

Appendix A4

University of Florida-
University of Florida Research Foundation, Inc. (UFRF)
Conflict of Interest Policy
regarding UFRF Equity Holdings

A. Introduction:

Various conflicts of interest may arise when the University of Florida Research Foundation, Inc. (UFRF) holds equity in companies that license technology and/or support ongoing research at the University of Florida. This policy concerns conflicts of interest other than the personal conflicts of interest that may arise when a faculty member or other employee stands to benefit financially from the results of his/her own research. The University has policies in place to deal with these conflicts. Basically, these personal conflicts are managed by requiring disclosure to the chairperson, dean, the Vice President for Research, and, in some instances, to the President and the Chancellor of the State University System. In cases of potentially significant conflicts, such as when a faculty inventor conducts research sponsored by a company that has licensed the technology, a plan to monitor the potential conflicts must be formulated and agreed to by the department chair and the dean. The purpose of this policy is to mitigate institutional conflicts (UFRF and the University) and to avoid the creation of other personal conflicts with regard to UFRF equity holdings.

An institutional conflict may develop when an academic unit, such as a department or college, RGP, or UFRF stands to benefit financially from the outcome of research ongoing at the University to support a license or a research agreement. UFRF, RGP, and/or academic units at the University, along with inventors, may receive future financial rewards by way of royalties or other fees if the product or service is commercially successful. Therefore, they have a financial interest in assuring the success of the product. If the returns are in the form of royalties, there is a control, however. The market must buy the product or service and will judge it on its merits, not on earlier university actions. Otherwise, there are no royalties.

UFRFI may hold equity in licensees, most often equity taken in lieu of royalties or other license fees. In these instances the potential institutional conflicts become more likely for several reasons:

- Equity markets are not perfect. Speculators reacting to information such as research results may cause substantial changes in market value. This may occur before any product sales.
- Unlike royalties, owners of equity may cash in their shares prior to the product or service passing the market test of generating sales. This creates a situation where UFRF and the inventor may enhance their positions relative to other shareholders by having superior or “insider” information.

- UFRF generally accepts a level of equity that could have substantial value if the product or service is successful. Therefore, the size of the transaction makes the potential institutional conflict even more serious.
- The University and UFRF, as well as the inventor, must avoid even the appearance of manipulating stock prices through issuing or using information that may later prove incorrect, such as promoting a drug discovery that later fails FDA tests. Such manipulation exposes these entities and individuals to significant criminal and civil liabilities.

Acceptance of equity in licensees of university technologies is within the overall mission of the University of Florida Research Foundation, Inc. There are three compelling reasons. First, many technologies are best developed within a small entrepreneurial company. In such cases, cash held by these companies may be better employed in product development and marketing rather than paying a cash license fee. Second, consistent with UFRF's Investment Policy as approved by the Board of Directors, UFRF may elect on occasion to invest directly in a licensee. UFRF must maximize its risk adjusted returns, and some startups may have outstanding potential. Such an investment must be approved by the Board of Directors upon the recommendation of the Investment Subcommittee of the UFRF Finance Committee. Finally, the development of technologies in a small company may enhance economic development within the region, which is also of benefit to the University of Florida and the State of Florida. By licensing to new companies that locate within the region, jobs are created. If the company is successful, many jobs may be created.

B. Hypothetical Situation:

To illustrate the issues involved in institutional conflicts of interest, consider the following hypothetical case. UFRF licenses a drug developed at the University to a start-up biotechnology company (BIO). As an alternative to a license fee, UFRF takes 100,000 shares of BIO stock which is 10% of the founders' shares. The stock has no market value initially and is carried on the books at a value of zero. Suppose that after the license agreement is entered into, the entrepreneur is successful in a private placement and raises \$5,000,000 for future research and development from venture capitalists at a price of \$4 per share. Thus, the UFRF position has now effectively grown to \$400,000 although there is no market for the stock.

The venture capitalists that invested in BIO anticipate that if the drug goes through clinical trials, it will create a valuation at 20 times their investment. Thus, UFRF looks at a potential stock price at a public offering of \$80. UFRF's position would then be worth \$8,000,000. Under current policy, UFRF would sell the stock as soon as practicable when it becomes publicly traded. The inventor would then will receive 25% or approximately \$2,000,000. The researcher's program would receive \$800,000, the researcher's department would receive \$800,000 and the researcher's college, \$800,000. UFRF would receive the remaining \$3,600,000. Additionally, if the stock reaches this value, it is likely that there will be many millions in royalty income over the life of the patent. These funds will also accrue to the inventor, the inventor's program, the department, the college, and UFRF.

With a potential \$6 million from the sale of stock, plus future royalties coming to the University, there is a large incentive for academic units to make this technology successful. Developmental research may be the key to success. This is widely known by the financial community that will become very interested in research progress reports. If research continues on the invention at the institution, and particularly if that research is partially or wholly conducted by the inventor, conflicts of interest or the appearance of such conflicts may occur. (The following analysis borrows heavily from Ezekiel Emanuel and Daniel Steiner, "Institutional Conflict of Interest," The New England Journal of Medicine, January 26, 1995.) Examples of situations in which such conflicts may lead to decisions not in the best interests of the University or UFRF are:

1. The inventor/researcher may elect to assign his/her graduate students to work on the project although this may not be in the best interests of the careers of the graduate students because of confidentiality reasons or simply the nature of the science or technology involved.
2. The researcher may inappropriately divert resources from research not funded by the licensee company (i.e., supported by a federal agency or another corporate sponsor) to development of the invention.
3. The department may assign excessive laboratory space or other resources to the project, crowding out more deserving science/technology in terms of research and educational value.
4. The department, the college, and the University will have an incentive to keep the researcher on the faculty and involved with the technology. This may conflict with normal tenure, promotion, and merit pay standards. For the same reason, the researcher may be allowed to enter into inappropriate consulting or other agreements with the company.
5. If future research involves clinical trials, there may be pressure on the institution to aggressively seek patients for these tests, to fail to inform patients of the potential conflict, and to ignore or minimize symptoms that suggest an adverse reaction to the drug.
6. There is a risk that the researcher will employ a research design or data collection that biases the study to obtain the desired results and that traditional institutional checks on the behavior will be ignored.
7. In reporting the results to the public or in other public relations activities, the University and the researcher have an incentive to portray research progress and the potential for the company in the best possible light to maximize investor interest in the company.
8. If another researcher at the institution invents an alternate therapy or product, which may be more efficacious for the patient or have more value for consumers, the University may not pursue further development or licensing because of economic competition with the existing invention.

C. Institutional Conflict of Interest Policy:

The University and UFRF have adopted the following procedures to deal with the potential and actual conflicts created when UFRF holds equity interests in commercial enterprises that license technology and/or support ongoing research at the University:

1. Disclosure and Responsibility for Monitoring:

a. Any material provided to the public, to scientific journals, or to professional organizations from the University, UFRF, or from their respective employees should include the disclosure that the University of Florida, UFRF, and/or the inventor(s) have significant financial interests in the licensing company. The person providing the material is responsible for making such disclosures.

b. When a research contract or grant is entered into by the University or UFRF with a company in which UFRF holds an equity interest, or when a research project is commenced dealing with a licensed product of a company in which UFRF holds an equity interest, the Director of Sponsored Research of the University or UFRF shall inform the appropriate officials of the potential conflict of interest of any faculty member or other employee (“Researcher”) working on that research project. Notification should be made to the department chair, to the department graduate coordinator, to the dean of the college, to the vice president responsible for that college, and to the Vice President for Research. The dean of the college, with oversight by the Provost, will be responsible for monitoring the situation, with special attention to resource allocation, employment practices, and graduate student assignments, and for informing the Researcher of this policy.

c. In cases (such as the BIO example) where potential conflicts are significant, the college dean must make annual written reports to the University’s General Counsel’s office, which will assist these persons in overseeing the disclosure and management of potential conflicts. A copy of the reports shall also be sent to the Provost’s office. In all cases in which UFRF has an ownership interest, any proposed changes in the license or research agreements involved or any potential sale of that interest must be immediately reported to the General Counsel’s office.

d. The financial interests of the University of Florida, UFRF, and the Researcher must be disclosed specifically and in writing to any research subject. The Researcher is responsible for making such disclosures.

2. Research Procedures:

a. The University should not be involved in any clinical trials/product testing of its licensed technology. In those exceptional circumstances in which the University must be involved (which must be specifically approved by the University’s Vice President for Research), the inventors should not participate in such trials/testing at the University and independent research should be conducted at other institution(s) to substantiate research results obtained by a Researcher.

b. Any research should be designed to minimize researcher discretion in interpreting results. The Researcher should keep extensive notes to detail results and other issues that came up during the study. These records should be kept a minimum of eight years.

3. Securities Decisions:

a. UFRF managers, which shall include its directors and officers, shall not acquire stock in any commercial enterprise which has provided UFRF an equity position as consideration under a license or other agreement or in which UFRF has otherwise acquired an equity interest. A list of such equity positions shall be found in the UFRF annual audit.

b. University department chairs and college administrators (deans, associate deans, assistant deans, and so forth) shall not acquire stock in any such company when the respective department or college may benefit financially from the license or other agreement.

c. If a research grant or contract is entered into with a company in which UFRF holds an equity interest, any UFRF manager who also has supervisory authority over the Researcher as a University employee shall recuse himself or herself from any UFRF discussions or decisions regarding the stock or regarding any agreement between UFRF and the company.

d. A Researcher or any other University employee who may have knowledge of the research shall not discuss current research results that have not been made public with any UFRF managers who have authority to make decisions on the stock. If the stock is publicly traded, the Researcher and those working with him on the research project and his/her department chair and dean shall be informed of the limitations imposed by federal securities law. Under federal securities law, it is generally illegal to buy or sell stock of publicly traded companies (“insider trading”) while in possession of material, non-public information (“inside information”) relating to such publicly traded companies.

e. UFRF managers will make decisions on the stock, including whether and when to sell the stock, based only upon publicly available information.

f. UFRF will sell its stock as soon as practicable on the market. Such a sale will be accomplished upon the advice of the UFRF Investment Subcommittee and UFRF’s investment manager. In order to limit potential conflicts, no University department chairs or college administrators shall serve on the Investment Subcommittee.

Adopted October 1, 1998