

Conflicts of Interest Bibliography

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Description

An annotated list of websites, books and journal articles discussing conflicts of interest in engineering and science.

Body

Guidelines

International Committee of Medical Journal Editors. <u>Author</u> Responsibilities: Conflict of Interest

This organization, whose guidelines are used across many disciplines as a guide for authorship policies, outlines the importance of strong conflict of interest policies for upholding the credibility of scientific publication and outlines guidelines for all participants in the peer review and publication process to follow.

National Institutes of Health Conflict of Interest Policies

A collection of policies and articles by the United States' National Institutes of Health detailing how they handle conflicts of interest in government-funded research.

National Science Foundation Conflict of Interest Policies

Policy of the U.S. National Science Foundation outlining their conflict of interest policy for recipients of NSF funding.

Organization for Economic Cooperation and Development. (2003).<u>Managing</u> Conflict of Interest in the Public Sector

This report outlines some guidelines for how to manage conflicts of interest for individuals working in the public sector, and includes a survey of legislation used in countries around the world dealing with conflict of interest.

United States Food and Drug Administration (FDA): Financial Disclosure By Clinical Investigators

Discusses guidelines for researchers involved in clinical studies used to determine whether products will be approved by the Food and Drug Administration.

Web Sites

American Chemical Society (2015). <u>Ethical obligations of reviewers of</u> <u>manuscripts.</u>

Outlines the obligations of peer reviewers when reviewing manuscripts for publication in an academic journal. See point number four for a short outline of the expectations of reviewers facing a potential conflict of interest.

Association of American Medical Colleges Forum on Conflict of Interest in Academe

The Forum on Conflict of Interest in Academe offers educational opportunities related to conflict of interest issues; provides a national forum for discussion of the development and application of conflict of interest standards related to research, medical education, and clinical decision-making; and serves as a resource for institutions, policymakers, the media, and the public.

Conflict of Interest Toolkit

Focusing on the biomedical sciences, this resource developed by the Federation of American Societies for Experimental Biology gives a clear introduction to what is meant by conflict of interest, guidelines for researchers, and links to further resources.

Shared Responsibility, Individual Integrity: Scientists Addressing Conflict of Interest in Biomedical Research

This report from a conference held in 2006 by the Federation of American Societies for Experimental Biology, gives an extremely good overview of the different types of conflict of interest that exist and guiding principles for addressing conflicts.

Books

Association of American Universities (AAU): Report on Individual and Institutional Financial Conflict of Interest, Oct 2001

Research universities are concerned about financial conflict of interest because it strikes to the heart of the integrity of the institution and the public's confidence in that integrity. This report identifies key values that universities should seek to protect and discusses individual, and institutional conflicts of interest, and methods for managing these conflicts while leaving universities the option to work with the private sector.

Davis, Michael.(2001). *Conflict of interest in the professions.* New York: Oxford University Press.

A collection of articles discussing issues of conflict of interest in the professions, including engineering, science, the social sciences and medicine.

Krimsky, Sheldon. (2003). *Science in the private interest: Has the lure of profits corrupted the virtue of biomedical research?* Lanham, MD: Rowman & Littlefield.

A strongly argued book by a physicist and policy analyst at Tufts University School of Medicine looking at the involvement of industry in the sponsoring of academic research, and how these kinds of partnerships can give rise to conflicts of interest and, in some cases, the undermining of the integrity of science.

Resnik, David B. (2007). *The price of truth: How money affects the norms of science*. New York: Oxford University Press.

In The Price of Truth, David B. Resnik examines some of the important and difficult questions resulting from the financial and economic aspects of modern science. How does money affect scientific research? Have scientists become entrepreneurs bent on making money instead of investigators searching for the truth? How does the commercialization of research affect the public's perception of science? Can scientists prevent money from corrupting the research enterprise? What types of rules, polices, and guidelines should scientists adopt to prevent financial interests from adversely affecting research and the public's opinion of science?

Spence, Roy G., David S. Shimm and Allen E. Buchanan. (1996). *Conflicts of interest in clinical practice and research.* New York: Oxford University Press.

This collection of essays examine a broad set of issues involving conflicts of interest in medicine and other fields, providing an overview of what constitutes a conflict of interest a detailed discussion of conflicts of interest in medicine, and a final chapter focusing on conflicts of interest between physician and the pharmaceutical industry.

Stark, Andrew. (2003). *Conflict of interest in American public life*. Cambridge: Harvard University Press.

Taking a broad approach to conflict of interest, this book analyzes the historical and recent debate and conception of conflicts of interest, and draws from case studies from a wide variety of disciplines.

Journal Articles

Anker, Jessica S., Annette Flanagan. 2007. A comparison of conflict of interest policies at peer-reviewed journals in different scientific disciplines. *Science and Engineering Ethics.* 13(2): 147-157. doi: 10.1007/s11948-007-9011-z

This article presents the results of a survey of high-impact peer-reviewed journals in twelve different scientific disciplines to compare their conflict of interest policies. The authors found that out of eighty-four journals, only twenty-eight had published policies, though a number of journals when contacted did respond that they did have such a policy. The authors found that frequency of policies varied among disciplines, with medical journals being the likeliest to have one and physics the least likely. Having a policy was correlated with the ranking of the journal, the highest impact journal in a discipline having a policy, as well as a reported history of conflict of interest problems. The authors found that though there was an increase in journals having conflict of interest policies from a study done in 1997, there is a further need for these policies to be readily available and to include a clear definition of conflict of interest and details about how disclosures would be managed during peer review and publication.

Bekelman, Justin E., Yan Li, and Cary P. Gross. 2003. Scope and impact of financial conflicts of interest in biomedical research. *JAMA* 289(4): 454-65. doi: 10.1001/jama.289.4.454.

This study sought to look at the extent, impact, and management of financial conflicts of interest in biomedical research. The authors found that financial relationships among scientific investigators, industry, and academic institutions are widespread, and that conflicts of interest arising from these ties can influence biomedical research in important ways.

Boyd, EA, and Lisa A. Bero. (2007). Defining financial conflicts and managing research relationships: An analysis of university conflict of interest committee decisions. *Science and Engineering Ethics* 13: 415-35. doi: 10.1007/s11948-007-9041-6

This article analyzes the discussions and decisions of three conflict of interest committees in California universities to look at the decision-making processes of these committees, as they struggle to understand complex financial relationships, reconcile institutional, state, and federal policies, and protect the integrity of the scientific process.

Curzer, H. J., & Santillanes, G. (2012). Managing Conflict of Interest in Research: Some Suggestions for Investigators. *Accountability in Research: Policies & Quality Assurance, 19*(3), 143-155. doi:10.1080/08989621.2012.678685

Since conflict of interest is unlikely to be eliminated or tamed by the professional--and institutional---level safeguards currently under discussion, individual researchers must make their own preparations. The authors offer individuals ten strategies for managing their own conflicts of interest.

Davis, Michael. (2012). Conflict of interest. *Encyclopedia of Applied Ethics.* San Diego: Academic Press.

This encyclopedia article provides a clear description of what is meant by a conflict of interest, different kinds of conflicts of interest that exist, and strategies for dealing with conflicts as they arise.

DeLong, G. (2012). Conflicts of Interest in Vaccine Safety Research. *Accountability in Research: Policies & Quality Assurance, 19*(2), 65-88. doi:10.1080/08989621.2012.660073

Using the vaccine-autism debate as an illustration, this article details the conflicts of interest each of these groups faces, outlines the current state of vaccine safety research, and suggests remedies to address COIs. Minimizing COIs in vaccine safety research could reduce research bias and restore greater trust in the vaccine program.

DuVal, Gordon. (2004). Institutional conflicts of interest: Protecting human subjects, scientific integrity, and institutional accountability. *Journal of Law, Medicine & Ethics* 32(4): 613-625. doi: 10.1111/j.1748-720X.2004.tb01967.x

Describes the difficulties arising from the conflicting interests of universities and research institutions overseeing research, and the potential threat these pose to human research subjects and research integrity. This is doubly true in regard to the shift of funding for biomedical research from government to industry, and the increasing commercial involvement in research.

Elliott, K. C. (2008). Scientific Judgment and the Limits of Conflict-of-Interest Policies. *Accountability in Research: Policies & Quality Assurance,* 15(1), 1-29. doi:10.1080/08989620701783725

This article argues that the three major elements of typical university conflict-ofinterest (COI) policies (i.e., disclosure, management, and elimination of conflicts via divestiture or recusal) are likely to be insufficient for screening out many worrisome influences of financial COIs. Identifying the limits of these policies highlights the importance of considering alternative strategies, such as encouraging more independently funded research, in order to maintain the integrity of science.

Farthing, M.A. 2006. Authors and publication practices. *Science and Engineering Ethics* 12(1): 41-52. doi: 10.1007/PL00022267

Article discusses the need for authors, editors and reviews to disclose any conflicts of interests they may have.

Friedman, P.J.(2002). The impact of conflict of interest on trust in science. Science and Engineering Ethics 8(4):413-420. doi: 10.1007/s11948-002-0063-9

The article discusses the erosive effect conflicts of interest have on the integrity of

scientific research and how it damages the way in which the public views scientists and their work, and the relationships among scientists themselves. The author recognizes disclosure as the key way to manage conflicts of interest, but also reviews other ways to improve the situation such as the improvement of rules and sanctions, new techniques for avoidance of financial conflicts by developing new funding resources for evaluative research, and new thinking about how to reduce institutional conflicts of interest.

Gingras, Yves, and Pierre-Marc Gosselin.(2008). The emergence and evolution of the expression "conflict of interest" in "Science": A historical overview, 1880-2006. Science and Engineering Ethics. 14(3): 337-43. doi: 10.1007/s11948-008-9063-8

The article discusses the development of the concept of "conflicts of interest" in the area of science, and shows that the content of discussions over conflicts of interest have changed over time with the transformation of the research system. The authors look at the presence of the phrase "conflicts of interest" in the journal Science over the past century to show how three different meanings have emerged, and how the changes in meaning are closely linked with the changing structure of the relations between the scientific community with the State and with industry.

Glaser, B.E. and L.A. Bero.(2005). Attitudes of academic and clinical researchers toward financial ties in research: A systematic review. *Science and Engineering Ethics.* 11(4):553-573. doi: 10.1007/s11948-005-0026-z

This article summarizes the data from seventeen surveys looking at the attitudes of researchers to financial ties in research. The literature review revealed that investigators are concerned about the impact of financial ties on choice of research topic, research conduct and publication, but this concern is less among investigators already involved with industry. Researchers approve of industry collaboration and financial ties when the ties are indirectly related to the research, disclosure is upfront, and results and ideas are freely publicized. However, their trust in disclosure as a way to manage conflicts may reveal a lack of awareness of the actual impact of financial incentives on themselves and other researchers.

Healy, David. (2003). In the grip of the python: Conflicts at the universityindustry interface. *Science and Engineering Ethics* 9(1): 59-71. doi: 10.1007/s11948-003-0020-2

The author discusses a case he was personally involved with where a pharmaceutical company he was working with infringed on his academic freedom.

The author discusses some of the disturbing observations he made during his involvement in the case, including evidence that pharmaceutical companies have miscoded raw data on suicidal acts and suicidal ideation caused by their antidepressants, and a growing body of examples of ghostwriting of articles in the therapeutics domain. Many of the tensions evident in this case, therefore, can be linked to company abilities to keep clinical trial data out of the public domain. This, the author argues, is the point at which the pharmaceutical python gets a grip on academia.

Johnson, J., & Rogers, W. (2014). Joint Issues -- Conflicts of Interest, the ASR Hip and Suggestions for Managing Surgical Conflicts of Interest. *BMC Medical Ethics*, 15, e1-E9. doi:10.1186/1472-6939-15-63

Financial and nonfinancial conflicts of interest in medicine and surgery are troubling because they have the capacity to skew decision making in ways that might be detrimental to patient care and well-being. The recent case of the articular surface replacement (ASR) hip provides a vivid illustration of the harmful effects of conflicts of interest in surgery.

Krimsky, S. and S. Rothenberg. (2001). Conflict of interest policies in science and medical journals: Editorial practices and author disclosures. *Science and Engineering Ethics* 7: 205-218. doi: 10.1007/s11948-001-0041-7

This study looks at how scientific and biomedical journals have adopted conflict of interest policies for authors, and if these policies have lead to any financial disclosure statements being published by the journals. Of the journal editors surveyed, about three-fourths do publish these kinds of disclosure statements. The authors conjecture that this low rate suggests that either authors have a low rate of financial interest in the subject matter of their publications, or there is poor compliance to journals' conflict of interest policies.

Krimsky, Sheldon. 2013. Do Conflicts of Interest Bias Research?: An Inquiry into the Funding Effect. Science, Technology & Human Values. 38(4): 556-587. doi: 10.1177/0162243912456271

In the mid-1980s, social scientists compared outcome measures of related drug studies, some funded by private companies and others by nonprofit organizations or government agencies. The concept of a "funding effect" was coined when it was discovered that study outcomes could be statistically correlated with funding sources, largely in drug safety and efficacy studies. Also identified in tobacco research and chemical toxicity studies, the "funding effect" is often attributed, implicitly or explicitly, to research bias. This article discusses the meaning of scientific bias in research, examines the strongest evidence for the "funding effect," and explores the question of whether the "funding effect" is an indicator of biased research that is driven by the financial interests of the for-profit sponsor. This article argues that the "funding effect" is merely a symptom of the factors that could be responsible for outcome disparities in product assessment. Social scientists should not suspend their skepticism and choose as a default hypothesis that bias is always or typically the cause.

Lind, R., & Swenson-Lepper, T. (2013). Measuring Sensitivity to Conflicts of Interest: A Preliminary Test of Method. *Science & Engineering Ethics, 19* (1), 43-62. doi:10.1007/s11948-011-9319-6

This study presents and develops test methods for assessing sensitivity to conflict of interest.

Loewenstein, George, Daylian M. Cain and Sunita Sah. 2011. The Limits of Transparency: Pitfalls and Potential of Disclosing Conflicts of Interest. American Economic Review, 101(3):423-28 doi: 10.1257/aer.101.3.423

This paper reviews evidence from published and ongoing research that disclosing conflicts of interest has unintended consequences, helping conflicted advisors and harming their advisees: With disclosure, advisors feel comfortable giving more biased advice, but advisees do not properly adjust for this and generally fail to sufficiently discount biased advice. Disclosure also increases pressure on advisees to comply with advice; following disclosure, advisees feel more uncomfortable in turning down advice (e.g., it signals distrust of the advisor's motives). Finally, the authors examine the effectiveness of policy interventions aimed at reducing these unintended consequences and discuss how to realize potential benefits of disclosure.

MacDonald, C., & Williams-Jones, B. (2009). Supervisor-Student Relations: Examining the Spectrum of Conflicts of Interest in Bioscience Laboratories. *Accountability in Research: Policies & Quality Assurance, 16*(2), 106-126. doi:10.1080/08989620902855033

When talking about conflict of interest, much attention has been given to financial conflicts of interest (COIs) but little attention has focused on other COIs that arise in supervisor--student relations. The authors examine a spectrum of related situations, ranging from standard graduate supervision through to dual relationships sometimes found in research with commercial potential. The authors conclude by providing two sets of recommendations: one for individual supervisors, and the other for institutions and policy-makers.

Marklin, Ruth. (2008). How independent are IRBs? *IRB: Ethics and Human Research* 30(3): 15-19.

This article explores the independence of institutional review boards and other ethical committees charged with reviewing research proposals. The author discusses issues of conflict of interest that can arise, and suggests some different arrangements that could minimize conflicts of interest and ensure the operation of truly independent research ethics committees.

Martin, Joseph B. 2002. Academic-industrial relationships: Opportunities and pitfalls. *Science and Engineering Ethics* 8(3): 443-454. DOI: 10.1007/s11948-002-0066-6

This article discusses a meeting of leaders in academic medicine convened by the leadership of the Harvard Medical School to formulate guidelines on individual conflicts of interest that often arise in industry sponsored clinical trials at universities.

Mecca, J., Gibson, C., Giorgini, V., Medeiros, K., Mumford, M., & Connelly, S. (2015). Researcher Perspectives on Conflicts of Interest: A Qualitative Analysis of Views from Academia. *Science & Engineering Ethics, 21*(4), 843-855. doi:10.1007/s11948-014-9580-6

The increasing interconnectedness of academic research and external industry has left research vulnerable to conflicts of interest. This study sought to identify themes in the perspectives of faculty researchers regarding conflicts of interest. Think-aloud interview responses were qualitatively analyzed in an effort to provide insights with regard to appropriate ways to address the threat of conflicts of interest in research. Themes in participant responses included disclosure of conflicts of interest, selfremoval from situations where conflict exists, accommodation of conflict, denial of the existence of conflict, and recognition of complexity of situations involving conflicts of interest.

Reidenberg, M.M. 2002. Conflict of interest and medical publication. *Science and Engineering Ethics* 8(3): 455-457. DOI: 10.1007/s11948-002-0067-5

The paper discusses the ethical requirement for researchers to publish the results of some medical studies, even if the data is "negative". Since publication is an

essential part of research and patients have been recruited into a study in the belief that they are participating in medical research, there is an ethical commitment to publish the observations made on volunteer subjects.

Resnik, David B. (1998). Conflicts of interest in science. *Perspectives on Science* 6(4): 381-408.

The essay gives an overview of some current conflict in interest policies, and distinguishes real, apparent, and potential conflicts of interest. It then looks at some short, fictional case studies and uses these to suggest some strategies for reducing the impact of conflicts of interest in science.

Resnik, D. B., & Elliott, K. C. (2013). Taking Financial Relationships into Account When Assessing Research. *Accountability in Research: Policies & Quality Assurance, 20*(3), 184-205. doi:10.1080/08989621.2013.788383

Many scientific journals, government agencies, and universities require disclosure of sources of funding and financial interests related to research, such as stock ownership, consulting arrangements with companies, and patents. Although disclosure has become one of the central approaches for responding to financial conflicts of interest (COIs) in research, critics contend that information about financial COIs does not serve as a reliable indicator of research credibility, and therefore, studies should be evaluated solely based on their scientific merits. The authors argue that, while it is indeed important to evaluate studies on their scientific merits, it is often difficult to detect significant influences of financial relationships that affect research credibility.

Sacco, D., Bruton, S., Hajnal, A., & Lustgraaf, C. (2015). The Influence of Disclosure and Ethics Education on Perceptions of Financial Conflicts of Interest. *Science & Engineering Ethics, 21*(4), 875-894. doi:10.1007/s11948-014-9572-6

Report of a study exploring how disclosure of financial conflicts of interest (FCOI) influences naïve or 'lay' individuals' perceptions of the ethicality of researcher conduct.

Sah, S., & Loewenstein, G. (2014). Nothing to Declare: Mandatory and Voluntary Disclosure Leads Advisors to Avoid Conflicts of Interest. *Psychological Science (Sage Publications Inc.), 25*(2), 575-584. doi:10.1177/0956797613511824

Professionals face conflicts of interest when they have a personal interest in giving

biased advice. Mandatory disclosure—informing consumers of the conflict—is a widely adopted strategy in numerous professions, such as medicine, finance, and accounting. Prior research has shown, however, that such disclosures have little impact on consumer behavior, and can backfire by leading advisors to give even more biased advice. We present results from three experiments with real monetary stakes. These results show that, although disclosure has generally been found to be ineffective for dealing with unavoidable conflicts of interest, it can be beneficial when providers have the ability to avoid conflicts.

Schieppati, Arrigo, Norberto Perico and Guiseppe Remuzzi. 2002. Conflict of interest as seen from a researcher's perspective. *Science and Engineering Ethics* 8(3):337-342. DOI: 10.1007/s11948-002-0053-y

Discusses how the expansion and the rush to market in the pharmaceutical industry is creating new conflicts of interest, and the need for academic medicine and governments to find means to sustain the development of independent clinical research to help avoid these conflicts from occurring.

Schrag, Brian, et al. (2003). Barking up the wrong tree? Industry funding of academic research: A case study with commentaries. *Science and Engineering Ethics* 9(4): 569-582. DOI: 10.1007/s11948-003-0050-9

This article presents a case study involving conflicts of interest arising from the industrial funding of academic research, and is accompanied by discussion questions and four commentaries about the case.

Sollitto, Sharmon, et al. (2003). Intrinsic conflicts of interest in clinical research: A need for disclosure. *Kennedy Institute of Ethics Journal* 13(2): 83-91. doi: 10.1353/ken.2003.0015

Though financial conflicts of interest are addressed by university policies, government regulations and professional guidelines, intrinsic conflicts of interest – or conflicts of interest in all clinical research, still pose many moral issues. They should be disclosed to research subjects and managed as assiduously as financial conflicts of interest.

Steiner, Daniel. (1996) Competing interests: The need to control conflict of interests in biomedical research. *Science and Engineering Ethics* 2(4): 457-468. doi: 10.1007/BF02583932

The author looks at the increasing concern over conflict of interests that occur in biomedical research, especially in regard to collaborative relationships between universities and industries that can make individual and organization financial conflicts of interest more acute. The author looks at the types of conflict of interest that can occur, and analyzes an actual problem posed by two proposed clinical trials.

Wagner, Wendy. (2005) The Perils of Relying on Interested Parties to Evaluate Scientific Quality. *American Journal of Public Health.* 95(S1): S99-S105. doi:10.2105/AJPH.2004.044792)

Recently, there has been a trend in both civil litigation and regulatory law to circumvent the scientific community's collective judgment on the quality of individual studies with an adversarial process of evaluating scientific quality using interest groups. The Supreme Court's Daubert v Merrell Dow Pharmaceuticals, Inc. opinion and two recent "good science" laws passed by Congress adopt an adversarial process informed by affected parties for reviewing and screening scientific quality. These developments are unwise. Both theory and experience instruct that an adversarial, interest group-dominated approach to evaluating scientific quality will lead to the unproductive deconstruction of science, further blur the distinction between policy and scientific judgments, and result in poor decisions because the courts and agencies that preside over these "good science" contests sometimes lack the scientific competency needed to make sound decisions.

Williams-Jones, B., Potvin, M.-J., Mathieu, G., & Smith, E. (2013). Barriers to Research on Research Ethics Review and Conflicts of Interest. *IRB: Ethics & Human Research, 35*(5), 14-20.

The article discusses potential barriers to research on research ethics reviews, focusing on occupational conflicts of interest that may inhibit research ethics boards or institutional review boards as of 2013. Topics include the moral aspects of research, empirical bioethics, risk management, challenges for research reviewers who are also research participants, and ethics training.

Yvette Pearson and Jason Borenstein. 2009. Taking Conflicts of Interest Seriously Without Overdoing It: The Promises and Perils of Academic-Industry Partnerships. *Journal of Academic Ethics*, 6(3): 229-243.

Academic-industry collaborations and the conflicts of interest (COI) arising out of them are not new. However, as industry funding for research in the life and health sciences has increased and scandals involving financial COI are brought to the public's attention, demands for disclosure have grown. In a March 2008 American Council on Science and Health report by Ronald Bailey, he argues that the focus on COI—especially financial COI—is obsessive and likely to be more detrimental to scientific progress and public health than COI themselves. In response, the authors argue that downplaying the potential negative impact of COI arising out of academic-industry relationships is no less harmful than overreacting to it.

Contributor(s)

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