Ethics in Action: Conducting Ethical Research Involving Human Subjects: A Primer

RESEARCH INVOLVING HUMAN subjects is a critical component of the profession of nutrition and dietetics. It provides the evidence base that informs the development of practice guidelines, assesses the impact of nutrition and dietetics programs and services on health outcomes, and determines priority areas for nutrition interventions. The *Compensation and Demand Study* suggested that 6% of the profession of nutrition and dietetics report education and research as their primary practice area[1]; however, involvement in research is more widespread. A recent survey by the Academy of Nutrition and Dietetics' (the Academy's) Dietetics Practice-Based Research Network (DPBRN) found that that majority of respondents (71%) had been involved in research at some point in their career, with about half of respondents reporting research involvement only as part of their education and training.[2] More than half of respondents (53%) had published or presented their findings, with fewer involved in developing research questions or protocols, or collecting and analyzing data. Only 34% of respondents had obtained Institutional Review Board (IRB) approval, and less than half had consented subjects.[2]

Interestingly about 45% of respondents suggested that lack of training in research was a barrier to conducting research.[2] The Academy created the DPBRN to facilitate the integration of research into practice by streamlining the process.[1] In addition to encouraging research through the DPBRN, the Academy has also created resources to help registered dietitian nutritionists (RDNs) understand and apply ethical principles in research. Along with research experts in research ethics, the DPBRN created and tested a set of four self-study modules on research ethics for the RDN.[3] These modules and three related fact sheets are free for members and are approved for 1.5 continuing professional education (CPE) credit after the completion of a quiz. Program directors may also want to use these modules with students (www.eatrightpro.org/resource/research/evidence-based-resources/dpbrn/research-project-resources).

As more RDNs integrate research into practice, it is important they understand the ethical underpinnings of research that involves human subjects.

OVERSIGHT BY INSTITUTIONAL REVIEW BOARD

Research involving human subjects requires oversight by IRBs to ensure safety and privacy of subjects. The National Institutes of Health has outlined seven principles of ethics for human subjects research that are critical for all researchers to adhere to.[4] These principles, based on the Federal Policy for the Protection of Human Subjects (Common Rule),[5] are criteria examined by IRBs and include:

1. **Social value**. Ethical studies involving humans should lead to improvements in the health and/or well-being of people and society. It is unethical to study people or place them at risk without societal benefit. It is also considered unethical to utilize funding and resources for projects that do not provide societal benefits. Student projects are considered to have social value even when they do not lead to new information because such activities are an essential component of research education. **Corresponds to Principle #3 of the Code of Ethics.** *The dietetics practitioner considers the health, safety, and welfare of the public at all times.*[6]
2. **Scientific validity**. Ethical research employs appropriate, rigorous scientific methods that contribute to the body of evidence for a specific field. Criteria to determine scientific validity may include the study methods utilized, the number of subjects anticipated to participate, the length of the study, the use of control groups or other control variables (when appropriate), and inclusion/exclusion criteria for subject eligibility.
   Scientifically valid research should be reproducible; research that cannot be replicated may be biased, reducing the validity of the findings. Bias is often accidental. For example, questions may inadvertently be written in such a way that they elicit a specific (often desired) response. Pilot testing questionnaires and peer- and expert-review of surveys, questionnaires, and intervention protocols can help to reduce the chances of bias.
3. **Fair subject selection**. The importance of subject selection for research is often overlooked. Ethical research assures

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- **Does it meet the definition of research?** Research is defined by the Common Rule as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…".[5] Under this definition, scholarly investigations that do not generate new knowledge are not subject to Institutional Review Board (IRB) approval. For example, a literature review of existing peer-reviewed journal articles would not require IRB approval.
  Generalizable knowledge can be thought of as outcomes that can be applied to the general population and that are generated with the purpose of disseminating the findings widely. Dissemination by means of peer-reviewed publication or presentation at an academic meeting would meet the definition of generalizable knowledge. Activities that generate knowledge solely for the purpose of improving client care or programmatic offerings (such as quality assurance or improvement activities) are usually not subject to IRB approval, as this knowledge is applicable only to the organization conducting the process and would not be disseminated publicly via academic presentations or publications.
- **Does your research involve humans?** A humans subject is defined by the Common Rule as "a living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individuals, or 2) identifiable private information."[4] Interventions include both physical procedures and manipulations of the subject and/or his or her environment.
  Interactions include both in-person and distance methods of contact such as surveys and questionnaires, interviews, behavioral observations, alterations to a person's diet or behavior, environmental alterations, physical measurements and procedures (eg, anthropometry), collection of specimens (eg, venipuncture), and exposure to experimental drugs, devices, or behavioral protocols.
  An important consideration to determine whether IRB approval is required is the focus of the outcome. Projects that have outcomes focused on policies, practices, or procedures (such as quality assurance or improvement projects) do not meet the criteria for human subjects research, even when the person who provides the information can be identified. Projects with outcomes that focus on aspects of a person (including changes in behavior and physiology) would be subject to IRB review and approval.

Is my research exempt from full IRB review? Research involving human subjects that carries minimal risk to the person is often exempt from a full IRB review; however, even exempt research requires the full consent of subjects to participate. Only the IRB can determine whether a project meets the criteria for exempt IRB status; thus, an IRB application is still required. There are six categories of exemption that have been identified through the federal definition of human subjects research. These include:

- Category 1: Investigational strategies in educational settings. This applies to projects conducted in education settings using normal educational practices.
- Category 2: Survey or interviews, standard educational test, and observations of public behavior. This applies to projects using educational tests (including diagnostic, aptitude, cognitive and achievement assessments) and observations of behavior in public places.
- Category 3: Public officials, surveys and interviews, educational tests, observations of public behavior. This category is similar to category 2 but applies specifically to human subjects who are appointed or elected to public office, including candidates for public office.
- Category 4: Existing data: records review and pathological specimens. Projects that examine existing documents and records, data, or specimens fall into this category. Secondary data analysis may fall under this category of exemption.
- Category 5: Reserved for federal governmental research. This category does not apply to local IRB committees.
- Category 6: Food quality and consumer acceptance studies. This category applies to projects that evaluate taste and food quality and/or consumer acceptance of food and other consumer products.

Figure. Determining whether a research project requires institutional review board approval. Adapted from references 4, 5, and 7.

the widest possible range of individuals be considered for inclusion to determine how the effects of interventions may vary among different groups. Researchers should carefully document reasons for excluding groups of people from participating in research studies, especially exclusion based on age, sex, race/ethnicity, and sexual orientation.

Certain populations are considered to be vulnerable in research settings and may require additional protective measures in order to participate. Such groups include pregnant women, human fetuses, neonates, children, and prisoners. Other groups that may be at increased risk include individuals who are cognitively or mentally impaired and those who are infirmed. **Corresponds to Principle #5 of the Code of Ethics.** *The dietetics practitioner provides professional services with objectivity and with respect for the unique needs and values of individuals.*[6]