Human Subjects Research Compliance and Quality Assurance

Institutional Review Board (IRB)

The Rocky Vista University (RVU) Office of Research Compliance and Quality Assurance (QRC-QA) provides compliance information and assistance to RVU students, faculty, and staff in the areas of research, grants, and Institutional Review Board (IRB) activities.

The Office carries out a number of functions in these areas, including:

- Maintains institutional compliance with regulatory issues related to research and scholarly activity.
- Oversees Human Subjects protection through program oversight, education, policy setting, and outreach.
- Provides training in the ethical conduct of research, biosafety (including OSHA training), use of animals in research and institutional review board requirements.
- Serves as a clearinghouse and repository for all research proposals and projects involving human subjects, and refers research protocol applications to the RVU IRB for formal review and approval.
- Provides administrative support to the IRB and assistance to investigators who are preparing IRB applications.
- Maintains records of IRB reviews and approvals for investigators, and tracks progress reports, renewal requests, and ensures adherence to regulatory requirements.
- Facilitates innovation, collaboration, and involvement across the RVU community.

Research at Rocky Vista University

Institutional Approval for Research

RVU faculty, staff, or students conducting human subjects research are required to seek RVU IRB approval before initiating the study. (The location of the study and the source of funding — if there is funding — do not determine if approval is needed.)

The following questions and related information will help you determine the process required for embarking on a research study and, if needed, seeking IRB approval. Please also review the Steps to Submitting a New IRB Application document.

In addition to this information, the Research and IRB Frequently Asked Questions document provides responses to additional questions you might have related to this process.

Are you Conducting Research?

The university's IRB has assured federal regulatory agencies that the institution will review and approve all research that meet the federal definition of human subjects research. Determining whether or not a project meets the federal definition of human subjects' research is a two-step process. The investigator must determine if the project meets the federal definition of research and, if so, determine if the project includes human subjects.

DHHS Regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. For purposes of IRB review, RVU further defines the following terms:

A "systematic investigation" as an activity involving a prospective plan that incorporates:

- the organized collection of quantitative and/or qualitative data, or biological specimens, and
- analysis (or anticipation of analysis) of those data or specimens to answer a question or questions.

"Generalizable knowledge" is information based on results or findings that are expected:

- to be reproducible, and
- apply broadly with the expectation of predictable outcomes.

FDA Regulations defines clinical investigation as any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. (21 CFR 50.3(c), 21 CFR 56.103(c), 21 CFR 312.3(b), and 21 CFR 812.3(h)).

Are You Conducting Human Subjects Research?

The Federal Policy for the Protection of Human Subjects (Common Rule) defines human subjects as "…a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." Notice that the definition of human subject focuses on what information or material is obtained from people. If **either** of the following is true, your research activity involves human subjects.

All human subjects research, and all other activities which in part involve human subject research regardless of sponsorship, must be reviewed and approved by (or registered exempt by) the RVU IRB prior to initiation.

Please review the Research and IRB Review Process Decision Tree to confirm if your research involves human subjects. If you determine that your study does involve Human Subjects Research, you must complete the IRB Research Protocol Involving Human Subjects, form 1004.

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).

For additional information about the IRB's constitution, see the IRB Constitution document. (section G.)

Research and IRB Review Categories

If you are conducting research that involves human subjects, you must determine which research application to submit. The IRB reviews and approves research under three distinctive categories, specified by federal regulations: Exempt, Expedited, and Full IRB Research Review.

A. Exempt Review

Certain research is exempt from the requirements of the HHS regulations. Nevertheless, a determination that research is exempt does not imply that investigators have no ethical responsibilities to subjects in such research. Rather, it means that the regulatory requirements related to IRB review, informed consent, and assurance of compliance do not apply to the research.

At RVU the IRB is responsible for determining whether proposed research is exempt from HHS regulations for the protection of human subjects. To determine if your prospective project may qualify as Exempt, please review the Exemption from IRB Review Document and the Research and IRB Review Process Decision Tree.

If the project meets the description of an Exempt project, please click here: "**Request for Review - EXEMPT Research**" and complete the form (1001).

B. Expedited Review

An Expedited review procedure consists of a review of research involving human subjects by the IRB Chairperson, or by one or more experienced reviewers designated by the Chairperson from among members of the IRB, in accordance with the requirements set forth in 45 CFR 46.110.

HHS regulations allow some categories of minimal risk research to be reviewed by the IRB through an Expedited review procedure. Expedited review procedures may be used for:

a. research in the *OHRP Expedited Review Categories*, and found by the reviewer to involve no more than minimal risk;
b. minor changes in previously approved research during the authorized approval period.

To determine if a project qualifies for Expedited Review, please review the OHRP Expedited Review Categories. If the project qualifies for an "Expedited review, please click here: "**Request for Review - EXPEDITED Review**" and complete the form (1002).

C. Full Review

All projects involving greater than minimal risk, and not qualifying as Exempt or for Expedited review, requires approval by the IRB. Research at RVU that requires full IRB committee review may include one or more of the following elements:

- Prisoners
- Pregnant women
- In vitro fertilization
- Deception
- Fetuses
- Decisionally-impaired
- The use of school records of identifiable students or interviewing instructors about specific students
- Survey or interview procedures with children (participants under the age of 18 years)
- FDA research except in emergency circumstances
- Observation of public behavior when the investigator(s) participates in the activities being observed
- Data collected that includes protected health or medical information when there is a direct or indirect link that would identify the participant
- Sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol

For a Full IRB Review, please click here: "**Request for Review - FULL Review**" and complete the form (1003).

IRB Review Process

The IRB office utilizes an initial pre-review screening process, during which the Compliance Officer reviews each submission for completeness and compliance.

The RVU Compliance Officer may ask the Principal Investigator (PI) to make changes to the submission before it is reviewed by the IRB (pre-review). The IRB reviewer(s) may also ask for changes or clarifications, which the Compliance Officer will communicate to the research team after IRB review (post-review).

IRB Review Procedures

A. Exempt Review

The IRB Chair or the IRB Chair's designee will determine whether a submitted research project meets the requirements for exemption from IRB review. The IRB Chair, or the IRB Chair's designee, can require Expedited or Full Review of any research at his/her discretion, even if the research would otherwise qualify for Exempt review status.

The decision to actually grant Exempt review status is initially made by the IRB Chair, or the IRB Chair's designee, who must review the full set of documents submitted by the investigator in reaching a decision during an Exempt review.

Please see Steps for Submitting a New IRB Application to determine which documents and forms must be submitted to the IRB for consideration of exempt review

If it is determined that Exempt review is appropriate for a study, and the IRB Chair or the IRB Chair's designee wishes to utilize this procedure, the IRB Chair or the IRB Chair's designee will document his/her determination of risk. The review is then performed by the IRB Chair or the IRB Chair's designee.

The IRB Chair or the IRB Chair's designee will evaluate research determined to be Exempt to ensure that it meets Rocky Vista University's ethical standards. Such an evaluation might include the following:

1. The research holds out no more than minimal risks to subjects.
2. Selection of subjects is equitable.
3. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
4. If there are interactions with subjects, there will be a consent process that will disclose such information including:

    a) that the activity involves research;
    b) a description of the procedures;
    c) that participation is voluntary;
    d) name and contact information for the investigator; and
    e) there are adequate provisions to maintain the privacy interests of the subjects.

When a study has been certified as Exempt from IRB review, continuing review and approval is not required. Certification of Exemption is effective for the life of the study. However, all modifications to a study that has been certified Exempt must be submitted to the IRB for prospective review and certification of exemption prior to implementation.

In some circumstances, changes to the protocol may disqualify the project from Exempt status. If it is determined that the proposed study is exempt, the PI will be provided with a *Certificate of Exemption* that will include under what category of exemption the study was granted.

If it is determined that the proposed study is not exempt or additional information is needed to determine Exempt status or certification is granted pending acceptance of requested modifications/clarifications, the PI will be notified of this information in written form.

B. Expedited Review

Expedited review may be carried out by the IRB chairperson or by one or more experienced IRB members designated by the chairperson. All of the requirements for IRB approval of research apply to Expedited review.

Expedited review should not be viewed as a less rigorous review. Under Expedited review, the reviewers may exercise all of the authorities of the IRB, except that the reviewers may not disapprove the research.

Please see Steps for Submitting a New IRB Application to determine which documents and forms must be submitted to the IRB for consideration of expedited review.

C. Full IRB Review

Human subjects' research that is not classified as exempt or expedited requires review by the full IRB at a convened meeting. These meetings are closed meetings that are not open to the public; however, Investigators may be invited to attend the meeting to answer questions from the board. At the conclusion of the meeting, the board votes and issues a determination.

Please see Steps for Submitting a New IRB Application to determine which documents and forms must be submitted to the IRB for consideration of full review.

Submission of Materials for IRB Review

Please email all application materials described above (and in the Steps to Submitting a New IRB Application document) to the Compliance Officer. Prior to submitting 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.

Length of Time for IRB Review

The time to process an application depends on the complexity of the research study and the quality and completeness of the application submitted to the IRB. Other variables include whether the application can be approved by the IRB Chair or Chair Designee (expedited review) or by the full board.

The most common problem with New Project applications is that not enough detail is provided for the IRB chair or full board to evaluate the study's purpose and/or procedures. The more complete the initial description is, the less likely that your application will be routed back and forth between you the IRB to fill in the details. Read each question in the application carefully. Provide a complete and accurate answer to each question, and make sure that details throughout the application are consistent.

Possible Determinations after IRB Review

1. Approved - the IRB Chair or full board has approved your application with no required changes. You can start your research as soon as the approval memo is released to you.

2. Approved Pending - the IRB full board has approved your application, pending the completion of specified required actions. You will receive notification, which will state the required actions. The IRB Chair can approve the project once the required actions have been completed successfully.

3. Tabled - the IRB full board has tabled your application and has specified required actions. Following completion of the required actions, the full board must review your application at another meeting.

4. Disapproved - the IRB full board has disapproved your research application. You must start a new project application if you wish to pursue this application further.

5. Withdrawn - the application has been withdrawn, either at the request of the PI, or by the IRB, if the PI failed to respond in a timely manner to requests for more information.

IRB Application Submission and Review Flow Chart

For a graphical depiction of the IRB application submission and review process, please see the IRB Application Submission and Review Flow chart. (Please note that the time estimates on the chart may vary as indicated above.)

Human Subject Protection Training

All campus-based, full-time faculty, staff and medical students involved in human subjects research at Rocky Vista University must complete a training course covering the privacy laws which apply to the Health Professions to meet requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

In addition, a basic training course in biosafety, as required by the Occupational Safety and Health Administration (OSHA), must be completed. The avenue chosen for completion of this training is the Collaborative Institutional Training Initiative (CITI), provided through the University of Miami.

Research and IRB Review Frequently Asked Questions (FAQ's)

1. How do I know if I am conducting research with human subjects?

Please follow the steps in the Research and IRB Review Process Decision Tree.

2. When am I required to submit a proposal involving research with human participants to the IRB?

All research projects that will involve human participants must be submitted for review and approval before beginning the study. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

3. I am just doing a simple survey; do I need to submit my proposal to the IRB?

Yes, if the study meets the definition for research with human participants, as explained above. RVU Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services states that all research being conducted under the auspices of this institution is subject to review and approval by the IRB. Written approval from the IRB must be in place before any interventions or interactions with human participants (e.g., recruitment) actually begin.

4. I am not collecting any identifying information in my human participant research project. Do I need to submit my proposal to the IRB for review?

Yes, if your research project involves active data collection. Federal regulations and RVU policy require that ALL research involving intervention or interaction with human participants, regardless of whether or not identifying information is being collected, must be submitted for review prior to beginning the research study.

However, if your research project involves use of existing information collected from human participants (e.g., secondary datasets, existing biological samples), but there are not any identifiers linking individuals to the data/samples, then the activity may not require IRB review.

5. Can researchers be subjects in their own studies? Does self-experimentation require IRB review?

Yes, researchers can be subjects in their own studies. However, RVU policy regards this type of research (investigator self-experimentation) as research with human participants, and generally requires the same review and approval as research that recruits other people as subjects.

Though investigator self-experimentation may not raise the conventional ethical concerns outlined in the Belmont Report, all human research projects should undergo ethical review to assure the safety of people involved and the integrity of the research at the university. While researchers may be aware of the risks of self-experimentation, they may also be more willing to accept risks that are ill-advised. Application for review with the IRB office allows a neutral third party to raise concerns and/or propose measures to promote the welfare of researchers.

6. If my research qualifies as Exempt, does this mean that I don't have to submit a protocol for review?

No. The Federal Regulations do make certain categories of research exempt from IRB review. However, RVU policy does not allow investigators to self-exempt their human participant research projects. Instead, determining if a project is Exempt from IRB review is an administrative review process handled by the IRB staff.

7. I will be collaborating with another institution. Do I need to submit to RVU's IRB and the other institution?

If you are a member of the RVU faculty or staff, or a RVU student, and you are the person responsible for the conduct of the study (PI), you must get RVU IRB approval to conduct your research regardless of where the research takes place. Investigators should contact the IRB office whenever collaborative research is occurring. Separate applications for each institution may be necessary; however, in order to avoid duplicate review, an IRB Authorization Agreement may be arranged with the other institution to establish one IRB as the designated IRB to review and approve the research.

8. My research will be done in another country. Do I have to obtain IRB review and approval from RVU?

Yes. If you are a member of the RVU faculty or staff, or a RVU student, and you are the person responsible for the conduct of the study (PI), you must get RVUIRB approval to conduct your research regardless of where the research takes place. You should also be aware that your project may need local IRB approval (or the equivalent ethical review) in addition to RVU.

9. I want to conduct a study that involves the use of deception. Is this allowed? What do I need to consider?

The use of deception in research is not prohibited by either the federal regulations or RVU. However, because at some level the use of deception in research violates the trust that the participant puts in the researcher, this method should be considered carefully. Deliberate deception of participants may occur only in situations where withholding information about the nature of the study is necessary to ensure valid results, and never to get participants to do something that they would not do if the information was fully disclosed to them.

Researchers should describe for the IRB the method, rationale and the process of informing participants of the purpose of the research as early as is feasible preferably at the conclusion of an individual's participation (but no later than at the conclusion of data collection) to permit participants to withdraw their data. Additionally, researchers should provide a justification for the deception techniques and document that there are no equally effective non-deceptive techniques available. Please refer to the American Psychological Association's Ethical Principles of Psychologists and Code of Conduct for further guidance.

10. I am planning to do an oral history project; do I need to submit my proposal to the IRB?

Some research involving the collection and use of oral histories or life histories meets the federal definition of 'human subjects research' and requires an application to the IRB office, while other research using the same methods does not.

11. I am developing case studies; do I need to submit my proposal to the IRB?

Studies that use multiple case studies to draw conclusions that are applicable in a generalizable context, or to address a hypothesis, meets the federal definition of 'human subjects research' and requires review by the IRB office. Other case studies may not require IRB review.

12. When may I begin data collection for my study?

You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis. A memo will be sent to you via e-mail when your project has IRB approval.

13. How long will it take for me to obtain approval to do my study?

That depends on the nature of your study and the characteristics of the people you intend to recruit. Research projects that involve only minimal risks are eligible for Expedited review, wherein you should allow 2-3 weeks for IRB review.

Research projects that involve greater than minimal risk to participants will need to go to the Full IRB Review, wherein you should allow at least 4-6 weeks for review and approval of your study.

14. Can the IRB approve a project retroactively?

No. There is no provision in the federal regulations that allow for IRB approval of research that has already been conducted. If data was collected for purposes that the IRB determines to be non-research (e.g., program evaluations for library or educational programs not initially intended to be used for research), IRB approval can be sought for the data analysis going forward.

15. Who can I talk to if I have a question about my research project involving human participants?

The IRB staff is available to provide assistance to investigators who are engaged in research with human participants. The Compliance Officer is your resource for any general questions.

Additional Resources

A. Principal Investigator (PI)

The Principal Investigator (PI) is charged to conduct objective research that generates independent, high quality, and reproducible results. The Principal Investigator is responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships. Additionally, the Principal Investigator is responsible for the direction and oversight of compliance, financial, personnel, and other related aspects of the research project and for coordination with school, department, and central administration personnel to assure research in is conducted in accordance with Federal regulations and University and sponsoring agency policies and procedures.

B. 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, review the Required Human Subject Training information.

Note: Not all projects require IRB review and approval. Before getting started, determine if IRB approval is required. Please retain a copy of your certificate to submit with your application.

Step 2: Determine Which Application to Submit

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: Types of IRB Review.

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 does accept scanned, faxed, or copied versions of the signature page. If you do not have access to a scanner, you can mail a copy of the signature page to the Compliance Officer. Be sure to include a cover sheet that indicates the study title and Principal Investigator.

For Student Investigators

- Be sure to include the Student Research Project Checklist form
- Your signature is required on the application
- Your Faculty Advisor must also sign the application and be listed as a co-investigator
- Some schools/departments have an IRB pre-reviewer and IRB applications must first be reviewed by the pre-reviewer. Student investigators are asked to check with their school's research administration and/or Faculty Advisor to determine if a pre-review is appropriate

For Faculty Investigators

- Your signature is required on the application
- Your Department Chair must also sign the application. If you are the Department Chair, your Dean must sign the application.

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 Review Form
    - Exempt - 1001
    - Expedited - 1002
    - Full Review - 1003
- Protocol Synopsis Form - 1004
- Declaration of Conflicts of Interest Form -1006
- IRB Research Protocol Involving Human Subjects (if needed) – 1008-02IRB Protocol Synopsis for Surveys (if needed) - 1009
- Outside IRB Authorization Agreement (if needed) – 1006
- Checklist for Student Research Projects (if needed) – 1009-02

- Completion of CITI Human Subjects Research Training certificate
- Consent/Assent forms or information sheet (submit as a Word document)
- Recruitment materials
- Questionnaires/Surveys
- A text version of any website or audio/video advertisements
- Grant application (intramural or external)
- A device description/manual
- FDA letters
- Drug label information/package insert, Investigator Brochure etc.
- Data and Safety Monitoring Board (DSMB) Memo (if needed)

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.

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.

C. Creating a Research Protocol

A complete description of the planned research (i.e., protocol) must be submitted with initial applications for IRB or exempt review. The research protocol should provide the information needed for reviewers to determine that the regulatory and Human Research Protection Program (HRPP) policy requirements have been met. There is no required format or template; different sections and formatting may be used, provided the necessary information is included.

For additional information on submission for IRB or exempt review, see HRPP policies, IRB Submission and Pre-Review and Exempt Research.

I. Objectives. The purpose of the study (research questions and / or study objectives) should be clearly and succinctly stated. In experimental designs, objectives will be stated as hypotheses to be tested.

II. Background and Rationale. Summarize and synthesize the available research (including published data) to provide justification for the study. Evaluate prior research for relevance to the research question under study. When the proposed research is the first of its type to involve human participants, the results of relevant animal studies must be included. Discuss the anticipated results and potential pitfalls. Describe the significance of the research including potential benefit for individual subjects or society at large. Discuss how public health and social welfare might be enhanced.

III. Procedures. The procedures should include the following:

A. Research Design
The research design should be identified and should be appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative) and specific study design that will be used (e.g. pre-test /post /

test control group design, cross-sectional design; prospective longitudinal cohort design; phase III double-blind randomized control group design).

B. Sample
Describe the sampling approach. For experimental designs, include justification for sample size determination. Identify the procedures that will be used to recruit, screen, and follow study volunteers. Specifically define the study sample (number of subjects to be enrolled, characteristics of subjects to be included in and excluded from the research).

C. Measurement / Instrumentation
Identify the variables of interest and study endpoints (where applicable). Justify measurement techniques selected. Provide validity and reliability data for selected measures.

D. Detailed Study Procedures/Methods
Methods for study data collection and for avoiding / minimizing subject risks should be included. Include a timeline for subject evaluations and the duration of subject participation in the project. Identify the plans the proposed safeguards for subject confidentiality (plans for coding data and for securing written and electronic subject records). Indicate how long personal information will be stored once the study is completed.

Methods will vary with the research approach used (qualitative, quantitative, or mixed). The selected methods should be sufficiently described to justify the use of the approach for answering the defined research question. Methods should also be described in adequate detail so that IRB members may assess the potential study risks and benefits.

E. Internal Validity
Threats to internal / external validity should be considered. Describe measures that have been taken to avoid study bias.

F. Data Analysis
Specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.

IV. Bibliography. Include a reference list of literature cited to support the protocol statement.

D. Exemption from IRB Review

The "Common Rule" (45 CFR 46 subpart A) defines a set of research activities that may be exempt from its purview, unless otherwise required by Department or Agency heads. Exempt research has very little, if any, associated risk. These research activities, as defined by 45 CFR 46.101(b), include six exempt categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

a. the human subjects are elected or appointed public officials or candidates for public office; or

b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

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.

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

a. if wholesome foods without additives are consumed or

b. 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.

Note: RVU policy allows the IRB to disallow exemptions that are allowable under federal law. Also, the IRB Chair and/or the IRB Chair's designee may determine whether a submitted research project meets the requirements for exemption from IRB review. If the research project does not meet criteria for exemption, the PI will be notified and the project will require resubmission for either expedited review or review by the full IRB.

E. Research and IRB Review Decision Tree

Q1: Does your proposed activity involve the use of "Human Subjects"?

1. Will You Collect or Utilize Data:

1. Physically gathered from a person?
2. By manipulating a person or their environment?
3. By communicating with a person (e.g., via verbal or written survey/interview)?

2. *Will you collect or utilize privately identifiable information (i.e., the identity of the subject can be readily obtained by the investigator or from the information) from/about a person?*

Examples include:

- Medical records/tests (including previously archived test data),
- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place,
- Any information provided by an individual which was/is reasonably expected to not be made public.

3. *Is there an intervention or interaction with a living person that would not be occurring, or would be occurring in some other fashion, but for your activity?*

If you answered "No" to ***every*** question, your activity does ***not*** need IRB approval. You need not contact the IRB.

If you answered "Yes" to ***any*** question above, your activity requires action by the IRB. Proceed to Question 2.

Decision Tree: Formal Review

Q2: Does your proposed human studies activity require formal IRB review?

Since your activity involves human subjects, some form of IRB action is required. **YOU MUST CONTACT THE IRB.** Please continue reading.

Does your proposed activity include a systematic investigation, (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge?

Example activities likely *not* designed to develop or contribute to generalizable knowledge:

- Course projects used to explore, teach "textbook" knowledge.

If you answered "No": Inform the IRB that approval is not required.

http://www.wpi.edu/offices/irb/mainfo40.htmlExample activities *likely* designed to develop or contribute to generalizable knowledge:

- Project whose results might be published in a scientific journal/conference.
- Most federally-sponsored investigations; most investigations sponsored by not-for-profit agencies; most industry-sponsored projects (even if the results may be held proprietary).

If you answered "Yes": Your activity requires IRB review. Proceed to Question 3.

Decision Tree: Exemption

Q3: Should you apply to the IRB for an "Exemption"?

The government exempts human studies activities for one of six specific reasons. To apply for an exemption, your activity must be contained within one or more of these categories. The categories are summarized in the Exemption from IRB document.

Do You Believe That Your Activity Is Contained Within One Or More of the Exemption Categories?

If you answered "Yes": Apply for an IRB exemption for your activity using the IRB Application Form to apply for an IRB Exempt Review (form 1001).

If you answered "No": Your activity is not exempt. Proceed to Question 4.

Decision Tree: Expedited Review

Q4: Since your research does not qualify for an exemption, should you apply to the IRB for an "Expedited Review"?

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

Example activities likely to be considered "minimal risk":

- Written or verbal surveys on non-controversial topics or on topics not likely to evoke strong emotion.
- Non-invasive physiologic recordings (e.g., ECG, EEG).

Example activities likely not to be considered "minimal risk":

- Written or verbal surveys on controversial topics or on topics likely to evoke strong emotion (e.g., incidents of assault, sexually transmitted diseases).
- Invasive physiologic recordings.

Is your activity of "minimal risk" to all human subjects involved?

If you answered "Yes": Submit a completed IRB Application Form to apply for an IRB Expedited Review (form 1002).

If you answered "No": Submit a completed IRB Application Form to apply for an IRB Full Review (form 1003).

F. Informed Consent

The purpose of an informed consent is to help investigators protect research participants by informing them about the nature of the research, including the procedures to be followed and any associated risks or benefits to participation. In compliance with federal regulations, the IRB carefully reviews informed consent documents.

Consent documents vary in the way they are written and formatted. The IRB discourages the use of a "model" consent document because it believes that participants' rights will be better protected if investigators determine the appropriate language, format, and tone of the consent based on what they feel will best convey study information that is accurate and understandable to their participants.

Regulations require that certain basic elements be included in an informed consent. As a general rule, the following points should be considered when writing an informed consent:

- Include the basic required consent elements specified by the federal regulations.
- Use simple language. Many IRBs suggest that a consent form be written at no more than an 8th grade reading level.
- Avoid technical and legal terms.

For additional information, please see Human Subject Protection (Informed Consent): 21 CFR Part 50.

G. RVU IRB Constitution

The RVU IRB has been designated to review all research protocols 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 Department of Health and Human Services. In accordance with Federal regulation, the RVU IRB Membership Roster includes:

- a minimum of five (5) members
- at least one (1) female and one (1) male member
- members of varied backgrounds and professions
- at least one (1) member whose primary experience is in nonscientific areas
- at least one (1) member whose primary experience is in scientific areas
- at least one (1) member who is not affiliated with Rocky Vista University

Federal regulations also stipulate that the membership of an institutional review board include:

- reviewers with expertise in all of the areas of research being reviewed*
- a diversity of backgrounds, including racial and cultural diversity
- members with sensitivity to community attitudes
- knowledge of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice
- knowledge and experience with vulnerable populations**
- a consideration of potential conflicts of interest amongst its membership†

*At its own discretion, the RVU HIRB may invite individuals with specific competency to assist in reviews when specific expertise is required.

**For protocols that involve vulnerable populations, the HIRB will consider including an individual with knowledge and experience with vulnerable subjects.

†A member who has a conflict of interest cannot participate in the review of the conflicting project, nor in the committee vote on that project.

These regulations and standards are designed to protect the rights and welfare of all individuals participating as subjects in research studies, and to insure that all studies conducted at, or in affiliation with, Rocky Vista University demonstrate the appropriate respect for involved persons, subject beneficence, and meet expectations of justice, as outlined in the Belmont Report on "Ethical Principles and Guidelines for the Protection of Human Subjects of Research".

H. RVU Human Subject Research Policy & Procedures

- IRB Membership Roster

I. Federal Regulations and Guidance

Office for Human Research Protections

- Office for Human Research Protections
- Human Subjects Regulations Decision Charts
- Protection of Human Subjects: 45 CFR 46

Food and Drug Administration

- Food and Drug Administration
- IRB Regulations: 21 CFR 56
- Information Sheets: Guidance for IRBs, Clinical Investigators, and Sponsors
- Investigational New Drug Application: 21 CFR Part 312
- Investigational Device Exemptions: 21 CFR Part 812

Ethical Principles & Codes

- Belmont Report
- Declaration of Helsinki (World Medical Association)
- NIH Bioethics Resources on the Web
- National Bioethics Advisory Commission (NBAC)
- Public Responsibility in Medicine and Research (PRIM&R)
- The President's Council on Bioethics

Good Clinical Practices

- Good Clinical Practice in FDA-Regulated Clinical Trials
- ICH E6: Good Clinical Practice: Consolidated Guidance
- Medical Devices (Device Advice) (FDA)

HIPAA

- IRBs and the HIPAA Privacy Rule (NIH)
- NIH Guidance on Protecting Personal Health Information in Research (NIH)
- NIH Guidance on Research Repositories, Databases, and the Privacy Rule (NIH)

J. IRB Application Submission and Review Flow Chart