



Ethical Considerations for Successfully Navigating the Research Process

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ETHICAL CONDUCT IN PRACTICE is an essential competency for all registered dietitian nutritionists (RDNs) and nutrition and dietetics technicians, registered (NDTRs). It is not only a moral imperative, but also a professional responsibility to promote and support high standards of practice.¹ Based on a recommendation from the Academy of Nutrition and Dietetics Board of Directors, the Commission on Dietetic Registration requires RDNs and NDTRs to complete a minimum of one unit of continuing professional education in ethics during each recertification cycle.² While all fields of practice can present ethical dilemmas, successfully navigating the research process can present unique challenges for students, early career researchers, and seasoned

professionals alike. Having a firm understanding of what ethical conduct is and who is responsible for ensuring ethical practice in research is critical for the quality of the research, the integrity of individual practitioners, and the credibility of the profession.

Ethical conduct is the responsibility of everyone on the research team from conception to completion. Whether a person is involved in collecting data, performing data entry, analyzing results, providing an intervention, or leading the project as the principal investigator (PI), anyone participating in the research process shares responsibility for study ethicality. Sharing responsibility for ethical conduct requires creating a culture of respect and dignity, whereby each member of the research team feels empowered to raise ethical concerns and question the research process. Fostering this culture requires mutual deference, trust, and parity across all members of the research team, regardless of their role or status. Developing respect within the research team creates an environment where ethical practice is held above all other project priorities and individual approaches.

Although promoting this culture may primarily be the responsibility of team leadership, each individual should be aware of what ethical conduct is and how to handle ethical dilemmas that may emerge. In 2009, the Academy of Nutrition and Dietetics (then called the American Dietetic Association) published the Code of Ethics for the Profession of Dietetics and Process for Consideration of Ethics Issues.¹ This guiding document outlines the nutrition practitioner's responsibilities to clients, fellow professionals, the profession as a whole, and the public at large. Agreeing to abide by the Code of

Ethics is a requirement for all RDNs and NDTRs, as well as members of the Academy who are not credentialed by the Commission on Dietetic Registration.¹ There are many resources available to assist practitioners with ethical decision making,³⁻⁵ working with Institutional Review Boards⁶ (IRBs), human subjects,⁷ and funders, be they industry, government, foundation, or private. The goal of this article is to complement these resources, by addressing some ethical dilemmas common to all research teams where RDNs and NDTRs can practice, including conflict of interest, bias, authorship, acknowledgements, intellectual property, and copyrights.

CONFLICT OF INTEREST

In general, society unreservedly believes science seeks the truth, yet, many powerful influences can blind research and affect results and conclusions drawn from the data.⁸ Conflict of interest (COI) is one influence, and it occurs when someone's financial, personal, professional, or political interests interfere or potentially interfere with their judgment.⁹ These influences do not have to be monetary, but can be driven by a need for recognition, academic advancement, and funding, to name a few. A COI arises when personal interest undermines scientific objectivity at any stage of the research process, including identifying a scientific question, developing a testable hypothesis, testing that hypothesis, using appropriate methods, evaluating the results using appropriate statistical approaches, and reporting the results. The following are two examples of situations that would be considered COIs in research. In addition to a COI, the first case also presents research bias, which will be discussed later.

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<http://dx.doi.org/10.1016/j.jand.2017.02.011>
 Available online 31 March 2017

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Case Study 1

D.P. is a research RDN at Prominent Medical Center. The cardiac rehabilitation unit at Prominent Medical Center is participating in a multicenter trial sponsored by Wonder Capsules. The purpose of the trial is to evaluate the impact of a proprietary soft-gel formulation on inflammatory markers at 3, 6, 12, and 24 months post-cardiac event. Wonder Capsules developed the study design, analyzed the data, and drafted the manuscript that will be submitted to the *Journal of High Impact* with D.P. as the third author. The manuscript draft indicates that, compared to placebo, both inflammatory markers and recurrent cardiac events were decreased with daily intake of the proprietary soft-gel. However, only data from the first 12 months are presented in the manuscript because there were no differences between the proprietary formulation and placebo at 24 months.

Case 1 shows how financial interest can interfere with research results and interpretation. In this situation, D.P. needs to assert herself to ensure that a manuscript for which she is an author meets the highest possible ethical standard. The data reporting has been modified so that it no longer reflects the original study design. The company may have presented the data showing soft-gel formulation has a positive effect at 12 months so they could improve sales of their product. The company neglected to include the 24-month data that shows no effect. By leaving out the 24-month data, the company has biased the conclusions because of a COI. Omitting the 24-month data from the publication is unethical and D.P. should present this issue to Wonder Capsules and request that all results be included in the manuscript. D.P. should also ensure that the manuscript discloses Wonder Capsules as the sponsor of the study. Because data ownership is often determined by a research contract or grant, in the future, D.P. should review and approve the terms of use within the contract, particularly items relating to authorship and manuscript approval, before beginning the research process. The Academy's Scientific Integrity Principles emphasize the need to publish research even when the results are negative.⁴

Case Study 2

M.J. owns a well-respected private practice, employing three RDNs who specialize in weight management and related health concerns. Miracle Botanicals company approaches M.J. about a research study that was recently approved by the Institutional Review Board at Prestigious Regional University. Miracle Botanicals is interested in recruiting obese clients from M.J.'s practice to serve as research subjects. To determine eligibility, Miracle Botanicals asks for M.J. and her RDN colleagues to conduct body fat assessments. The company will provide M.J.'s practice with a multifrequency segmental body composition analyzer, as well as \$25 per client who enrolls in the research study. Miracle Botanicals is also willing to sponsor continuing professional education for the RDNs in M.J.'s practice.

In Case 2, M.J.'s financial gain may influence the subjects she recruits as well as the results obtained. For example, she might recruit clients whom she feels may be most likely to adopt behavior changes or follow specific elements of the study protocol. This is an important ethical concern, but one that might not be fixed by the IRB. The role of an IRB is to protect the rights and welfare of human subjects by reviewing and overseeing research to ensure that the research meets established ethical standards and complies with federal regulations. However, an IRB is not necessarily responsible for mitigating COI. In this case, a data safety monitoring board may be called upon to monitor the data collected in the study for adverse outcomes and that recruitment is conducted according to plan. As researchers, it is important to weigh the benefits (ie, financial, educational, and professional) associated with research participation. Given the time required for M.J. and her RDNs to complete ethics training needed to consent clients, the staff time needed to recruit subjects and perform body fat testing, \$25 per client may not represent a true financial gain for her practice. Similarly, continuing professional education provided may be driven by the fiscal ambitions of Miracle Botanicals and may not actually benefit M.J. or her staff. M.J. should think carefully before deciding

whether to participate in this study. There is no evidence to suggest that M.J. or her RDN colleagues' clinical practice may be compromised due to their participation in the research study. However, this case presents potential COIs.

How do nutrition researchers protect the research process against COI? Many institutions and organizations consider transparency and disclosure important safeguards. Disclosing one's interests, financially or personally, allows for clarity and encourages all parties to evaluate potential conflicts. For example, many journals require researchers to disclose funding sources in their published papers. The *Journal of the Academy of Nutrition and Dietetics* requires authors to "disclose all potential conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject of their manuscript."¹⁰ Scientists and practitioners reading the article may pay more careful attention to the methods, results, and interpretations of papers where COI is declared. In Case 2, M.J. should disclose to all recruited individuals that she is receiving a monetary payment if that client agrees to participate in the study. Some institutions take disclosure a step further and have committees that manage the COI that the researcher discloses. For example, in the second case, M.J. would disclose her relationship to such a committee at Prestigious Regional University. Management of conflict through disclosure helps promote integrity and trust in the scientific process.

BIAS

COI and bias are not the same, but are often confused. Bias occurs when a person has an inclination or prejudice in favor of a particular viewpoint.¹¹ Bias is a deviation from the truth, intentionally or unintentionally. Just like a COI, there are many well-known forms of scientific and publication bias. Case 1 is an example of reporting bias. The company has knowingly left out results to bias their findings. This bias was likely the result of a COI. In Case 2, there is no bias, only a potential COI. Although if M.J. only recruits clients who she knows to be adherent to their diet, then she could bias the data. Bias can occur in many steps of the research

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