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SPECIAL ISSUE

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REQUEST FOR COMMENT ON PROPOSED GUIDELINES FOR POLICIES ON
CONFLICT OF INTEREST 1
National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration
Index: NATIONAL INSTITUTES OF HEALTH
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

REQUEST FOR COMMENT
ON
PROPOSED GUIDELINES
FOR POLICIES ON CONFLICT OF INTEREST

developed by
THE NATIONAL INSTITUTES OF HEALTH
and
THE ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Public Health Service, Department of Health and Human Services

P.T. 04, 34; K.W. 1014004, 1014006

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) seek comments from the public on the following draft issuance, intended to protect against conflicts of interest related to NIH-and ADAMHA-supported research. The NIH and ADAMHA are particularly interested in receiving comments on issues presented below from individual researchers, scientific societies and associations, independent science advisory bodies, members of Congress, other Federal agencies that support or conduct research, and institutions that receive funds from NIH or ADAMHA to conduct or support biomedical or behavioral research. Interested individuals and parties are encouraged to submit their comments by December 15, 1989.

Please address your comments in writing to:

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National Institutes of Health
Shannon Building, Room 144
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Bethesda, Maryland 20892

For further information, please contact Dr. Bick at (301) 496-1096.

BACKGROUND:

The section of the PHS Grants Policy Statement on Standards of Conduct for Employees (of Grantee Organizations), page 55, provides that, "Recipient organizations must establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business, or other ties. Therefore, each institution receiving financial support must have written policy guidelines on conflict of interest and the avoidance thereof. These guidelines should reflect State and local laws and must cover financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery. These rules must also indicate the conditions under which outside activities, relationships, or financial interests are proper or improper, and provide for notification of these kinds of activities, relationships, or financial interests to a responsible and objective institution official." It also sets forth an outline of what those rules of conduct must contain, namely "a provision for prompt notification of violations to a responsible and objective grantee official, and must specify the type of administrative action that may be taken against an individual for violations."

The purpose of this draft issuance is to provide further guidance for the extant PHS Grants Policy Statement and to provide greater detail to the stated policies of the current guidance. It is formulated to assist institutions who receive support for biomedical or behavioral research from the NIH or ADAMHA to establish acceptable criteria for their own conflict-of-interest policies. Institutions that receive such funds are expected to adopt policies that build upon this framework and that reflect their specific needs. Signature of the responsible institutional official on the application or proposal constitutes certification that the institution either has formulated, enacted, and is enforcing such policies, or will do so no later than the date of any award.

NIH- and ADAMHA-supported investigators appear to be involved increasingly in non-Federally supported activities. This situation represents some obvious philosophical and potential practical advantages, including rapid technology transfer and cooperative research ventures that facilitate efficient exchange of research results from the research laboratory or clinical trial to utilization in the private sector. With the increased involvement of NIH- and ADAMHA-supported investigators in non-Federally supported activities, particularly those sponsored by industry, have come some complex questions. Intense competition for Federal research funds, often resulting in partial funding for some research projects, also has stimulated or required investigators to seek additional research funding from non-Federal sources. In addition, recent research advances in biomedical science have produced major opportunities for commercialization of research findings.

The establishment and maintenance of a healthy research environment in which innovation flourishes clearly depend on the integrity and objectivity demonstrated by individual investigators, other individuals associated with research projects, and recipient institutions. This draft issuance was developed with those goals in mind. The intention in formulating them is to ensure that NIH- and ADAMHA-supported research is carried out in a completely objective manner, and that research results are not influenced by the possibility of financial gain.

These proposed guidelines should not stifle research creativity or technology transfer from the research laboratory to commercial use but, rather, provide guidance concerning the safeguards needed to ensure unbiased performance and reporting of research results. Such safeguards are particularly important for situations in which conflicts of interest exist but are not publicly discernible. The proposed guidelines do not apply to research supported under the Small Business Innovation Research Program, established by the Small Business Innovation Development Act of 1982 (P.L. 97-219). This Act was intended to increase the involvement in research and development of small, innovative firms by making Federal research and development funds more readily available to them, so that they may participate more fully in technological innovation and in strengthening the economy.

On June 27 and 28, 1989, NIH and ADAMHA sponsored an open meeting to discuss issues related to the problem of conflict of interest. Discussion at that meeting addressed a number of issues that have served as a basis for this draft issuance. There was general agreement that institutions that receive biomedical research funds from the NIH or ADAMHA should develop their own policies with respect to conflict of interest. NIH and ADAMHA have developed the proposed guidelines in this document to serve as a point of departure for further discussion on procedures for ensuring high integrity in the performance, reporting, and utilization of research results, and in the appropriate use of public funds for public purposes.

We request comments on the proposed guidelines that are presented below. We also request specific comments on the following questions, as well as on any other issues related to conflict of interest.

- o What policies does your institution already have in place to deal with conflicts of interest? How does this draft issuance compare with them?
- o How should information be disseminated regarding conflict-of-interest policies?
- o What is your perception of the impact of your institution's adoption of policies, based on the framework presented here, on your own research or, more broadly, on basic biomedical research, clinical trials, technology transfer, product development, and commercialization of research results?

Proposed Policy

Research activities supported by NIH or ADAMHA must be conducted in an objective manner, free of any potential for undue influence arising from the private financial interests of those responsible for the conduct of the research. Public funds must be expended to advance public purposes, in this case, the conduct of biomedical and behavioral research. Private financial interests can adversely affect the accomplishment of this public purpose by directly affecting the manner in which the research is conducted, by creating the appearance that the research has been influenced by those financial interests, or by inhibiting the dissemination of research results.

Recipients of research funds are responsible for ensuring that the funds are expended for the public purposes for which they were awarded. As part of this

responsibility, recipients must adopt procedures that will prevent the research from being influenced or potentially influenced by the private financial interests of those responsible for the conduct of research. The following proposed guidelines establish minimum standards for the procedures to be adopted by recipients, including identification of those financial interests which are incompatible with the need to ensure that publicly funded research is conducted objectively.

I. PROPOSED RESPONSIBILITIES OF NIH AND ADAMHA, AWARDEE INSTITUTIONS, AND INDIVIDUALS:

A. NIH and ADAMHA:

The NIH and ADAMHA are responsible for formulating and disseminating conflict-of-interest guidelines to assist institutions to develop their own conflict-of-interest policies. The NIH and ADAMHA also are responsible for:

In specific instances, reviewing institutions' conflict-of-interest policies.

Routinely reviewing actions that the institutions have taken with respect to waivers and exceptions.

Assuring that the necessary terms and conditions are discharged satisfactorily prior to making an award. In the absence of fulfillment of the necessary terms and conditions, funding may be affected.

B. Awardee Institutions:

Institutions that receive NIH or ADAMHA funds are responsible for establishing and implementing policies and procedures in accord with this draft issuance. Upon request, institutions shall provide copies of their policies and procedures and information regarding their implementation to the appropriate NIH or ADAMHA officials. The institutions also are responsible for:

Maintaining records of disclosures made and actions taken regarding persons associated with any NIH or ADAMHA award for a period of at least three years beyond the termination of that award.

Promptly notifying the funding agency if they identify any practice or situation involving a conflict of interest which could potentially affect one or more NIH or ADAMHA-supported projects.

Resolving any failure to comply with these proposed guidelines prior to accepting an award.

Policies

Each institution that applies for assistance to the NIH or ADAMHA for any project or program that involves the conduct of biomedical or behavioral research shall certify by the institutional signature on its application or proposal that it has institutional policies in place that are in accord with this draft issuance or will have such policies in place no later than the date that any award would be accepted.

Institutions are encouraged to adopt policies that build upon this framework and that reflect their specific needs and situations.

Education

Institutions are expected to establish a means of informing all investigators applying for or receiving funding from the NIH or ADAMHA, as well as all relevant research employees, consultants, and administrative staff at that institution who are in a position to make decisions about or to affect the outcome of the research, of the institutional policies covering conflicts of interest. This information should include, at a minimum, identification of prohibited financial interests, disclosure procedures, and sanctions for non-compliance.

C. Individuals:

These proposed guidelines apply to all investigators, key employees, consultants, and persons with primary management, advisory, or supervisory responsibilities for NIH- or ADAMHA-funded research, and all persons who are in a position to have a critical influence on, or substantive control over, that research. Those persons are responsible for avoiding circumstances that

would put them in a conflict-of-interest situation with that research. These provisions also apply to the spouses, dependent children, and other dependents of the individuals mentioned above.

Full disclosure of all financial interests and outside professional activities, by all who are in a position to make decisions concerning one or more NIH- or ADAMHA-supported projects, shall be made to the institution at the time a research application or proposal is submitted to the NIH or ADAMHA. This shall include the financial interests of their spouses, dependent children, and other dependents. These disclosures shall be updated to the institution annually.

All individuals for whom these proposed guidelines apply shall comply with the conflict-of-interest policies of the institutions through which the NIH or ADAMHA funding is provided and shall report immediately any conflicts of interest to the appropriate institutional officials.

II. DISCLOSURES:

Full disclosure of all funding other than that from the applicant institution is required of all personnel of awardee institutions as described above who are currently involved in, or currently applying for, research funds from NIH or ADAMHA. This disclosure includes support for laboratory activities, special instrumentation or other products, services, consultancies, honoraria, and other benefits.

All disclosures and waivers shall be reviewed at the institution in a timely manner by knowledgeable and objective individuals appointed by institutional officials. In order to assure timely and objective evaluations, institutions may wish to appoint a panel of at least 3 members, one of whom has no institutional affiliation and one of whom is the institutional official responsible for signing the grant application or contract proposal.

Confidentiality shall be maintained at all times unless that confidentiality would interfere with the interests of the institution or the Federal Government.

Institutions may grant waivers in unusual situations when it can be demonstrated that the financial interest is so insignificant that it would not compromise the objectivity of the research results or the interests of the Federal government or the public. The NIH or ADAMHA shall be informed within thirty days of any such waiver granted to an individual involved in any way with a NIH- or ADAMHA-funded project related to the waiver.

If a conflict-of-interest situation is identified that involves one or more NIH- or ADAMHA-supported project(s), the NIH or ADAMHA and appropriate institutional official(s) shall be notified immediately, and the institution shall take immediate steps to safeguard Federal funds until such time that the conflict-of-interest situation is eliminated.

Disclosure information shall be updated to the institution at least once per year. Changes that could reflect possible conflicts of interest should be reported immediately to the responsible institutional official(s).

The institution shall maintain records of disclosures, waivers, and of all actions in response to review of disclosures for personnel associated with NIH- or ADAMHA-supported projects for a period of three years after the termination of that project.

III. PROHIBITED SITUATIONS:

Institutions may establish their own policies on prohibited situations. However, the following are basic standards for all institutions.

1. No investigator, key employee, consultant, or other persons with primary research, management, advisory, supervisory, or purchase authorization responsibilities, or their spouses, dependent children, or other dependents, shall be allowed to have personal equity holdings or options in any company that would be affected by the outcome of the research or that produces a product or equipment being evaluated in the research project. This does not apply to equipment or products that are commonly found in research laboratories, such as commercially available centrifuges, pH meters, and common reagents. This prohibition does not include blind trusts, diversified mutual funds, or other financial interests over which the individual investor has no discretionary control. The institution may grant a waiver to this requirement if it determines that such holdings are so insignificant they do

not have the potential of influencing research results or the direction of the research.

2. Information and/or research products derived from NIH- or ADAMHA-funded studies shall not be shared with any company with which a conflict exists unless or until the information or research products are made publicly available.

3. Specific requirements shall apply if an investigator, key employee, consultant, or other involved person receives funds from NIH or ADAMHA as well as commercial funding, for any of their research, as follows:

All research funding for all research projects must be disclosed as required in the appropriate sections of applications and proposals to the NIH or ADAMHA (under the "Other Support" section), as well as to the institutional official(s) responsible for conflict-of-interest review.

Institutional conflict-of-interest reviews need to be particularly careful to ensure that private companies are not in a position to influence the research plan, results, or the reporting or interpretation of results of NIH- or ADAMHA-supported research.

An investigator, key employee, consultant, or other involved person may not receive honoraria, fees for service, or a management position from a private source if that individual is involved in an NIH- or ADAMHA-supported project that is evaluating or testing a product of the source. Honoraria, fees for service, or management positions from other sources are allowed provided that their acceptance does not jeopardize the recipient's objectivity with respect to the NIH- or ADAMHA-supported project or result in special access to information that is not publicly available, and that full disclosure is made to designated institutional officials. For example, care must be taken to ensure that the private company has no role in any decisions that would impede the standard practices for the publication or other dissemination of research results related to NIH- or ADAMHA-supported research.

IV. CRITERIA FOR WAIVERS AND EXCEPTIONS:

The institution may grant waivers in certain circumstances if it determines that such holdings do not have the potential for influencing research results, the reporting of research results, the direction of the research, or putting the individual in a situation of being able to derive special advantage because of information he/she has available through the NIH/ADAMHA research results.

All waivers and exceptions shall be reported to the Deputy Director for Extramural Research, NIH, if they relate to NIH-supported projects, or to the Associate Administrator for Extramural Programs, ADAMHA, if they relate to ADAMHA-supported projects, prior to accepting an award or, if disclosure is made after the award, within thirty days of granting the waiver or exception.

The NIH or ADAMHA may allow a conflict-of-interest situation to exist if it has been reported to NIH or ADAMHA and the agency determines that this is in the best interests of the public and of NIH or ADAMHA.

V. REMEDIES:

If situations involving a conflict of interest related to NIH- or ADAMHA-supported research are discovered, the awardee institution has the first responsibility to resolve the problem. If the institution does not resolve the problem in a timely manner, then the NIH or ADAMHA will take action.

Awards will be made without prejudice if prohibited conflict-of-interest situations are rectified prior to the award date.

Institutions are required to notify the funding agency immediately if prohibited conflict-of-interest situations are detected or develop after awards have been made and the conflict is not resolved promptly.

NIH or ADAMHA may include special terms and conditions in an award if (1) an institution is not complying with these proposed guidelines or (2) to resolve a conflict-of-interest situation that has not been resolved by the institution. Failure on the part of the institution to meet these special terms and conditions could affect funding.