult with the chair of the Science and Mathematics department in the College of Arts and Sciences.

5.5 What is Considered Research? (also see Section 5.1.3)

The Code of Federal Regulations defines 'research' as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (see 45 CFR 46.102(i))

If you are a faculty, staff, or student at Regent University and your research involves the use of human subjects (either directly or through records or other data) and you intend to externally disseminate the results (e.g., via publication, presentation, grant application, etc.) then your research requires an IRB review. Here are some exceptions:

A. ***Course Assignments*** that are part of normal, typical coursework that are not intended for dissemination are not required to undergo IRB review; however, faculty are responsible for informing students of proper procedures regarding the conduct of such research and for monitoring the work done by students. Human subjects data collected in such class assignments may not be used in future publications or presentations. There will be no ex post facto approval of such activities to legitimize turning these studies into approved human research.

B. ***Program or Institutional Improvement Surveys.*** When conducting surveys or collecting data strictly for enhancing programs or institutional quality (e.g., accreditation self-studies, regulatory reporting, etc.), and without dissemination intentions, there is no need for an IRB review. Regardless, it is important that these evaluations uphold ethical standards and safeguard participants' rights. Data from these evaluations, concerning human subjects, should not be considered for subsequent publications or public discourses nor would the IRB transition them into officially recognized human research.

5.6 Applying for Regent IRB

5.6.1 Who Should Apply?

If you are considering research that involves human subjects, it is important to know whether you need to seek approval from the Regent IRB. The primary criterion is affiliation with one of the research centers, schools or colleges within Regent University. This affiliation includes as a faculty member, student, or administrative staff member.

A. ***Faculty.*** All faculty members, regardless of their department or specialization, are required to seek IRB approval if they are conducting research that involves human

subjects as the PI. This includes research done for professional, academic, or personal purposes.

B. ***Students*** involved in research as part of their master's or doctoral program, especially if the research is for a thesis or dissertation, must apply for IRB approval. In addition to postgraduate students, any undergraduate student engaged in research projects (e.g., capstone projects or honors theses that involve human participants) should also seek approval from the IRB before commencing their research. No student from Regent is permitted to participate in any human subjects' research as the PI while representing themselves as a student of Regent without obtaining approval from the IRB. If Regent students are involved in research through an external organization, such as in a professional capacity, they must not attribute their research activities to their status as Regent students. Instead, they should seek approval for their research from the relevant ethical review authority in that particular organizational context.

   Note. **It is a requirement that all student research projects are conducted under the supervision and sponsorship of a faculty member.**

   I. ***Books for Publication.*** If a student's work, such as a book, is primarily a commercial project and does not involve the university beyond the student's affiliation, it can be argued that it is outside the direct oversight of the university's IRB. Hence, Regent students writing a book intended for publication, which is separate from their academic requirements (e.g., thesis, dissertation), should consider the following:
      1. ***Direct Association with Regent.*** If the research or content of the book directly relates to Regent University, involves its resources, faculty, or leverages the student's association with the university, then an IRB review is necessary.
      2. ***Independent Projects.*** If the book is entirely an independent project, as determined by respective department/school/college, without any association or representation of Regent University, and is not used to meet any academic requirements, it may fall outside the purview of the university's IRB. However, ethical considerations should still be made by the student, especially if human subjects are involved.

C. ***Administrative Staff*** members who are conducting research only on behalf of Regent, outside of their regular job responsibilities or in collaboration with a faculty or students, should seek the IRB approval.

5.6.2 Who Should Not Apply?

A. ***Unaffiliated Researchers.*** Individuals who are not directly affiliated with Regent University and are not collaborating with someone affiliated with the university are typically not eligible to apply.

B. ***Independent Researchers.*** Alumni or other individuals who are conducting research independently and not using Regent resources or participants are not eligible to apply.

5.6.3 Resource Considerations

While it is essential to ensure that all research associated with Regent University meets ethical standards, it is equally important to use IRB resources judiciously. Here are some further considerations, in addition to what has been discussed in 5.6.1:

A. ***Resource Management.*** Overloading the IRB with projects not directly related to academic work can strain its resources. This can lead to delays for other research projects that are directly related to academic requirements.

B. ***Ethical Responsibility.*** While managing resources as 'good stewards' (1 Corinthians 4:7), it is important that Regent University researchers strike a balance to ensure that all research involving human subjects, even if it is for commercial purposes, meets ethical standards.

While all research should be ethical, the Office of Academic Affairs encourages faculty, staff, and students to utilize IRB resources for projects most aligned with the university's academic mission. Students or faculty unsure of where their project falls should consult with the Office of Research and Sponsored Programs for guidance.

6. Guidelines for Specially Recognized University Centers

6.1 Definition of Research Centers

Specially Recognized University Centers (SRUCs) denote entities at Regent University that receive formal recognition and are recommended by the Office of Academic Affairs after first being approved by the Executive Vice President for Academic Affairs (EVPAA), the Executive Vice President for Finance and Administration (EVPFA), and the Chancellor. These entities can alternatively be identified with other titles such as “Institute” or “Clinic”. While other organizational entities use similar titles, only entities that a formally approved by the EVPAA and EVPFA, have the status of a specially recognized university center.

At their core, SRUCs are devised to operate as hubs of excellence, fostering intensive research, outreach programs, and other educational initiatives that significantly contribute to the broader scholarly and community discourse. The activities conducted by these centers are diverse, including a range of scholarly endeavors, from empirical research projects to educational initiatives and community outreach programs. These centers act as converging points for scholars, researchers, and students to collaborate, innovate, and foster a culture of academic excellence and research integrity.

To further underscore their close affiliation and integration with the university structure, SRUCs are branded with specific titles that explicitly mention their association with the university. For example, they might be named “The Regent University Center for Constitutional Law” or “The Charis Institute at Regent University,” thereby denoting a strong connection with the university's overarching objectives and ethos.

The establishment of SRUCs symbolizes a dedicated physical or virtual space where academic rigor meets innovative thinking, while at the same time encouraging a synergistic approach to tackling contemporary issues and fostering knowledge growth. These centers are pillars of expertise in their respective domains, often drawing attention from both the academic circle and the industry for their contributions to their fields.

SRUCs are expected to operate in alignment with the university’s mission, vision, and values, reflecting the institution’s commitment to nurture scholarly pursuits that are grounded in excellence and innovation. Through their operations, SRUCs not only contribute to the academic enrichment of Regent University, but also potentially facilitate partnerships with external organizations, thereby extending the university’s influence and impact in the broader community.

6.2 Classifying SRUC

The classification of SRUC serves to streamline the functions of the different entities while ensuring that their objectives align with the broader goals of the university. For example, SRUCs can be diverse and multifaceted, differing considerably in terms of their core focus areas. These focus areas might span across various disciplines and specialties, ranging from social sciences, healthcare, humanities, and arts to applied sciences and technology. Depending on their specialization, SRUCs may concentrate on fostering scholarly research, advancing STEM science, promoting arts and culture, or any other significant topic.

In addition to focus areas, SRUCs may also vary based on the range of activities they endorse and facilitate. These activities might include workshops, conferences, research projects, community outreach programs, and educational initiatives that encourage academic collaboration and discourse. These centers can serve as incubators for innovative ideas that would foster a nurturing environment where knowledge can be cultivated and disseminated.

The classification takes into account the level of financial and infrastructural support needed by the respective SRUC entity. This support is pivotal in ensuring the smooth functioning and sustainability of the centers. During the approval process, a detailed plan and proposal outlining the necessary resources is drafted, noting provisions for dedicated facilities or equipment, personnel recruitment and management, and fiscal procedures that govern the center's operations (see subsequent pages). One such financial procedure could be the establishment of a *restricted cost* center, a mechanism to streamline the allocation and monitoring of funds to ensure financial transparency and accountability.

The classification process evaluates the potential synergies between the proposed center and existing university departments or faculties. This involves assessing how the center can complement the ongoing efforts at the university, such that it contributes to fostering collaborations and cross-disciplinary projects that enhance the quality and scope of academic pursuits in our institution.

The classification also considers the governance structure of SRUCs, outlining the roles and responsibilities of the directors and administrative staff, and stipulating guidelines for leadership assignment and reassignment. The approved SRUC's governance framework must aim to foster a harmonious and productive working environment within the centers in order to promote a culture of excellence and cooperation.

6.3 SRUC Classification Framework

The different classifications of SRUCs are based on several multifaceted criteria, including their research focus, funding models, collaboration scope, and outreach potential. Here is a structured framework we have adopted:

6.3.1 Category A: Research-Domain Expertise Scope

A. ***Interdisciplinary Centers.*** These centers focus on integrating knowledge from diverse fields to address complex issues, fostering collaboration and cross-disciplinary research.
B. ***Discipline-Specific Centers.*** These centers concentrate on a particular discipline, aiming to foster depth in research and advancements within that specific field.
C. ***Technology and Innovation Centers.*** These entities focus on technological advancements that foster innovation and facilitate the development of cutting-edge solutions in various sectors.

Expectations:

A. Contribute to Regent's research portfolio, whether through interdisciplinary, discipline-specific, or technological advancements.
B. Engage in continuous knowledge dissemination through publications, seminars, conferences, and workshops.
C. Collaborate across various departments and, potentially, outside institutions to bring fresh insights to research topics.
D. Consider how the objectives of the center would change the trajectory of the specific domain-research scope.
E. Operate within an approved budget model.

Compliances:

A. Ensure efficient allocation and utilization of research grants when funded (e.g., recruiting a post-doctoral researcher or graduate assistant), irrespective of their interdisciplinary or discipline-specific scope.
B. Prioritize funding towards projects that align with the center's research focus.

6.3.2 Category B: Funding Scope

A. ***Self-Sustained-Externally Centers:*** These centers operate primarily through time-bound self-generated funds, utilizing revenues from projects, endowment funds, industry partnerships, governmental support, or other initiatives to finance their activities.
B. ***University-Funded Centers.*** These centers rely on substantial financial support from the university, utilizing allocated funds to operate and manage their activities and infrastructure. Also consider the government-operational scope as an alternative to this sub-category; the only difference being that there is an allocated fund to support a university-funded center whereas this may not be the case with centralized and decentralized centers within the government-operational scope.

Expectations:

A. Develop a clear financial plan and timeline, whether relying on self-generated funds, university allocations, or external sources.
B. Demonstrate financial stability and effective fund management to ensure continued operations and research pursuits for the duration of the funding.

Compliances:

A. Adhere to funding source-specific guidelines to ensure transparency in financial dealings.
B. Regularly report on financial status, including revenue streams, expenditures, and future projections.

6.3.3 Category C: Collaboration-Partnership Scope

A. ***Internal Collaboration Centers.*** These centers mainly collaborate with other departments and entities within the university to foster a collaborative research environment and share resources internally.
B. ***External Collaboration Centers.*** These centers focus on building partnerships and collaborations with external organizations, including industry players, government bodies, and other academic institutions.

Expectations:

A. Foster an environment of collaboration, whether internally with other Regent colleges, schools, students, or departments or externally with industry, government, or other institutions.
B. Engage in initiatives that enhance the Regent's reputation and expand its research or academic footprint.

Compliances:

A. Maintain transparent financial dealings with collaborators, ensuring clear terms of partnership.
B. Navigate and manage funds or resources that are shared or jointly owned, ensuring equitable distribution, with guidance from the Regent's Executive Vice President for Finance and Administration and Executive Vice President for Academic Affairs.

6.3.4 Category D: Outreach-Community Scope

A. ***Community Engagement Centers.*** These centers actively engage with the community, facilitating outreach programs, educational initiatives, and community development projects.

B. ***Global Outreach Centers.*** These centers focus on global issues, fostering international collaborations and initiatives that have a wider, possibly global, impact.

Expectations:

A. Actively engage in initiatives that benefit the broader community or address global issues.
B. Develop and maintain programs that facilitate knowledge dissemination, community development, or global collaboration.

Compliances:

A. In collaboration with the Office of Academic Affairs and community partners, allocate funds effectively for outreach activities to ensure maximum community impact. For guidelines on managing collaboration with external entities (e.g., addressing conflict of interests) see Section 11 of this handbook.
B. Seek and manage external funds or grants geared towards community engagement or global initiatives. And in doubt, always consult with Regent's Executive Vice President for Finance and Administration in such matters.

6.3.5 Category E: Governance-Operational Scope

A. ***Centralized Centers.*** These centers operate with a high degree of autonomy, with centralized governance structures allowing for relatively independent decision-making processes that align with the vision of the University (e.g., a SRUC initiative initiated by the Chancellor or the Board of Trustees).
B. ***Nested Centers.*** These centers adhere to a nested governance structure, aligning closely with the Regent's administrative and policy frameworks (e.g., a university-wide SRUC initiative initiated by the Office of Academic Affairs or the Dean's Council).

Note on points of difference: Decentralized Centers are characterized by their capacity to make independent decisions and manage operations with minimal oversight, and align their initiatives with the university's vision while operating under the broader endorsement of the Chancellor or the Board of Trustees. Centralized Centers, in contrast, are tightly integrated within the university's main administrative and policy frameworks, with their initiatives and decisions closely guided and often initiated by centralized authorities like Academic Affairs or the Dean's Council.

Expectations:

A. Operate within a governance structure that aligns with Regent's overall vision and values.

B. Ensure that the center’s operations, decision-making processes, and policies are clear, transparent, and consistent.

Compliances:

A. Operate within the financial governance model set by the university, ensuring financial accountability and integrity.
B. Regularly review and adjust financial practices based on the operational model’s requirements, whether centralized or decentralized.

Proposals for new SRUCs are evaluated and classified accordingly based on this framework to ensure a structured and systematic approach to the establishment and management of these entities.

6.4 *Modus operandi* for University Centers

SRUCs play a crucial role within the Regent ecosystem, fostering research, education, and community engagement.

6.4.1 Leadership and Governance

SRUCs operate under the careful guidance of a director/advisor who is endorsed by the university. This director is responsible for overseeing the center's activities, ensuring alignment with the university's policies, and facilitating fruitful collaborations both within and outside the university. The university holds the prerogative to reassign leadership roles and direct collaborations or other significant activities within these centers, thus maintaining a level of oversight and integration with the broader university objectives.

6.4.2 Intellectual Property Management

SRUCs adhere strictly to the university's intellectual property policy. This means that the university retains the rights over various intellectual outputs generated by the centers, including but not limited to work products, research findings, and materials developed. In scenarios where founding faculty or staff members depart, the university preserves the right to continue using the center's title and materials in order to foster a sense of continuity and preserve institutional knowledge. Noteworthy here is the exception concerning third-party published works, where copyrights might be owned by external publishers.

6.4.3 Financial Sustainability

Even though generating revenue is not necessarily the primary objective, SRUCs are expected to maintain financial self-sufficiency. They must adeptly manage their finances to prevent incurring expenses beyond their self-funding capabilities. This financial prudence is guided by specific directives from the Executive Vice President for Academic Affairs (EVPAA), who must authorize any expenses that are not offset by the center's own revenues.

6.4.4 Financial Accountability

In tandem with the principle of financial sustainability, SRUCs are held accountable for their financial operations. In situations where a center incurs expenses beyond its revenue capabilities, the burden of covering these expenses falls upon the sponsoring school or college within the university. If a center fails to secure adequate funding to cover its expenses by the end of a fiscal year, it might face dissolution, as it violates the ethos of financial accountability and prudent management.

6.4.5 Alignment with University's Vision and Policies

SRUCs are obligated to align their functions and activities with the mission, vision, values, and policies of Regent University. This alignment ensures that the centers operate in harmony with the broader goals of the university, contributing positively to the academic community and upholding the reputation and standards of the institution. Centers found not aligning appropriately may risk losing their official recognition.

6.5 Applying for SRUC

Applying for a new SRUC demands adherence to a structured set of guidelines to ensure that the proposed center aligns well with the university's vision and principles. When pre-existing or new Regent School/College entities obtain a SRUC status, the center is recognized for its excellence and is entitled to specific privileges, including funding opportunities, university-wide promotion, and access to specialized resources.

Eligibility:

A. The center must be affiliated with a department or school or college within Regent University.
B. The center should have a clear and unique focus that differentiates it from other SRUC entities within the university.
C. The center must demonstrate a track record of scholarly research, outreach, or educational innovations over time.
D. The proposed center must fit one of the SRUC classifications (Category A to E; see 6.2)

E. The proposed center must include a budget plan that will indicate how its costs will be covered.

6.5.1 Application Process for SRUC Status

A. Initial Proposal Submission

I. Complete the SRUC Application Form (see 6.5.3).
II. Attach a detailed proposal outlining the objectives, significance, and expected outcomes of the center.
III. Include a list of Regent faculty affiliates and their qualifications.

B. Department/School Endorsement

I. Obtain a written endorsement from the respective department or school's dean or head.

C. Submit to Office of Academic Affairs for Review

I. The Office of Academic Affairs reviews the SRUC application for its merit, significance, feasibility, and compatibility with Regent's SRUC framework.
II. Feedback and recommendations will be provided.

D. Presentation and Approval

I. Center director may be invited by the Office of Academic Affairs to present the center's vision to the Office of Academic Affairs, as well as plans to meet all respective considerations.
II. Upon successful evaluation and presentation, the SRUC director along with the dean of the school or college where the respective center will be housed will receive a final approval confirmation, with signatories from the EVPAA, EVPFA, and Chancellor.
III. Applicants will be notified of the decision within 30 to 60 days of the presentation.

6.5.2 Privileges

Once approved:

A. Centers will receive the title "Specially Recognized University Center" (SRUC)
B. Institutional support consistent with the approved mission of the SRUC
C. Periodic review to ensure continuous excellence and relevance.

6.5.3 SRUC Application Form

Section A: Applicant Details

1. Name of the Center: _____

2. Department/School/College Affiliation: _____

3. Primary Contact Name and Regent Job Title:
_____

4. Contact Email: _____

5. Contact Phone Number: _____

Section B: Center Description

6. Mission Statement: (Provide a brief mission statement that encapsulates the center's primary goals and objectives.)
_____
_____
_____

7. Objectives: (List the main objectives of the center.)

a) _____
b) _____
c) _____

(Add more lines as necessary.)

8. Significance: (Describe why this center is important for the university and the broader community.)
_____
_____
_____

9. Classification: (Classify the center and respective sub-category, and explain how the center vision aligns with selected category)

a) Category A
b) Category B
c) Category C
d) Category D

e) Category E

Section C: Affiliated Faculty & Qualifications
(List faculty members affiliated with the center and provide a brief description of their qualifications)

10. Faculty Name: _____

Qualifications: _____
_____

11. Faculty Name: _____

Qualifications: _____
_____

(Add more lines as necessary.)

Section D: Supporting Documents

12. Endorsement Letter: A written endorsement from the respective department or school's dean or head.

13. Please attach a pdf/doc document addressing the following:

Foundation and Purpose of the Center:

- Why do you see the need for the establishment of this center? Is there any other way to accomplish the same goals without the establishment of such a center?
- What are the distinctive characteristics of the center?
- Describe its purpose and function.
- How do the vision and mission of the center connect to the overall university Christian vision and mission statements?
- What are the goals/outcomes for this center?
- Has anything of this nature been done at other universities? If so, which ones, where, and how successful were they?

Operational Details:

- Who will operate the center?
- Will additional staff need to be hired to sufficiently operate the center? If so, has this been worked into the overall budget process for your school?
- Will faculty load be affected in the operation of this center? If so, how do you plan to accommodate that?
- Who will the center serve primarily? Secondarily?

Financial and Logistical Aspects:

- What is the approximate cost estimated in order to start and operate this center each year?
- How will this center be funded?
- If funding outside the school's budget is to be sought, is this center cleared by the appropriate dean and added to that school's key-funding priorities list established with the Office of Academic Affairs? Has this been communicated by the Dean to the Office of Academic Affairs?
- Will the center collaborate with anyone outside of the university in order to support/operate the center? If so, who? If appropriate, has a memo of understanding been drafted between Regent University and this outside entity?

Physical Presence and Longevity:

- Will the center have a physical location? (Building on campus, web, off-campus site) If so, where will it be located?
- How long do you anticipate the need or operation of this center?

Impact and Assessment:

- How is overall effectiveness of the center going to be evaluated? How often?
- Will the establishment of this center affect enrollment at any of the schools at Regent University? If so, how?

Accreditation and Compliance:

- Are there any accreditation issues that need to be addressed for the establishment and maintenance of this center?

Section E: Declaration

I _____hereby declare that the information provided in this application and its supporting documents is accurate and true to the best of my knowledge.

Signature: _____ Date: _____

Submission Instructions:

Please submit the completed form along with the required supporting documents to the Office of Research and Sponsored Programs.

7. Risk Management and Compliance

Regent's risk management and compliance program is structured to manage risks and uphold the standards of safety and ethical conduct that govern research processes. This section explains what this looks like for Regent University.

7.1 Risk Assessment

Before the start of any research project, carefully examine and understand the possible risks involved. Risk assessment is essential to help spot, study, and minimize potential risks associated with research activities. This method consists of several key steps:

A. ***Identify Possible Risks.*** At the outset, Regent researchers need to pinpoint any risks that might come up during their study. These risks could be physical, like potential accidents or health issues, or ethical, where there might be concerns about how people or information are handled. It is about foreseeing what could go wrong, taking into account both participant's safety and moral considerations.

B. ***Analyze and Evaluate the Risks.*** After spotting these potential risks, the next step is to study them closely. This involves figuring out how serious these risks might be and how likely they are to happen. This involves understanding what kind of impact these issues could have, thus helping to paint a clearer picture of what might be at stake.

C. ***Create Strategies to Reduce the Risks.*** With a clear understanding of what the risks are, researchers then should develop plans to reduce or manage these risks effectively. This could mean creating safe procedures to follow (e.g., the subject may discontinue participation at any time without penalty or loss of benefits; see 45 CFR §46.116(a)(8)) or putting in place safeguards to protect the subject's privacy (e.g., seeing Regent counseling services). It is about planning carefully to make sure everyone involved is protected and the research is conducted ethically.

D. ***Stick to the Rules.*** Throughout all these steps, it is important to follow the rules and regulations in our Faculty and Academic Policy Handbook, Employee Handbook, and those set by the federal and Virginia state authorities (see 2.1). This ensures that the research is conducted within a framework that respects all necessary legal and ethical boundaries. Keeping in line with these rules is fundamental to making sure that the research stands up to scrutiny and maintains the highest standard of integrity.

7.2 Safety Protocols

Safety protocols act as the strong foundation that holds the structure of risk management. It serves to protect the well-being of everyone participating in research activities. These

procedures, which are in harmony with federal and states regulations, include several essential elements:

A. ***Preventive Measures.*** The first step in maintaining safety is putting in place measures to prevent potential dangers before they even occur. For our institution, this might involve conducting training sessions and workshops to educate researchers (see next section on training) and participants about the possible risks and how to avoid them. These preventative strategies can range from simple guidelines to more comprehensive programs, designed to foster a culture of safety and vigilance. Regent offers a range of training programs for researchers conducting human subjects research (see 8.1 and 8.2).

B. ***Emergency Response Plans.*** Despite the best preventive measures, emergencies can still occur. This makes it essential to have robust response plans in place, capable of quickly and effectively addressing any unforeseen incidents during the research phase. Regent researchers are encouraged to have such plans in case of an emergency, including contacts for emergency services and a clear withdrawal procedure. It is about being prepared to act swiftly and decisively to protect all human subjects involved.

C. ***Equipment and Facilities Safety.*** Ensuring the safety of research environments is another important aspect of these protocols. It entails making sure that all facilities and equipment used in the research are up to the mark in terms of safety standards. This could mean regular safety checks and maintenance to prevent accidents, as well as ensuring that the facilities are designed with safety as a primary consideration. The goal here is to create and maintain a secure and safe environment that minimizes the risk of accidents and other safety hazards.

D. ***Communication and Reporting.*** Alongside these, establishing a clear channel for communication with the human subjects and reporting is essential. This facilitates timely updates and reporting of any safety concerns, allowing for immediate action to rectify any issues and maintain the safety and integrity of the research process.

E. ***Ongoing Education and Training.*** The Office of Research and Sponsored Programs actively facilitates continuous education and training for Regent researchers. This ensures that our researchers are well-informed about the most recent safety practices. The initiative includes regular training sessions for members of Regent IRB, and researchers, as well as circulating updates on the latest safety procedures and protocols, thereby nurturing a culture of constant learning and progress in maintaining safety standards.

7.3 Monitoring and Auditing Procedures

Monitoring and auditing procedures are critical mechanisms put in place to foster continuous improvement and ensure compliance with the prevailing regulations. These measures are instituted to safeguard the integrity of all research projects at Regent. The procedures are summarized below:

A. ***Regular Monitoring.*** This entails the ongoing surveillance of research projects to verify adherence to the stipulated safety protocols and ethical guidelines. It is a proactive approach where the focus is on preventing issues rather than reacting to them. This continuous oversight ensures that all activities align with the university's commitment to fostering a safe and ethical research environment. Regular IRB meetings, reports, and updates form part of this monitoring process, helping to keep all stakeholders informed and engaged.

B. ***Internal Audits.*** Internal audits act as a checkpoint and allow Regent's Office of Academic Affairs to assess the effectiveness of existing risk management strategies critically. It provides an opportunity to identify both strengths and areas where improvements can be implemented. These audits involve a thorough analysis of various facets of existing research projects, scrutinizing the adherence to safety protocols, ethical considerations, and compliance with established regulatory requirements.

C. ***Feedback and Adjustments.*** Following the monitoring and auditing processes, feedback is gathered across departments and used to make necessary adjustments to the existing protocols and procedures that guide our research practices. This could involve tweaking safety measures to align with institutional values, revising ethical guidelines, or making any other improvements deemed necessary.

D. ***Regulatory Compliance.*** At the heart of these procedures is an unyielding commitment to upholding the standards mandated by state and federal regulations. This includes adhering to the stipulated reporting procedures in this handbook, keeping relevant authorities (e.g., the IRB) informed of the research progress and any incidents, if they occur.

7.3.1 Monitoring and Auditing Responsibilities

The responsibilities outlined in section 7.3 for monitoring and auditing procedures suggest a multi-tiered approach that likely involves collaboration between various entities within Regent. Below is a breakdown of entities that are responsible for specific aspects of the monitoring and auditing procedures.

A. ***The Office of Research and Sponsored Programs (ORSP).*** Typically, the ORSP would oversee the regular monitoring and auditing of research projects. The ORSP is responsible for establishing the monitoring protocols, conducting regular oversight of active research to ensure compliance with safety and ethical standards, and facilitating IRB meetings and reports.

B. ***The Researcher.*** Individual Regent researchers are accountable for maintaining adherence to safety protocols and ethical guidelines in their daily operations of their projects. They may also be expected to provide regular updates and reports to the ORSP or the IRB as part of the ongoing monitoring process.

C. ***Office of Academic Affairs.*** The role of conducting internal audits fall to the Office of Academic Affairs, assessing the effectiveness of the research risk management strategies in place. The ORSP reports to the EVPAA who oversees Regent projects to ensure consistent compliance with institutional and regulatory standards.

D. ***College/School/Departmental Committees.*** Specific departments or committees within Regent Schools/Colleges are also responsible for monitoring the research activities of their faculty or student, ensuring compliance within their specific disciplines.

8. Training and Education

Regent researchers should be well-versed with the necessary knowledge and skills to conduct research responsibly. To ensure that this is the case, the Office of Research and Sponsored Programs mandates some educational and training programs for all human subject researchers. The training is designed to equip students, staff, and faculty with the knowledge and understanding required to uphold the ethical and safety standards in their research projects. This education includes an in-depth understanding of laws governing research practices and relevant research trends to strengthen the research culture of the university.

8.1 Training and Education for Researchers

At Regent, fostering a culture of responsible research is a priority. This commitment is reflected in the educational and training programs administered by the Office of Research and Sponsored Programs, which are tailored to ensure that all prospective researchers are well-equipped with the requisite knowledge and competencies to undertake ethical and safe research projects.

A. ***Research Handbook Orientation.*** This research handbook contains information on the fundamental principles of ethical research. It is informed by established regulations (e.g., Belmont Report, the Common Rule, etc.) guiding human subjects research. All Regent researchers are encouraged to study the handbook and familiarize themselves with its content before undertaking a research role in order to understand the responsibilities and expectations associated with their position.

B. ***Ethical Conduct and Human Subjects Training.*** This CITI training module is a requisite for all researchers involved in human subjects research at Regent. It is designed to equip researchers with the knowledge and skills necessary to conduct research involving human participants responsibly and ethically. The training involves various elements including, but not limited to, an overview of the ethical principles governing human subjects research, informed consent process, risk assessment, and safeguarding participant confidentiality. Completing the CITI training via Regent's IRB portal ensures that researchers are well-acquainted with the principles of responsible conduct in research, including respect for persons, beneficence, and justice, which form the foundation of the Belmont Report.

8.2 Mandatory Certifications

Regent has collaborated with the CITI Program to offer free ethics training tailored for our research community. To that end, all researchers are required to complete the two specific training modules below and show evidence of their CITI certifications before applying for their IRB approval.

A. ***CITI Responsible Conduct of Research.*** The National Institutes of Health (NIH), National Science Foundation (NSF), and U.S. Department of Agriculture (USDA) require all researchers doing human subjects research to undertake Responsible Conduct of Research (RCR) training. While RCR is essential for researchers across all funding sources, it comprises a basic refresher course on communicating research findings, and facilitator guides. Although the training primarily addresses the needs of graduate students and postdoctoral researchers, it is also beneficial for everyone involved in research, from upper-level undergraduates to seasoned faculty members. This training and guides serve to enhance the quality of both in-person and online research training sessions.

B. ***Human Subjects Research (HSR).*** The Human Subjects Research (HSR) courses, split into Biomedical (Biomed) and Social-Behavioral-Educational (SBE) tracks, are tailored for researchers, policy-makers, and Institutional Review Boards. They offer both Comprehensive and Foundation versions, covering various aspects like informed consent, vulnerable populations, and big data research. Refresher courses and additional modules for specific roles, such as IRB and public health researchers, are available. Courses also address updates from the revised Common Rule and offer legacy versions for historical context. **Unless a researcher is involved in biomedical research, all Regent researchers are required to submit certification for the Social-Behavioral-Educational (SBE) track.**

Note. Upon the successful completion of these two training modules, researchers will be furnished with electronic certificates. These certificates not only symbolize their dedication to ethical research but are also vital components of their application toolkit. It's imperative for researchers to remember that this certification remains valid for a span of three years from the date of completion. Therefore, it is crucial that they ensure this certificate accompanies their application (by uploading this certification on Cayuse) to showcase their adherence to Regent's stringent ethical standards.

8.3 Ad Hoc Training (Not-compulsory)

Though not compulsory, Regent researchers may also pursue the following ad hoc training if the course or training is pertinent to their specific research interests or area of expertise.

A. ***CITI HIPAA for Education and Research.*** This module is specifically designed to guide researchers in educational institutions on complying with HIPAA regulations while conducting research. It provides insights into the appropriate use and disclosure of protected health information in research settings.

B. ***CITI HIPAA Basics for Healthcare Professionals.*** This module provides researchers, particularly those involved in healthcare research, with an understanding

of the Health Insurance Portability and Accountability Act (HIPAA). It covers essential aspects such as patient rights, privacy rules, and how to safeguard sensitive health information, which are vital in conducting research ethically and responsibly. It is designed to impart knowledge on how to handle personal health information correctly to avoid breaches of confidentiality.

C. ***Research Workshops and Seminars.*** Periodic workshops and seminars will be organized by the Office of Research and Sponsored Programs to help researchers stay abreast of the latest methodologies and tools in their field. These sessions are designed to enhance the researchers' technical skills, promoting innovation and excellence in university-wide research projects. Researchers are encouraged to participate in these research workshops and seminars.

9. Records and Documentation

Proper record-keeping is not merely an administrative function; it safeguards the rights and welfare of human subjects, upholds the integrity of the research process, and ensures that accountability is ingrained in every phase of a Regent-approved research project.

9.1 Maintenance and Retention

The following procedures and considerations are guidelines for managing data records and documentation.

Procedure:

A. All research-related records, including signed informed consent forms, research protocols, data sets, and correspondence, must be retained for a minimum of three years after the completion of the research (as per Section 8.4.2 of the NIH Grants Policy Statement) However, specific requirements can vary depending on the funding agency, the nature of the research, and other regulatory bodies involved. Regent researchers can extend beyond the federal minimum if there are good reasons for such extension. Researchers should always check the specific requirements of their funding agency to ensure compliance.
B. Records related to research that has been terminated before the expected end date must also be retained for a period of three years from the date of termination.
C. The researcher is responsible for the secure storage of records, and must ensure they are preserved in good condition, and are easily retrievable when required. Data should be stored electronically whenever feasible.

Considerations:

A. As we increasingly rely on digital platforms for research, frequent backups are paramount. As such, electronic records should be backed up regularly, and hard copies should be stored in a secure, climate-controlled environment to prevent degradation over time.
B. Duration of retention is not just about safeguarding data but ensuring that its handling aligns with legal mandates. It is not merely a regulatory necessity but bolsters the credibility of the research and the institution.

9.2 Accessibility and Confidentiality

While maintaining transparency and accountability is central to the research process, Regent recognizes the importance of protecting the confidentiality and privacy of the human subjects and the sensitive data they provide. The following should guide this process.

Procedure:

A. Only authorized personnel will have access to research records. This restriction ensures that personal and sensitive data remains confidential and protected from unauthorized access, alteration, or misuse.
B. Electronic files should be encrypted, password-protected, and stored in secure databases, while hard copies must be kept in locked cabinets in restricted-access areas.

Note: The Regent library has an Alma-D repository subscription. Contact the Dean of the Library if you need access to store your research files and dataset on the repository.

C. Requests for access to research records by external entities, be it for audit, regulatory oversight, or any other purpose, will be processed through established protocols in order to ensure a balance between compliance and confidentiality.

Considerations:

A. Regular audits should be conducted to ensure adherence to these protocols. Any breaches or lapses in data security should be addressed immediately and thoroughly investigated.
B. Regent researchers will be regularly trained and updated on the best practices for data management (see Section 8.1), ensuring they are well-equipped to handle and protect the valuable and often sensitive information they are entrusted with.

10. Problem Reporting and Resolution

The success of any research project lies in open communication and a commitment to rectifying concerns or issues promptly. When issues arise, whether anticipated or unexpected, Regent's response is characterized by transparency, urgency, and a dedication to upholding the highest standards of research integrity. The following are ways we resolve and report research-related issues.

10.1 Reporting Unanticipated Problems

The unforeseen nature of some problems makes them particularly challenging. Recognizing and addressing such issues swiftly safeguards the credibility of our research and ensures the protection of all involved. In the event that an unanticipated problem arises during the course of research, the following are procedures to follow:

Procedure:

A. Researchers are expected to report any unanticipated problems or adverse events immediately to the IRB upon discovery. This includes, but is not limited to, unforeseen risks to participants or breaches in confidentiality.
B. Such reports should be detailed in an email report to the IRB, clarifying the nature of the problem, its potential impact, and any immediate actions taken to address it.

Considerations:

A. Federal regulations, specifically 45 CFR 46.103(b)(5), emphasize the importance of ensuring prompt reporting of unforeseen issues to the IRB, appropriate institutional officials, and any relevant federal department or agency heads.
B. A swift response not only aligns with our ethical obligations but also can mitigate potential negative consequences. For instance, if a data breach occurs, immediate action can reduce the number of individuals affected.

10.2 Handling Complaints and Non-compliance

Open channels for reporting complaints and non-compliance are essential in preserving the trustworthiness and reliability of research projects.

Procedure:

A. Any member of the research community, participants, or the public can file a complaint regarding non-compliance with established protocols or ethical standards.
B. The IRB will review all complaints, assess their validity, and recommend appropriate corrective actions.

Considerations:

A. Non-compliance with IRB-approved protocols can lead to suspension or termination of research (see 45 CFR 46.113). Hence, addressing complaints seriously and promptly is not just good practice but also a regulatory requirement.
B. Confidentiality should be maintained for individuals reporting non-compliance to encourage open communication without fear of retaliation.

10.3 Appeal Procedures

We recognize that disagreements can arise, and hence this policy provides clarification for researchers on how to appeal decisions they feel might have been made prematurely or without considering all facets of the issue.

Procedure:

A. Researchers can initiate an appeal process via the Office of Research and Sponsored Programs (ORSP) if they disagree with a decision made by the IRB. The appeal process can be initiated via an email sent to the Director of ORSP, stating the reasons for the appeal and providing detailed information about the specific IRB decision in question. This should include the date of the IRB decision, the nature of the research project, and a clear explanation of why the researcher believes the decision should be reconsidered. It is also advisable to attach any relevant documents or data that support the appeal. The Director of ORSP will review the appeal and may consult with additional experts or the IRB itself before making a final determination on the matter.
B. A review panel, separate from the initial IRB review committee, will assess the appeal and ensure that all perspectives are considered before reaching a final decision.

Considerations:

A. While 45 CFR 46.110 and 45 CFR 46.111 outline the criteria for IRB approval of research, having an appeal process in place ensures that researchers feel their perspectives and concerns are genuinely considered.
B. The appeal process reaffirms our commitment to a transparent, fair, and inclusive research environment that promotes trust and mutual respect between the research community and the IRB.

11. Collaboration with External Entities

Collaboration is at the heart of research innovation. Therefore, working alongside external entities offers an unparalleled opportunity to pool resources, expertise, and insights. However, with these collaborations come unique challenges that require tailored guidelines to ensure the sanctity of ethical research. As we bridge our work with outside institutions and organizations, our commitment remains unchanged to upholding the highest standards of research integrity.

11.1 Inter-Institutional Agreements

Inter-institutional agreements (IIAs) are an essential part of the collaborations between Regent University and external entities (e.g., funding bodies, community partners). For collaborative research initiatives, Regent researchers should include additional details pertaining to the collaborating entity in the IRB application. Concurrently, submission of a duly signed research agreement is necessary and should be presented alongside the IRB application. Approval from the IRB will be contingent upon receiving this document when the Regent faculty is a PI in an externally funded or partnership project. While these agreements outline the roles, responsibilities, copyright, and expectations of each party involved—ensuring that the collaboration operates smoothly and ethically—they may be subject to legal review by Regent University's legal counsel.

Note: It is important to clarify that not all collaborative research necessitates an IIA. Specifically, if a Regent faculty member is invited to partake in a grant-funded project at another institution without assuming a PI role, an IIA may not be mandatory. However, in scenarios where a Regent faculty member is a PI, or in similar capacities, an IIA is a prerequisite. This might create a potential 'chicken-and-egg' situation where the university might be hesitant to formalize an IIA without confirmation of research approval and funding. Nevertheless, the approval of such research projects by the IRB remains contingent upon the submission of the relevant IIA documentation.

Key Components of IIAs:

A. ***Scope of Collaboration.*** Outlines the specific objectives and deliverables of the partnership in order to ensure that all parties have a clear understanding of the project's aim.

B. ***Resource Allocation.*** Details about resource sharing, including funding, infrastructure, and human resources. It is important to specify any shared facilities, equipment, or data and how they will be accessed or used by each party.

C. ***Data Management and Ownership.*** This is a critical aspect, given the proprietary nature of research data. The agreement should clarify ownership rights, storage, sharing protocols, and data protection measures.

D. ***Publication Rights.*** If applicable, determines how the collaborative research will be published and the attribution of credit. Acknowledgment of both institutions and the specific contributors is important.

E. ***Resolution Mechanism.*** Should disagreements or issues arise, the IIA needs a defined process for resolving disputes to ensure and sustain the collaboration between both institutions. Though such processes would be in alignment with Regent's existing dispute resolution polices.

11.2 Collaborative Research Guidelines

While IIAs form the structural foundation of collaborations, the everyday functioning and success of these ventures depend on research guidelines. These guidelines serve as a roadmap, guiding the researchers as they navigate the collaborative landscape.

Key Elements of the Guidelines:

A. ***Clear Communication.*** Essential for any collaboration, there should be open channels for dialogue between all parties. Regular meetings, updates, and feedback sessions can prevent misunderstandings and ensure alignment with the project's objectives.

B. ***Ethical Adherence.*** While institutions might have individual ethical guidelines, collaborative research should develop a unified ethical standard that all parties commit to, ensuring that the rights, safety, and dignity of all research subjects are upheld.

C. ***Roles and Responsibilities.*** Clearly delineating the roles of each researcher or team can prevent overlap and ensure that every aspect of the research process is covered.

D. ***Conflict Resolution.*** Despite best intentions, conflicts can arise. A predetermined mechanism for addressing and resolving these disagreements can help maintain harmony within research teams.

Considerations:

A. Given the heterogeneous nature of collaborative research, it is important to account for diverse methodologies, tools, and datasets. Ensuring compatibility can enhance the synergy of the collaboration.
B. Both federal guidelines and Virginia state regulations emphasize the importance of maintaining the rights and well-being of research subjects. In a collaborative setting,

unified adherence to these regulations, such as 45 CFR Part 46, is non-negotiable and even in collaborative research arrangements, Regent employees are primarily subject to our university policies.

12. Cost Consideration

All grant management activities at Regent are underpinned by the principle of stewardship (1 Corinthians 4:2). This ensures financial integrity, ethical use of funds, and alignment with our institutional mission. Proper stewardship guarantees that resources are used effectively and in ways that honor both the intent of the grantor and the values of the university.

12.1 Stewardship in Grant Management

Stewardship in grant management at our institution is defined by three pillars:

A. ***Financial Responsibility.*** Every grant dollar has a predetermined purpose. It might be allocated for research, infrastructure enhancement, or community initiatives. We are committed to ensuring that these funds are allocated responsibly. This commitment is upheld through detailed budgeting, periodic financial assessments, and rigorous auditing to confirm funds are utilized as intended.

B. ***Ethical Considerations.*** Beyond fiscal responsibility, the ethical use of grant funds is paramount. This means ensuring no misuse of funds, avoiding conflicts of interest, and upholding the highest standards of integrity in all grant-funded activities.

C. ***Mission Alignment.*** Every project we undertake is in alignment with our mission. It is imperative that grant funds not only meet the specific objectives set out by the grantor but also resonate with our broader institutional goals.

12.1.1 Scriptural Foundations for Stewardship

Our approach to stewardship is deeply informed by biblical teachings, which offer a rich tapestry of guidance on responsible resource management.

Several passages in Scripture emphasize the importance of being good stewards. For instance, Luke 16:11 highlights the value of trustworthiness with worldly resources as a reflection of one's character. Our policies and procedures for grant management seek to mirror these teachings, ensuring that every financial decision is made with integrity and in alignment with our Christian values.

12.1.2 Principles of Ethical Financial Management

Ethical financial management is non-negotiable in our grant management process. The principles that guide our approach include:

A. ***Accountability.*** We take full responsibility for every financial decision related to grant funds. Documentation is maintained for all transactions, ensuring transparency and a clear record for review.

B. ***Integrity.*** Funds are allocated and used strictly for their designated purposes. Any changes or deviations are communicated to relevant stakeholders and documented, ensuring transparency.

12.1.3 Grant Oversight

Each grant we receive is both a financial resource and a responsibility. Oversight mechanisms are in place to ensure that grant funds further our mission. This includes periodic reviews, internal audits, and feedback channels. Our goal is to ensure that projects funded by grants not only achieve their specific objectives but are also in harmony with our university's broader vision and values.

12.2 Guiding Principles and Cost Standards

When managing grants, we adhere to a strict set of principles and standards in order to ensure that every financial decision is made with transparency, accountability, and efficiency. These principles are not just in place to ensure compliance with grantor guidelines but also to ensure that we maintain our commitment to financial integrity and our institutional mission.

12.2.1 Recognized Cost Principles

Every grant comes with stipulations on how funds can be used. These stipulations are not arbitrary; they are based on widely recognized cost principles that ensure grant funds are used effectively and ethically. At Regent University, we commit to understanding and adhering to these principles in all our grant management activities.

12.2.1.1 Overview of Cost Principles

Cost principles serve as the foundation for financial decisions in grant funds. They provide guidelines on what costs can be charged to a grant, under what/which circumstances, and how these costs should be documented and reported. The following principles are designed to ensure that grant funds are used for their intended purposes and that there is a clear and transparent record of all financial transactions related to a grant.

While different grantors might have specific guidelines, several overarching principles apply universally:

A. ***Reasonableness.*** Costs charged to a grant should be reasonable, reflecting what a prudent person would pay in a similar circumstance.

B. ***Allocability.*** Costs should be allocated to a grant in proportion to the benefits received by the grant project.

C. ***Consistency.*** Costs should be treated consistently across different grants and funding sources. For example, if a particular type of expense is treated as a direct cost in one grant, it should be treated similarly in other grants.

D. ***Documentation.*** Every cost charged to a grant should be documented with appropriate evidence, such as invoices, receipts, or payroll records.

E. ***Sustainability.*** Costs should account for project sustainability within the timeframe stipulated by the grant. Strategies for sustaining the project post-funding should be compatible with the Memorandum of Understanding and mindful of the impact on broader institutional resources.

12.2.1.2 Determining Allowability of Costs

Determining whether a cost is allowable under a grant is a crucial step in grant management. Allowability is not just about checking if a cost fits within the budget; it is about ensuring that it aligns with both the grant's guidelines and our institutional policies.

To determine allowability:

A. ***Review the Grant Agreement.*** Start by reviewing the grant agreement or contract. This document will have specific guidelines on what costs are allowable and any restrictions or limitations.

B. ***Check Institutional Policies.*** Our university has policies in place for financial management (see respective Faculty & Academic Policy Handbook - 5.51ff and the Employee Handbook section on Governance, Management & Disclosure Policies - pp. 50ff). Ensure that the cost aligns with these policies or the policy in this handbook.

C. ***Ensure Adequate Documentation.*** Before charging a cost to a grant, ensure there is adequate documentation to support it.

D. ***Seek Clarification.*** If there is any doubt about the allowability of a cost, seek clarification. This might involve reaching out to the grantor or consulting with our Office of Research and Sponsored Programs.

12.2.1.3 Commonly Accepted Costs

While each grant will have its own specific guidelines on allowable costs, several costs are commonly accepted across most grants:

A. ***Personnel Costs.*** Salaries and wages for individuals working directly on the grant project.

B. ***Materials and Supplies.*** Items necessary for the project, such as lab equipment, research materials, or educational resources.

C. ***Travel.*** Travel expenses related to the grant project, including conference registration, transportation, accommodation, and per diem allowances.

D. ***Subcontracts.*** Costs associated with subcontracting part of the grant work to another entity.

E. ***Indirect Costs.*** Costs that are not directly attributable to the grant project but are necessary for its execution. This might include utilities, administrative support, or facility maintenance (see Section 12.3.2 for our indirect costs policy)

***Note*:** It is important to note that even these commonly accepted costs need to be reviewed for each grant to ensure they align with specific grantor guidelines and our institutional policies.

12.3 Direct and Administrative Costs

This section provides a detailed breakdown of how we handle both direct and administrative (or indirect) costs. Categorizing these costs is vital for the transparent and responsible management of grants at Regent.

12.3.1 Allocation of Direct Costs

Direct costs represent the core expenses directly attributable to a project or activity funded by a grant. At Regent University, the allocation of direct costs is based on a systematic and consistent method that ensures accuracy. Allocating these costs accurately is not just about bookkeeping—it is about trust, transparency, and ensuring the project's success.

12.3.1.1 Definition of Direct Costs

What exactly are direct costs? In simple terms, these are the costs we can directly link to a specific project or activity. If a project did not exist, neither would these costs. Think of them as the costs that are front and center in the project—salaries for the project team, specific

equipment or materials purchased for the project, or any specialized services or travel directly tied to project activities.

12.3.1.2 Costs Directly Attributable to Projects

When we talk about costs directly attributable to projects, we are referring to:

A. ***Personnel.*** This is often the largest chunk. The salaries and benefits of the people who are working full-time or part-time on the project can be accounted for here. Whether it is a researcher, a technician, or a project manager, if they are working on the project, their compensation is a direct cost.

B. ***Materials and Equipment.*** Need a new piece of equipment specifically for your project? Or specialized materials that are used up during the research? That is a direct cost.

C. ***Travel.*** If team members need to travel specifically for the project—maybe to collect data, attend a project-specific conference, or collaborate with a partner institution—that is a direct cost too.

12.3.1.3 Exclusions and Exceptions

Not everything that seems like a direct cost actually qualifies. Please take note of these nuances:

A. ***Shared Resources.*** If a piece of equipment is used for multiple projects, it might not be the best decision to charge its entire cost to one project. Similarly, if a team member is working on multiple projects, only the portion of their time dedicated to a specific project is charged as a direct cost to that project.

B. ***Capital Expenses.*** Large expenses like buying land or constructing a building do not usually count as direct costs for a project, unless the project specifically calls for such a purchase.

Occasionally, there are exceptions—costs that might typically be indirect but, due to the unique nature of a project, are treated as direct. But these exceptions are rare and are always well-documented and justified.

12.3.2 Indirect (Facilities and Administrative – F&A) Costs

Beyond the direct costs, every project incurs expenses that support its broader environment. These costs, which we term as “administrative” or “indirect,” are equally important. They sustain the infrastructure and services that make our projects possible. These costs include

building maintenance and depreciation, equipment upkeep and capital improvements, utilities, general administrative support, research administrative services, libraries, accounting services, procurement and purchasing departments (see 2 CFR 200.414).

Regent University's indirect rates have been established in line with the federal Uniform Guidance (see 2 CFR Part 200).

12.3.2.1 Methods for Calculating Indirect Costs

To help Regent staff and faculty understand and calculate the indirect (F&A) costs, here is an elaboration on Regent's adopted method.

Adopting the 10% *de minimis* rate of Modified Total Direct Costs (MTDC):
In accordance with 2 CFR § 200.68 and the flexibility offered in § 200.414(f), Regent University elects to apply a *de minimis* rate of 10% of MTDC for indirect costs. This simplified method is available to our institution, given that we do not currently have a federally negotiated indirect cost rate. The 10% *de minimis* rate applies to the following:

- Salaries and wages
- Employee benefits
- Travel expenses related to the project
- Costs of materials, supplies, and other services
- The first $25,000 of each subcontract

However, MTDC does not cover everything. Not covered under the 10% *de minimis* rate are:

- Costs for participant support
- Capital expenditures (such as equipment, land, and buildings)
- Patient care expenses
- Tuition waivers or scholarships
- Rental costs of off-campus facilities
- Subcontract amounts exceeding the initial $25,000 of the institution's total expenditures.

Calculating Indirect Costs at using the 10% *de minimis* Rate Scenario:

Imagine Regent University is managing a federally funded research project. The project has the following direct costs:

- Salaries and Wages: $60,000
- Employee Benefits: $15,000
- Travel: $5,000
- Materials and Supplies: $10,000

- Contractual Services: $8,000
- The first $25,000 of a subcontract with XYZ Corp: $25,000
- Equipment (capital expenditure, thus not included in MTDC): $30,000

To calculate the indirect costs using the 10% de minimis rate, you would:

A. **Add up all the MTDC eligible costs:**
   Sum of Salaries and Wages, Employee Benefits, Travel, Materials and Supplies, Contractual Services, and the first $25,000 of the subcontract: $60,000 + $15,000 + $5,000 + $10,000 + $8,000 + $25,000 = $123,000.

   (***Note***: Equipment cost of $30,000 is not included as it is a capital expenditure and not part of MTDC)

B. **Apply the 10% *de minimis* rate to the MTDC:**
   10% of $123,000 = $12,300.

C. **Total Project Costs:**
   With this calculation, the total project costs would be the sum of the direct costs and the calculated indirect costs.

   - Total Direct Costs (including Equipment): $123,000 (MTDC) + $30,000 (Equipment) = $153,000.

   - Calculated Indirect Costs using the 10% *de minimis* rate: $12,300.

   - Therefore, Total Project Costs: Direct Costs ($153,000) + Indirect Costs ($12,300) = $165,300.

In this example, applying the 10% *de minimis* rate yields indirect costs of $12,300, making the total project cost $165,300.

Exceptions and Sponsor-Specific Guidelines:
While adopting the 10% de minimis rate simplifies the calculation of indirect costs, it is still important to adhere to any specific guidelines provided by project sponsors. If a sponsor requires an indirect cost rate different from the 10% de minimis, this should be clearly documented and provided to the Office of Research and Sponsored Programs with the proposal materials.

There are times when sponsors will indicate that certain expenses should not be included in the indirect calculation. For example, a sponsor's guidelines may request that indirect costs should only be based on direct salaries and the associated benefits, in such scenarios we may use the salary and benefits as the base for our calculations.

Always check the guidelines of the sponsor, as they often specify what costs are allowable and which are not. **If a sponsor asks the Office of Research and Sponsored Programs to use a lower indirect (F&A) rate than our standard, please include a copy of the sponsor's policy with the proposal materials as proof.**

Our decision to apply the *de minimis* rate is in line with our commitment to transparency and ease of administration, ensuring compliance with federal regulations while effectively managing project costs.

12.3.2.2 Supporting Mission and Operations

Every dollar spent on administrative costs supports Regent's mission. These expenditures ensure that our campus remains a thriving, supportive environment for research and innovation. While administrative costs support institutional operations, the intent of research grants is to support research, and therefore the majority of grant funds should follow suit.

12.4 Ethical Reimbursement Practices

Reimbursement practices play a vital role in the financial health and ethical stance of any institution. Regent University is committed to ensuring that these practices not only meet regulatory standards but also uphold our Christian values. Here is a breakdown of our reimbursement protocols:

12.4.1 Transparent Reimbursement

Transparency is fundamental to ethical reimbursement. Every stakeholder in the Regent community, from faculty and staff to external partners and donors, should understand how reimbursement rates are determined, applied, and reconciled.

12.4.1.1 Basis for Reimbursement

Reimbursements are typically based on the actual expenses incurred in line with the approved budget for a specific project or activity. Documentation such as receipts or expense reports is essential to validate any claims. Every reimbursement should align with the predefined terms of the grant or project agreement.

12.4.1.2 Factors Affecting Reimbursement Rates

Reimbursement rates can vary depending on several factors:

A. ***Nature of the Expense.*** Operational costs may be reimbursed at different rates than capital expenses or salaries.

B. ***Terms of the Grant.*** Some grants may specify caps or limits on particular types of expenses.
C. ***Timeliness.*** Expenses reported promptly are more likely to be fully reimbursed, while delays can sometimes lead to reduced reimbursement if they push costs outside of grant periods.
D. ***Availability of Funds.*** Sometimes, the total grant fund availability might affect the rate or amount of reimbursement.

12.4.1.3 Reconciliation and Adjustments

At the end of a grant period, or at specified intervals, a reconciliation process is undertaken by the EVPFA and ORSP. This ensures that the total of all reimbursements matches the actual expenses incurred. If discrepancies are found, adjustments are made. This can result in either additional funds being reimbursed to the Office of Research and Sponsored Programs or funds being returned.

12.4.2 Limitations and Exceptions in Reimbursement

12.4.2.1 Common Limitations in Grant Reimbursements

There are some typical limitations that one might encounter:

A. ***Cap on Indirect Costs.*** Some grants will have a maximum allowable rate for indirect or F&A costs.
B. ***Exclusion of Certain Expenses.*** Items like entertainment, alcohol, or first-class travel are often excluded from reimbursements.
C. ***Time Restrictions.*** Expenses incurred outside the grant period, even if they relate to the project, may not be reimbursable.

12.4.2.2 Exceptions Based on Project Nature

Certain projects might have unique reimbursement rules:

A. ***Humanitarian Projects.*** Projects aimed at community welfare or emergency relief might have more flexible reimbursement rules, recognizing the unpredictable nature of such projects.
B. ***Long-Term Research.*** Multi-year research projects might have carry-forward provisions, allowing unspent funds from one year to be available in the next.
C. ***Collaborative Projects.*** When working in partnership with other institutions or organizations, there might be joint funding agreements that affect reimbursement rates and methods.

Regent University adheres to a principle of integrity in all reimbursement practices. We believe in being good stewards of the resources entrusted to us and ensuring that every dollar is accounted for transparently and ethically.

12.5 Transparent Cost Transfers

Proper management of cost transfers and overruns is needed to maintain financial integrity and ensure the effective use of grant funds. Regent University prioritizes transparency and accountability in these processes, ensuring that all transactions adhere to both our missional values and external regulatory requirements.

Cost transfers involve reallocating expenses from one account or project to another. These transfers are executed with complete transparency to maintain trust and ensure compliance with grant conditions. Such transfers are reviewed or approved by someone outside of the grant participants to ensure compliance (e.g., business office, ORSP, etc).

12.5.1 Criteria for Cost Transfers

Cost transfers should only be undertaken when:

- An expense is erroneously charged to a project and needs correction.
- An interim account was used because the final account was not established at the time the expense was incurred.
- A portion of the expense benefits multiple projects, and the cost needs to be distributed among them.

Please note that frequent, late, or inadequately explained transfers, especially ones that clear overruns or move expenses to a grant nearing its end, will raise questions about the propriety of the transfers.

12.5.2 Documentation and Justification for Transfers

All cost transfers must be supported by documentation that clearly indicates the:

- Reason for the transfer.
- Original charge and the justification for its reallocation.
- Details of the projects or accounts involved.

Transfers should be made as soon as the need for them is identified but no later than 90 days after the original transaction. Exceptions to this rule need strong justifications.

12.5.3 Audit Considerations

Cost transfers are subject to scrutiny during audits. To ensure we pass any such reviews, we need:

- Clear and concise documentation for each transfer.
- Proper justification for the reallocation, especially if it falls outside the typical time frame.
- Immediate corrective actions for any identified discrepancies or errors.

These audit considerations ensure that all transactions align with the terms of the grant and that funds have been used appropriately.

12.6 Addressing Overruns with Accountability

Budget overruns can pose challenges for any institution, but Regent University approaches them with a commitment to accountability and responsibility. By identifying, reporting, and managing overruns effectively, we ensure that our financial stability is maintained and that we continue to uphold the trust of our stakeholders and grantors.

12.6.1 Identifying and Reporting Overruns

Budget overruns occur when actual expenses exceed the approved budget for a particular project or activity. Good grant stewardship tends toward monitoring the process such that one hopefully sees the potential overrun coming and can make suitable adjustments before spending the funds. Things don't always go as expected, and we want to encourage good stewardship and transparency to mitigate the downside effects of problems.

Process of Identification:

- ***Regular financial reviews.*** Colleges/Schools/Departments should conduct periodic checks, comparing actual expenditures against budgeted amounts.
- ***Financial systems alerts.*** Automated systems (such as our research administration software, e.g., Cayuse) may notify departments when expenses are nearing, or have exceeded, their allocated budgets.

Reporting:

- Once an overrun is identified, it must be promptly reported to the appropriate administrative unit. In most cases, this should be to the EVPFA and ORSP.
- Detailed documentation should accompany the report, explaining the reasons for the overrun and any corrective actions taken or planned.

Note: Financial mismanagement of a grant could result in institutional intervention or restrictions on future institutional support of grant activity.

12.6.2 Strategies for Managing Overruns

Upon identifying an overrun, it is necessary to take swift and decisive action to manage and mitigate its impact.

Immediate Action:

- Freeze any non-essential expenses related to the project until a resolution is found.
- Review all recent transactions to ensure there are no errors or misallocations.

Long-term Solutions:

- Restructure the project's remaining tasks or activities to operate within the available budget.
- Seek additional funding or reallocate resources from other areas, after thorough consideration and approval from relevant authorities.
- If necessary, consider scaling back or altering the project's scope to fit within the available funds.

13. Forms and Templates

Regent University utilizes standardized forms and templates for the research process. These tools provide a structured framework, ensuring that researchers have a clear pathway to submit, document, and evaluate all facets of their research activities. They also ensure compliance with the institution's guidelines and adherence to both federal and Virginia state regulations.

Regent IRB forms can be accessed via the Cayuse research administration portal.

Form templates for the Informed Consent and other relevant document can also be downloaded at the Regent IRB website: https://regent.edu/irb

14. Resources and Additional Readings

Federal Policy for the Protection of Human Subjects. Commonly known as the "Common Rule." This policy governs the ethical treatment of human subjects in research funded by the U.S. federal government. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Belmont Report (1979). Ethical principles and guidelines for the protection of human subjects in research. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Office for Human Research Protections (OHRP). Provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services. http://www.hhs.gov/ohrp

45 CFR 46. The U.S. Code of Federal Regulations that pertains to the protection of human subjects in research. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

Virginia State Research Regulations. https://www.dss.virginia.gov/files/about/irb/procedures_sections/irb_operations/Virginia_Laws_Human_Subjects_Research.pdf

The Association for the Accreditation of Human Research Protection Programs (AAHRPP). An organization that promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs. https://www.aahrpp.org/

Collaborative Institutional Training Initiative (CITI) Information. Offers a wide range of online courses on human subjects research, animal research, and responsible conduct of research https://www.regent.edu/app/uploads/sites/2/2019/12/CITI-Training-Instructions.pdf

National Institute of Health Office of Extramural Research. Protecting Human Research Participants Tutorial: https://phrp.nihtraining.com/users/login.php (paid service)

Regent's Office of Research and Sponsored Programs. https://regent.edu/orsp

Office of Teaching Resources in Psychology. An excellent resource for faculty interested in conducting Research on Teaching and Learning: http://www.teachpsych.org/Resources/Documents/otrp/resources/martin14.pdf

Office of Research Integrity. This office oversees and directs Public Health Service research integrity activities for the U. S. Department of Health and Human Services. http://ori.hhs.gov

U. S. Department of Education. http://www2.ed.gov/about/offices/list/ocfo/humansub.html

U.S. Food and Drug Administration.
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118862.htm

Regent University's Faculty & Academic Policy Handbook.
https://www.regent.edu/academics/academic_affairs/documents/FacultyHandbook.pdf

Regent University's Employee Handbook.
https://www.regent.edu/admin/hr/portal/EmployeeHandbook.pdf