Development and Pilot Testing of a Human Subjects Protection Training Course Unique to Registered Dietitian Nutritionists

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THE HOUSE OF DELEGATES OF the Academy of Nutrition and Dietetics recently selected research engagement as a mega-issue because research is critical to showing the value of the registered dietitian nutritionist's (RDN's) services, but many RDNs do not consider research as part of their role or believe they lack the skills to participate.[1] Dietetics Practice Based Research Network (DPBRN) projects have provided evidence to support RDN services in containing costs and improving patient outcomes.[2] Engaging a diverse array of members in a culture of research is particularly relevant given the recent House of Delegates mega-issue. After identifying human subjects protection training (defined and described later) as a barrier to research participation, the Academy's DPBRN developed and pilot-tested a research ethics course specific for RDNs. This article describes the development and pilot-testing of this course as well as next steps for all Academy members to use this resource.

In a 2002 survey of RDNs, only 27% of respondents had participated in research.[3] The most frequently selected barrier to conducting research was not having research skills (65% of those who had not conducted research), followed by lack of time or staff (41% of those who had not conducted research).[3] However, RDNs consistently believe that research is important to the profession and many would like to participate.[4] This is not unique to the dietetics profession; previous studies have shown a lack of participation in research by health care providers not associated with academic institutions, such as a practicing RDN. One barrier to participating in research is the requirement for human subjects protection training. To overcome this barrier, the Academy worked with research ethics experts to create a human subjects protection training specific to nutrition and dietetics.

Protection of human subjects in research is a key concern of both investigators and research regulators such as the institutional review boards (IRBs). IRBs must ensure that all individuals listed as key personnel on funded National Institutes of Health grants are educated in the protection of human subjects.[5] To address this need, most institutions (or their IRBs) require a human subjects protection training course for all researchers who interface with human subjects or their data.[6] The majority of these courses are based on the assumed needs of academic researchers and require a baseline level of research knowledge for comprehension.[6] Given the traditional target audience of these training programs, nonacademic researchers frequently perceive the content as not relevant or inaccessible. These programs may not fulfill the needs of nontraditional researchers such as clinicians and community partners regarding the type of ethical dilemmas or concerns that arise outside the traditional academic research context.[6] For example, clinicians who are also acting as researchers, including RDNs, may serve multiple roles (clinician and researcher) in relation to a single patient/subject. These dual roles usually have different priorities, and the difference may not be obvious to patients, which can affect the ethics of recruiting and obtaining informed consent.[7]

Community-based participatory research (CBPR) has also encountered the challenge of making training in human subjects protection relevant to nontraditional researchers. To overcome these barriers and ensure that community researchers have the training needed to conduct studies ethically, some institutions have developed alternative human subjects protection trainings to meet the needs of community researchers.[6] Examples include the CIRTification (Community Involvement in Research Training) from the University of Illinois at Chicago, the Field Training Guide for Human Subjects Research Ethics from Johns Hopkins University, and Protecting People Who Participate in Research from the University of North Carolina-Chapel Hill.[6]

Given that a baseline knowledge of research terminology and regulations (such as how research is defined and the differences between research and standard clinical care) is assumed in many of the existing human subjects protection training courses,[6] lack of research knowledge and skills adds another level of difficulty to completing the course. Thirty-one percent of RDNs surveyed in 2000 indicated that their preferred route to research knowledge was through training tailored to clinical dietitians,[8] showing that RDNs are more interested in research when concepts are specific to them. The need for the learner to perceive applicability to be interested in a topic is not unique to RDNs; the study of adult education emphasizes the importance of the learner's internal motivation, past experience,

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Content Area	CITI[a] Social and Behavioral Research	Research Ethics for the Registered Dietitian Nutritionist Self-Study Modules
Introduction to Research/Defining Research with Human Subjects	Interpretation of definitions of terms *human subject* and *research* for social and behavioral research	• Dietetics Code of Ethics • Research vs standard of care vs quality improvement • What is a human subject?
History of Research Abuse, Ethics, and Federal Regulations	• History of abuses in research • Development of federal regulations from SBR[b] perspective • Why ethics are necessary for HSR[c]	• History of abuses in research • Development of federal regulations in response to abuse • Necessity of federal regulations for HSP[d] • Who has to follow federal regulations for HSP?
Ethical Principles	• Belmont Principles	• Belmont Principles • Dietetics Code of Ethics
Federal Regulations	• Overview of federal regulations • Pertinence to social and behavioral research • Requirements for/types of review necessary for social and behavioral research	• Overview of federal regulations
Institutional Review Boards	• Composition • Functions • Review process	• Review process
Informed Consent	• Required and optional elements • Obtaining informed consent • Waivers of informed consent	• Information, understanding, and voluntariness • Required elements • Obtaining informed consent • Waivers of informed consent • Waivers of informed consent documentation
Risk/Benefit	• Identifying risks • Evaluating risks vs potential benefits • Managing risks • Addressing risks during the informed consent process	• Severity and types of risks • Possible protections • Distribution of risks and benefits
Privacy and Confidentiality	• Definitions of privacy and confidentiality • Private vs public behavior	• Definitions of privacy and confidentiality

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Figure. Standard human subjects protections topics and their coverage in the Research Ethics for the Registered Dietitian Nutritionist course. [a]CITI (Collaborative Institutional Training Initiative) Basic Courses in the Protection of Human Research Subjects. Description of all CITI modules: https://www.citiprogram.org/citidocuments/forms/Human%20Subjects%20Research%20(HSR)%20Catalog.pdf. [b]SBR=Social and Behavioral Research. [c]HSR=Human Subjects Research. [d]HSP=Human Subjects Protection. [e]HIPAA=Health Insurance Portability and Accountability Act. Adapted with permission from CIRTification: Community Involvement in Research Training, developed by Emily E. Anderson and available at www.go.uic.edu/CIRTification.