Approved 06/25/19

Rocky Vista University

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

BYLAWS AND PROCEDURES FOR THE OPERATION OF THE

ROCKY VISTA UNIVERSITY

INSTITUTIONAL REVIEW BOARD FOR PROTECTION OF HUMAN SUBJECTS

Role of the Institutional Review Board (IRB)

Mission: The mission of the RVU Institutional Review Board (IRB) is to assure adequate protections of the rights and welfare of human subjects research. To achieve this, the RVU IRB advises investigators in designing research projects in a manner to minimize potential harm to human subjects, review all planned research involving human subjects prior to initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ascertain that human subjects are indeed protected.

Function: The RVU Institutional Review Board (IRB) reviews all research protocols, submitted by students, faculty and/or staff involving human subjects. The IRB has the authority to approve, require modification, or to disapprove any research project, in accordance with standards set by the U.S. Department of Health and Human Services (HHS), Office of Human Research Protection (OHRP).

Ethical Principles Governing Research

The RVU IRB supports the advancement of research by creating a collaborative relationship with the research community to ensure that research with human participants is conducted in accordance with the ethical principles of *Respect for Persons, Beneficence,* and *Justice,* as put forth in the Belmont Report. The principle of respect for persons is applied through the informed consent process. The principle of beneficence is applied through the risk/benefit analysis which includes a review of the design of the study and the procedures in place to minimize risks. The principle of justice is applied through recruitment strategies and selection of research participants.

These ethical principles are the basis of the regulations which govern the protection of human participants in research, and apply regardless of the regulatory category (i.e., exempt, expedited, or full board) under which a study is approved. Furthermore, the IRB assures that equal protections will apply to all research involving human participants, regardless of funding source.

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