



ROCKY VISTA UNIVERSITY
COLLEGE OF OSTEOPATHIC MEDICINE

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

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:

Position and Location Name if not an RVU employee or student:

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 or institution 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 or institution, 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 checked YES to any of the boxes above, I've attached a letter of explanation for consideration by the IRB. If I have checked NO in all boxes above, 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