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HUMAN RESEARCH
PROTECTION PROGRAM

RCOI Policy FAQ Sheet

Who Does the RCOI Policy apply to?

All researchers who rely on the Vail Health IRB for review and approval of research studies.

When is the annual call for RCOI disclosures?

The annual call for researchers to submit their updated RCOI disclosure starts July 1st and ends August 14th of each year.

When must an updated RCOI disclosure form be submitted?

If a researcher's disclosure changes within the year, a new disclosure form is to be submitted: before engaging in any activity that involves or appears to involve the new COI; and within 30 days of learning of the change in COI.

Who all reviews RCOI disclosures?

The RCOI Program Manager reviews all RCOI disclosure forms and cross checks them with IRB study submissions. If the Program Manager identifies any potential or apparent conflicts between a disclosure form and study submission a RCOI management plan is drafted and sent to both the RCOI committee and IRB for review and approval. During the drafting of the management plan, the conflicted researcher is invited to review the proposed plan and provide feedback on the proposal.

What happens after a RCOI management plan is implemented?

The implemented management plan is filed in the conflicted researcher's IRBManager account. The management plan is monitored by the RCOI program manager on an annual basis through an administrative review. If no issues are identified the management plan continues to be upheld as approved. If issues are noted in compliance, these issues may be brought to the RCOI committee to determine if non-compliance has occurred and to determine corrective actions. For studies that are FDA regulated, the management plans will be monitored for one year following the closure of the study. For studies that are PHS regulated, if the management plan is for a conflict that meets the definition of a significant financial interest, additional reporting is provided to the PHS funding agency.

What training/education is required of the RCOI office?

All researchers must complete education on VH RCOI policies (currently provided through Elsevier) and regulatory training through either the Vail Valley Medical Center CITI COI module or through NIH: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

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I have a clinical study that is being conducted for an application submitted under sections 505, 506, 510(k), 513 or 515 of the FDA or section 351 of the PHS Act; what forms must I submit to the FDA?

Clinical investigators participating in a clinical study must complete either *Form FDA 3454* to attest absence of financial interests or complete *Form FDA 3455* disclosing their financial interests. It is the *applicant's responsibility* to obtain and submit the appropriate documentation for all clinical investigators on the study. Please see section 14.11 of the HRPP policies and procedures for further information.

What is considered a significant financial interest?

A "significant financial interest" (SFI) is one that exceeds a financial threshold defined by PHS. PHS sets a threshold of remuneration exceeding $5,0000 in aggregate from a privately or publicly traded entity in the twelve months preceding the disclosure, Intellectual property (IP) rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests; and/or, an offer or a promise of future employment (or engagement as independent contractor) made by a sponsoring entity to research personnel.

What must be disclosed in a RCOI disclosure form?

Individuals must disclose any financial interests or conflicts of interest, regardless of amount, which reasonably appear to affect the individual's institutional responsibilities, including clinical, administrative, or research. Such conflicts may be real, potential, or apparent, and may involve situations in which an individual or an immediate family member has a personal interest, financial or non-financial, that may compromise, or provide the incentive to compromise, the individual's behavior in the conduct of research and study activities.

I have a conflict of interest; did I do something wrong?

No, the mere existence of a conflict of interest shall not necessarily imply wrongdoing on anyone's part. A conflict of interest may be allowable with special safeguards in place through the development of a Management Plan for Conflicts of Interest (MP). The goal of managing conflicts of interest is to reduce or eliminate the appearance of any potential bias in study conduct and outcomes.

What are some common examples of management plan actions taken to minimize a conflict of interest?

Common management plan actions utilized to minimize or eliminate a perceived conflict of interest include: A disclosure of the income, relationship, or interest in the Informed Consent and HIPAA Authorization document, a disclosure of the income, relationship, or interest in public releases of information about the study (e.g., advertising, press releases, abstracts, presentations, publications), and limits on the conflicted individual's role in the study (e.g., may not serve as principal investigator, may not be involved in administering informed consent, may not analyze data, etc.).

Management plan action are not limited to these examples, additional actions can be taken depending on the nature of the conflict.

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What happens if the RCOI Committee finds non-compliance with a management plan?

Non-compliance with a MP will result in corrective action, as determined by the RCOIC, Vail Health Administration and/or regulatory agencies. Corrective action may include, but is not limited to:

- Completion of additional research education as determined by the VH RCOIC, or PHS agency.
- Restrictions on the use of data derived from the research.
- Suspension or termination of the research project.
- Withdrawal of funding.
- Loss of research privileges at Vail Health.
- Formal corrective action.
- Report of actions to external regulatory agencies.
- PHS funded studies must undergo a retrospective review (audit) of the investigator's regulatory files and financial interests.

Who can I contact with questions regarding the RCOI policy?

Questions can be directed to the following:

RCOI Program Manager: Sierra Willis sierra.willis@vailhealth.org
HRPP Director: Nancy McCormick Nancy.mccormick@vailhealth.org
RCOI Office: researchconflictofinterest@vailhealth.org

Section 14.11 of the HRPP policies and procedures addresses RCOI policies in further detail.