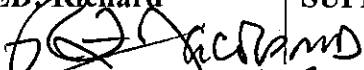


ARKANSAS CHILDREN'S HOSPITAL RESEARCH INSTITUTE
LITTLE ROCK, ARKANSAS

SUBJECT: Conflict of Interest and Conflict of Commitment	DATE: 1/18/08	PAGE 1 of 8
	APPLICATION:	ACHRI
	DISTRIBUTION:	Interdepartmental Policy and Procedure
	APPROVED BY:	Richard Jacobs, MD ACHRI President
RECOMMENDED: Richard Jacobs, MD 	SUPERSEDES:	4/30/97

PURPOSE

The purpose of this policy is to provide appropriate guidelines for the oversight and management of potential conflicts of interest and/or conflicts of commitment on the part of the Principal Investigators and Research Staff performing research at Arkansas Children's Hospital Research Institute (ACHRI). ACHRI acknowledges that many of the Principal Investigators are full-time faculty members of the University of Arkansas for Medical Sciences (UAMS) and will be subject to similar conflict policies adopted by the UAMS Board of Trustees. This policy is intended to operate in conjunction with the UAMS policy as well as provide clear guidelines for Principal Investigators and Research Staff not affiliated with UAMS. This policy is further intended to promote objectivity in research by establishing a framework to ensure that the design, conduct and reporting of research will not be biased by any conflicting interests of individuals.

INTRODUCTION

ACHRI recognizes that outside activities contributing to personal and professional growth are beneficial to the individual, to ACHRI and to the public. Therefore, ACHRI fully supports and encourages the continuing development of the knowledge, skills and expertise of its Principal Investigators and Research Staff through outside activities. However, involvement in such outside activities may create conflicts between the demands of these activities and the primary obligations to ACHRI and the research conducted therein. Furthermore, the involvement in multiple enterprises may offer opportunities for divergence of personal or private interests from those of ACHRI. In research and other activities at ACHRI which are funded in whole or in part by external sponsors, there may be occasion for yet further conflicts of interests. ACHRI has an institutional responsibility to ensure compliance with guidelines of both the sponsor and

any federal and state regulations. Some external activities or interests may be so far removed from the roles and responsibilities of the individual at ACHRI that the only considerations become those of the impact on the time and energy available for the individual's primary duties at ACHRI. Other activities or interests may not divert any time or energy from the duties at ACHRI but may introduce concerns regarding the possible impact on objectivity in ACHRI duties or activities. Still other external activities or interests may introduce both types of concerns (conflict of interest and conflict of commitment).

Due to the overlap of these concerns in some activities and as a single disclosure mechanism can support the management of both types of concerns, they are both addressed in this policy. This policy sets forth procedures for disclosure of potential conflicts of interest or conflicts of commitment. It also establishes guidelines for the management of such conflicts as they arise.

DEFINITIONS

Conflict of Interest - A conflict of interest is a divergence of interests away from an individual's professional responsibilities to ACHRI and/or the external sponsors of research and toward the individual's private or personal interests. A conflict of interest is present where an unbiased observer would find it difficult to determine whether the individual's professional actions or deeds are determined by personal considerations of gain, financial or otherwise, which are not in the best interests of ACHRI and/or the external sponsor of research. In particular, a conflict of interest exists in, but is not limited to, situations where a "significant financial interest" could directly and significantly affect the design, conduct or reporting of research.

Conflict of Commitment - A conflict of commitment is a significant distraction of an individual's attention or effort from obligations to ACHRI or under a specific grant or contract because of external activities. Such activities include, but are not limited to, professionally-related activities such as consulting, textbook authorship, involvement with professional societies or organizations, and participation in review panels. All of these activities are generally encouraged by ACHRI and are typically expected of academic staff members to promote professional development and to enrich their contributions to the Institute, their profession, and the community.

Immediate Family - The immediate family, as defined by the U.S. Internal Revenue Service, includes spouse, domestic partner and dependent children.

Principal Investigator - A Principal Investigator is an individual partially or wholly responsible for the design, conduct or reporting of research or educational activities. The definition includes anyone who is paid by or whose work is supported by a grant or contract from an external source (whether governmental or private). This includes UAMS faculty or staff, ACH staff or others who are eligible to apply for grants or contracts through ACHRI. The term specifically includes postdoctoral fellows, research associates or assistants, and graduate students performing research at or through ACHRI.

Research Staff - Research Staff refers to all research associates, research assistants, nurses, technicians, and any other staff who are involved in the conductance of research. They typically are under the direction and/or supervision of the Principal Investigator and are not responsible for but assist in the performance of the research. The definition includes anyone who is paid by or whose work is supported by a grant or contract from an external source (whether governmental or private).

Responsible Administrator - With respect to disclosure and management provisions of this policy, Responsible Administrator refers to the President of ACHRI.

Significant Financial Interest - A significant financial interest is anything of monetary value, including but not limited to, salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stock, stock options or other equity ownership interests), and intellectual property rights (e.g. patents, copyrights and royalties from such rights). The term does not include the following:

- (1) Salaries, royalties or other remuneration from ACHRI or UAMS;
- (2) Income from occasional seminars, lectures or teaching engagements sponsored by public or non-profit entities;
- (3) Income from service on advisory committees or review panels for public or non-profit entities;
- (4) An equity interest that, when aggregated for the Principal Investigator and his/her spouse and dependent children, meets both of the following tests:
 - Does not exceed \$10,000 in value as determined through the reference to public prices or other reasonable measures of fair market value; and
 - Does not represent more than a five percent (5%) ownership interest in any single entity.

GENERAL PRINCIPLES

The external activities of Principal Investigators and Research Staff should never be allowed to compromise or undermine the basic missions, goals and objectives of ACHRI nor prohibit the performance of any obligation under the terms of a grant or contract. Moreover, such activities should not be permitted to influence the design, conduct or reporting of research. Arrangements relating to the external activities of Principal Investigators and Research Staff should be specifically constrained to minimize distraction from primary obligations to ACHRI. Such activities should also be constrained so as to minimize the potential for placing either the individual or ACHRI in a position of having or appearing to have a conflict of interest or conflict of commitment. When such conflicts or the potential for such conflicts arise, they should be disclosed in writing to ACHRI and managed in accordance with this policy.

DISCLOSURE AND REVIEW

Annual Disclosure - External activities or significant financial interests of Principal Investigators engaged in research projects at or through ACHRI must be disclosed annually in writing to the Responsible Administrator using the Conflict of Interest Disclosure Form. Such disclosure forms may be obtained from the ACHRI administrative offices or from the ACHRI website. In instances where such disclosure is also required under UAMS policy, a copy of the completed UAMS disclosure form will satisfy the requirements of ACHRI.

All significant financial interests which are directly or indirectly related to the professional activities of the Principal Investigator must be disclosed. Any external commitment which might be perceived as presenting a conflict of commitment or conflict of interest must be disclosed. Any potential conflict of interest or conflict of commitment which arises between reporting periods must immediately be disclosed in writing to the Responsible Administrator. See Appendix I for examples and exceptions.

Disclosure for Federal Grants - At the time of submission of a proposal for any federal grant, the Principal Investigator of the grant must disclose any significant financial interests for all Research Staff involved in the proposed research. In the event that the proposed federal grant is awarded, the Principal Investigator shall be responsible for assisting in and developing an assurance of management of conflicts of interest or commitment. If any portion of the federally funded research is to be carried out by subgrantees, contractors or collaborators, the Principal Investigator is responsible for securing compliance with this policy from the other investigators.

Maintenance of Records - All financial disclosures and records of actions taken by ACHRI shall be maintained for at least three years from the date of submission of the final expenditure report for any federally funded project. Such information shall be provided to the funding agency upon appropriately authorized request.

Conflict of Interest Committee - A Conflict of Interest Committee shall be appointed by the President of ACHRI. The ACHRI Executive Committee has been designated as the ACHRI Conflict of Interest Committee. This Committee shall review disclosures forwarded from the Responsible Administrator for possible conflicts. In cases of conflicts, the Committee shall advise the appropriate officials on the management of the situations. The ACHRI Conflict of Interest Committee shall coordinate efforts with the UAMS Conflict of Interest Committee to provide for efficient discovery and management of conflicts as defined in this policy.

MANAGEMENT

Resolution of Conflict of Commitment - Ordinarily, conflicts of commitment shall be resolved at the first level of review by the Responsible Administrator. Each Principal

Investigator and Research Staff shall work with the Responsible Administrator and the Conflict of Interest Committee to successfully resolve any actual or potential conflicts of commitment.

Resolution of Conflict of Interest - The Responsible Administrator shall, in the primary review, attempt to identify and resolve potential conflicts of interest and shall attach any recommendations to the disclosure form prior to forwarding to the Conflict of Interest Committee. In the case of potential or actual conflicts of interest, one or more of the following steps shall be taken under the guidance of the President of ACHRI, the administrative staff of ACHRI, and/or the Conflict of Interest Committee:

1. Public disclosure of significant financial interests;
2. Monitoring of research by independent reviewers;
3. Modification of the research plan;
4. Withdrawal from participation in all or a portion of the research to which the conflict applies;
5. Divestiture of significant financial interests;
6. Severance of relationships which create actual or potential conflicts.

In the event that there appears to be no satisfactory arrangement to resolve or manage a conflict of interest related to externally sponsored research or other activities, the President or administrative staff of ACHRI shall so inform the appropriate officials of the sponsoring agency or entity.

ADMINISTRATIVE ACTIONS, SANCTIONS AND APPEALS

Failure to disclose conflicts of interest or conflicts of commitment in an appropriate and timely manner and/or failure to comply with procedures to resolve such conflicts as recommended by the Conflict of Interest Committee shall result in administrative sanctions. Such sanctions shall be determined by the Conflict of Interest Committee. In cases in which the individual is also affiliated with UAMS, any administrative sanctions shall be coordinated with officials at UAMS (the appropriate Dean or other administrative officials). If the failure of the Principal Investigator or Research Staff to comply with this policy has biased the design, conductance or reporting of federally funded research, ACHRI shall promptly notify the awarding agency of the corrective action taken or to be taken. Administrative sanctions may include oral admonishment, written reprimand, disqualification from submitting proposals for external research support through ACHRI, or separation.

Appeal of any determination may be made to the Conflict of Interest Committee. Appeal of any sanctions determined as above shall be made to the Department Chairman, whose decision shall be final.

GOVERNANCE

This policy is governed by the policies of ACHRI and is subject to change as those policies are amended. Nothing in this policy shall be construed to supersede state or federal laws, the ACHRI Board of Directors, or the policies of UAMS.

APPENDIX I

Examples of activities or interests which require disclosure and which may require special procedures because of potential conflicts of interest and/or commitment:

1. Any significant financial interest (see definitions included in policy) on the part of a Principal Investigator, Research Staff member, or his/her immediate family that (a) would reasonably appear to be affected by research for which external funding is sought or (b) in entities whose financial interests would reasonably appear to be affected by the research.
2. The undertaking of research when the Principal Investigator or his/her immediate family has a significant financial interest in either the sponsoring entity or in the entity producing the product to be evaluated or in a competing entity.
3. Gifts, favors or gratuities from suppliers, research sponsors, organizations, corporations, or persons who have business dealings with ACHRI if such gifts, favors or gratuities exceed a nominal value.
4. Side agreements to any contracts or business dealings between ACHRI and suppliers, research sponsors, corporations or other entities or persons.
5. Use of institutional supplies or equipment to support the research or other efforts of an independent company, agency or institution in which the Principal Investigator or Research Staff has a significant financial interest.
6. Use of the name of ACHRI, ACH, UAMS, or any of their departments in a manner to produce personal financial benefit.
7. Accepting research support under terms or conditions in which the information will not be published in a timely manner. It is recognized that, for proprietary reasons, sponsoring agencies or commercial companies may delay publication for finite, but limited, periods. This is not considered a delay in timely publication.

8. Negotiation of contracts between ACHRI and companies in which the Principal Investigator or Research Staff has a significant financial interest.
9. Accepting external sponsorship for research or for a contract without processing through the normal administrative channels (through the Research Support Center at ACHRI).
10. The conducting of research externally which would ordinarily be conducted within ACHRI and/or its affiliates (ACH, UAMS) in view of the primary commitment to ACHRI.
11. The publication by a Principal Investigator of research results of a clinical trial or other investigation in which the Principal Investigator has a significant financial interest in those results.
12. Participation in ACHRI committee, purchasing or contracting decisions that are in any way related to a business enterprise in which the Principal Investigator or Research Staff has a significant financial interest.
13. Assumption of an executive position in any institution or agency (whether for-profit or not-for-profit) engaged in biomedical research.
14. Use of employees of ACHRI to perform personal or commercial services unless these personnel are administratively separate, are compensated for work performed during off hours, and the work is not related in any way to their responsibilities at ACHRI.

Examples of activities that are normally allowed and need not be disclosed:

1. Salary, royalties or other remuneration received from ACHRI or UAMS, including equity ownership.
2. Receipt of royalties for published scholarly works and other writings.
3. Acceptance of honoraria for papers, occasional lectures and seminars as long as the honoraria are not excessive and are sponsored by public or not-for-profit entities.
4. Occasional income from service on advisory committees or review panels for public or not-for-profit entities.
5. Significant interests in business enterprises or entities on the part of an Principal Investigator and his/her immediate family which are not in any way related to the Principal Investigator's professional role and obligations to ACHRI.
6. Any "arm's length" financial interests which occur through participation in mutual funds or employer's retirement plans.

7. Participation in research sponsored by companies in which the Principal Investigator or Research Staff holds no financial interest or in which financial interest has been divested, provided that the research project has been reviewed by the ACHRI administrative staff.