

What are Conflicts?

General - A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

Current conflict of interest policies and practices have evolved over more than four decades of increasing relationships with industry in medical education, research, and practice. The increase has been accompanied by intensifying discussions about how the risks and the expected benefits of these relationships should be evaluated and balanced. Since 1995, **the U.S. Public Health Service (PHS) has required most research grantees to establish policies and procedures to ensure that the design, conduct, or reporting of research funded by PHS grants not be “biased by any conflicting financial interest of an Investigator” (42 CFR 50.601).** The regulations allow grantees considerable discretion in formulating policies and procedures. To provide more specific and comprehensive guidance to academic institutions on conflict of interest policies, the Association of American Medical Colleges, the Association of American Universities, AAMC and AAU jointly, and the Council on Government Relations have issued several reports with recommendations. The Federation of American Societies for Experimental Biology (FASEB) created a conflict of interest tool kit that offers extensive online resources and guidance for academic institutions, researchers, academic and professional societies, journal editors, and industry. In 2008, the trade associations representing major pharmaceutical and medical device companies revised their codes on company interactions with health care professionals. In addition, a number of academic medical centers, professional societies, medical journals, and other institutions have revised their policies in recent years.

Most conflict of interest policies include the basic elements:

- Disclosure of financial relationships
- The prohibition of certain relationships
- Management of conflicts of interest that have been identified
- Definitions
- specification of who is subject to the policies
- enforcement provisions
- identification of which officials or units within an organization are responsible for administering and monitoring conflict of interest policies and procedures
- person responsible for reviewing initial disclosures

Steps Used to Identify and Respond to a Conflict of Interest.

A given individual may be covered by several conflict of interest policies. For example, a medical school faculty member may have to understand and follow the policies not only of the medical school but also those of several other institutions. Depending on his or her activities,

these other policies might include those of a medical journal, a provider of continuing medical education, a professional society, or a federal advisory committee. If a faculty member is engaged in research to support an application for marketing approval of a medical product by the Food and Drug Administration (FDA), the researcher can expect the study's sponsor to ask for the disclosure of his or her financial interests related to the company and the investigational product so that the sponsor can submit the required information to the FDA. (A recent report by the Office of the Inspector General [OIG] of the U.S. Department of Health and Human Services criticized the administration of these policies and indicated that they were deficient in several respects). Private organizations that fund research, such as the Howard Hughes Medical Institute, also may have conflict of interest policies, which they may oversee directly rather than following the practice of the National Institutes of Health (NIH) of delegating most administrative responsibility to the research institution.

Disclosure—that is, revealing to others information that may otherwise be private or confidential—is a frequent response to concerns about conflicts of interest in various sectors of society. Disclosure by physicians and researchers to their academic or other institution is essential because institutional officials cannot evaluate and respond to individuals' relationships with industry if they are not aware of them. Consistent with the conceptual framework. Disclosures should provide sufficient information about the nature, scope, duration, and monetary value of relationships to allow institutions to assess the risk that secondary interests might unduly influence judgments about research, clinical care, education, or other primary interests.

The committee distinguished disclosure to the physician's or researcher's institution from disclosure beyond the institution, for example, to patients, research participants, or the public. One rationale for disclosure—especially public disclosure—is the deterrence of questionable or inappropriate relationships. As Supreme Court Justice Louis famously expressed it, “sunshine is said to be the best of disinfectants.” In a similar vein, the code of ethics of the American College of Physicians suggests that physicians considering the acceptance of gifts or other relationships with companies should ask themselves what their patients, the public, or their colleagues would think about the arrangement. The *Nature* publishing group urges authors to avoid “any undeclared competing financial interests that could embarrass you were they to become publicly known after your work was published”.

Disclosure should have beneficial consequences if it leads physicians to avoid gifts, the use of industry-controlled presentations, and other relationships that create a risk of compromising their decisions and their professional independence. It could also have harmful consequences if physicians or researchers react by avoiding relationships that promote important societal goals and that are accompanied by adequate measures to protect objective judgment.

In addition to requiring disclosure to the institution, policies may also require that financial relationships or conflicts of interest be disclosed to individuals who might be affected by the relationship. These might include research colleagues, research participants, journal readers, students, or patients.

The management of a conflict of interest is necessary when an assessment of an individual's financial relationships identifies a conflict of interest and when disclosure alone is inadequate but elimination of the conflict is a requirement that is too severe. AAMC has recommended that medical schools create conflict of interest committees to make these assessments and propose management strategies, when appropriate. Professional societies may rely on senior staff or members (e.g., chairs of guideline development panels) for assessments of relationships and responses.

The management options will vary depending on the nature of the conflict and the activity under consideration. Examples of management options follow:

- asking an individual with a conflict of interest to reduce the value of a financial relationship so that it falls below a threshold amount;
- requiring that an individual forgo participation in committee votes, deliberations, or decisions about a topic related to that individual's conflict of interest;
- modifying the design of a research project or having a researcher with no conflict of interest serve as the principal investigator; or
- Providing an observer to monitor and evaluate the content of a continuing education course conducted by an individual with a conflict of interest for bias.

The available data suggest that institutions vary considerably in how they oversee and manage conflicts of interest. reported that 76 percent of medical schools responding to the 2003 AAMC survey had established, as recommended by AAMC, a standing committee to evaluate conflict of interest disclosures, and 21 percent included at least one committee member from outside the institution, also as recommended by AAMC. Eighty-one percent of the medical schools responding to the AAMC survey allowed investigators with a significant financial interest to conduct research involving human participants when compelling circumstances exist. Only 61 percent of the respondents indicated that they had adopted the rebuttable presumption or a similar strategy, and only 26 percent indicated that they had a definition of the compelling circumstances or similar conditions that would allow rebuttal of the presumption.

If an organization's policy requires more than just disclosure, the next step is a review to assess whether a disclosed relationship constitutes a conflict of interest and what risks or potential benefits the relationship presents. As described earlier, a department chair or similar individual

may review disclosures and identify conflicts of interest or may refer potential conflicts of interest for further review by a conflict of interest committee or other group or official.

Risks and Potential Benefits to Consider in Assessing the Severity of a Researcher's Conflict of Interest. Risks to human subjects: to what extent could the conflict of interest increase the risk (considering the role specified for the researcher).

The FDA has developed guidance on whether an individual with a conflict of interest should be allowed to serve on one of its advisory committees.

In 2008, the NIH announced the development of and began testing an electronic reporting and tracking tool that would allow grantee institutions to prepare and submit required conflict of interest reports and search past reports. Consistent with one of the OIG report's recommendations, the tool would also provide a central web-based location for grantee conflict of interest reports received across NIH. In addition, NIH has initiated procedures and training to ensure proper NIH staff oversight of conflict of interest issues involving grantees.

Recommendations:

- 1) ACOM should adopt, implement, and make public conflict of interest policies for individuals that are consistent with the other recommendations in this report. To manage identified conflicts of interest and to monitor the implementation of management recommendations, institutions should create a conflict of interest committee. That committee should use a full range of management tools, as appropriate, including elimination of the conflicting financial interest, prohibition or restriction of involvement of the individual with a conflict of interest in the activity related to the conflict, and providing additional disclosures of the conflict of interest.
- 2) ACOM should establish a policy that individuals generally may not conduct research with human participants if they have a significant financial interest in an existing or potential product or a company that could be affected by the outcome of the research. Exceptions to the policy should be made public and should be permitted only if the conflict of interest committee (a) determines that an individual's participation is essential for the conduct of the research and (b) establishes an effective mechanism for managing the conflict and protecting the integrity of the research.
- 3) For all faculty, students, residents, and fellows and for all associated training sites, academic medical centers and teaching hospitals should adopt and implement policies that prohibit
 - the acceptance of items of material value from pharmaceutical, medical device, and biotechnology companies, except in specified situations;

- educational presentations or scientific publications that are controlled by industry or that contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;
- consulting arrangements that are not based on written contracts for expert services to be paid for at fair market value;
- access by drug and medical device sales representatives, except by faculty invitation, in accordance with institutional policies, in certain specified situations for training, patient safety, or the evaluation of medical devices; and
- the use of drug samples, except in specified situations for patients who lack financial access to medications.

4) Physicians, wherever their site of clinical practice, should

- not accept items of material value from pharmaceutical, medical device, and biotechnology companies except when a transaction involves payment at fair market value for a legitimate service;
- not make educational presentations or publish scientific articles that are controlled by industry or contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;
- not enter into consulting arrangements unless they are based on written contracts for expert services to be paid for at fair market value;
- not meet with pharmaceutical and medical device sales representatives except by documented appointment and at the physician's express invitation; and
- not accept drug samples except in specified situations for patients who lack financial access to medications.

5) Groups that develop clinical practice guidelines should generally exclude as panel members individuals with conflicts of interest and should not accept direct funding for clinical practice guideline development from medical product companies or company foundations. Groups should publicly disclose with each guideline their conflict of interest policies and procedures and the sources and amounts of indirect or direct funding received for development of the guideline. In the exceptional situation in which avoidance of panel members with conflicts of interest is impossible because of the critical need for their expertise, then groups should

- publicly document that they made a good-faith effort to find experts without conflicts of interest by issuing a public call for members and other recruitment measures;

- appoint a chair without a conflict of interest;
 - limit members with conflicting interests to a distinct minority of the panel;
 - exclude individuals who have a fiduciary or promotional relationship with a company that makes a product that may be affected by the guidelines;
 - exclude panel members with conflicts from deliberating, drafting, or voting on specific recommendations; and
 - Publicly disclose the relevant conflicts of interest of panel members.
- 6) Establish a standing committees on institutional conflicts of interest. committees should
- have no members who themselves have conflicts of interest relevant to the activities of the institution;
 - include at least one member who is not a member of the board or an employee or officer of the institution and who has some relevant expertise;
 - create, as needed, administrative arrangements for the day-to-day oversight and management of institutional conflicts of interest, including those involving senior officials; and
 - Submit an annual report to the full board, which should be made public but in which the necessary modifications have been made to protect confidential information.

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