CONFLICTS OF INTEREST & COMMITMENT

4.1 CONFLICTS OF INTEREST & COMMITMENT

Background

We often find ourselves in situations where two or more competing interests create the perception - or the reality - of an increased risk of bias or poor judgment. Such challenging situations come up regularly in both our personal and professional lives. Collectively, we refer to these as conflicts of interest. Such conflicts are not inherently bad. Instead, they should be expected. It is how they are handled that can lead to improper, inappropriate, or bad outcomes.

Scientists have professional, fiduciary, and ethical interests in the responsible conduct of research, but these interests may be compromised by personal interest. A common worry is that financial interest in the outcomes of research can result in unethical behavior or even criminal misconduct. However, it is also plausible that interests other than financial interests could compromise the responsible conduct of research. Examples of non-financial interests that might conflict with the integrity of science include career advancement, publishable results, service to patients or students, fame, power, or family and friendships. Another potential conflict can come in the form of conscience. An individual might suffer a conflict of interest if the mission or expectation of, for example, the institution is not compatible with his or her personal values.

4.2 CONFLICTS OF INTEREST AT THE INDIVIDUAL LEVEL

Bias in Judgment

Objectivity is the sine qua non of scientific discovery. But bias in judgment is virtually impossible to eliminate. There are often subtle and not so subtle, pressures that can influence how we perceive and how we act. All research professionals understand the pressures to publish, to get funding, appointments, promotions, and to earn respect from peers. Many strive for the ultimate validation and highest order of recognition - the Nobel Prize. In an effort to succeed, there are myriad areas where bias can influence judgment and diminish objectivity. A desire to validate a “pet theory”, overconfidence about a particular concept, over reliance on a belief held by a special group, ruling out data that don't support a hypothesis, and internal or external pressures to get a specific result are all influences that may lead to distortions in objectivity. Any of these biases or pressures may lead to what sociologists call selective in attendance. Your mind-set may cause you to overlook important data or to misperceive critical observations. Bias can be too subtle to recognize and too difficult to control. It can creep into how research questions are selected and framed, the choice of research design, the selection of research participants, and how the data are collected, analyzed, interpreted, and ultimately published. Whether you describe the glass as half empty or half full is influenced by what you want your results to look like. Bias can even influence the sharing of the results of the study.

Academic Conflicts of Interest or Intellectual Bias

"Academic scientists have special responsibilities to disseminate knowledge, to maintain academic standards, to critique the current state of knowledge, to synthesize existing knowledge, and to apply knowledge to solve basic and applied problems."

The peer-review system is the benchmark of the scientific process. An academic conflict of interest could occur if an individual interferes with the peer-review process for some type of intangible personal gain. For example, bias can cause a reviewer to respond positively to a manuscript because it presents results favoring a method or production in which the reviewer has a personal interest or a reviewer may act to delay the publication of a competitor's manuscript in order to strengthen his or her own chances for publication or funding. There are studies which mentioned that publication practices of researchers which found that researchers reported delaying of publication of results for their own advantage. In addition, negative results are less likely to be published but that even positive findings are withheld if this is perceived as advantageous for the authors. In one study, 20% of researchers reported delaying publication of results for their own advantage. These are intangible interests, and they are indigenous to every researcher. Indeed, the drive for recognition can be overwhelming, particularly when a future position or livelihood depends on these public achievements. These are the sources of "intellectual bias" that have long been recognized by the research community but that must also be recognized and addressed by the individual researcher.

Other Types of Conflicts of Interest

In addition to academic conflicts of interest, there are other intangible conflicts that can compromise objectivity. For example, conflicts of commitment, which may also be called conflicts of effort or conflicts of obligation, occur when the extent of time spent on a secondary activity competes with the time expected to be spent on teaching, research, or service by the primary employer. Most institutions and or universities have policies allowing 20% of a faculty member's effort, or one day a week, for outside activity. (Do confer with your institution’s policies and guidelines.)

A conflict of conscience occurs when personal beliefs influence objectivity in research. For example, a scientist may have a particular view on abortion that influences his or her view of the scientific merit of a study that uses human embryonic stem cells.

Clinical Research

Clinical researchers subscribe to three basic elements: scientific integrity, patient safety, and investigator objectivity. Yet these researchers are likely to experience conflicts of interest by virtue of their altruistic dedication to the pursuit of knowledge while striving to maintain the welfare of the human volunteers participating in their investigations. Bias and decreased objectivity are of particular concern in the clinical-research setting, where the rewards and risks are both potentially great. Here, bias in judgment might creep in not only to influence the questions pursued and the choice of research design but also affect the selection and retention of research participants, the reporting and attribution of adverse events, and the collection, statistical analysis, interpretation, and reporting of the data It is in the clinical setting that bias and loss of objectivity not only could it damage the entire research enterprise, which we know reduces the public's trust in research, but could also, more grievously, lead to injury and harm to study participants.

In assessing conflicts of interest, we need to consider the likelihood of bias as well as the consequences of the conflict of interest, because at times the consequences can be lethal.

Safeguards

Fortunately, there are safeguards that can be put into place to help reduce bias and improve objectivity. Conscientious application of the scientific method is one such safeguard. However, the investigator should declare to DSRB if conflicts of interests arise during the conduct of the study.

Financial conflicts of interest

Financial conflicts of interest are considered tangible conflicts, because they can be seen and measured. While they appear easier to deal with than intangible conflicts of interest, they may not be. Financial arrangements with sponsors are affecting many areas of scientific life. A growing literature is documenting, with disturbing accounts, how the new entrepreneurial environment is altering the publication practices and prescribing patterns of investigators and clinicians. Intangible conflicts of interest, as previously described are problematic, but they are widely recognized and shared. What has captured the attention of governments, the scientific community, and the public are those conflicts caused by money and financial relationships, the tangible conflicts of interest. Many fear that the cost of these relationships could be the integrity of science itself.

4.3 HOW TO PREVENT CONFLICTS OF INTEREST & COMMITMENT

Introduction

When there is a divergence between an individual's interests and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that individual are unduly influenced by their own actions, is known as a conflict of interest.

In the research arena, conflict of interest is common and it is important that they are disclosed and properly dealt with. Conflict of interest has a high potential in compromising judgments and decisions that should be made with impartiality. Such a compromise could undermine the community's trust in research.

Financial conflict of interest are always on the public's mind, however, other conflicts of interest may also occur in research, which may include personal, professional and institutional advantages. It is also a serious matter and raises concerns about the integrity of the individuals and or the management practices of the institution should a perception that a conflict of interest exists.

There should be a readily available comprehensive policy in place within research community and institutions, looking at actual and potential conflicts of interest.

A. Responsibilities of Institutions

Maintain a policy

All institutions should have a policy for the management of conflict of interest. There should be a range of responses, depending on the nature of the conflict, to prevent researchers from influencing decisions unfairly and avoid unwarranted perception that a deaf ear has been turned unto a conflict of interest.

Institutions and organizations should ensure that the policies or guidelines on advising the management of conflicts of interest are made available. In addition to the individual's institution policies and guidelines, the following guides should be observed:

- The institution should ensure that the policy is clearly written and readily available to all.

- Encourage a full disclosure by those involved of the circumstances giving rise to concerns about each conflict of interest. A small group in confidence should be provided for people who are unwilling to disclose publicly. In situations where those involved are unwilling and unable to make any disclosure at all, they should withdraw from process that could be influenced by conflicts.

- When a circumstance constitute a conflict of interest, or may lead people to perceive a conflict of interest, the individual must not take part in decision making processes. The most satisfactory approach is for a complete withdrawal (e.g. leaving the room while the outcome of a review is being deliberated).
- Records must be kept of how each conflict is managed, even if confidential information is removed. The possibility of conflict of interest is acknowledged in each case along with a summary of how it was managed, is important.
- The policy should encompass the full range of possible conflict of interest, and the policy must be reviewed regularly to enable amendment informed by experience and legislative and regulatory developments.

B. Responsibilities of Researchers

Disclose conflict of interest

Researchers may have frequent conflict of interest that cannot be avoided. In research, decision making processes often require expert advice, and the community of experts in a field can be so minute that all the experts are linked with the matter under decision. An individual researcher should therefore preempt the conflict from time to time, and be alert and ready to acknowledge the conflict and make the disclosures appropriately.

Researchers' should deploy the following approach to manage conflict of interest:

- Read and understand the institution's policy on conflict of interest.

- Maintain records of activities that may potentially lead to conflicts, examples (but not limited to) board of directors, membership of committees, selection committees and financial delegation of in receipt of stocks or shares or cash from external parties to support research activities.

- When an individual is invited into a committee or equivalent, review current activities for actual or apparent conflicts and bring possible conflicts of interest to the attention of those running the process.

- Individuals must disclose any actual, apparent or perceived conflict of interests.

Do you know?

In the US, federal regulations defer, in part, to institutional definitions of conflicts of interest. Not surprisingly, institutional standards vary greatly. Regarding stock ownership, many use the federally defined threshold of $10,000 or 5% of total shares as a definition of significant financial interest that must be declared. However, some institutions have been somewhat stricter. For example, Harvard scientists are prohibited from working for a company in which they have more than $20,000 in stock.

Professional societies and journals are another important source for guidance on the management of conflicts of interest. These are quite variable in their scope and rarely enforced, but two examples are noteworthy. The first is a policy statement from the American Society of Gene Therapy (ASGT). In a statement adopted in April of 2000, the ASGT concluded that 'investigators and team members directly responsible for patient selection, the informed consent process and/or clinical management in a trial must not have equity, stock options, or comparable arrangements in companies supporting the trial.'

The second example is the stated requirements for publication in the New England Journal of Medicine. As early as 1984, the journal requested that 'all authors disclose to [the Editor] any associations they had with businesses that could be affected by their work – including direct employment and consultancy, stock ownership, and patent-licensing arrangements. These guidelines and regulations represent recognition by regulatory and scientific communities that the integrity of science is placed at risk by the presence of unmanaged or substantial conflicts of interest.

Professional Societies and Associations

Clinical researchers must be able to design and conduct their studies in an unbiased and objective manner that is free from conflicts caused by significant financial involvement with the commercial sponsors of the research. In this case, the only sure safeguard is for the investigator to have absolutely no financial relationship with entities that support his or her research. This approach has often been referred to as "zero tolerance."

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