Nutrition Professionals Are Obligated to Follow Ethical Guidelines when Conducting Industry-Funded Research

Theresa A. Nicklas, DrPH; Wahida Karmally, DrPH, RD, CDE, CLS, FNLA; Carol E. O’Neil, PhD, MPH, RD, LDN

STATEMENT OF PURPOSE

The fiscal climate for research reflects the increasing difficulty in obtaining competitive government and foundation funds. Thus, nutrition professionals conducting research may need to work with industry. However, there is a growing concern about real or perceived conflicts of interest and the potential influence that industry funding may have on research findings and the integrity of the researchers. Scientists recently defined “white hat bias” to be “bias leading to distortion of research-based information in the service of what may be perceived as righteous ends” (1-4). This can be interpreted to be bias resulting from industry funding (1). However, “white hat biases” can also exist in opposition to the interests of industry. To begin an important dialogue among nutrition professionals, this Ethics in Action column presents 10 guidelines that can be used to preserve the integrity and credibility of food and nutrition science to benefit public health. These guidelines can be used to reduce bias from industry-funded nutrition research and to safeguard the integrity of research and the scientists in dietetics. Nutrition research, clinical and applied, needs to continue to be regarded as a science of truth.

ADA/CDR CODE OF ETHICS AND STRUCTURE

The Code of Ethics for the Profession of Dietetics developed by the American Dietetic Association (ADA) and the Commission on Dietetics Registration (CDR) reflects the values and ethical principles guiding all areas of dietetics practice, including research (5). The Code includes principles 1, 6, 15, and 18 on honesty, integrity, fairness, conflict of interest, and any considerations affecting professional judgment that directly affects those conducting industry-funded research.

TYPES OF ETHICAL VIOLATIONS

Despite the mandated ethical principles of universities, research institutions, and funding organizations, scientific misconduct in research practices is believed to be widespread, and the problem often stems from academic pressures to publish for promotion and tenure and competition for funding. The most common form of scientific misconduct is fabrication of data, whereby scientists publish deliberately false or misleading research or actually manufacture research data. This practice includes the omission of critical data and is often referred to as reporting bias or suppression/nonpublication of data. A case in point is where scientists only report positive outcomes and not adverse outcomes. Data may be suppressed or remain unpublished because the findings are perceived to challenge the interests of the sponsoring agent or because they fail to support the ideological opinions of the researcher.

Other types of fabrication are the falsification of the data whereby research materials, equipment, or processes are manipulated or the results are changed or omitted to prevent results from being accurately represented in the scientific literature. Another form of fabrication is making unsubstantiated claims, including cases where the scientists reference material that gives the appearance that their arguments are universally accepted, but are actually falsely constructed or do not support the argument.

Finally, research misconduct includes not only excluding authors that have made a contribution to the research, but also includes adding authors that did not make a substantial contribution to the research. The test for appearance of impropriety is whether the conduct would create in reasonable minds a perception that the dietetics practitioner’s ability to carry out professional responsibilities
with integrity, impartiality, and competence is impaired” (5).

The Impact of Scientific Misconduct
Although perceived as widespread, it is difficult to quantify and document the degree of scientific misconduct that occurs. Industry funding is not the only type of funding susceptible to bias or falsification. One survey of more than 3,000 scientists who received funding from the National Institutes of Health found that 16% of them changed the design methods or results of a study in response to pressure from a funding source, and 10% withheld details of methods or results in articles. An average of 24 cases is submitted to the US Office of Research Integrity annually (6). Scientific misconduct costs a substantial amount of money, both directly (eg, investigative costs) and indirectly (eg, lost grant money). Arthur Michalek and colleagues (7) were among the first scientists to develop a model of the cost of scientific research misconduct. They conservatively estimated that direct costs, in the United States alone, are in excess of 100 million US dollars each year.

Nutrition professionals in research are not only obligated to adhere to institutional ethical standards and to the ADA Code of Ethics (5), but develop their own standards for explicit guidelines when interacting with industry. Nutrition professionals need to be totally transparent in their research efforts to report the “scientific truth.”

Ten Guidelines for Industry-Funded Research

1. Require a signed full disclosure of funding sources and financial interests in publications, conference presentations, and media releases.
2. Ensure that there is no conflict with the confidentiality agreement signed by the Principal Investigator and the funding agency.
3. Establish up-front control and ownership of the data by the Principal Investigator but provide accessibility to the data and statistical analyses to the funding agency and other appropriate entities.
4. Plan the research so that it is designed objectively and is scientifically sound in its approach and analytical plan.
5. Generate clearly stated a priori research questions or hypotheses rather than those generated a posteriori or using a preconceived conclusion.
6. Ensure that the Principal Investigator maintains control of all aspects of the study and has the final authority on the design or conduct of the study; the collection, management, analysis, or interpretation of the data; and the preparation and approval of the peer-reviewed manuscript.
7. Make certain that publications do not favor a particular outcome or that unfavorable findings are not withheld from the scientific community. The Principal Investigator must retain full rights to publish all results, including those unfavorable to the client.
8. Invite the client to submit comments on a sponsored article under the strict stipulation that the Principal Investigator has the ultimate control of content.
9. Maintain objectivity in the interpretation of the results so that they are not biased and that a balanced discussion is presented based on the available science.
10. Ensure that all presentations are developed fully and media releases are endorsed by the Principal Investigator.

Summary
Although disclosure of all funding sources, including those from industry, is mandatory for publication, it is no longer adequate. Given the skepticism surrounding industry-funded research (1-4), we need guidelines for communication with funding organizations and publication venues, and we need to safeguard and preserve research and scientific integrity.

References