Approved 06/25/19

Rocky Vista University Institutional Review Board (RVU IRB) for Human Subjects Research – Bylaws, Standard Operating Procedures, and Forms

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IRB Bylaws/ Standard Operating Procedures

Approved on June 25, 2019 by the Rocky Vista University Institutional Review Board (IRB)

Note: "45CFR46" refers to wording of Title 45 Code of Federal Regulations Part 46 Protection of Human Subjects (Revised Common Rule effective January 21, 2019)

INSTITUTIONAL REVIEW BOARD MEMBERSHIP

Composition of the IRB

The Institutional Review Board shall consist of at least six members and preferably eight members:

Including "at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas."(45CFR 46.107(c))

Including at "least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." (45 CFR 46.107 (c))

Including, whenever possible, a diversity of members in consideration of gender, race and cultural background. (45 CFR 46.107(a))

Including, whenever possible, members who are knowledgeable about and experienced in working with vulnerable populations, such as children, prisoners, pregnant women, or handicapped or mentally disabled individuals. (45CFR46.107 (a))

Including members representing graduate programs likely to generate research with human subjects.

Determination of IRB members

The Institutional Review Board, as a Human Subjects Research Review Board, reports to the Chief Academic Officer. New members may be recruited by the IRB, but shall be appointed by the Chief Academic Officer.

Length of Term and Frequency of Meetings

The term of appointment shall be three years, on a staggered basis, with a new member selected each year. A member may serve a maximum of two consecutive terms. Terms begin with the academic year. The board will meet at least 6 out of 12 months a year with more frequent meetings when required for full research reviews.

Training

The chair or his/her designee should provide an initial training session to new members prior to the first meeting of the academic year, and additional training for all members as required by current federal regulations.

Chairperson and Vice Chairperson

The chairperson of the IRB shall be elected by the board for a two-year term of service. The chair shall not normally be drawn from members in their first year of service. The vice chairperson shall be elected by the board for a two-year term of service with the intent that he/she will be elected as the chairperson after two years have been served by the existing chairperson.

IRB Compliance Administrator

The compliance administrator of the IRB shall keep minutes of the full-board meetings. He/she will handle forms and IRB information for requests from researchers and keep all IRB-approved research in organized files. He or she will also assist in tracking the status of all IRB proposals.

RESPONSIBILITIES OF THE IRB

Quorum

A quorum consists of a majority of the board or four members, whichever is greater, including at least one scientific and one non-scientific member. These members may include the chair and the vice chair. (45CFR46.108(b) requires a majority of the members, including at least one nonscientific member).

Voting

A motion may be made by any member and seconded by a different member. Voting shall normally occur by a show of hands, in order that the number of affirmative and negative votes may be recorded.

"In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting" (45CFR46.108(b))

"If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing." (45CFR46.109(d)).

IRB Member Submitting Research Proposal

When a member, or the chair, of the IRB is also an investigator or advisor for a proposal being submitted, that member may provide information relating to the proposal. However, the member shall not vote, and will be excused from the room at the time of the vote. (45CFR46.107(e)). The member shall also be excused from serving as part of the process of approval when the proposal is submitted as "exempt" or "expedited".

Minutes and Agenda

Meeting minutes or agenda should include an informational record of proposals accepted as "Exempt" and proposals approved through the Expedited process, as well as those considered by the Full Institutional Review Board.

For proposals considered by the full board, meeting minutes should include a summary of the discussion (or an indication of no discussion, if warranted), and a specific accounting of the number of "aye," "nay," and "abstain" votes for the proposal. (45 CFR 46.115 (a) (2)).

Meeting minutes should contain the wording of any motion voted upon and the results of the motion.

Approval Process for Exempt, Expedited, and Full Reviews

The chairperson (or an experienced member designated by the chairperson) will review proposals submitted as qualifying for "Exempt". An additional IRB member will be asked to assist with "Limited Exempt" reviews, specifically under Exempt categories (2)(iii) and (3)(C) and (3)(iii) in order to determine that there are adequate provisions for protecting privacy and confidentiality. (See IRB Levels of Review – Appendix C)

The chairperson or vice chairperson will review proposals submitted as qualifying for "Expedited", and if a proposal is deemed by that person to require a full board review, it will be submitted to the full board.

Proposals not approved as Exempt or Expedited will not be disapproved, but will be referred to the Full IRB for consideration. Notification and reasons for modifications or referral will be provided in writing to the investigator(s). If the proposal is referred to the full board, the investigator may choose to modify the proposal prior to the meeting of the full board, as long as normal time lines for submission to the full committee are observed.

Approved research proposals shall be for a period of one year, and an annual progress report shall be submitted by the investigators to the IRB for continuing review after one year.

Any research proposal deemed to contain a higher than minimal level of risk for physical or mental injury or for a breach in personal privacy shall be submitted to the Full IRB for review.

The **IRB CANNOT** give retroactive approval to a study that meets the definition of Human Research. The primary role of the IRB is to administer and monitor the federal protections of participants in research. The IRB cannot ensure that federal protections have been followed or enforced once the study is underway or has been completed, therefore the federal regulations do not have a provision for retroactive approval.

Notification of Approval/Disapproval

Written notification of approval or disapproval through the Exempt or Expedited formats shall be provided by the IRB chair or vice chair to the principal investigators and a copy kept by the compliance administrator.

Written notification of approval or disapproval by Full Board Review, or of modifications required to secure IRB approval of the research activity, shall be sent by the chair/vice chair to the principal investigators, with copies to the IRB members.

"If the IRB decides to disapprove research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person or in writing."(45 CFR 46.109 (d))

Modifications of Proposal

Once approved, a research protocol may not be modified without permission of the board. The investigator should be reminded of this in writing at the time of approval.

Approval is for no more than one calendar year from the official date of approval. If data collection continues past that time, the proposal must be resubmitted with an annual progress report and a request for a continuation. The investigator should be reminded of this in writing at the time of approval. (45 CFR 46.109 (e)).

The IRB shall speak only to the issues of appropriate treatment of human subjects. Should any member of the board wish to provide feedback regarding other aspects of methodology, this should be clearly indicated as informal and not part of the approval process, and the member so involved should make clear that any change in methodology would require a resubmission of the proposal.

Records

A copy of the human subjects research policies, IRB meeting minutes, and research proposals received and action taken, shall be kept for at least three years. (45 CFR 46.115 (b)). Records of continuation shall include the initial approved proposal. This filing does not preclude transmission of similar copies to the next chair or administrator.

Institutional Consent for Data Collection

Prior to conducting research using human subjects, the investigator shall provide a full description of the proposed research to the institutional representative where data is to be collected, and have this approved.

(1) When the institution where data is to be collected is other than Rocky Vista University, an indication/agreement of institutional consent should be provided with the proposal given to the IRB.

(2) When Rocky Vista University is the institution both for IRB approval and for data collection, IRB approval will constitute institutional consent.

ROLE of the IRB

The IRB must comply with HHS and FDA regulations in 45 CFR part 46 and 21 CFR parts 50 and 56, respectively, when reviewing research subject to those regulations. Both the HHS regulations at 45 CFR 46.103(b)(4) and (5) and the FDA regulations at 21 CFR 56.108(a) and (b) state that IRBs must follow procedures for the following functions and operations:

1. Conducting initial and continuing review of research and reporting findings and actions to the investigator and the institution;

2. Determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

3. Ensuring prompt reporting to the IRB of proposed changes in a research activity and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects;

4. Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (i.e., OHRP) for research conducted or supported by HHS, and FDA for FDA-regulated research of any:

- Unanticipated problems involving risks to human subjects or others;

- Instance of serious or continuing noncompliance with the applicable HHS and FDA regulations or the requirements or determinations of the IRB;
- Suspension or termination of IRB approval.

IRB Review of Potential Risks to Subjects

Potential risks fall into five broadly-defined categories. The IRB will weigh the potential risks of research against the potential benefits as part of the review process. Researchers are expected to take steps to minimize potential risks.

- **Physical Risks**

Physical risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. A physical risk may result from the involvement of physical stimuli such as noise, electric shock, heat, cold, electric magnetic or gravitational fields, etc. Engaging a subject in a social situation which could involve violence may also create a physical risk.

- **Psychological Risks**

Psychological risks include the production of negative affective states such as anxiety, depression, guilt, shock and loss of self-esteem and altered behavior. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are examples of psychological risks.

- **Social/Economic Risks**

Social/Economic risks include alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling a subject in a way that will have negative consequences, or in some way diminishing those opportunities and powers a person has by virtue of relationships with others. Economic risks include payment by subjects for procedures not otherwise required, loss of wages or other income and any other financial costs, such as damage to a subject's employability, as a consequence of participation in the research.

- **Loss of Confidentiality**

In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Subjects have the rights to be protected against injury or illegal invasions of their privacy and to preservation of their personal dignity. The more sensitive the research material, the greater the care that must be exercised in obtaining, handling, and storing data. In order to minimize the risk for loss of confidentiality, investigators should only collect personal information that is absolutely essential to the research activity. If personal data must be collected, it should be coded as early in the activity as possible and securely stored so that only the investigator and authorized staff may access it. Identities of individual subjects must never be released without the express consent of the subject. In addition, if an investigator wishes to use data for a purpose other than the one for which it was originally collected and the data are still identifiable (e.g. a code list for the data still exists), the investigator may need to obtain consent from the subjects for the new use of the data.

- **Legal Risks**

Legal risks exist when the research methods are such that the subject or others will be liable for a violation of the law, either by revealing that the subject or others have or will engage in conduct for which the subject or others may be criminally or civilly liable, or by requiring activities for which the subject or others may be criminally or civilly liable.

Considerations for Vulnerable Subjects

The IRB shall consider whether the study involves subjects that are likely to be vulnerable to coercion or undue influence, and if so, whether additional safeguards have been included to protect their rights and welfare.

INFORMED CONSENT

When reviewing research subject to the revised Common Rule, the RVU IRB will evaluate the provisions for informed consent as described with the below variations. Investigators conducting research subject to the revised Common Rule must adhere to these requirements.

General Requirements for Informed Consent [§45CFR 46.116(a)]

The following specific requirements for consent, whether written or oral, apply to research subject to the revised Common Rule:

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR)

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence

3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR

4. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information

5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Generally, the beginning of an informed consent should include a concise explanation of the following:

a. The fact that consent is being sought for research and that participation is voluntary;

b. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;

c. The reasonably foreseeable risks or discomforts to the prospective subject;

d. The benefits to the prospective subject or to others that may reasonably be expected from the research; and

e. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

However, based upon the facts of an individual protocol, the IRB may require that different (or additional) information be presented at the beginning of an informed consent to satisfy this requirement.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.

No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Elements of Consent – added to General Requirements

In addition to the elements of informed consent, the following additional elements are required for research subject to the revised Common Rule.

Basic Elements [§ .116(b)]

1. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements (must be included when appropriate) [§ .116(c)]

1. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

2. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;

3. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Broad Consent [§ .116(d)]

The RVU IRB will not implement the new regulatory "Broad Consent" option as an informed consent process at this time. Exemptions 7 & 8, which rely on Broad Consent, also will not be implemented.

Waiver or Alteration of Informed Consent [§ .116(e) and (f)]

When reviewing research subject to the revised Common Rule, the IRB will evaluate requests for waivers or alterations of informed consent in accordance with the requirements and criteria specified in the revised rule and summarized below. The IRB's determination will be documented in the IRB record and communicated to the investigator via the project approval letter.

General Waiver or Alteration of Consent

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the RVU IRB must determine and document that the below criteria are satisfied.

1. The research involves no more than minimal risk to the subjects;

2. The research could not practicably be carried out without the requested waiver or alteration;

3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

5. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration") under this provision, the RVU IRB must determine and document that the below criteria are satisfied:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

a. Public benefit or service programs;
b. Procedures for obtaining benefits or services under those programs;
c. Possible changes in or alternatives to those programs or procedures; or
d. Possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

Restrictions:

1. Waivers – a. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

2. Alterations – a. An IRB may not approve a request to alter or omit any of the general requirements for informed consent for public benefit or service programs.

Screening, Recruiting, or Determining Eligibility of Prospective Subjects

The revised Common Rule removes the requirement for partial waivers of consent for the use of information or specimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects for inclusion in the research. Pursuant to the revised rule, the RVU IRB may approve a research proposal in which an investigator will obtain information or biospecimens for these purposes without the informed consent of the prospective subject or the subject's LAR if either of the following conditions is met:

1. The investigator will obtain information through oral or written communication with the prospective subject or LAR, or

2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing public records or stored identifiable biospecimens.

When research is subject to the revised Common Rule, and the above conditions are met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe the activities in the application or protocol submitted to the IRB. The above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a subject (including the use of their identifiable private information or biospecimens) in other research activities.

Documentation of Consent [§ .117]

The revised Common Rule modifies the requirements for documentation of consent as described below. When reviewing research subject to the revised Common Rule, the RVU IRB will apply the requirements summarized below.

Unless the requirement for documentation of consent is waived by the IRB, informed consent must be documented by the use of a written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy must be given to the person signing the ICF.

The ICF may be either of the following:

1. A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or

2. A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's LAR and that the key information required by § .116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. When this method is used:

a. The oral presentation and the short form written document should be in a language understandable to the subject; and

b. There must be a witness to the oral presentation; and

c. The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary);

d. The short form document is signed by the subject;

e. The witness must sign both the short form and a copy of the summary; and

f. The person actually obtaining consent must sign a copy of the summary; and

g. A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

Waiver of Documentation of Informed Consent [§ .117(c)] The revised Common Rule adds a third condition under which an IRB may waive the requirement for an investigator to obtain a signed informed consent form. When reviewing research subject to the revised Common Rule, the RVU IRB may also approve a request for a waiver of documentation of consent if it finds that:

1. The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

The IRB's determination will be documented in the IRB record and communicated to the investigator.

IRB Review of Grant Applications

The revised Common Rule removes the requirement that the IRB review the Federal grant application or proposal for consistency with the protocol submitted to the IRB. Unless required by the Federal department or agency conducting or supporting the research, or by foreign, state, or local laws or regulations (including tribal law), the RVU IRB will no longer require submission of, or conduct review of, Federal grant applications or proposals when research is subject to the revised Common Rule.

Posting of Clinical Trial Consent Forms [§ .116(h)]

The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency (such as the FDA) after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. This requirement may be satisfied by either the awardee or the Federal department or agency. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

Appendices

A. RVU IRB Registration Information (Office of Human Research Protections) and Federalwide Assurance

B. Research Protocol Approval Criteria – IRB Members

C. IRB Levels of Review – Full, Expedited, Exempt

D. Informed Consent Template – Research Participant Consent Form

E. Request for Waiver of Informed Consent Form

F. Conflict of Interest Policy and Declaration

G. IRB Research Modification Form

H. Annual Progress Report – Research Review

I. Student Research Approval Form

J. Definition of Human Subject Research

K. IRB Steps for Investigators Before Conducting Research

L. Checklist for Submission of Full Review Request

M. Request Application for Full Review of Proposed Research

Appendix A

RVU IRB

(Rocky Vista University Institutional Review Board)

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human subjects recruited to participate in a research study conducted under the auspices of the institution with which it is affiliated. The role of the IRB is to ensure the protection of human participants in a research study. Any institution that receives federal funding to conduct research with human participants is required to establish an IRB and to review and approve studies prior to collection of research data. The RVU IRB operates under a Federalwide Assurance (FWA 0000) through the U.S. Department of Health and Human Services and is registered with the Office of Human Research Protections.

IRB Organization Information

IORG0006156 - Rocky Vista University (Active)

Located at: Parker, COLORADO
Expires: 02/20/2022

IRBs for this Organization: 2
Agency Only Access

IRB#	IRB Name	City	State/Country	Status	IRB Type
IRB00007408	Rocky Vista University College of Osteopathic Medicine IRB #1	Parker	COLORADO	Active	OHRP Only
IRB00011973	Rocky Vista University IRB #2 - Clinical	Parker	COLORADO	Active	OHRP/FDA

Institutional Review Board Information

Parent Institution/Organization: IORG0006156 - Rocky Vista University (Active)

Located at: Parker, COLORADO
Expires: 02/20/2022

IRB00007408 - Rocky Vista University College of Osteopathic Medicine IRB #1

Located at: Parker, COLORADO
Membership Last Updated: 02/20/2019

Assurances Relying Upon this IRB

Agency Only Access

Assurance #	Assurance Name	City	Loc
FWA00021272	California Health Sciences University	Clovis	CALIFORNIA
FWA00019481	Rocky Vista University	Parker	COLORADO
FWA00020371	Rocky Vista University	Parker	COLORADO

Appendix B

Research Protocol Approval Criteria for IRB MEMBERS

Meeting or Expedited or Full Review Date: __/__/____

IRB #: _____

Reviewer: _____

Risks to Participants are minimized.

- ☐ Risks include both the probability and magnitude of harm, including physical, psychological, social, legal, financial harms and/or other.
- ☐ Scientific review to determine that research design is sound:
  - o Testable hypothesis
  - o Adequate summary of the literature
  - o Appropriate data collection to test hypothesis
  - o Adequate description of statistical methods
  - o Justification of sample size (power calculation)
- ☐ No unnecessary exposure to risks.
- ☐ Utilizes procedures already being performed for diagnostic or treatment purposes when possible.
- ☐ Risk Assessment:
  - o Study qualifies as minimal risk (risks are comparable to those ordinarily encountered in daily life or routine medical care).
  - o Study is greater than minimal risk
    - ▪ Direct benefit to participants
    - ▪ No direct benefit to participants

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

- ☐ Anticipated benefits outweigh the expected risk
- ☐ When research is more than minimal risk, benefits must be maximized/risks minimized and justified by the scientific merit.
- ☐ Only consider those risks and benefits which may result from the research as distinguished from those of therapies the participant would receive even if not participating in the research.
- ☐ Possible long-range effects of applying knowledge gained in the research (e.g., changes in public policy) should not be considered among the research risks and benefits.

Selection of Participants is Equitable.

- ☐ If populations requiring special consideration will be involved, include the appropriate population checklist.
- ☐ Is participation restricted by age, gender, minority status, pregnancy status or other criteria and is that restriction justified by the nature of the research?

- ☐ Is the participant population compromised by taking into account the purposes of the research or the setting in which the research will take place?

Informed consent will be sought from each prospective participant or the participant's legally authorized representative or surrogate.

- ☐ Consent of participant, LAR, or surrogate will be obtained.
- ☐ Consent waived. Attached waiver of consent request.
- ☐ Are there third party participants? If so, will consent be obtained or waived?
- ☐ Is there deception involved? If so, is it justified by the research and will participants be debriefed after participation or study conclusion?
- ☐ Recruitment plan presents research accurately and does not over-emphasize compensation and/or benefits.

Informed consent will be appropriately documented.

- ☐ Full consent form to be signed by participant, LAR, or surrogate.
- ☐ Short form or online consent will be used.
- ☐ Qualifies for waiver of documentation of consent.

The research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.

- ☐ A formal Data and Safety Monitoring plan is not needed due to the nature of the research; PI will monitor the study and review data.
- ☐ Is a Data and Safety Monitoring Plan needed and included? Is it adequate based on the risk?
- ☐ Does the monitoring plan include provisions for incidental findings?

There are adequate provisions to maintain confidentiality.

- ☐ Are there risks that could be further minimized by better data confidentiality/security?
- ☐ Are all identifiers being collected necessary?
- ☐ Will identifiers/code be maintained after completion of the study and if so is this justified, and will the data be adequately secured?
- ☐ Will sensitive information be collected and retained? Should a Certificate of Confidentiality be pursued?

Does the study require review more often than annually?

- ☐ Is there uncertainty in the risks such that the IRB should review this project more frequently than annually?
- ☐ Are there other reasons to consider that the IRB review this project more frequently than annually?

Research studies have the resources necessary to protect participants:

- ☐ Adequate time for the researchers to conduct and complete the research
- ☐ Adequate number of qualified staff
- ☐ Adequate facilities

- ☐ Access to a population that will allow recruitment of the necessary number of participants
- ☐ Availability of medical or psychosocial resources that participants might need as a consequence of the research.

Please send this form to the IRB Compliance Administrator at: ldement@rvu.edu or call 720-874-2481.

Appendix C

IRB LEVELS OF REVIEW

Initial Review of Research

The IRB Chair and IRB (Board) are charged with the initial review of a study and determining the type of review category under which a research proposal falls. It is the responsibility of the investigator to obtain approval from the IRB Chair prior to conducting a research study.

Research involving human subjects will fall into one of three overall categories: full review, exempt from review, or expedited review. A project may need to undergo a limited review before being placed in the exempt category in order to ensure that adequate privacy safeguards are in place regarding any identifiable private information. All research involving human subjects conducted by persons associated with Rocky Vista University, regardless of category of review or where the research is performed must be submitted to the IRB for review. If a research project will be published or presented for generalized knowledge (beyond the university), the proposal must go through the expedited or full review process as decided by the Chair.

Types of Review

Full Board Review

Full Board review of proposed research is conducted at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in nonscientific areas. Research that involves more than minimal risk may be required to go through full board review. All proposals that are not granted exempt or expedited review and all projects involving "vulnerable groups" (i.e., children/minors, institutionalized people, individuals with impaired decision-making ability) require a Full Board review. In both Colorado and Utah, a child is legally defined as a person who is under 18 years of age. Other projects that may involve more than minimal risk (e.g., sensitive questions, unusual interventions) to the subject also must have Full Board review.

Exempt Review

Some research projects involving human subjects are exempt from continuing review and oversight by the IRB once approved. However, the Board (or Chair) must review all proposed research and provide approval of the exemption to investigators. Investigators cannot determine on their own that their research is exempt. Certain types of research may qualify for exemption according to federal regulations contained in the **Department of Health and Human Services Code of Federal Regulations 45CFR46.101(b)**. All applications that are not granted exempt status must receive expedited review or full board review. The IRB Chair is authorized to provide an exempt action. Consent of participating subjects may be required for exempt studies. Some exempt proposals may require investigators to obtain consent from the subjects. The Board may take such action in the interests of protecting subjects and encouraging investigators to become more familiar with the concept of informed consent. Exempt proposals for research extending beyond one year must be resubmitted annually. In exempting proposals, the Board may require that, if the research is continuing, the proposal be resubmitted after one year. If no changes to the proposal are made, the researcher needs to address the progress of the research as noted under the "Annual Progress Report for Research" form.

Exempt Review Categories

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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

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

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

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

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

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

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

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

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be

ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

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

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

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

(6) Taste and food quality evaluation and consumer acceptance studies:

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

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below

the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by Sec. 46.111(a)(8).

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

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with Sec. 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Sec. 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by Sec. 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section;

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Expedited Review

Expedited review of research proposals can be performed by the IRB chair or a designated voting member(s) rather than by the entire IRB. The **Department of Health and Human Services Code of Federal Regulations 45 CFR 46.110** permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Continuing reviews are required for projects in this level of review. Research cannot be disapproved using the expedited process. However, review may be delayed until a proposal can be reviewed by a full IRB meeting, if necessary.

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories listed below are usually categorized as expedited. The activities listed should not be considered of minimal risk simply because they are included on this list. Inclusion on this list merely

means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human subjects.

Expedited Review Categories

1. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
2. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
3. Collection of data from voice, video, digital, or image recordings made for research purposes.
4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
5. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal

and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

6. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electro-cardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
7. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required, or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

For further questions or information, please contact the RVU IRB Compliance Administrator at: ldement@rvu.edu or 720-874-2481.

LIMITED IRB REVIEW

The revised federal regulations governing human subjects research, effective January 21, 2019, require a new type of review called "limited IRB review" for certain exempt and expedited protocols.

The new provision for limited IRB review allows certain research to be categorized as exempt, even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for exemption, the study must meet the standards of the limited IRB review. If the information is both identifiable and sensitive or potentially harmful, the safeguards offered by the limited IRB review may allow an exemption determination to be made.

Limited IRB review is required in the following circumstances:
Exempt category 2 (educational tests, surveys, interview or observations of public behavior) and Exempt category 3 (benign behavioral interventions): When the information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.

Reviews Related to Privacy and Confidentiality
The purpose of limited IRB review is to assure adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data. In order to assure these protections, the limited IRB review may consider the following topics:

- The nature of the identifiers associated with the data
- The justification for needing identifiable materials to conduct the research
- The feasibility of conducting the research with fewer identifiers (to lower the risk of a breach)
- Characteristics of the study population
- The proposed use of the information
- The overall sensitivity of the data being collected
- Persons or groups who will have access to study data
- The process used to share the data
- The likely retention period for identifiable data
- The security controls in place:
    - Physical safeguards for paper records
    - Technical safeguards for electronic records
    - Secure sharing or transfer of data outside the institution, if applicable
- The potential risk for harm that would occur if the security of the data was compromised.

Individuals Performing the Limited IRB Review
Limited IRB review must be performed by the IRB Chair or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. Disapprovals must be made by the convened board. If the limited IRB review does not result in approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories.

Appendix D

RESEARCH PARTICIPANT CONSENT FORM

[Insert Title of Study and IRB Tracking #]

Note to investigators: *this template encompasses all of the required and some additional elements of informed consent that are relevant to minimal risk research, as required by federal regulations. These requirements (bolded black text) must be included. If your research is FDA-regulated, greater than minimal risk, and/or is a clinical trial, please check to ensure that all relevant required and additional elements are included in the final version submitted to the IRB. Text that does not apply to your research should be deleted or modified as appropriate. The red text is intended to be instructional rather than declarative. The gray, bracketed areas must be filled in. Be sure to delete all instructive text, which is in red, italicized font throughout the document, and also any gray highlighting and brackets before submitting the informed consent for IRB review.*

You are invited to be in a research study of [Insert a brief, general statement with KEY, COMPREHENSIBLE information about study].
We ask that you read this form and ask any questions you may have before agreeing to be in the study. Your participation is entirely voluntary.

This study is being conducted by [Name of researcher, department (indicate University affiliation)].*

**If the Researcher is an RVU student, use the following (delete if none):*
This study is being conducted by [Name of researcher, department (indicate University affiliation)], **under the direction of** [Name of Faculty Adviser, department (indicate University affiliation)]

Purpose of Study

The purpose of this study is
[Explain research question and purpose in lay language]
You were selected as a prospective participant in this study because [tell why subject is being asked to participate]

Procedures

If you agree to be in this study, we will ask you to do the following things:
[Provide a detailed description of what participants will be asked to do, taking care to use easily understandable terms. Include discussion of any data about the participant that will be gathered that is not received directly from the subject. Subjects should be told about audiovisual recording, assignment to study groups, length of time for participation, frequency of procedures, etc.]

Duration

Participation in the study involves the following time commitment:
[Explain expected time commitment for any study related tasks.]

If clinically relevant research results will be returned, describe the circumstances under which this will be done.
The study team [will/will not] return clinically relevant information to you. *(Delete if not clinical research.)*
If the study involves biospecimens, the following information must be included:
This research [will/will not] include whole genome sequencing. *(Delete if no biospecimens being used.)*

Risks and Benefits of Being in the Study

The study involves the following foreseeable risks and/or discomforts: *(Risks must be explained, including the likelihood of the risk. This section must be consistent with the risks as explained in the protocol submitted to the IRB. If risk potential is minimal, state as deemed to be very low risk. Keep in mind that loss of confidentiality is almost always a risk in research. If physical injuries or mental health risks are present, a sentence must be included that states whether treatment will be provided from the research team or from the research team's resources or from subject's own health insurance.)*
[Risk(s) and/or Discomforts]

The benefits to participation are: *(List direct benefits to subjects. If none, state. If appropriate, list the broader societal benefits briefly (e.g. "More broadly, this study may help the researchers learn more about [topic] and may help [future populations with a similar issues/future researchers design interventions to help with a topic] etc. This section must be consistent with the benefits as explained in the protocol submitted to the IRB.)*
[Benefit(s)]

Compensation and/or Costs

(If subjects receive compensation for travel and/or time or any other form of compensation, include that information here. OR Note here if there will be no compensation.)
You will receive payment:
[Include payment or reimbursement information here.]
OR There will be no compensation for your participation in this study, but your help is appreciated by the researchers. OR There may be costs involved for you as the participant such as: [include if they will pay for traveling or any other special item they need to be aware of]
If biospecimens collected as part of this research project will be used for the research team or institution's commercial profit, you must include the following statement. Delete if not applicable:
Your biospecimens, even once de-identified, may be used for [research team's/sponsor's/institution's, etc.] commercial profit. You [will/will not] share in that commercial profit.

Confidentiality

Edit the section below as appropriate for the particular study but KEEP the bolded text. Address then delete red, instructional text once complete. Bracketed text must be modified as appropriate or deleted as applicable according to instructional text:

Participation in research may involve some loss of privacy; however, the researchers will make every effort to ensure that information about you remains confidential. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study. *Delete the following bracketed text if not applicable for research involving focus group/ethnographic/oral history research projects):* [However, it may be possible for someone to recognize your particular story/situation/response.] *Include the following bracketed text if your research is in a group setting:* [While we will ask all group members to keep the information they hear in this group confidential, we cannot guarantee that everyone will do so.]

We will collect your information through [audiovisual recordings, interviews, audio recordings, surveys, records reviews, email, etc.]. **This information/data will be stored and safeguarded by** [in a restricted access folder on an encrypted, password protected, cloud-based storage system, a locked drawer in a restricted-access office, etc.].

Choose one of the following statements. Only delete one or the other – not both. **Your identifiable private information or identifiable biospecimens collected as part of the research will <u>not</u> be used or distributed for future studies, even if identifiers are removed. OR Identifiers may be removed from your identifiable private information or identifiable biospecimens, and after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research without additional informed consent.**

If the data has identifiers that will be separated and destroyed, state the timeframe for doing so: [state time frame here] *If the data is necessarily identifying (e.g. videos, extensive demographic data, etc.), please state the timeframe for destruction of that data and what, if anything, will be kept:* [state time frame and describe what will be kept

here]. **This informed consent form will be kept for three *(required minimum)* years after the study is complete, and then it will be destroyed.**

Include the following text if using an online survey or data collection tool. Delete if not:
The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person's everyday use of the internet.

The section below must be included.
It is unlikely, but possible, that others such as the Rocky Vista University Institutional Review Board (IRB), or state or federal officials may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Voluntary Nature of the Study

Participation in this study is entirely voluntary. Your decision whether or not to participate will not affect your current or future relations with the researchers or Rocky Vista University. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Delete this section if none, or if the research does not involve experimental procedures:
Appropriate alternatives:
[Disclose any appropriate alternative procedures or courses of treatment that may be advantageous to the participant.]

Contacts and Questions

The Institutional Review Board (IRB) for the protection of human research participants at Rocky Vista University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at [Phone number], [E-mail address]. **If you have questions about your rights or would simply like to speak with someone other than the research team about the questions or concerns, please contact the IRB administrator at (720) 874-2481 or via email at: ldement@rvu.edu . All reports or correspondence will be kept confidential.**

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP FOR YOUR RECORDS.

Statement of Consent

I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

Participant Name (Printed) _____

Participant Signature (18 or older): _____ **Date:** _____

Signature of Investigator: _____ **Date:** _____

Signature of parent or guardian:_____ **Date:** _____
(If minors or those having legally authorized representatives are involved. Otherwise, you may delete this signature line.)

Appendix E

Waiver of Informed Consent

For Requesting a Waiver of the Informed Consent Process

All forms must be typewritten and submitted via email to the IRB Compliance Administrator.
Please email this form with IRB submission to: ldement@rvu.edu

Section 1. PROTOCOL INFORMATION

1A. Principal Investigator:
1B. IRB Research Protocol Number:
1C. Project Title:
1D. Is this research regulated by the US Food and Drug Administration?[1] ☐ Yes ☐ No
1E. Is this research regulated by the US Department of Defense?[2] ☐ Yes ☐ No

Section 2. REQUEST FOR WAIVER

A protocol which does not include an informed consent process may be approved by the IRB under certain conditions. To request IRB approval of a protocol which does not include an informed consent process, please provide a response to all of the following questions. Please be specific in explaining why each statement is true for this research.
2A. Explain why and how the research involves no more than minimal risk to the subjects.
2B. Explain why the waiver will not adversely affect the rights and welfare of the subjects.
2C. Is the research team collecting identifiable private information and/or identifiable biospecimens? ☐ Yes ☐ No **If yes, explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**
2D. Explain why the research could not be practicably be carried out without the waiver of informed consent.
2E. If a waiver of informed consent is approved by the IRB, will subjects be provided with additional pertinent information after participation? ☐ Yes ☐ No **Explain/describe why or why not:**

Principal Investigator Name Printed	*Principal Investigator Signature*	*Date*

[1] FDA regulated research is not eligible for a waiver of alteration of informed consent.
[2] If the research subject meets the definition of 'experimental subject,' a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of 'experimental subject,' the IRB may waive consent.

Appendix F

CONFLICT of INTEREST POLICY and STATEMENT **IRB#**

ALL research involving human subjects requires review and consideration by the RVU Office of Research Compliance & Protection (ORC-QA) and the RVU Human Investigations Review Board (IRB).

Each protocol submitted to the IRB for review must be accompanied by a completed and signed COI Disclosure for each investigator/key personnel who is directly involved in the treatment or evaluation of research subjects in the proposed study.

Protocols submitted without the COI Statement will not be accepted or reviewed until all appropriate COI documents are received.

Address any questions to the Office of Research Compliance & Quality Assurance (ORC-QA) at 720.874.2481.

Rocky Vista University ORC-QA & IRB
POLICY on CONFLICT of INTEREST in Research Activities

PURPOSE

The intention of this policy is to protect and serve human subjects and potential subjects of research. The policy cannot, nor is it intended to, eliminate all situations of conflict of interest, but is intended to help those involved recognize and resolve situations that may potentially be deemed as compromising the integrity of the research, and/or the safety and welfare of the participants (both Investigators and Subjects).

To assure the confidence of the public in the activities and judgments of RVU Faculty involved in human subjects research, all persons identified as "Key Personnel" on any project are required to disclose any real, potential, or perceived conflicts of interest. Such disclosure is based on the presumption of the highest standards of honesty and integrity expected of Faculty, and should be an important aspect of the regular review of Faculty professional activity.

POLICY

Individuals directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied. When an Investigator (or other Key Person) is in a position where their own interest **may** be placed above the best interests of research subjects, a conflict of interest issue is created. Conflicts involving the IRB itself or conflicts involving the institution must be managed.

In order to manage such conflicts, the IRB must be informed of all potential conflicts of interest. Investigators, and other Key Persons, named on submitted protocols involving human subjects **must** disclose all interests that may be perceived as being in conflict with the best interests of the subject(s) in order for the proposal to receive IRB approval.

IMPLEMENTATION:

A. Investigators/Key Personnel must complete and submit the ORC-QA/IRB "Declaration of Conflict of Interest (COI)" Form attached to this policy statement.
B. Investigators/Key Personnel who have completed a financial disclosure form required by another agency or the research sponsor for the same project may submit a copy declaration to the IRB.
C. Based on the information submitted by the Investigators/Key Personnel for review, the IRB may determine that:
    1. no conflict exists, or
    2. a conflict exists and must be disclosed to the subjects in the informed consent statement, or
    3. a conflict exists and the conflict must be resolved before the research can be approved.

EXAMPLES OF REPORTABLE AND NON-REPORTABLE ACTIVITIES

1. Non-Reportable Activities

The following activities and relationships do not need to be reported and do not represent a conflict of interest because they have been generally accepted practices and do not violate fundamental ethical principles.

a. Receiving royalties for published scholarly works and other writings.
b. Accepting honoraria for commissioned papers and occasional lectures.
c. Receiving payment for reasonable travel and lodging expenses related to presentations of scholarly work or to a person's academic endeavor.
d. Investing in mutual funds.
e. Participating in a University approved practice corporation.
f. Payments for clinical research to an approved practice corporation or to a department fund for salary or other expenses of conducting clinical trials.

2. Reportable Activities

a. Conducting research in applied and/or clinical research on a technology developed by the investigator or a member of his/her immediate family (spouse, children, parent, in-laws, siblings).
b. The financial relationship of an investigator or his/her immediate family member with the sponsor of his/her research (acting as scientific advisor or consultant, or receiving honoraria exceeding $5,000 annually, or acting as director or other executive).
c. Conducting applied and/or clinical research on a technology owned by a business in which the investigator or a member of his/her immediate family holds 5% or more of the outstanding stock or stock options.
d. Receiving royalties under institutional royalty-sharing policies from marketing the drug, device or procedures that is the subject of the research.
e. Receiving payments directly from the sponsor, rather than through the University or an approved RVU entity, for recruiting subjects.

DECLARATION of CONFLICT of INTEREST (COI)

The Rocky Vista University (RVU) Office of Research Compliance and Protection (ORC-QA) requires that **each** protocol submitted for review to the RVU IRB must be accompanied by a declaration of COI for **each** "Key Person" directly involved in accomplishing or evaluating research involving human subjects in the proposed study. This "Declaration of Conflict of Interest (COI)" must be completed and submitted (with signature) for each Initial Application, and for each Continuing Application, for IRB review

Principal Investigator:

Title of Protocol:

Key Person Completing this Declaration:

In order to protect subjects from financial conflicts of interest or perceived conflicts of interest, the IRB requires that such potential conflicts be disclosed. If the IRB determines that a conflict exists that could influence the research or jeopardize the well being of subjects, the IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the subject in the Informed Consent Statement.

If you or any member of your immediate family (spouse, children, parent, in-laws, and siblings) has a financial interest in either a public or private company whose drug, procedure, technique, device, or software is used or tested in this study, please indicate the following:

☐ Yes ☐ No I own equity (stock ownership in excess of 5%, Stock Options, Real Estate, or other ownership interest in any amount) in the company whose product (drug, procedure, technique, device, software, etc.) is being studied.

☐ Yes ☐ No The company holds patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings).

☐ Yes ☐ No I, or a member of my immediate family, hold(s) a senior management, or director position in the company whose drug, procedure, technique, device, or software being studied.

☐ Yes ☐ No I am a scientific advisor or consultant to the company, and receive honoraria exceeding $5,000 annually.

☐ Yes ☐ No I acknowledge that if the device, technique, software, or procedure being studied is marketed, I or a member of my immediate family will get royalty income or other income from the sale of the product.

☐ Yes ☐ No Any other financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent.

Please include a separate letter of explanation if there is further information that the IRB should consider.

If I have not checked any of the boxes above, or attached a letter of explanation for consideration by the IRB, my signature below is my representation that I have no financial or other conflict of interest that could adversely affect a subject in this study.

I acknowledge that I am required to notify the IRB within 10 business days if any change of my disclosure status occurs.

_____ _____

Signature Date

Appendix G

MODIFICATION FORM – HUMAN SUBJECTS RESEARCH

INVESTIGATOR INFORMATION	
PROTOCOL TITLE:	**DEPARTMENT/ FACULTY:**
CAMPUS ADDRESS: (Utah or Colorado)	**PHONE:** **DATE:** **EMAIL:**
CO-INVESTIGATORS:	**IRB # :**

TYPE OF MODIFICATION (CHECK ALL THAT APPLY)
Please upload any revised documents (forms, scripts, etc). Upload a brief summary of the proposed changes as well as a justification.

☐	New Procedures	Upload a description of the new procedures and a revised consent form.
☐	Study Title Change	What is the new title?
☐	Change in Study Personnel Click or tap here to enter text.	☐ Add (include the name, role, and contact information). Include signature of department chair or principal investigator. Click or tap here to enter text. ☐ Delete X_____ *Authorized Signature*
☐	Change in Location or Study Participants	☐ Add (include the name and location. If this changes the enrollment that should be noted below.) ☐ Modify ☐ Delete
☐	Change in Enrollment	Upload a narrative justifying the change. If this will affect the consent, send a revised consent form as well.
☐	Consent Change	Upload a copy and describe the change(s).
☐	Advertisement	Upload copies of the advertisement or announcement.
☐	Instruments (surveys, questionnaires, interviews, etc)	Upload copies of the proposed instruments and describe any changes from the approved protocol. If you are adding or deleting any instruments or items to an instrument, describe what the changes are and submit the revised materials.
☐	Other	Describe the changes. If this affects the consent process, submit a revised consent form.

Please justify why this change/modification is being requested. **(next page)**

Appendix H

PROGRESS REPORT (Annual Review or As Requested by IRB)

ALL research involving human subjects requires review and reconsideration by the RVU Office of Research Compliance & Quality Assurance (ORC-QA) and the Institutional Review Board (IRB).

As a condition of project approval, the IRB provides for regular reviews (in the form of a Continuing Review or a Final Report) of all research projects involving human subjects. These reviews are required, at a minimum, on an annual basis (or more frequently, appropriate to the degree of subject risk).

The information provided by the prompt completion and submission of the Progress Report will provide the basis for continued approval of your project.

Please answer all questions.

Do not leave items blank. If a question is not relevant to the project, please mark "None" or "N/A", as appropriate.)

Please note that an INCOMPLETE or INACCURATE Progress Report (attachments missing, incomplete forms, faulty data entries, illegible writing, etc.) will be returned without review, and may result in the loss of IRB approval, which would entail suspension or termination of the research protocol.

Additionally, Federal regulations require all documentation for projects involving human subjects to be submitted in a timely manner, even if the project has been completed. Failure to comply with this requirement will result in revocation of IRB approval, and may delay processing of future IRB applications.

IRB#_____ (found on original Review Request) ☐ **Continuing Review** ☐ **Final Report**

PROJECT INFORMATION

Project Title:

_____

Name of Principal Investigator:

_____

Name of Contact Person (if not PI):

_____

Department/Program: _____

Telephone: _____ ***Email:*** _____

Sponsoring Entity:

_____

Sponsor's Grant/Protocol Number:

_____

PROJECT STATUS:

- ☐ Actively Enrolling new subjects
- ☐ Subject enrollment complete; ongoing subject research involvement
- ☐ Subject enrollment and research involvement complete; subject follow-up ongoing
- ☐ Subject enrollment, research involvement, and follow-up complete; data analysis continues
- ☐ Project NOT YET STARTED (list reason and date expected to begin)

  _____

- ☐ Project ON HOLD (list reason and date expected to resume)

  _____

- ☐ Project COMPLETED / CLOSED (list date completed/closed)

  _____

- ☐ Project terminated before completion (list date and reason project terminated)

  _____

- ☐ Project has not been and will not be conducted (list reason project not pursued)

  _____

PROJECT AMENDMENTS and/or PROTOCOL MODIFICATIONS:

Have any changes or modifications been made to the protocol since the most recent IRB review?
(This includes changes to: Amendments; investigator brochure revisions; safety addendums; sponsor changes, or sponsor-requested changes to informed consent; etc.)

- ☐ No
- ☐ Yes

If YES, please attach or insert a brief summary of all protocol changes made since the last IRB review.

SUBJECT ENROLLMENT:

Number of Subjects (max) approved by IRB	
Date of FIRST subject enrollment* *(month/year)*	
Date of MOST RECENT subject enrollment* *(month/year)*	
Total number of subjects reported previously **	
Number of new subjects†	
Total number of subjects reported to date	

* Subject enrollment defined as date of signing Informed Consent document(s)
** If this is the 1st Progress Report for this study, place a zero in this blank.
† Report the number of new subjects enrolled since the most recent progress report.
If this is the 1st progress report for this study, report the total number of subjects enrolled to date.

Of the total number of reported subjects, please provide the following information regarding the current status of study participants.

	Total Number of Subjects to Date *
Subjects actively involved in the research protocol	
Subjects involved in follow-up data collection only	
Subjects completed research protocol & follow-up	
Subjects lost to follow-up	
Subjects withdrawn from protocol by PI	
Subjects self-withdrawn from protocol	
Subject deaths**	

* The summed figures in these boxes should equal the total number of subjects enrolled to date (above).
** NOTE: Subject deaths, as with all serious adverse events (SAEs), must be reported to IRB Immediately.

Please answer the following questions (if applicable):

Reasons subjects were withdrawn from the protocol by the PI *(during this reporting period):*

Reasons Subjects self-withdrew (their decision) from the protocol *(during this reporting period):*

SUBJECT ENROLLMENT (cont'd):

Gender Distribution of Study Subjects

	Enrolled to Date
Female	
Male	

Ethnic Distribution of Study Subjects

	Enrolled to Date
African-American (Black)	
Native American/American Indian	
Asian	
Caucasian (White)	
Hispanic/Latino	
Native Hawaiian/Pacific Islander	
Other/Unknown Origin	

Federal regulations require that women and minorities be included in all studies unless there is a valid scientific rationale for excluding these individuals as subjects.

Is there a valid scientific rational for excluding specific individuals bases on gender/ethnicity?

☐ No ☐ Yes *(If YES, please describe, briefly)*

If no women or minorities are included in the above numbers, has a specific recruitment plan to recruit female and minority subjects been developed/implemented?

☐ No ☐ Yes *(If YES, please describe below)*

CONSENT DOCUMENT STATEMENT:

Was informed consent obtained on all human subjects?

☐ Yes ☐ No If NO, please explain:

Copies of the executed consent forms are maintained at: _____

Briefly describe any problems you have encountered in obtaining and documenting informed consent from participants:

SERIOUS ADVERSE EVENTS:

Did any serious adverse events (SAEs) occur since you last reported on this study?

☐ No ☐ Yes

If YES, please indicate number of the following: **On-site** SAEs _____

Off-site SAEs _____

Was an IRB SAE Report (form ORC-QA-1001) completed for each SAE? ☐ No ☐ Yes

Was it necessary to modify consent forms as a result of reported SAEs? ☐ No ☐ Yes

If yes, provide date of IRB approval of revised consent: _____

Based on your knowledge of the adverse events for this study, do you feel there is a significant increase in risks to subjects?

☐ No ☐ Yes (*If YES, please explain, briefly)*

If your protocol described safeguards which were designed to avoid risks or detect complications, were these safeguards adequate?

☐ Yes ☐ No (*If NO, please explain, briefly)*

SUBJECT COMPLAINTS:

Did research subjects register any complaints about this study since the most recent IRB Progress Report was filed?

☐ No ☐ Yes (*If YES, please explain, briefly)*

DATA SAFETY MONITORING BOARD (DSMB) REPORT:

For some protocols, a Data Safety Monitoring Board (DSMB) is required.

All DSMB reports **MUST** be submitted to the IRB within 10 working days of receipt.

If this study requires a DSMB, please indicate the date of the most recent DSMB Meeting/Report:

Date: _____

Attach copies of all DSMB Reports filed since the last IRB Progress Report submission*

RISK/BENEFIT ASSESSMENT:

Has anything occurred since initial IRB review and approval which may have altered the risk/benefit relationship?

☐ No ☐ Yes *(If YES, please provide a current assessment of the risk/benefit relationship of the research*)*

*Base this assessment on research data obtained; SAE occurrences, and all other relevant factors.

Has any new literature or findings been reported since you last reported on this study which would significantly impact the design of this study or the risks associated with this study?

☐ No ☐ Yes (*If YES, please attach a summary of these findings)*

SIGNATURES AND ASSURANCES

In accordance with federal regulations, all individuals identified as "key personnel" must complete (at protocol submission), and update (during continuing review) a current "Conflict of Interest Disclosure" for each research project involving human subjects.
The COI form must be completed and signed by EACH individual named as "Key Personnel" on the protocol. New "Key Personnel" must be added to the protocol, and must complete and sign a COI form at the start of their involvement on the project.

As a condition of continuing approval, the Principal Investigator (PI) certifies that the above research project and protocol has been and will be conducted in full compliance with all applicable federal, state, and local regulations and with all RVU policies pertaining to research involving human subject research.

The PI also asserts that the information in this Report is accurate.
The PI recognizes that any change(s) in the research activity, research proposal and consent forms must be reviewed and approved by the IRB prior to implementation.
The PI recognizes that all serious adverse events must be reported to the IRB.
The PI attests that any new knowledge that would significantly impact this study especially associated with subject risk, (relevant publications, new unpublished findings, etc.) will be noted in IRB reports.
The PI assures that all "Key Personnel" associated with the project have successfully completed educational training in the protection of human research subjects.
The PI assures that all "Key Personnel" associated with the project have completed and signed Conflict of Interest Disclosures relevant to this research project.

PRINCIPAL INVESTIGATOR

Name	Signature	Date

STUDENT OR CLINICAL RESEARCH COORDINATOR (if applicable)

Name	Signature	Date

REQUIRED PROGRESS REPORT ATTACHMENTS IF RESEARCH IS CONTINUING:

To this Signed Progress Report, please attach:

New/Updated) CONFLICT OF INTEREST (COI) forms
Please include a form for each individual listed as "Key Personnel" on this project.
NOTE: If this is a Close-Out or Final Report, no Conflict of Interest forms are required.

Refer to the Research Project Renewal Notice Memo for a listing of additional documents required for review.

Appendix I

STUDENT RESEARCH APPROVAL FORM

NOTE: THIS FORM MUST BE COMPLETED BEFORE BEGINNING ANY RESEARCH PROJECT AND TURNED INTO THE DIRECTOR OF RESEARCH, DR. DUANE BRANDAU IN CLINICAL AFFAIRS AT: DBRANDAU@RVU.EDU

Proposed Project Title: Click or tap here to enter text.

Student Investigator: Click or tap here to enter text. **Program/Grad.Yr.** Click or tap here to enter text.

Student Contact (Phone and Email): Click or tap here to enter text.

When will the research be done (dates)? Click or tap here to enter text.

Faculty Mentor: Click or tap here to enter text.

Department or Affiliation of Mentor: Click or tap here to enter text.

Mentor's Contact Information (Phone and Email): Click or tap here to enter text.

PROJECT DESCRIPTION

Click or tap here to enter text.

Note: The following CITIProgram Online courses must be completed prior to beginning the research project.
(Contact ldement@rvu.edu to request login instructions.)

Human Studies – **Introduction to Research: Date completed** Click or tap here to enter text.
Bench/Lab Research – **Basic Biosafety/Biohazard Training for Medical Students Date completed** Click or tap here to enter text. *(OSHA Biosafety is an annually required course)*

- **If the project involves human subjects, please go to linked document and complete the IRB worksheet to determine required level of IRB approval.** *(hover mouse over linked document and press control/click)*

Faculty Mentor's Signature: _____ **Date:** _____

Off-Campus Research Supervisor Signature (If Applicable): _____

Student Signature: _____ **Date:** _____

Send to: dbrandau@rvu.edu

Approval Signature: Director of Research: _____

Date: _____

Appendix J

Does My Research Project Need IRB Review?

It may be sometimes difficult to tell if a project needs to be reviewed by the IRB. Your research project must be submitted to the IRB if it involves the collection of data from human subjects and fits the following definition of "human subject research":

What is **HUMAN SUBJECT RESEARCH**?

The final rule expanded the definition of "human subject" to cover the collection of biospecimens (this does not include non-identified biospecimens). The new definition includes "a living individual about whom an investigator, whether professional or student conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Intervention includes both physical procedures by which data are gathered, manipulations of the subject or the subject's environment for research. *Interaction* includes communication via surveys, emails, phone calls, in-person, etc. or any interpersonal contact between investigator and subject.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research can include a wide variety of activities, including experiments, observational studies, surveys, tests, and recordings designed to advance the knowledge of a particular field. It generally DOES NOT INCLUDE such operational activities such as quality assurance, quality improvement, certain aspects of public health practice, program evaluations, marketing studies, fiscal or program audits, journalism, history, biography, philosophy, "fact-finding" inquiries (such as criminal investigations, intelligence gathering), and simple data collection for other purposes.

What you do with your results matters…

If you plan to publish, present, or archive your research, or otherwise share the results of the study, including the uploading of your results to an online or cloud-based platform, IRB review will likely be required. Please be aware that you must submit your research project application to the IRB for approval prior to initiating the research. However, human subject research that is not disseminated (e.g., it is conducted as part of coursework and is not shared outside of the classroom; university or departmental assessments that are not shared beyond the university; etc.) is NOT subject to review by the IRB.

Appendix K

IRB Steps for Investigators Before Conducting Human Subjects Research

Principal Investigators / Student Investigators

Steps for Submitting a New IRB Application

Step 1: Complete the Required Human Subject Protection Training

Principal Investigators and their co-investigators/study staff are required to take a human subjects protection training. To begin your training, request the Required Human Subject Training course information/instructions from the IRB Compliance Officer.

Step 1.b.: Students must fill out and have signed the "Student Research Approval Form" by a faculty mentor and the Director of Research.

Step 2: Determine Which Application to Submit and Request Forms from the IRB Compliance Officer at: ldement@rvu.edu

Projects that involve human subjects' research may undergo one of three types of review:

- Exempt Review
- Expedited Review
- Full Board Review

The type of review depends on the risk level of the research and if the research falls into one of the expedited or exempt categories as defined by the federal regulations.

For assistance in determining which application should be completed for your study, please refer to the IRB's guidance: IRB Human Subject Research and Compliance at: www.rvu.edu/academics/research
Once the application is received by the Compliance Officer, the IRB Chair will make the final determination on the type of review.

What happens if you send in the wrong application?

The IRB may be able to obtain the necessary information from the application that was initially submitted. If additional information is needed, the IRB will let you know. In some cases, the IRB will ask that you complete the correct application for your study type.

Step 3: Obtain Appropriate Signatures & Approvals

There are several signatures required on the IRB application. The IRB accepts original, scanned, faxed, or copied versions of the signature page. If you do not have access to a scanner, you can digitally sign a .pdf copy of the signature page and send it to the Compliance Officer.

For Student Investigators:

- Be sure to include the Student Research Approval form signed by your faculty mentor and the Director of Research.
- Your signature is required on the IRB review application.
- Your faculty mentor/advisor must also sign the application and be listed as a co-investigator.
- RVU has an IRB pre-review process and IRB applications must first be reviewed by the IRB

Compliance Officer.

For Faculty Investigators:

- Your signature is required on the application
- You are asked to be accountable for ensuring the student investigator(s) conduct ethical and compliant human subjects research.

Step 4: Assemble Study-Related Documents for IRB Review

The IRB reviews most study-related documents. The following documents should be included with your submission, as applicable:

- Appropriate Request for IRB Review Form
  - Exempt – 1001
  - Expedited – 1002
  - Full Review – 1003
- Declaration of Conflicts of Interest Form – 1006
- Informed Consent Template (filled in with study information)
- Outside IRB Authorization Agreement (if applicable)
- Completion of CITI Human Subjects Research Training certificate
- Recruitment materials
- Questionnaires/Surveys (if being used in the research)
- A text version of any website or audio/video advertisements
- Grant application (intramural or external) (if applicable)
- A device description/manual (if applicable)
- FDA, DHHS letters related to sponsorship (if applicable)
- Drug label information/package insert, Investigator Brochure etc.(if applicable)
- Data and Safety Monitoring Board (DSMB) Memo (if applicable)

If the project is federally funded and RVU is the prime awardee, submit a full copy of the grant application. If RVU receives a subcontract, submit relevant sections of the grant application and/or the scope of work. Additional steps are required if the project is related to grant funding.

Step 5: Email Application to the Compliance Officer

Prior to sending in your application, ensure that:

1. You and your study staff/co-investigators have taken the required human subjects protection training
2. You have completed the appropriate IRB application
3. You have obtained all of the proper signatures
4. You have assembled all study-related documents

After you complete the above steps, you may email your completed application and relevant documents to the Compliance Officer at: ldement@rvu.edu .

Exempt and Expedited submissions are reviewed on a rolling basis. If the study qualifies for Full Board review, it will be reviewed at the next Full Board meeting. Full Board meetings occur four times per year in March, June, September, and December or more often as determined.

PLEASE DO NOT CONDUCT HUMAN SUBJECTS RESEARCH WITHOUT IRB APPROVAL!!!

Appendix L

CHECKLIST FOR IRB FULL REVIEW REQUEST

Please submit in electronic format to Ms. Laura Dement, ORC-QA IRB Compliance Officer
ldement@rvu.edu

Please include with this submission, the following:

- ☐ **The Request for FULL REVIEW of Proposed Research Project**
- ☐ **Informed Consent Documents**
- ☐ **Subject Recruitment Materials (ads, flyers, questionnaires, etc.)**
- ☐ **Surveys, Study Materials, Research/Data Collections Tools, Medications Used, Medical Instruments Used, Risk Data, etc.**
- ☐ **Conflict of Interest (COI) statement(s) for EACH Listed Project personnel**
- ☐ **Certificate of Human Subjects Research Training for EACH Listed Project Personnel/Student (Faculty may provide a CV listing research experience and publications and have it evaluated for human subjects research background)**
- ☐ **Submitted Grant Proposal (if applicable)**
- ☐ **Clinical Protocol (for Clinical Trials)**
- ☐ **Investigator's Brochure (if applicable and for Clinical Trials)**
- ☐ **Medical Device or Drug Approvals (if applicable)**
- ☐ **All correspondence related to this protocol from the Sponsoring entity (if applicable)**
- ☐ **Outside IRB Authorization Agreement (if an IRB other than RVU's)**

* RVU Institutional Data must be requested from Office of Institutional Effectiveness

Appendix M

ROCKY VISTA UNIVERSITY

OFFICE OF RESEARCH COMPLIANCE & QUALITY ASSURANCE (ORC-QA)
INSTITUTIONAL REVIEW BOARD (IRB)

Request for FULL REVIEW of Proposed Research Project **IRB# _____**

ALL research involving human subjects requires review and consideration by the RVU Office of Research Compliance & Quality Assurance (ORC-QA) and the RVU Institutional Review Board (IRB).

Attach an additional page(s) if more space is needed to provide the requested information for any of the below.

NOTE: Proof or declaration of Human Subjects Research Training for all study personnel must accompany any submission to the IRB. Intro. to Research can be taken at: www.citiprogram.org Incomplete applications and/or supporting documentation will delay ORC-QA/IRB review and approval of this project. If you have questions, contact Compliance Officer, Laura Dement at: ldement@rvu.edu

PROJECT INFORMATION

Title of Research Activity: _____

Name of Principal Investigator: _____ ***Signature:*** _____

Department: _____ ***Phone:*** _____ ***Email:*** _____

Student Investigator: _____ ***Ph:*** _____ ***Email:*** _____

FUNDING INFORMATION: Indicate the category of the sponsor:

- ☐ Local Government
- ☐ State Government
- ☐ Federal Government
  - If YES, identify specific agency: _____)
  - If NIH, list specific Institute: _____)
- ☐ Industry (other than pharmaceutical)
  - If YES, identify specific sponsor: _____)
- ☐ Pharmaceutical Company (or other For-Profit Sponsor)
- ☐ External Non-Profit Foundation/Institution
- ☐ RVU Institutional Seed Research Program

TYPE OF RESEARCH PROJECT:

- ☐ Investigator-Initiated Study
- ☐ Student Research Project
- ☐ Clinical Trial (Drug or Device)
  - If Drug Trial, please identify phase: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
  - If Device Trial, check as applicable:
    - ☐ N/A (No FDA-regulated devices involved)
    - ☐ Non-Significant Risk
    - ☐ Significant Risk
      (i.e., presents serious risk to subjects' health, safety, or welfare by: use as an implant; supporting or sustaining human life; diagnosing, curing, mitigating or treating disease; preventing health impairment; or other means)

OTHER STUDY PERSONNEL *(Key Persons):*

Name	***Role***	***phone #***	***email address***

LOCATION(S) WHERE RESEARCH WILL BE PERFORMED

☐ RVU Facilities

☐ Other sites (Please list below)

Name of Site	Address of Site

☐ Multi-Center Clinical Trial (Please list other Centers below)

Name of Site	Address of Site

Has approval/ agreement been obtained from off-campus sites/ facilities.

☐ No

☐ Yes *(If Yes, please attach written documentation)*

Are other IRBs involved in the approval of this project?

☐ No

☐ Yes *(If Yes, please attach other IRB approval documents)*

DURATION OF STUDY:

Proposed Dates for Conducting the Research?

From: ____/_____ To: ___/_____

(Include month and year; MM/YYYY. If an ongoing study, indicate start date only.)

PROJECT DESCRIPTION:

Briefly state the objective(s) and procedures associated with this project in the space provided.

NOTE: Incomplete or unclear information will delay IRB review and approval.

PROPOSED INFORMED CONSENT STATEMENT

Is a signed Informed Consent document being used?

☐ No *(If NO, please attach written rationale [see 45 CFR 46. 116 (d)] as a separate document.)*

☐ Yes *(If Yes, please attach Informed Consent document.)*

What is the reading grade level of the Informed Consent document? _____

Will a Certificate of Confidentiality be requested from NIH?

☐ No

☐ Yes *(If YES, answer the following items)*

NOTE: For studies involving information that needs to be protected from subpoena, a Certificate of Confidentiality may be desirable. A protocol does *not* have to be NIH funded in order to obtain a Certificate. (*For more information on Certificates of Confidentiality see:* http://grants1.nih.gov/grants/policy/coc/index.htm)

Does the consent form tell the subject of situations where the PI may voluntarily comply with state laws? *(e.g. reporting of child abuse, elder abuse, or immediate danger to self or others)*

☐ No

☐ Yes

Has the confidentiality statement been modified to be consistent with the Certificate of Confidentiality protections (if not applicable, leave blank)?

☐ No

☐ Yes

Does the consent form include HIPAA Privacy Rule Information for the use of Protected Health Information (PHI)?

☐ No

☐ Yes

SPECIMEN STORAGE and/or BANKING

Does the study involve storage or banking of human specimens or identifiable private information for use in future studies (e.g., submission to a repository)?

☐ No

☐ Yes (*If yes, describe stored/banked specimens, and note where this is discussed in the Informed Consent.)*

_____

GENETIC TESTING and/or DNA/RNA EXTRACTION

Does the study involve genetic testing or DNA/RNA extraction?

☐ No

☐ Yes *(If yes, please describe.)*

Test results will:

☐ be given directly to subjects.

☐ be given to treating physicians

☐ not be given outside the research

In a separate attachment, please describe:

(i) the testing or extraction process;

(ii) the arrangements for storage of DNA/RNA samples; and

(iii) the duration of storage.

Please note page where these issues are discussed in the Informed Consent document(s).

FDA PRODUCTS (IF APPLICABLE and/or AVAILABLE)

DRUGS IND Sponsor: _____ **DEVICES** IDE Sponsor: _____

Please list all study drugs/devices by generic name only. (If no name, list study drug number.)

	FDA Approved?	FDA Approved for this Indication?	Is the drug being compared to Placebo?
1. _____	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
2. _____	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
3. _____	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
4. _____	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
5. _____	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
6. _____	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes

SUBJECT SELECTION and RECRUITMENT

Number of Subjects

Minimum _____ Maximum _____ Number to be Randomized *(for Clinical Trials)* _____

Age Range of Subjects _____

Ethnicity/Race of Subjects _____

Will this research study recruit subjects from the following categories? *(Check all that apply)*

☐ Pregnant Women ☐ Minors (aged<18y/o) ☐ Cognitively Impaired
☐ Prisoners ☐ RVU Students ☐ Military Personnel
☐ Employees of RVU ☐ Employees of sponsor ☐ Third Party Subjects
☐ Economically disadvantaged (homeless, evacuees)
(In an attachment, please describe the subject population.)

Does this study include any of the following as subjects?

☐ Normal Volunteers ☐ Patients ☐ Fetuses ☐ Genetics

Please indicate all that apply to this protocol for research involving minors (age<18y/o).

☐ Not involving greater than minimal risk.
☐ Involving greater than minimal risk with no direct benefit to individual subjects.
☐ Involving greater than minimal risk with no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject disorder or condition

How will you recruit and correspond with subjects for this study?

☐ Referrals (note: referral fees not allowed) ☐ Private Practice
☐ Corporate Practice ☐ Telephone ☐ Other: __
☐ Advertising *(check all that apply; attach copies of all ad/recruitment materials.)*
☐ Newspaper ☐ E-mail ☐ Website ☐ Poster ☐ Brochure
☐ Radio or TC (script; tape) ☐ Patient Recruitment Letter

Will Subjects be compensated (paid) for their participation in this study?

☐ No
☐ Yes *(If YES, please describe payment schedule, including TOTAL amount.)*

_____

Describe and justify any anticipated COSTS to study subjects (if not applicable, state N/A):

_____

How long will each subject be involved in the study?
(In an attachment, describe time and extent of subjects' participation; # of visits, hours per visit, total time, etc.)

RESEARCH DESIGN

Will audio taping or videotaping of subjects occur?

☐ No
☐ Yes If YES, how long will recordings be maintained? _____

Will any of the following instruments/methods be used? (*Check all that apply. Include copies for review.*)

☐ Interview (attach script/guide) ☐ Focus Group (attach guide)
☐ Surveys/ Questionnaires ☐ Standardized (published) tests/assessments *(Please list)*

_____
_____
_____

ETHICAL ISSUES *(Please respond to ALL Items)*

Does the study involve: (check all that apply)

☐ Painful or aversive stimuli
☐ Emotional stress
☐ Deception
☐ Withholding of critical information
☐ False information
☐ False feedback
☐ None of these

Please explain all checked items, and address the question of potential psychological harm to participants.

What residual effects of the procedures have been explored?

How will the project be monitored so that any unexpected or adverse events that pose a risk to subjects are promptly brought to the attention of the principal investigator?

What safeguards have been taken to insure protection against risks for any participant who is especially sensitive or vulnerable?

ETHICAL ISSUES cont'd *(Please respond to ALL Items)*

If the study involves deception, false information, false feedback, or withholding of critical information, will the participant be told why, or will they be debriefed?

☐ No
☐ Yes *(If YES, please explain)*

Are participants aware that data are being recorded or that they are under observations?

☐ No *(If NO, please explain)*
☐ Yes

Will any other data of a personal nature be gathered about the participant from other sources?

☐ No
☐ Yes *(If YES, please explain and answer the following question.)*

If the answer to the item above is "Yes", will the participant be asked to consent to this collection of personal data from other sources?

☐ No *(If NO, please explain)*
☐ Yes

Are there any aspects of the study which might constitute an invasion of the participant's privacy for which consent has not expressly and implicitly been given?

☐ No
☐ Yes *(If YES, please explain and answer the following question.)*

Participants must be able to withdraw at any time without difficulty, undue embarrassment, or negative consequences. Please describe how participants are made aware of their right to withdraw from the study?

SIGNATURES and CERTIFICATION.

A. The principal investigator agrees to accept responsibility for the scientific conduct of the project, that the scientific portion of the protocol is original and contains no false, fictitious, or fraudulent statements or data. Signature certifies that all listed investigators have reviewed the proposal and that the research will be conducted in full compliance with RVU research policies and federal regulations.
B. The principal investigator certifies that the Conflict of Interest Disclosure Statements enclosed are up-to-date for all key personnel on this project.
C. The principal investigator certifies that the Principal Investigator has sufficient staff and facilities to conduct the research.
D. The principal investigator certifies that all project personnel have the proper education, experience and expertise to conduct the study.
E. Continuing review is required in order to maintain the approval status and that the Principal Investigator is aware that progress reports must be submitted to the IRB in a timely manner.
F. The principal investigator certifies that ALL personnel involved in carrying out the research are familiar with the ethical guidelines for research involving human participants and have taken such training and other related training required by the RVU ORC-QA and/or IRB.
G. All changes in the study must be approved by the RVU IRB **prior** to implementation.
H. All adverse events must be reported to the RVU IRB.

PRINCIPAL INVESTIGATOR	Signature	Date

NOTE: If this is a "Student Project", the Principal Investigator signing above agrees to be fully responsible for all aspects of this project, and to serve as the Faculty Mentor/Advisor for the Student Investigator. The ORC-QA/IRB must be notified of such any change immediately.

STUDENT INVESTIGATOR	Signature	Date

Department Chair/Supervisor	Signature	Date

ORC-QA Responsible Official	Signature	Date

Other Signing Authority *(as necessary)*	Signature	Date

Please submit in electronic format to Ms. Laura Dement, ORC-QA Compliance Officer
ldement@rvu.edu

Please include with this submission, the following:

- ☐ **This Request for FULL REVIEW of Proposed Research Project**
- ☐ **Informed Consent Documents**
- ☐ **Subject Recruitment materials (ads, flyers, questionnaires, etc.)**
- ☐ **Conflict of Interest (COI) statement(s) for EACH Listed Project personnel**
- ☐ **Certificate of Human Subjects Research Training for EACH Listed Project Personnel/Student**
- ☐ **Submitted Grant Proposal (if applicable)**
- ☐ **Clinical Protocol (for Clinical Trials)**
- ☐ **Investigator's Brochure (if applicable and for Clinical Trials)**
- ☐ **All correspondence related to this protocol from the Sponsoring entity**

C.F.R. §46.102 on Investigators

Investigator means any individual responsible for the conduct of research involving human subjects, either for the study as a whole or for an individual site. If the research is conducted by a team at a study site, the investigator is the responsible leader of the team. The responsible person may also be called the principal investigator.

§46.104 Responsibilities of Investigators.

a. *As appropriate to their role in the research, investigators are responsible for ensuring that research is conducted according to:*

1. *sound research design and methods;*

2. *the IRB approved study plan (protocol);*

3. *the applicable terms of the grant, contract and/or signed funding agreements;*

4. *applicable laws and regulations, including those for protecting the rights, safety, and welfare of human subjects.*

Investigators are responsible for ensuring that members of the research team, including study staff and trainees, are appropriately qualified, trained and supervised

a. *Unless exempt from review, investigators are responsible for obtaining initial IRB approval, prior approval for any modifications to the research and, as required, continuing review of the research.*

b. *Investigators are responsible for providing the IRB with sufficient information and materials to make the required determinations in §46.111.*

c. *Unless waived by the IRB, investigators are responsible for ensuring that informed consent is obtained in accordance with §46.116 and as approved by the IRB.*

d. *Unless waived by the IRB, investigators are responsible for ensuring consent is documented to the extent required by §46.117 and as approved by the IRB.*

e. *Investigators are responsible for providing a copy of the informed consent document to each subject, unless the requirement of a written consent document is not part of the IRB approval.*

f. *Investigators are responsible for providing subjects with significant new findings developed during the course of the research that may relate to their willingness to continue participation, in accordance with §46.116.*

g. *When vulnerable populations are involved in research, investigators are responsible for implementing any additional safeguards as required by the IRB.*

h. *Investigators are required to permit and facilitate monitoring and auditing, at reasonable times, by the IRB of record, funding entities, sponsors, the Secretary, and other federal and state regulatory agencies, as appropriate.*

i. *Investigators shall ensure prompt reporting to the IRB of any noncompliance with the approved protocol or requirements of the IRB, and unanticipated problems involving risks to subjects or others.*

j. *Investigators are responsible for personally conducting or supervising the research.*

k. *Investigators are responsible for complying with regulatory and institutional requirements, including those relating to financial interests, which are relevant to the research.*

§46.105 Qualification Standards for Investigators.

a. *As appropriate to their role in the research, investigators must be sufficiently qualified by education, training, and experience to assume responsibility for the proper conduct of the research.*

b. *Investigators must assure that they have sufficient time and resources to properly conduct or supervise the research for which they are responsible.*

§46.106 Investigator Records, Reports and Documentation.

a. *Investigators are responsible for the safe and secure storage of research data (whether in paper or electronic formats) and for protecting the confidentiality of the data in accordance with the approved protocol.*

b. *Investigators are responsible for the accuracy and completeness of study data.*

c. *Investigators must maintain records appropriate to the research (e.g., the study plan, consent forms, and correspondence from the IRB) and permit inspection of the research records in accordance with §46.104(j).*

d. *Investigators must maintain records for at least three years after the research ends or for the length of time specified in applicable regulations or applicable institutional or sponsor requirements, whichever is longer, and should take measures to prevent accidental or premature destruction of these documents.*

e. *Investigators must submit written reports to the IRB as required by the IRB.*
