



Whose interest comes first?

## 5. Conflicts of Interest

Researchers work hard, often spending long hours and sometimes weekends in the laboratory, library, or at professional meetings. Their motivation for working hard stems from many sources. Research:

- ✓ advances knowledge,
- ✓ leads to discoveries that will benefit individuals and society,
- ✓ furthers professional advancement, and/or
- ✓ results in personal gain and satisfaction.

Each of these incentives or *interests* is commonly recognized as responsible and justifiable.

Researchers are allowed to and even encouraged to profit from their work (see the discussion of the Bayh-Dole Act, below). Professional advancement as a researcher depends on productivity. Society expects researchers to use the

### Case Study

Early in his undergraduate education, Dr. Sam M. decided to dedicate his studies to finding a cure for a psychological disorder that seemed to run in his family. As a biology major, he pursued independent research projects and worked long hours as a lab assistant. He then enrolled in a PhD program in psychopharmacology and is now completing a 3-year postdoc in the neurosciences.

During his postdoc he worked on a promising compound he first discovered during his graduate years. His work has gone well and he feels the time is right to explore clinical applications. After more than a decade of living on student and postdoc wages, he is also ready for a better paying job.

As Sam weighs the options of an academic versus an industry job, he begins to wonder about who owns or will own the useful applications of his work, if and when there are any. Will it be owned by:

his graduate institution, where he first worked on the promising compound?

his postdoc institution, where he refined his ideas?

his future academic or industry employer?

himself, based on his hard work and innovative ideas?

society, which funded parts of his education and most of his research?

Who has a legitimate interest in Sam's work and when do his own personal financial interests create a conflict of interest?

funds it supplies to advance knowledge and to make useful discoveries. Personal gain and satisfaction provide strong incentives for doing a good job and acting responsibly.

Researchers' interests can and often do conflict with one another. The advancement of knowledge is usually best served by sharing ideas with colleagues, putting many minds to work on the same problem. But personal gain is sometimes best served by keeping ideas to oneself until they are fully developed and then protected through patents, copyrights, or publications. Legitimate research interests can create competing responsibilities and lead to what is commonly called *conflicts of interest*.



It is important to understand that *conflicts of interest* are not inherently wrong. The complex and demanding nature of research today inevitably gives rise to competing obligations and interests. Researchers are expected to serve on committees, to train young researchers, to teach, and to review grants and manuscripts at the same time they pursue their own research. Conflicts of interest cannot and need not be avoided. However, in three crucial areas:

- ✓ financial gain,
- ✓ work commitments, and
- ✓ intellectual and personal matters,

special steps are needed to assure that conflicts do not interfere with the responsible practice of research.

### 5a. Financial conflicts

Personal interests and the prospect of financial gain should not, but unfortunately can, improperly influence a researcher's fundamental obligation to truth and honesty. Although researchers should not, they can find ways to delay unfairly a competitor's work in order to secure a patent or some other financial advantage for themselves. Financial interests can provide a strong incentive to overemphasize

or underemphasize research findings or even to engage in research misconduct (Chapter 2). *Financial conflicts of interest* are situations that create perceived or actual tensions between personal financial gain and adherence to the fundamental values of honesty, accuracy, efficiency, and objectivity (Section I).

Financial interests are not inherently wrong. Researchers are permitted to benefit financially from their work. A 1980 Congressional law known as the Bayh-Dole Act encourages researchers and research institutions to use copyrights, patents, and licenses to put research ideas to use for the good of the public. Prior to this time, there were no uniform policies regulating the ownership of ideas developed with public funding. Bayh-Dole essentially gives that ownership to research institutions as an incentive to put ideas to work for the overall good of society. It not only approves of but, in fact, strongly encourages researchers and research institutions to have financial interests as a way of ensuring that the public's investment in research is used to stimulate economic growth.

While financial interests should not and in most instances do not compromise intellectual honesty, they certainly can, especially if the financial interests are *significant*.

#### Bayh-Dole Act (Public Law: 96-517)

##### *Policy and Objective*

35 USC Part II, Chapter 18, Section 200

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

<http://www.uscode.house.gov/DOWNLOAD/35C18.DOC>

Universities are currently starting hundreds of new businesses based on researchers' ideas. Some of these businesses will generate significant profits (hundreds of thousands to millions of dollars each year). If the difference between commercial success and failure rests on one key publication, the pressure to put the best face on that publication can be considerable.

Financial conflicts also arise from the ever-present pressure researchers have to secure funds to support their research. A private sponsor might withdraw support from a project if it does not produce the "right" results. Success in the stiff competition for research grants can rest on having the "right" preliminary results. Research is expensive, funding often in short supply. The pressure simply to survive, much less profit personally, can and does create financial conflicts of interest.

**Federal policies.** Concerns about the actual or potential adverse effect of financial interests on research prompted the Public Health Service (PHS) and the National Science Foundation (NSF) to adopt conflict of interest policies in the mid-1990's. These policies require research institutions to establish administrative procedures for:

- ✓ reporting *significant* conflicts before any research is undertaken;
- ✓ managing, reducing, or eliminating *significant* financial conflicts of interest; and
- ✓ providing subsequent information on how the conflicts were handled.

*Significant* financial conflict is defined as:

- ✓ additional earnings in excess of \$10,000 a year, or
- ✓ equity interests in excess of 5 percent in an entity that stands to benefit from the research.

The financial interests of all immediate family members are included in these figures.

## Department of Health and Human Services

### *Conflict of Interest Definitions*

#### 45 CFR 94.3

Significant Financial Interest means 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., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (1) Salary, royalties, or other remuneration from the applicant institution;
- (2) Any ownership interests in the institution, if the institution is an applicant under the SBIR program;
- (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (4) Income from service on advisory committees or review panels for public or nonprofit entities;
- (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
- (6) Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not reasonably expected to exceed \$10,000.

[http://www.access.gpo.gov/nara/cfr/waisidx\\_02/45cfr94\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/45cfr94_02.html)

**State and local policies.** Although the Federal requirements apply only to PHS- and NSF-funded research, many research institutions have adopted global policies that apply to all researchers. Many also use different values for defining *significant*, to as low as any financial interest. Researchers therefore should check their local conflict-of-interest policy to find out when and what they are required to report. They also need to keep in mind that many states have their own conflict-of-interest policies, which apply to all state-paid employees.



### AAMC Task Force Recommendations

#### *Financial Conflicts of Interest in Clinical Research*

(December 2001)

- B. In the event of compelling circumstances, an individual holding significant financial interests in human subjects research may be permitted to conduct the research. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research....
- C. Institutional policies should require full prior reporting of each covered individual's significant financial interests that would reasonably appear to be affected by the individual's research, updated reporting of any relevant change in financial circumstances, and review of any significant financial interests in a research project by the institution's COI committee prior to final IRB approval of the research. COI committee findings and determinations should inform the IRB's review of any research protocol or proposal, although the IRB may require additional safeguards or demand reduction or elimination of the financial interest....

<http://www.aamc.org/members/coitf/firstreport.pdf>

### New England Journal of Medicine

#### *Conflict of Interest Policy*

June 13, 2002

[B]eginning with this issue of the Journal, we have modified the statement in Information for Authors to read as follows:

Because the essence of reviews and editorials is selection and interpretation of the literature, the Journal expects that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article.

The addition of the word "significant" acknowledges that not all financial associations are the same. Some, such as the receipt of honorariums for occasional educational lectures sponsored by biomedical companies, may be appropriately viewed as minor and unlikely to influence an author's judgment. Others, such as ownership of substantial equity in a company, are of greater concern. It is our intent to focus on the financial relationships that, in our judgment, could produce bias, or the perception of bias, in an article.

<http://content.nejm.org/cgi/content/full/346/24/1901#R6>

### *Professional societies and journal policies.*

A number of professional societies have issued reports or made recommendations on appropriate ways to handle conflicts of interest. Similarly, more and more journals now require researchers to disclose real or potential financial conflicts. Sometimes disclosure must be made to the journal editor, who decides what, if any, action is needed. Sometimes disclosures must be included in the publication itself. Before submitting an article to a journal for publication, researchers should carefully check and make sure they have followed that publication's conflict of interest policies.



### 5b. Conflicts of commitment

Conflicts of commitment arise from situations that place competing demands on researchers' time and loyalties. At any time, a researcher might be:

- ✓ **working on one or more funded projects;**
- ✓ **preparing to submit a request for a new project;**
- ✓ **teaching and advising students;**
- ✓ **attending professional meetings and giving lectures;**
- ✓ **serving as a peer reviewer;**
- ✓ **sitting on advisory boards; or**
- ✓ **working as a paid consultant, officer, or employee in a private company.**

Each of these activities requires time and makes demands on a researcher's institutional commitments. Care needs to be taken to assure that these commitments do not inappropriately interfere with one another.

**Allocation of time.** Researchers must be careful to follow rules for the allocation of time. Federally funded researchers must follow the rules for cost accounting published by the Office of Management and Budget in a document known as *Circular A-21*. Most research

institutions also have rules for how researchers spend their time, particularly time serving as paid consultants, giving paid lectures, or working as an employee in a private company.

At a minimum, these rules require that researchers:

- ✓ honor time commitments they have made, such as devoting a specified percentage of time to a grant or contract;
- ✓ refrain from charging two sources of funding for the same time; and
- ✓ seek advice if they are unsure whether a particular commitment of time is allowed under an institution's or the Federal Government's policies.



Although researchers will frequently work on several projects at the same time, in the final analysis primary work obligations must be met. In addition, the time devoted to one project ordinarily cannot be billed to another.

**Relationships with students.** Academic researchers involved in start-up ventures often have opportunities to hire students. This puts them in a situation where they can hire their own students. As mentors, they have a primary obligation to help students develop into independent researchers. As heads of start-up companies, their primary obligation is to see promising ideas commercialized. While the two responsibilities can complement one another, they can also be in conflict. Should an individual who is both the researcher's student and employee be advised to develop a promising idea that could lead to an independent career or to work on a more routine problem that will benefit the start-up company? Situations such as these create conflicts and should be avoided or appropriately managed.

**Use of resources.** Equipment and supplies purchased with public funds can easily be used to advance private research interests. While this might seem like a harmless practice, particularly if the equipment is not in constant use, unless a researcher has permission to use the equipment to support private research, this practice is not

### Stanford University Conflict of Commitment Policy

1. Outside consulting privileges are not normally available to Academic Staff. They may consult only with permission, as noted below. Under no circumstances may any Academic Staff member's outside consulting work exceed the limits imposed by the faculty consulting policy, i.e., 13 days per calendar quarter (that is, one day in seven) on a full-time equivalent basis.... Academic Staff may not use University resources, including facilities, personnel, equipment, or confidential information, except in a purely incidental way, as part of any outside consulting activities nor for any other purposes that are unrelated to the mission of the University.
2. Academic Staff must maintain a significant presence on campus (main or overseas) throughout each quarter in which they are employed by Stanford, consistent with the scope of their appointment.
3. Academic Staff must not allow other professional activities to detract from their primary allegiance to Stanford. For example, Academic Staff employed on a full-time basis must not have significant outside managerial responsibilities nor act as a principal investigator on sponsored projects that could be conducted at Stanford University but instead are submitted and managed through another institution.

<http://www.stanford.edu/dept/DoR/rph/4-4.html>

appropriate. The equipment can be used for other university work since this is allowed by the government. But it cannot be used for a personal project without permission. It also cannot be used for research that is explicitly prohibited by the Federal government, such as stem cell research using lines not authorized by the President's policy.

**Disclosure of affiliations.** It is widely agreed that outside affiliations that create conflicts of interest should be listed on academic publications, but should researchers list their academic affiliations on other publications? As president or CEO of a new company, is it appropriate for a researcher to also note in the end-of-the-year financial report that she or he is also a full professor at a prestigious university? Should researchers who serve on private boards list their academic affiliation? Researchers must be careful to separate their academic or institutional work from their



private work. In particular, they should not inappropriately use their institutional research affiliation to advance their private interests by implying, for example, that private work has the support of their research institution if it does not.

**Representing outside entities.** The results researchers commercialize in private ventures, such as drugs used in a university hospital, a software program used in an accounting office, or a consultation service for employees, might be used by their primary employer. In these cases, the researcher could be the resident expert on the goods and services in question. Each employer in this case presumably wants the best deal on the goods and services, whereas the researcher is also interested in personal profits, creating a conflict of commitment.

Since the situations described above are often not subject to specific policies or guidance, judgments about responsible conduct often rest with the researcher. In making judgments about the best way to deal with institutional conflicts, it is helpful to take into consideration:

- ✓ how others will view your commitments and
- ✓ the judgment of someone who has no stake in the outcome.



In addition, it is always a good idea, even if it is not required, to seek advice from an institutional official.

### 5c. Personal and intellectual conflicts

Researchers are also expected to avoid bias in proposing, conducting, reporting, and reviewing research. They therefore should be careful to avoid making judgments or presenting conclusions based solely on personal opinion or affiliations rather than on scientific evidence.

Personal conflicts are usually the easiest to identify and resolve. Researchers generally should not serve as reviewers for grants and publications submitted by close colleagues and students. Their presumed *interest* in seeing

their colleagues and students succeed could conflict with their obligation to make judgments based solely on the evidence at hand. Most granting agencies require reviewers to disclose conflicts of interest, including personal conflicts, as a condition of service.

Intellectual conflicts are more difficult to identify, but are nonetheless important. If a researcher holds strong personal views on the importance of a particular area of research or set of research findings, those views should be disclosed so that others can take them into consideration when judging the researcher's statements. The same is true of strong moral convictions that could influence a researcher's scientific opinions. This is particularly true when researchers serve as expert witnesses or advisors. It is for precisely this reason that the National Academy of Sciences, which has provided essential science advice to the Federal Government since the Civil War, carefully considers all conflicts of interest when it sets up advisory panels (see box, below).

#### **Federal Advisory Committee Act Public Disclosure Requirements Applicable to the National Academy of Sciences** January 5, 1997

The Academy shall determine and provide public notice of the names and brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee. The Academy shall determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the Academy determines such prior comment is not practicable, in the period immediately following the appointments. The Academy shall make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable, (B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed, and (C) the final report of the Academy will be the result of the Academy's independent judgment. The Academy shall require that individuals that the Academy appoints or intends to appoint to serve on the committee inform the Academy of the individual's conflicts of interest that are relevant to the functions to be performed.

<http://www4.nas.edu/NAS/nashome.nsf/Multi+Database+Search/9F5DB50425874D65852566EA0078DB98?OpenDocument>

#### 5d. Reporting and managing significant conflicts

If a researcher has a significant conflict of interest, as defined by Federal, state, institutional, journal, or other policies, it must be reported and managed or eliminated. “Managing” a conflict means finding a way to assure that the interests do not adversely influence the research. Some options for managing conflicts of interest include:

- ✓ **requiring full disclosure of all interests so that others are aware of potential conflicts and can act accordingly;**
- ✓ **monitoring the research or checking research results for accuracy and objectivity; or**
- ✓ **removing the person with the conflict from crucial steps in the research process, such as the interpretation of data or participating in a particular review decision.**

These and other options are either worked out by a conflict of interest review committee or an administrator charged with overseeing conflicts of interest.

If the conflicts cannot be managed and could have an adverse impact on the research, then they must be eliminated, by divesting equity, reducing the income received from the research, assigning supervisory responsibilities to someone else, stepping out of the room when a particular proposal is discussed, or some other action.



Finally, it is important to note that research administrators, funding agencies, journal editors, and conflict of interest committees, not the researcher, should make final decisions about the management of conflicts of interest. This protects the researcher from charges of acting in her or his own interest and helps assure that the most responsible decisions are made.

#### Questions for discussion

- 1** Is \$10,000 or a 5 percent equity stake an appropriate level for raising concerns about possible conflicts of interest or should other values be used?
- 2** Should researchers be allowed/encouraged to profit personally from their research apart from their normal compensation?
- 3** What are appropriate mechanisms for managing financial conflicts of interest?
- 4** What are appropriate mechanisms for protecting students from a mentor’s conflict of commitment?
- 5** What are appropriate mechanisms for managing intellectual and personal conflicts of interest?

## Resources

### Policies, Reports, and Policy Statements

- Association of American Medical Colleges. *Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research*, Washington, DC: AAMC, 1990. (available at: <http://www.aamc.org/research/dbr/coi.htm>)
- National Institutes of Health. "Objectivity in Research," *Federal Register* 60, 132 (1995): 35809-35819. (available at: <http://grants2.nih.gov/grants/guide/notice-files/not95-179.html>)
- National Science Foundation. "Investigator Financial Disclosure Policy," *Federal Register* 60, 132 (1995): 35820. (available at: <http://www.nsf.gov/pubs/stis1996/iin118/iin118.txt>)
- US Congress. 105th Congress. First Session. *Federal Advisory Committee Act Amendments of 1997*, PL 105-153 (1997). (available at: <http://thomas.loc.gov/>)
- Office of Management and Budget. *Circular A-21*, Washington, DC: OMB, 2000. (available at: <http://www.whitehouse.gov/omb/circulars/a021/a021.html>)
- Association of American Universities. *Report on Individual and Institutional Financial Conflict of Interest*, Washington, DC: AAU, 2001. (available at: <http://www.aau.edu/research/conflict.html>)
- Food and Drug Administration. *Guidance: Financial Disclosure by Clinical Investigators*, Washington, DC: FDA, 2001. (available at: <http://www.fda.gov/oc/guidance/financialdis.html>)
- Office for Human Research Protections. Public Health Service. *Draft Interim Guidance: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection*, Washington, DC: OHRP, 2001. (available at: <http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm>)
- Association of American Medical Colleges. Task Force on Financial Conflicts of Interest in Clinical Research *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*, Washington, DC: AAMC, 2002. (available at: <http://www.aamc.org/members/coitf/>)
- Council on Government Relations. *Recognizing and Managing Personal Conflicts of Interest*, Washington, DC: COGR, 2002. (available at: [http://www.cogr.edu/files/publications\\_research.htm](http://www.cogr.edu/files/publications_research.htm))
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- Institute of Medicine. National Academies of Science. *Study Conduct: Bias and Conflict of Interest*, Washington, DC: IOM, nd. (available at: <http://www.iom.edu/subpage.asp?id=5350>)

### General Information Web Sites

- Association of American Universities. *Conflict of Interest and Misconduct*, nd. <http://www.aau.edu/research/conflict.html>
- Association of University Technology Managers. *Home Page*, nd. [http://www.autm.net/index\\_ie.html](http://www.autm.net/index_ie.html)
- National Institutes of Health. Office of Extramural Research. *Conflict of Interest*, nd. <http://grants1.nih.gov/grants/policy/coi/>

### Additional Reading

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- Campbell, TID. "Understanding the Potential for Misconduct in University-industry Relationships: An Empirical Study." In *Perspectives on Scholarly Misconduct in the Sciences*, edited by John M. Braxton, 259-282. Columbus, OH: Ohio State University Press, 1999.
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