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Conflict of Interest Policy

- ❖ Conflict of Interest
- ❖ Conflict of Interest Agreement

The Conflict of Interest Agreement
is for CRAB employees only.

Conflict of Interest Policy:

Applicability: This policy is applicable to all CRAB employees.

“Institutions, in which faculty, staff, or students conduct research involving human subjects, must ensure that the safety and welfare of those subjects and the integrity of the research are never subordinated to or compromised by financial interests or the pursuit of personal gain.”¹

A conflict of interest occurs when there is a divergence between an individual’s private interests and his or her obligations to the research conducted at CRAB, such that an independent observer might reasonably question whether actions or decisions made in the workplace are determined by the individual’s personal gain, financial or otherwise, direct or indirect, for the individual or another person.

The term “significant financial interest” does NOT include the following types of financial interests: salary, royalties, or other remuneration paid by CRAB (the Institution) to the employee if the employee is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights or any ownership interest in the Institution held by the employee. It also does not include any income from seminars, lectures, or service on advisory committees (or review panels) for a Federal, state, or local government agency, a US institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

A conflict of interest depends on the situation and not on the character or actions of the individual. Conflicts of interest can arise and are often difficult to avoid. Nonetheless, employees of CRAB should conduct their affairs so as to avoid or minimize such conflicts of interest and to respond appropriately when conflicts arise.

CRAB strongly recommends that CRAB employees refrain from owning stocks (mutual funds and retirement accounts are excluded as long as the employee or family member does not directly control the investment decisions of these accounts) or forming partnerships or sitting on Boards of Directors with pharmaceutical companies that produce drugs that are investigated in clinical trials at CRAB. Payments **above and beyond** the contracted agreement for services (salary, consulting fees, in-kind compensation, expense reimbursements, etc.) from a for-profit entity must not exceed \$100 per calendar year.

CRAB **will not** permit the acceptance of payment for particular research results. Outcomes of CRAB research reported in publications must be free and independent.

An institution may have conflicts of interest in human subject’s research. It is the policy of CRAB as a corporation that it will not receive ownership interests (stock, stock options, partnership interests) from pharmaceutical companies with which it does business.

Conflicts may exist. All potential conflicts of interest must be reported to the Professional Conduct Committee (PCC). Employees must complete an annual conflict of interest statement.

¹ Protecting Subjects, Preserving Trust, Promoting Progress – Task Force on Financial Conflicts of Interest in Clinical Research of Association of American Medical Colleges. Dec. 2001

Any change in the CRAB employee conflict of interest status during the year (e.g. you receive remuneration of \$100 in excess of usual and customary fee for service or reimbursements, or you or a family member purchase pharmaceutical stocks during the year) must be forwarded to QA/ Regulatory within 30 days of when they occur. If appropriate, the information will be forwarded to the PCC for review.

The PCC will determine how to manage, reduce or eliminate significant conflicts of interest or other problematic conflicts. Solutions may include, but are not limited to, public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research), modification of the research plan, recommending the CRAB employee remove him/herself from a study in which they have a conflict of interest, that stock be sold, agreements be voided, or termination of employment at CRAB. The PCC will report to the employee, the officers, the Board of Directors and the IRB their findings. Records relating to all CRAB employee disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, will be retained for at least three years or as required by applicable government regulations, whichever is longer.

Definitions:

- *Research Product.* A research product includes, but is not limited to a result, a drug, a technique or a technology.
- *Conducting Research.* With respect to a research protocol, designing research, directing research, enrolling research subjects, or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.
- *Covered Individual.* Includes any employee of CRAB who conducts research involving human subjects.
- *Family Member.* A family member means spouse, domestic partner, or dependent child.
- *Financial Conflict of Interest.* A significant financial interest that could directly and significantly affect the design, conduct or reporting funded research.
- *Financially Interested Company.* A commercial entity (publicly or non-publicly traded) with financial interests that would reasonably appear to be affected by the conduct or outcome of the research. This term includes companies that compete with the sponsor of the research or entities acting as the agent of a financially interested company (e.g. a Contract Research Organization).
- *Research.* A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.
- *Significant Financial Interests in Research.* Interests of the covered individual and his or her family members, including, but not limited to:
 - Consulting fees, honoraria, gifts or “in kind” compensation from a financially interested company, whether for consulting, lecturing, travel, service on an Advisory Committee or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research

agreement) that in the aggregate, have in the prior year, exceeded the de minimis amount established (currently \$100) or are expected to exceed that amount in the next 12 months.

- Equity interests, including stock options, of any amount in a not-publicly traded Financially Interested Company (or entitlements to the same).
 - Equity interests (or entitlements to the same) in a publicly traded, financially interested company that exceeds the defined de minimis amount of \$5,000.
 - Royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work.
 - Any non-royalty payments or entitlements to payments (including intellectual property rights and interests such as patents or copyrights) in connection with the research that are not directly related to the reasonable costs of the research.
 - Service as an employee, officer, director or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service.
- *Other Interests in Research.* Membership on advisory boards or Boards of Directors of companies whose agents are under study should also be reported to the PCC.

Regulatory Reference:

42 CFR Part 50 Subpart F: "Promoting Objectivity in Research"

Conflict of Interest:

The guidelines for Financial Conflict of Interest are clear in that employees and other interested parties (e.g. family members) must disclose their potential financial conflicts of interests to CRAB's Professional Conduct Committee and that CRAB's Professional Conduct Committee determine how to manage, control and minimize the potential conflict.

I have read CRAB's Financial Conflict of Interest Policy and agree to comply with the Policy.

I, or my family members (spouse, domestic partner or dependent children), hold more than \$5,000 of the following stocks in a commercial entity whose products may be investigated in SWOG or CRAB trials:

(if this is not applicable, please write in "N/A")

I have received or anticipate receiving more than \$100.00 above the reasonable costs for conducting the research per contract from the following companies:

(if this is not applicable, please write in "N/A")

I have also identified the following potential Conflicts of Interest as that term is defined in CRAB policies:

(if this is not applicable, please write in "N/A")

I agree that I will not accept payments for particular research results or successful research outcomes. _____ (Initials)

Signature

Date

Print Name