

The Pennsylvania State University
Guidelines for the Development of a Conflict of Interest Resolution Plan and the
Preparation of Memorandum of Understanding

August 1, 1995

General Instructions:

The following guidelines are intended to assist faculty and staff in complying with two separate but related University policies: RA-12, "Technology Transfer and Entrepreneurial Activity," and RA20, "Individual Conflict of Interest." Instructions are provided for the development of a Conflict of Interest Resolution Plan ("Resolution Plan"), designed to manage, reduce, or eliminate potential conflicts of interest, and for the preparation of a Memorandum of Understanding ("MOU") as may be required by the two policies. While "research" is addressed specifically in these guidelines, it should be understood that they apply equally to educational or service projects which present potential conflicts of interest.

Areas addressed by these guidelines include, but are not limited to:

- performance of sponsored projects in which a University investigator has a "significant financial interest," as defined in the University Policy RA-05;
- performance of research at the University which is sponsored by a company in which the faculty member has a significant financial interest;
- a researcher who is a paid consultant of one company who is conducting a federally sponsored efficacy and safety study on a product that is manufactured by that company or by a rival company;
- a researcher involved financially and technically in a start-up company who is concurrently doing federally sponsored research on the same product as one made by the start-up company; or
- faculty involvement in start-up companies.

As discussed below, faculty are responsible for developing a Resolution Plan. The Resolution Plan must be approved by the appropriate college and department or IRP unit research office. After which it becomes incorporated into an MOU. Accordingly, each MOU must be separately negotiated between the employee and the cognizant administrator for the relevant college or IRP unit, as each situation is based upon a separate set of facts and circumstances. When sponsored projects are involved, the Resolution Plan and the MOU must also be approved by the University's Conflict of Interest Review Committee (CIRC).

The attached Resolution Plan Questionnaire (RPQ), shown in Appendix A, is intended to serve as the basis for the developing the Resolution Plan and MOU. Care should be taken in completing the RPQ to record accurate and complete information regarding your financial interests or entrepreneurial activities, as it will most likely be directly incorporated into the MOU. In many instances, completion of this survey will require one or more discussions with either your department head or the research dean for your college or IRP unit. In addition, when there is an issue which requires research oversight, it will be necessary to discuss the nature of the research in question with a qualified colleague in order to obtain the colleague's agreement to provide oversight to the research. As a result, adequate time should be reserved to complete the RPQ. In the case of a sponsored project, the resolution plan must be in place and the MOU must signed prior to expenditure of awarded funds.

Set forth below are instructions for the faculty or staff member ("Employee") to fill out the RPQ. If, in attempting to complete the RPQ, questions arise which you and your cognizant administrative officer or college/IRP research administrator are not able to answer, these questions may be referred to the Office of Sponsored Programs.

1. Significant Financial Interest Disclosure. Federal Government and University policy require investigators to disclose any significant financial interest in companies which might present a potential conflict of interest in regard to a sponsored research project. (See University policies RA-12 and RA-05.)

2-5. Employee Involvement in Company. These three questions seek information regarding the Employee's relationship to the Company in question. In many instances, the Employee may be a major shareholder, an officer, and a member of the Board of Directors of a start-up company. In completing this section, the emphasis should be upon delineating the specific financial interests that are held, the nature of the Employee's duties to the Company, and the amount of time those duties are expected to require. It is not infrequent for a faculty member to underestimate the time demands of: 1) financial accounting or "keeping the books" for the Company; 2) negotiations for the purchase of materials used by the Company; or 3) negotiations for the sale of product. Employees are urged to carefully consider the realistic time demands imposed by a business plan which has been developed for the Company. It is advisable to involve knowledgeable business people in the development of such a business plan and may be advisable to discuss it with your College Administrator.

6-7. Related Federal Research. In the event a Company is seeking funding from the Federal government for research, it is important to set forth why the research could not adequately be performed at the University or what justification there is for performing the work in the private, for-profit setting. For instance, a company which is submitting a proposal to perform basic research could be considered competing with the University and therefore the faculty member involved with the Company could be said to have a specific conflict of interest. However, if the nature of the research is such that it would be inappropriate for a University setting (such as trade secret information of a for-profit

corporation or sensitive information of the military, either of which would be inappropriate for research leading to publications within the University), it may be possible to justify conducting the research by the separate entity. In some instances, it may be possible for the Company to subcontract a portion of the work to the University, where that portion would appropriately be performed at the University.

8-9. Student Involvement. As prescribed in RA-12, the involvement of undergraduate or graduate students in the entrepreneurial activities of an Employee should be pursued only with the most rigid restrictions to protect the student from undue influence and to protect the faculty member from third party criticism. Although it is the purpose of RA-12 to accommodate a myriad of factual situations, it is almost invariably a bad idea to have the graduate student performing research related to the thesis or graduate work that will directly benefit the financial interests of an Employee, especially if such research is to be performed at the Employee's company.

Even where the nature of the work performed by the student is different than that contained in the thesis, rigid safeguards must still be instituted to ensure that the student does not even perceive that graduate work has been affected by the Company-student employment relationship. For instance, a faculty member who pressures a student to complete work at the faculty member's Company could easily affect the graduate student's completion of graduate studies in a timely and appropriate fashion.

In such an instance, the faculty members' interest in obtaining Company research results in which the faculty member has a proprietary interest has therefore adversely affected the student's graduate research and/or scholarly activities. Such a result must absolutely be prohibited, and accordingly, rigid guidelines must be implemented. These issues should be carefully considered by the Employee and the College Administrator when the Employee is utilizing graduate students at a Company.

When completing this section of the information survey, particular care should be given to address this situation if applicable.

10-12. Company Sponsored University Research. Quite frequently, a company in which a faculty member has an interest may wish to support research at the University. This is particularly true where the company is capitalized through venture capital, and the business plan of the company is based upon a technology which is still being developed in part at the University. Safeguards, such as those described in items 13-16 below and in University policy RA-05, need to be implemented to ensure that the University's research is not unduly influenced by the Company or the Employee's desire to promote the Company.

13. Public Disclosure of Significant Financial Interests. The disclosure of significant financial interests that are held by an author of a publication (journal article, presentation, poster session, etc.) is required to alert all readers of the potential for bias in the research results, even if such bias is unconscious and unintended. Many journals now

require such disclosures by their authors. Disclosure in all presentations or publications is required whenever disseminating the results of clinical trials or studies of health-related technologies or products.

14-16. Research Oversight By a College. Where the research at the University which is sponsored by the Employee company will be performed by or under the direction of the Employee, a clear potential exists for the Employee to bias the research to promote the business plan or product of the company. Even in the event no such bias exists, the very relationship subjects the Employee, the company and the University to potential criticism from third parties regarding the potential bias. This is particularly true with pharmaceutical or medical related technology, but also applies with other technology groups. This situation also can exist when a faculty member has some other significant financial interest in a company which may be affected by research sponsored by some third party, including the Federal government.

Accordingly, where this relationship exists, it is essential for the employee to identify an appropriate colleague to provide oversight to: a) the research protocol itself; and, b) the conducting of the research under that protocol. The colleague's role of providing oversight must be more than superficial. The colleague must be willing to understand the nature of the research and provide guidance to the faculty member in how to avoid biased results and ensure an objective, legitimate investigation. In some instances, such as research which involves a pharmaceutical product, it may be inappropriate to have the research performed, even with oversight. This decision must be made on a case by case basis by the Employee and the College Administrator. The role of providing oversight is essential to managing a conflict of interest or the potential for one. It should be made known to the colleague agreeing to serve in that capacity that the colleague's integrity and reputation may be positively or adversely affected by the success or failure to protect the integrity of the research.

17-20. University Facilities and Resources. If the Employee intends to use University equipment, facilities, or staff (including clerical or other support staff) for your Company, you must obtain the prior written approval of your department head in the form of a letter of agreement. Often, this will require that you ascertain equipment usage charges which are similar to those the University charges to other non-University companies or entrepreneurs. Similarly, the Employee or Company must not receive preferential or unusual access to the facilities or equipment involved. Finally, it is important to list the physical location of the equipment for purposes of determining whether the facility in which the equipment is located, or the equipment itself, was financed by the University with tax-exempt bonds. In that event, use by a for-profit Company will probably be prohibited.

21-22. Stock Ownership. The conditions under which an Employee owns stock in the Company can be relevant in managing a conflict. For instance, if the Employee will be involved in research which demonstrates the commercial viability of a technology marketed/sold by Company, it might be appropriate to require that the Employee be

prohibited from trading the stock until a set time has elapsed after introduction of the product to market. This would ensure that the value of the stock enjoyed by the Employee is a result of actual market acceptance, as opposed to market reaction to preliminary results. This is particularly true in the case of pharmaceuticals and technologies affecting the health or welfare of consumers.

23. Parallel Consultancy. In many instances, a faculty member who is involved with a start-up company will serve as a consultant to the Company as well as conducting activities at the University in furtherance of the Company's objectives. In those instances, it is important to have the role of the consultancy well delineated and a clear demarcation between the consulting activities and the University's activities. Finally, the consideration for the bargain between the Company and the University and the Company and the consultant must be different. This will ensure against the Company downstream arguing that it has "paid twice" for the same research or data.

Completion. Once the employee has completed the RPQ and has discussed its content with his/her department head and cognizant University administrator, the MOU may be developed. If the RFQ involves a sponsored project, the RFQ must be sent to the Office of Sponsored programs for the review and approval of the Conflict of Interest Review Committee. An MOU is then written by the Office of Sponsored Programs, and the MOU is then executed by the Employee, department head, and the dean of the college (director of IRP) on behalf of the University. If no sponsored project is involved the RFQ is appended to an MOU developed by the College/IRP (see Appendix B). It is then executed by the College/IRP and the Employee.

Resolution Plan Questionnaire (RPQ)
For the Development of a Conflict of Interest Resolution Plan and
Memorandum of Understanding under RA-05 and RA-12

Name: _____ College: _____

Date Submitted: _____ Dept/Unit: _____

1. Please provide documentation identifying the business enterprise or entity ("Company") involved and the nature and amount of the financial interest.

- Information already provided on an RA-05 Significant Financial Interest Disclosure Form.
OSP #: _____
- Documentation attached.

- 1a. *In your analysis*, will any disclosed Significant Financial Interest *reasonably appear to be directly and significantly affected* by the research, educational, or service activities funded, or proposed for funding, by an external sponsor; or will any disclosed Significant Financial Interest in *an entity whose financial interest reasonably appear to be directly and significantly affected* by the research, educational, or activities funded, or proposed for funding, by an external sponsor?

- Yes No

Please explain:

2. Are you an officer of the Company in which you have a financial interest (hereafter "the Company")?

- Yes No

3. If so, what are your responsibilities, and how much time do you expect to dedicate?

4. Are you a member of the governing Board of Directors for the Company?

Yes

No

5. If so, describe the general nature of the Board and your responsibilities as a Board member.

6. Does the Company plan to submit proposals for federal funding?

Yes

No

7. If so, is it for research which could be performed in your laboratory at the University? (Please provide a brief description.)

Yes

No

8. Do you intend to employ any undergraduate or graduate students at the Company?

Yes

No

9. If so, for each student, please set forth: a) the nature of the work to be performed; b) how the work relates to the student's studies or thesis; and, c) the number of hours anticipated per month.

10. Does the Company intend to sponsor any work at the University?

Yes

No

11. If so, will it be necessary or preferable for the work to be performed in your laboratory? (Please provide a brief description.)

Yes

No

12. Describe the significance of the research to any commercial product that the Company will sell or manufacture.

13. Will you agree to disclose your relationship in Company in any publications, presentations and papers you submit regarding the research, and abide by all submission requirements from journals or organizations?

Yes

No

NOTE: Disclosure in all publications or presentations is REQUIRED when disseminating the results of clinical trials or studies of health-related technologies or products.

14. In the event you and/or your cognizant University officer believe that research oversight is required (please see attached guidelines), please list a colleague, preferably within your department or college, who would be willing to review your research protocol for objectivity.

15. In the event you and/or your cognizant University officer believe that research oversight is required (please see attached guidelines), please list a colleague, preferably with your department or college, who would be willing to provide oversight during the duration of the research project to ensure adherence to protocol and other sound scientific practices.

16. Have you obtained the concurrence of the person(s) listed in numbers 14 and 15 above to serve in the capacity of reviewer/overseer?

Yes

No

17. Do you intend to use any University facilities on behalf of the Company?

Yes

No

18. If so, please list each piece of equipment which will be used, the nature and extent of the use, and the physical location of the equipment (i.e., name of the building and room number).

23. Are you intending to or do you now serve as a consultant to Company?

Yes

No

If so, please describe the general nature of your consultancy and where applicable attach a copy of the agreement or its provisions governing intellectual property.

Faculty Member / Employee:

Department Head:

Name:

Name:

Cognizant University Administrator:

Name: