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The challenge for NIH ethics policies: Preserving public trust *and* biomedical progress

ABSTRACT

Recently updated ethics rules for employees of the National Institutes of Health (NIH) aim to prevent inappropriate influences on research decisions while preserving employees' professional and scientific interactions. Specific provisions require NIH employees to report their financial holdings in "substantially affected organizations" and require senior employees to divest all holdings greater than $15,000 in any single such organization. Outside institutions that receive NIH grants are bound by separate disclosure requirements. Public-private partnerships have become more important to NIH efforts to advance biomedical research in light of flat NIH budgets in recent years. Such partnerships open the door, however, to financial conflicts that must be prevented or managed in order to maintain scientific integrity and public trust.

When it comes to conflicts of interest, the biomedical community in general and federal health agencies in particular are under a microscope from the public, the Congress, the media, and the Office of Inspector General of the US Department of Health and Human Services.

This article describes ethics and conflict-of-interest policies in place at the federal agency for which I work, the National Institutes of Health (NIH). I will focus on newly updated ethics rules for NIH employees, requirements for institutions conducting extramural NIH research, and the philosophy guiding NIH partnerships with the private sector. **Table 1** provides a framework of some general concepts that underlie my discussion here.

DUAL NATURE OF NIH

Conflict-of-interest policies at the NIH must be understood in the context of the agency's dual nature. The NIH is a unique institution with a campus in Bethesda, Maryland, that houses some 17,000 NIH employees, about 6,000 of whom are scientists. At the same time, the NIH directs the funding of research at more than 3,000 institutions across the country and around the world, supporting an estimated 300,000-plus individual researchers. A full 83% of the $28 billion allocated to the NIH in the federal budget goes to this "extramural" research at non-NIH institutions, and that is the research that I help to oversee.

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RULES FOR NIH EMPLOYEES

Basic tenets

The NIH has a set of ethics rules for its own employees (including scientists), which boil down to three basic tenets, expressed here in my own layperson-friendly terms:

I may not serve two masters. An NIH employee cannot have another financial interest in the work that he or she performs for the NIH.

I may not double-dip. Since the taxpayers pay for the work of NIH employees, someone else may not pay an NIH employee again for that same work.

I may freely speak, write, and teach. Within the bounds of the first two rules, NIH employees are free to speak, write, and teach in their areas of expertise. This principle aims to protect employees' ability to have constructive interactions with other scientists and preserve the free marketplace of ideas.

Guiding principles

These ethics rules for NIH employees were recently updated in a formal final rule published in the *Federal Register* in August 2005.[1,2] The following principles guided the development of the final rules:

- The public must be assured that research decisions made at the NIH are based on scientific evidence and not on inappropriate influences.
- Senior managers and others who play an important role in research decisions must meet a higher

TABLE 1
Central concepts in conflict-of-interest discussions

Types of conflicts
Real
Apparent
Financial
Personal
Who is subject to conflicts of interest?
Individuals
Groups or collections of individuals
How are conflicts managed?
Regulation
Policy
Guidelines
Societal and cultural norms

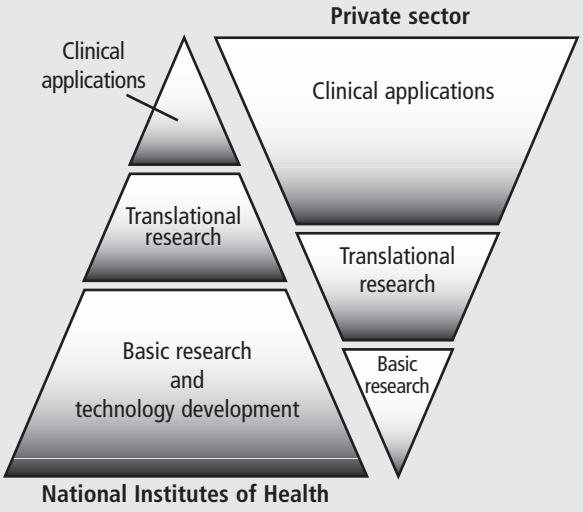

FIGURE 1. Relative contributions to US biomedical research spending by the public and private sectors.

standard of disclosure than employees who are not decision makers.

- To advance science and remain on the cutting edge of research, NIH employees must be allowed interaction with professional associations, participation in public health activities, and genuine teaching opportunities.

Specifics from the final rules

The updated ethics rules for NIH employees contain a number of noteworthy specific provisions that I have again expressed in my own layperson's terms:

- As in the past, no outside consulting by NIH staff with a "substantially affected organization" (generally, pharmaceutical, biotechnology, and device companies) is allowed.
- Holdings in substantially affected organizations in excess of $15,000 per company are not permitted and must be divested; this rule applies to all senior NIH employees and their spouses and minor children, unless a waiver is given.
- Receipt of monetary awards is contingent on prior approval and is limited to awards determined to be bona fide through a prescreening process.
- Financial holdings in substantially affected organizations (including holdings of spouses and minor children) must be reported by high-level employees and those involved in clinical research.
- Contingent on prior approval and to the extent allowed under existing government-wide rules, the following outside activities are allowed:

(1) Outside activities with professional or scientific organizations, and service on data and safety monitoring boards and scientific grant review committees
(2) Compensated academic outside activities such as teaching courses, giving grand rounds lectures, writing textbooks, reviewing manuscripts and editing for journals, and the practice of medicine or other health professions.

REPORTING REQUIREMENTS FOR EXTRAMURAL INSTITUTIONS

Outside institutions that receive NIH grants are bound by reporting requirements as well. At the time of application for an NIH grant, outside investigators must report any significant financial interests to their institution. Before expenditure of funds, the institution must report any financial conflict of interest to the NIH and assure us that it has been managed, reduced, or eliminated. Any financial conflict identified after the initial report must be reported by the institution to the NIH within 60 days of its identification, and the institution must assure us that it has been managed, reduced, or eliminated.

RATIONALE FOR PUBLIC-PRIVATE PARTNERSHIPS

We are in an era of unprecedented biomedical advances, unprecedented scientific opportunities (in genomics, molecular libraries, etc.), and a transformation from curative to preemptive medicine. As a result, the NIH believes that medicine will become increas-

ingly predictive, personalized, and preemptive and that advances in these areas will require the participation of all players in the biomedical community. In addition, at the same time that scientific opportunities are unprecedented, budgets are constrained, prompting both the NIH and academic institutions to look to outside sources to help fund their research agendas.

Both of these factors have contributed to the NIH's increasing participation in public-private partnerships, which are critical for the translation of research from bench to bedside. The main contribution of the NIH in this equation is basic research and technology development, followed by translational research and more distantly by clinical applications. The private sector, which spends two to three times as much as the NIH does on biomedical research and development, does the bulk of the clinical applications portion of research **(Figure 1)**.

Examples of NIH partnerships

The Osteoarthritis Initiative is one public-private partnership of the NIH whose purpose is to find biomarkers of osteoarthritis. Participants include several NIH institutes and centers, as well as outside universities and hospitals, industry, and the Foundation for the National Institutes of Health (FNIH). The FNIH is a congressionally mandated nonprofit organization that helps the NIH further its mission, often by brokering interactions between the NIH and industry.

Medicine will become increasingly predictive, personalized, and preemptive, requiring the participation of all players in the biomedical community.

The Alzheimer's Disease Neuroimaging Initiative is a public-private partnership whose purpose is to find neuroimaging and other noninvasive biomarkers for early Alzheimer's disease. As with the Osteoarthritis Initiative, participants include several NIH institutes and centers, industry, and the FNIH.

Partnerships raise issues

Despite the promise of public-private partnerships, they raise a number of issues and potential concerns that must always be addressed:

Conflict of interest. The NIH needs to be able to identify conflicts early and manage or eliminate them.

Technology transfer and sharing of intellectual property represent a large part of how the NIH now functions, and agreements must be in place addressing how to govern these portions of a partnership with a private company.

Sharing of information is also necessary; NIH employees must be free to speak and write, but in some cases compromises must be made in this area consistent with the NIH ethics rules outlined above.

Human subject protections are paramount. We must ensure not only the safety of human research subjects but also the privacy and confidentiality of the information collected about them.

CONCLUSION

The NIH recognizes that maintaining scientific integrity and the public trust is critical, both in our public-private partnerships and in our policies for our employees and extramural institutions. Like the rest of the biomedical community, we need to prevent, eliminate, and manage conflicts of interest not because we are under a microscope but because it is the right thing to do.

I would like to close with a personal observation. People are capable of both enormous altruism and enormous greed—a fact that we ignore at our peril. Our discussions of conflict of interest in the biomedical community might benefit greatly from the expertise of behavioral social scientists and others who could bring insights into the ways that groups of people interact. We should consider bringing these experts into our discussions moving forward.

REFERENCES

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