

Research

F O U R T H E D I T I O N

Successful Approaches in Nutrition and Dietetics

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and Judith Beto, PhD, RDN
Editors

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and Dietetics

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Research: Successful Approaches in Nutrition and Dietetics, Fourth Edition
ISBN 978-0-88091-946-3 (print)
ISBN 978-0-88091-947-0 (eBook)
Catalog Number 199919 (print)
Catalog Number 199919e (eBook)

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10 9 8 7 6 5 4 3 2 1

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Library of Congress Cataloging-in-Publication Data

Names: Van Horn, Linda, editor. | Beto, Judith A., editor. | Academy of Nutrition and Dietetics, issuing body.

Title: Research : successful approaches in nutrition and dietetics / [edited by] Linda Van Horn and Judith Beto.

Other titles: Research (Van Horn)

Description: 4th edition. | Chicago, IL : Academy of Nutrition and Dietetics, [2019] | Includes bibliographical references and index.

Identifiers: LCCN 2018060019 (print) | LCCN 2018061669 (ebook) | ISBN 9780880919470 (eBook) | ISBN 9780880919463 (print : alk. paper)

Subjects: | MESH: Nutritional Physiological Phenomena | Research Design | Data Collection | Dietetics--methods | Epidemiologic Methods

Classification: LCC TX367 (ebook) | LCC TX367 (print) | NLM QU 145 | DDC 613.2072--dc23

LC record available at <https://lcn.loc.gov/2018060019>

Contents

<i>List of Boxes, Tables, and Figures</i>	<i>vii</i>
<i>Editors</i>	<i>xiii</i>
<i>Contributors</i>	<i>xv</i>
<i>Reviewers</i>	<i>xvii</i>
<i>Foreword</i>	<i>xix</i>
<i>Acknowledgments</i>	<i>xxi</i>
<i>About the Fourth Edition</i>	<i>xxiii</i>

Section 1: An Introduction to Discovery Through Research in Nutrition and Dietetics

CHAPTER 1	
Advancing the Research Continuum <i>Linda Van Horn, PhD, RDN</i>	2
CHAPTER 2	
Building the Research Foundation: The Research Question and Study Design <i>Carol J. Boushey, PhD, MPH, RDN, and Jeffrey Harris, DrPH, MPH, RDN, LDN, FAND</i>	8

Section 2: Establishing and Maintaining a Research Environment

CHAPTER 3	
Conducting and Presenting Research Ethically <i>Rosa K. Hand, PhD, RDN, LD, FAND</i>	34
CHAPTER 4	
How to Write Proposals and Obtain Funding <i>Dianne Neumark-Sztainer, PhD, MPH, RD, and Nicole Larson, PhD, MPH, RDN</i>	53

Section 3: Descriptive Research

CHAPTER 5	
Descriptive Epidemiologic Research <i>Maureen Brady Moran, MPH</i>	74
CHAPTER 6	
Qualitative Research <i>Judith Beto, PhD, RDN</i>	84

Section 4: Observational and Experimental Research

CHAPTER 7

Analytic Nutrition Epidemiology | *Lyn M. Steffen, PhD, MPH, RDN, FAHA* 102

CHAPTER 8

Guidelines for Developing and Implementing Clinical Nutrition Studies | *Alison L. Steiber, PhD, RDN; Rosa K. Hand, PhD, RDN, LD, FAND; and Constantina Papoutsakis, PhD, RDN* 126

CHAPTER 9

Nutrition Monitoring in the United States: Sources of Data and Their Uses | *Sharon I. Kirkpatrick PhD, RD* 153

Section 5: Integrative and Translational Research

CHAPTER 10

Systematic Reviews: Backbone of Evidence-Based Practice | *Deepa Handu, PhD, RDN; Lisa Moloney, MS, RDN; Feon Cheng, PhD, MPH, RDN, CHTS-CP; and Mary Rozga, PhD, RDN* 192

CHAPTER 11

Bridging Disciplinary Boundaries | *Madeleine Sigman-Grant, PhD, RD, and Sharon M. Donovan, PhD, RD* 217

Section 6: Evaluation and Assessment Methods in Research

CHAPTER 12

Survey Research Planning and Questionnaire Design | *Jacqueline A. Vernarelli, PhD, and Barbara E. Millen, DrPH, RD, FADA* 230

CHAPTER 13

Dietary Assessment Methods and Validation | *Linda Van Horn, PhD, RDN* 250

CHAPTER 14

Food Composition Data and Databases | *Catherine M. Champagne, PhD, RDN, LDN, FTOS, FAHA FADA, FAND; Pamela R. Pehrsson, PhD; and David Haytowitz, MSc* 271

CHAPTER 15

Using the Dietary Reference Intakes to Assess Intakes | *Regan L. Bailey, PhD, MPH, RD; Connie Weaver, PhD; and Suzanne P. Murphy, PhD* 294

CHAPTER 16	
Biomarkers in Nutrition Research <i>Yasmin Mossavar-Rahmani, PhD, RD</i>	311
CHAPTER 17	
Research Methods in Appetite Assessment <i>James H. Hollis, PhD, BSc (Hons)</i>	331

Section 7: Key Aspects of Research in Food, Nutrition, and Dietetics

CHAPTER 18	
Outcomes Research and Economic Analysis <i>William Murphy, MS, RDN, and Rosa K. Hand, PhD, RDN, LD, FAND</i>	350
CHAPTER 19	
Research in Diet and Human Genetics <i>Marilyn C. Cornelis, PhD</i>	380
CHAPTER 20	
Behavior Change Theory–Based Dietary Research <i>Geoffrey W. Greene, PhD, RD, LDN; Colleen A. Redding, PhD; Miryam Yusuf, PhD; and Jade McNamara, PhD</i>	405
CHAPTER 21	
Research Methods for Dietary Supplementation Research <i>Cynthia Thomson PhD, RDN, and JoAnn E. Manson, MD, DrPH</i>	422
CHAPTER 22	
Research in Foodservice Management <i>Veronica McLymont, PhD, RD, CDN, and Lianne Russo, MS, RDN, CDN</i>	445
CHAPTER 23	
Dietetics Education Research <i>Mary B. Gregoire, PhD, RD, FADA, FAND, and Kevin Sauer, PhD, RDN, LD, FAND</i>	456

Section 8: Application of Statistical Analysis in Nutrition and Dietetics Research

CHAPTER 24	
Estimating Sample Size <i>Jeffrey Harris, DrPH, MPH, RDN, LDN, FAND, and Carol J. Boushey, PhD, MPH, RDN</i>	468
CHAPTER 25	
Fundamentals of Statistical Applications <i>Philip Gleason, PhD; Mary C. Naglak, PhD, RD; and Carol Koprowski, PhD, RDN</i>	480

Section 9: Presentation of Research Data

CHAPTER 26	
Techniques and Approaches for Presenting Research Findings <i>Joanne Kouba, PhD, RDN</i>	512
CHAPTER 27	
Illustrating the Results of Research <i>Shortie McKinney, PhD, RD,</i> <i>FADA, and Kelsey Mangano, PhD, RD</i>	541
CHAPTER 28	
Research Publications: Perspectives of the Writer, Reviewer, and Reader <i>Jeffrey Harris, DrPH, MPH, RDN, LDN, FAND</i>	558

Section 10: Applications of Research to Practice

CHAPTER 29	
Bridging Research into Practice <i>Judith A. Gilbride, PhD, RDN, FAND,</i> <i>and Laura D. Byham-Gray, PhD, RDN, FNKF</i>	570
CHAPTER 30	
Community-Based Research with a Focus on Diet <i>Linda Snetselaar,</i> <i>PhD, RDN, LD, FAND; Angela Odoms-Young, PhD; and</i> <i>Maria O. Scott, MPH</i>	592
<i>Index</i>	607

List of Boxes, Tables, and Figures

Boxes

Box 3.1 Information Requested in an Institutional Review Board Application	40	Box 9.2 Healthy People 2020 Objectives for Improving Health: An Example of the Use of Nutrition Monitoring Data for Assessing Progress on Public Health Goals	156
Box 3.2 Components of an Informed Consent Form	40	Box 9.3 Centers for Disease Control and Prevention (CDC) Growth Charts: An Example of the Use of Nutrition Monitoring Data to Inform Reference Standards Related to Nutritional Status	168
Box 3.3 The 18 Patient Identifiers That Must Be Removed to Meet the Health Insurance Portability and Accountability Act Safe Harbor Method	42	Box 9.4 Nutrition Monitoring Data in Action: Mandatory Folic Acid Fortification and Neural Tube Defects	170
Box 3.4 Guidelines for Scientists in Communicating Emerging Science on Nutrition, Food Safety and Health	48	Box 9.5 Overview of Key Food Composition and Supplement Databases Developed and Maintained by the US Department of Agriculture and Its Partners	171
Box 4.1 Review Criteria for National Institutes of Health Proposals	57	Box 9.6 Selected Sources of Federal Information on Nutrition Research, Surveys, and Data Sets	176
Box 4.2 Typical Budget Items for a Grant Proposal to Develop, Implement, and Evaluate a Community-Based Nutrition Intervention Program	66	Box 10.1 Questions from the Quality Criteria Checklist: Primary (Original) Research	203
Box 5.1 Calculation of Cumulative Incidence: Colon Cancer Cumulative Incidence Expressed as Risk of Disease	76	Box 10.2 Roles in Academy of Nutrition and Dietetics Evidence Analysis	211
Box 5.2 Key Epidemiologic Calculation Terms	77	Box 10.3 Resources for Systematic Reviews and Guideline Development	213
Box 6.1 General Similarities Between Qualitative and Quantitative Research	86	Box 11.1 Elements for Successful Multidisciplinary Research	224
Box 6.2 Contrasting Characteristics of Qualitative and Quantitative Research	86	Box 12.1 Colinearity and Confounding Variables	232
Box 6.3 Examples of Qualitative Research Approach	87	Box 12.2 Example of Data Cleaning	236
Box 6.4 Selected Qualitative Research Topic Areas in Nutrition	89	Box 12.3 Key Terms in Sampling Methodology	237
Box 6.5 Examples of Qualitative Research Designs	90	Box 12.4 Closed-Ended vs Open-Ended Questions	243
Box 6.6 Common Qualitative Research Sampling Methods	91	Box 12.5 Question Criteria for Response Categories	243
Box 6.7 Selected Software for Qualitative Data Analysis	95	Box 14.1 Example of Order of Food Description Terms in a Database	283
Box 7.1 Measures of Association	104	Box 14.2 Examples of Food Name Synonyms	283
Box 7.2 Bradford Hill Criteria for Causation	105	Box 15.1 Dietary Reference Intake Definitions	295
Box 8.1 Resources for Conducting Clinical Nutrition Research Studies	128	Box 16.1 Examples of Short-, Medium-, and Long-Term Biomarkers	314
Box 8.2 Recommended Quality Improvement Procedures in a Clinical Nutrition Study	149	Box 16.2 Definitions of Systematic and Random Error	321
Box 9.1 Nutrition Monitoring Data Support Policy Making and Research in the United States in Different Ways	155	Box 17.1 Applications of Appetite Research Methods for Weight Management	332

Box 17.2 Internal vs External Validity	334	Box 25.3 Examining the Relationship Between Bariatric Surgery and Diabetes Remission	501
Box 17.3 Study Design Terminology	336	Box 25.4 Comparing Mean Hemoglobin A1c Levels at Different Time Periods by Type of Surgery	503
Box 18.1 Outcomes Examples by Type	352	Box 25.5 Constructing a Linear Regression Equation to Predict Hemoglobin A1c Levels 12 Months After Bariatric Surgery	506
Box 18.2 Comparison of Efficacy vs Effectiveness Research	357	Box 26.1 Practical Suggestions for Conference Poster Presentations	530
Box 18.3 The Nine Dimensions of the Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) Instrument and the Defining Questions for Each	358	Box 26.2 Sample Slide Organization for Research Presentation	533
Box 18.4 Outcomes and Effectiveness Research: Planning and Conducting a Study	360	Box 26.3 Sample Roundtable Discussion Questions	535
Box 18.5 Evidence Analysis Library Conclusion Statements Related to the Cost-Effectiveness of Medical Nutrition Therapy	363	Box 26.4 Information to Include in a Webinar Introductory Script	538
Box 18.6 Quality-Adjusted Life Years	365	Box 27.1 Tips for Creating Research Data Tables That Are Easy to Read and Understand	545
Box 18.7 Perspectives for Economic Analysis	367	Box 27.2 Elementary Tasks in Graphical Perception in Decreasing Order of Accuracy	551
Box 18.8 Types of Costs Used in Economic Analysis	368	Box 28.1 Signs of a Predatory Journal	561
Box 20.1 Effect Size	408	Box 28.2 Tips for Improving Communication Between Author and Editor	561
Box 20.2 Example of a Social Cognitive Theory-Based Intervention	413	Box 28.3 Questions Reviewers Should Ask When Reviewing a Manuscript	563
Box 20.3 Example of Transtheoretical Model-Based Intervention and Randomized Controlled Trial	416	Box 28.4 Questions a Reader Should Ask to Critically Evaluate a Research Article	565
Box 21.1 Key Web-Based Government Information for Guiding the Development of Quality Research Projects on Dietary Supplementation	430	Box 29.1 Practical Tips for Keeping Up with the Research Literature	572
Box 21.2 Additional Dietary Supplementation Informational Resources	431	Box 29.2 Self-Assessment Questions for Determining Potential for Increasing Research Involvement in Nutrition and Dietetics Practice	573
Box 22.1 Data Collection Techniques for Foodservice Research	448	Box 29.3 Ways to Disseminate Practice-Based Research	585
Box 23.1 Definitions and Examples of Observational and Experimental Studies in Nutrition and Dietetics Education	458	Box 30.1 Institute of Medicine Classification System Showing Where Research Sits on the Translational Research Spectrum	594
Box 23.2 Types of Methods Used in Explanatory Research	461	Box 30.2 Qualitative Research Strategies	597
Box 24.1 Sample Size Calculation Software and Websites	478	Box 30.3 Parental Consent for Children Participating in Research	600
Box 25.1 Hypothesis Testing and Criminal Trials	487		
Box 25.2 Clinical Study Example Used to Illustrate Statistical Methods: Remission of Type 2 Diabetes in Patients Undergoing Bariatric Surgery	491		

Tables

Table 3.1 Resources for Training in Human Subjects Protection	38	Table 9.1 Federal Nutrition Monitoring Surveys and Surveillance Activities	158
Table 4.1 Types of Grant Programs of the National Institutes of Health	56	Table 10.1 Study Design, Distinguishing Characteristics, and Important Quality Considerations	203
Table 4.2 Impact Evaluation Measures: New Moves	61	Table 10.2 Evidence Summary Table (Summary of Findings Table)	205
Table 7.1 Advantages and Disadvantages of Observational Study Designs	113	Table 12.1 Statistical Tests to Compare Groups	247

Table 14.1 History of Special Interest Databases Released by the US Department of Agriculture	276	Table 21.2 The 2015–2020 National Institutes of Health–Funded Centers for Advancing Research on Botanical and Other Natural Products (CARBON) Program Centers	430
Table 15.1 Nutrients That Have Special Considerations When Applying the Dietary Reference Intake Framework	299	Table 21.3 Biomarkers of Nutrient or Phytochemical Exposure Available for Use in Dietary Supplement Intervention Trials	438
Table 15.2 Evaluation of a 74-Year-Old Man’s Diet Based on Usual Intake from Food and Supplements	303	Table 21.4 Possible Outcome Biomarkers for Use in Dietary Supplementation Research	440
Table 16.1 Biomarkers for Dietary Assessment of Macronutrients	315	Table 22.1 Foodservice Management Research Designs	449
Table 16.2 Blood Concentration Biomarkers Useful in Assessing Nutrition or Monitoring Dietary Intakes	316	Table 24.1 Possible Outcomes When Drawing Conclusions from Statistical Results	469
Table 16.3 Biochemical Indicators Useful as Biomarkers of Plant-Based Diets	317	Table 24.2 Standard Normal Distribution Multipliers (Z values) for Values of α and β	472
Table 18.1 Assessing Nutrition-Related Surrogate Outcomes	354	Table 25.1 Parametric Statistical Tests and Their Nonparametric Counterparts	489
Table 18.2 Analytic Methods Used in Economic Analysis	364	Table 25.2 Prevalence of Obesity Among Adults in the United States	493
Table 19.1 Genome-Wide Association Studies of Diet-Related Traits	385	Table 25.3 Measures of Central Tendency and Dispersion for Prestudy Body Mass Index	494
Table 19.2 Examples of Known and Hypothesized Gene-Diet Interactions	391	Table 25.4 Suggested Statistical Methods for Evaluating Differences Between Samples or Groups	500
Table 19.3 Examples of Randomized Control Trials Assessing the Impact of Genotype-Based Risk Estimates on Risk-Reducing Dietary Behaviors	395	Table 26.1 International Scientific Institute Impact Factors 2016–2017 for Selected Journals and Guideline Websites	517
Table 20.1 Similarities Across Key Constructs by Behavior Change Theory	407	Table 27.1 Categories of Information Necessary for a Complete Representation of Data in Tables	546
Table 21.1 Dietary Supplement Label Claims and Relevance to Research	424		

Figures

Figure 2.1 Basic cross-sectional study design (or survey) for determining prevalence rates of a health outcome (eg, hypertension) or a behavioral outcome (eg, fruit and vegetable consumption)	13	Figure 3.1 Institutional review board application and approval process	39
Figure 2.2 Basic cross-sectional study design (or survey) for examining a relationship between exposure and outcome	14	Figure 4.1 Theoretical framework example from the Eating and Activity in Teens (EAT) study of changes in young people’s eating and activity behaviors from 2010 through 2018	63
Figure 2.3 Basic randomized controlled trial study design	17	Figure 4.2 Timeline example	64
Figure 2.4 Basic study design for the crossover randomized controlled trial where participants are represented in both treatment and control (placebo) arms	19	Figure 5.1 Schematic description of the screening test indexes sensitivity and specificity and their calculation	78
Figure 2.5 Example of a 2p factorial design in which two factors are at two levels each.	22	Figure 5.2 Schematic description of the predictive values of a screening test	79
Figure 2.6 Basic prospective cohort study design	23	Figure 5.3 Comparison of positive predictive values in populations with differing prevalence of disease	80
Figure 2.7 Basic case-control study design involves ascertaining cases after onset of disease and assessing exposure via recall of status before the onset of disease	26	Figure 7.1 Relative risk	105
		Figure 7.2 Comparison of predictive values	111
		Figure 8.1 Examples of hypotheses and null statements	130

<i>Figure 8.2</i> Parallel-design randomized controlled clinical trial	131	<i>Figure 13.2</i> National Cancer Institute comparison of dietary assessment instruments	257
<i>Figure 8.3</i> Crossover experimental trial design	132	<i>Figure 14.1</i> Screenshot of the US Department of Agriculture's Branded Food Products Database, a typical food composition database	275
<i>Figure 8.4</i> Factorial experimental trial design	133	<i>Figure 14.2</i> Sodium variability among brands of kosher dill pickles available in the United States	286
<i>Figure 8.5</i> Cluster randomized experimental trial design	134	<i>Figure 15.1</i> Relationship among Dietary Reference Intakes	295
<i>Figure 8.6</i> Stepped-wedge experimental trial design	135	<i>Figure 15.2</i> Example of a requirement distribution: magnesium requirements for women aged 19 to 30 years	301
<i>Figure 8.7</i> Sample template for the Consolidated Standards of Reporting Trials (CONSORT) showing the flow of participants through each stage of a randomized trial	136	<i>Figure 15.3</i> Hypothetical nutrient distribution with and without usual intake methods applied	304
<i>Figure 8.8</i> Nutrition intervention studies of varying control	137	<i>Figure 16.1</i> Fraction of biomarker (doubly labeled water) variance explained by dietary self-report in energy and participant characteristics	322
<i>Figure 10.1</i> Example of an analytic framework to help develop questions for systematic review	195	<i>Figure 17.1</i> Example of a visual analogue scale	338
<i>Figure 10.2</i> Steps to identify the best and most relevant research	197	<i>Figure 17.2</i> Example of a category scale	338
<i>Figure 10.3</i> Example Search inclusion and exclusion criteria	198	<i>Figure 18.1</i> An evidence-based practice research cycle including outcomes research	351
<i>Figure 10.4</i> Snapshot of the Academy of Nutrition and Dietetics Data Extraction Tool	199	<i>Figure 18.2</i> Validation process for surrogate outcome	353
<i>Figure 10.5</i> Sample evidence summary	206	<i>Figure 18.3</i> Relationships among diseases, outcomes, interventions, and valid and invalid surrogate end points	355
<i>Figure 10.6</i> Sample conclusion statement	206	<i>Figure 18.4</i> Chain of outcomes of nutrition care	356
<i>Figure 10.7</i> Criteria and definitions for grading the strength of the evidence for an Evidence Analysis Library conclusion statement	207	<i>Figure 18.5</i> Chain of outcomes resulting from weight management program (12-month period)	356
<i>Figure 10.8</i> Sample recommendation statement	208	<i>Figure 18.6</i> Spectrum of internal and external validity by study design	357
<i>Figure 10.9</i> Rating scheme for the strength of the recommendations, Academy of Nutrition and Dietetics	209	<i>Figure 19.1</i> DNA and a diagram of a typical human structural gene	382
<i>Figure 11.1</i> Illustration of the parable of the six blind men and the elephant	218	<i>Figure 20.1</i> Flow Diagram of interventions from concept to evaluation	409
<i>Figure 11.2</i> Comparison of multidisciplinary, interdisciplinary, and transdisciplinary research	220	<i>Figure 20.2</i> The stages of change spiral from the transtheoretical model	414
<i>Figure 11.3</i> Schema depicting multiple disciplines for studying determinants of eating and physical activity	222	<i>Figure 21.1</i> Key approaches to dietary supplementation scientific investigation	426
<i>Figure 12.1</i> An ecological model of diet and health outcomes with dietary patterns	233	<i>Figure 21.2</i> The scientific process: dietary supplement research model for a randomized controlled trial	428
<i>Figure 12.2</i> Steps for design and implementation of a survey	235	<i>Figure 21.3</i> Sample dietary supplement use data collection form	441
<i>Figure 12.3</i> Sample statements and questions on an ordinal scale	244	<i>Figure 22.1</i> Matrix displaying research areas in foodservice management	447
<i>Figure 12.4</i> Reliability vs validity	246	<i>Figure 22.2</i> Future directions in foodservice management research	452
<i>Figure 13.1</i> National Cancer Institute Diet Assessment Primer Roadmap	252	<i>Figure 25.1</i> Classification of types of variables	482
		<i>Figure 25.2</i> Example of serial and replicate measures	485

<i>Figure 25.3</i> Example of transforming data (folate intake) used in statistical modeling of usual dietary intake	488	<i>Figure 27.3</i> Rate ratios for death from all causes in white men (n = 57,073) and women (n = 240, 158) by World Health Organization body mass index categories (underweight = 18.4 or less; normal range = 18.5 to 24.9; preobese = 25.0 to 29.9; class I obese = 30.0 to 34.9; class II obese = 35.0 to 39.9; class III obese = 40+)	549
<i>Figure 25.4</i> Example of a statistical outlier illustrated via scatterplot	491	<i>Figure 27.4</i> Inappropriate graph overemphasizes the importance of data	550
<i>Figure 25.5</i> Example of how a histogram can be used to summarize a single variable such as type of diabetes treatment (diet, oral medication, insulin)	492	<i>Figure 27.5</i> Stacked bar graph (A) compared with dot chart with grouping (B)	552
<i>Figure 25.6</i> Histogram showing the distribution of diabetes remission among four different types of bariatric surgery	493	<i>Figure 27.6</i> Curve-difference graphs	553
<i>Figure 25.7</i> Comparison of standard error and standard deviation	496	<i>Figure 27.7</i> Distribution maps	554
<i>Figure 25.8</i> Scatterplot of prestudy weight and height	505	<i>Figure 27.8</i> Example of a flow chart	554
<i>Figure 26.1</i> Example of a structured abstract in a journal	520	<i>Figure 30.1</i> The translational science spectrum	593
<i>Figure 26.2</i> Techniques for improving the presentation of research data in table format	523	<i>Figure 30.2</i> Sample observational study designs and potential findings	595
<i>Figure 26.3</i> Example of an organizational publication	524	<i>Figure 30.3</i> Sample experimental/quasi-experimental designs and potential findings	595
<i>Figure 26.4</i> Example of a poster presentation	526	<i>Figure 30.4</i> Sample screening form for participants in a study on blood pressure management	601
<i>Figure 26.5</i> Example of an abstract in which the authors have been blinded for a poster presentation at a professional conference	528	<i>Figure 30.5</i> Sample community-based study design	602
<i>Figure 27.1</i> Examples of original and improved methods of depicting the same data	544	<i>Figure 30.6</i> Staggered recruitment and intervention strategy	602
<i>Figure 27.2</i> Example of how the information presented in a data table should complement but not duplicate the information presented in the text of the research article of which it is a part	547	<i>Figure 30.7</i> Study status update form	604

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Foreword

Research: Successful Approaches in Nutrition and Dietetics, now in its fourth edition, remains a touchstone for all nutrition and dietetics researchers. This text contains the collective knowledge of our field, with each chapter authored by a distinguished nutrition and dietetics researcher. This newest edition will continue to serve as a reference and educational foundation for our profession.

While the scientific method underpinning research has not changed in hundreds of years, the complexity of our research questions and research tools have increased appreciably. Professors Van Horn and Beto do an excellent job orienting readers to the full-spectrum of nutrition and dietetics research throughout this text, including clear indications of pros and cons for different tools and methodological approaches. Chapters 1 through 4 orient the reader, walk through the scientific method, describe how to obtain monetary support for research, and explain the ethical responsibility of researchers, respectively. The remaining chapters largely dive deeper into the array of different approaches, methods, and tools used in nutrition and dietetic research. This format easily allows the reader to simply choose topics of interest or to read through all topics for a more global understanding.

In 2017, the Academy of Nutrition and Dietetics celebrated its centennial, and, on behalf of the Research Dietetic Practice Group, I am beyond pleased to see the prominence of research within the Academy of Nutrition and Dietetics strategic plan. This is especially vital right now because research is more complex than ever and is being communicated to the public in smaller and smaller sound bites. Indeed, the Academy of Nutrition and Dietetics designated research as the first of four strategies to fulfill their mission to “Accelerate improvements in global health and well-being through food and nutrition.” For over 25 years the Academy of Nutrition and Dietetics has committed to publishing this text, which demonstrates the long-standing dedication of the Academy of Nutrition and Dietetics, and its membership, to quality research.

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Acknowledgments

We are grateful to each of our talented authors. Their expertise is evident in these chapters, which provide the most current and credible information available in their respective areas of concentration. We highly respect these individuals for their hard work and creativity in presenting complex concepts in new and novel ways. We want to further give our appreciation to past authors whose contributions in earlier editions modelled certain topic areas.

We sincerely thank the Academy of Nutrition and Dietetics for supporting the development of this new edition. Specifically, the Publications, Resources, and Products team is recognized for its commitment to excellence, ongoing involvement, and dedication. Without them, this book could not have been produced.

We also wish to remember our former colleague and past editor of the *Journal of the Academy of Nutrition and Dietetics*, Elaine Monsen, PhD, RD, whose initiative launched the first edition of this book. Her commitment to teaching and training nutrition researchers has inspired countless investigators to take the tools and tips provided to design, implement, and publish remarkable findings and new discoveries.

Finally, we thank you, the readers, for your interest, scientific curiosity, and ambition. We encourage each of you to discover “successful approaches” to developing high impact nutrition research of your own!

Linda Van Horn, PhD, RDN
Judith Beto, PhD, RDN

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About the Fourth Edition

The fourth edition of *Research: Successful Approaches in Nutrition and Dietetics* is a timely and comprehensive update on designing, conducting, and evaluating nutrition research. This text strategically targets nutrition students, their professors, and practitioners who seek a deeper understanding of the evidence base that forms nutrition policy and practical applications. There is an emphasis on the modern integration of nutrition science, epidemiology, clinical translational relevance and food-based practices. Advances in biostatistical analyses, biological mechanisms, and newly emerging biomarkers are encompassed throughout.

The book's ten sections capture the excitement of research discovery, the importance of establishing a supportive research environment, and details specific to conducting observational, integrative, and translational research in the modern era.

Section 1 follows in the footsteps of the previous edition, laying a general foundation for the importance of discovery through research. Examples have been updated to give readers a glimpse of current research models to illustrate the main points.

Section 2 brings to the reader the most up-to-date information on advancing science through ethical research. Detailed information on writing proposals has been revised to feature the most current resources in grant writing and proposal funding resources.

Section 3 explores, in depth, the unique attributes of descriptive research with a new focus on efficiency in data collection.

Section 4 has been expanded to introduce the topic of consistency in study findings and includes new figures and illustrations to elaborate on clinical nutrition studies. Chapter 9 has been augmented to offer the latest in nutrition monitoring.

Section 5 includes a brand new chapter on bridging disciplinary boundaries and working on teams with members from varied backgrounds.

Section 6 incorporates key components relevant to evaluation and assessment methods in research, ranging from surveys to assessment methodology, as well as the importance of the food composition databases and dietary reference intakes that are essential to all aspects of nutrition research. A detailed and up-to-date review of existing biomarkers and how to apply them is included, as well as a specific focus on research involving appetite assessment.

Section 7 includes six chapters that are fundamental to the food, nutrition, and dietetics arena. New to this section is the subject of diet and human genetics, which is rapidly evolving. This topic is an essential component of understanding nutrition research in the modern era.

Section 8 concentrates on statistical applications that are vital to nutrition research and an invaluable component of understanding as well as writing nutrition research papers that merit publication in high impact journals.

Section 9 further describes best approaches to illustrate, evaluate, and integrate nutrition research data within the development of subsequent studies and their interpretation.

Finally, **Section 10** brings it all together in the process of applying research in practice. The importance of community-based research in implementing public health benefits is the new culminating chapter to further emphasize applied-side nutrition and dietetics.

Authors who have contributed their time and talents to the fourth edition are uniquely qualified to address each topic, and their individual areas of expertise are well recognized and respected in the published literature. This text aims to enhance, expand, and energize readers to embrace the excitement of nutrition research, ignite new ideas and approaches, and achieve a better understanding of the importance of diet and nutrition in health throughout the life course.



SECTION 1

An Introduction to Discovery
Through Research in Nutrition
and Dietetics



Chapter 1		Chapter 2	
Advancing the Research Continuum	2	Building the Research Foundation: The Research Question and Study Design	8
Forces for Research	3	Designing a Research Study	9
Advancing Your Own Research	6	Descriptive Research Designs	11
		Experimental Study Designs (Randomized-Trials)	16
		Prospective (Cohort, Follow-Up) Studies	22
		Case-Control Studies	25

Chapter

1

Advancing the Research Continuum

Linda Van Horn, PhD, RDN

LEARNING OBJECTIVES

1. Introduce the overall premise of this book.
2. Highlight key topics and research elements addressed.
3. Encourage readers, whether novice or experienced, to apply these principles and strategies to their own research as they move forward with their careers.

Nutrition research is fundamental to the evidence-based practice of nutrition and dietetics. Well-designed, carefully executed, quality-controlled studies offer insights and breakthroughs that drive the field forward. Research fosters objective measurement of complex environments and demands rigorous evaluation of procedures, treatments and outcomes. Through research, associations can be identified, hypotheses tested, programs compared, and protocols validated. Research documents practice, monitors approaches, ensures credibility, and assesses cost-effectiveness. The strength of a discipline, whether in health sciences or management, is characterized by the quality and quantity of evidence in its research base. Strong and consistent research is essential to a vibrant profession, pending active involvement of professionals in keeping abreast of the dynamic findings.

FORCES FOR RESEARCH

Monsen¹ identified driving forces that continue to influence nutrition research today. These include recognizing unexpected findings, extending existing data, posing point-counterpoint comparisons, and responding to socioeconomic, political, and behavioral influences of a culturally diverse environment. Included in modern applications of research are the numerous influences conferred by social media and the rapid-fire communication of results that can undermine careful consideration of unintended consequences.

Recognizing the Unexpected

An exciting by-product of a research study is sometimes the hidden finding that launches new topic areas of study. This is more commonly known as the “Aha!” moment. Discovery of the first vitamin is a clear example. In the 1700s, a British naval surgeon, James Lind, gave a great deal of thought to the vast occurrence of scurvy among English sailors. The disease was particularly rampant on long voyages. In 1747, Lind completed the first controlled dietary study where he proved that citrus fruits cured scurvy. Six years later Lind² published his treatise, and in 1796, 43 years after his publication, the British navy officially introduced lemon juice as a prophylactic against scurvy.

More than a century later, in 1906, the concept of developing accessory food factors was introduced. In 1932, 185 years after Lind’s first controlled study, crystalline vitamin C was prepared from lemon juice. While no one can plan for a breakthrough (such as the dietary importance of citrus fruit), investigators should always be alert for the unexpected. For example, the findings from the Women’s Health Initiative reported completely unexpected results regarding the use of progestin-containing hormone therapy, which was long considered protective; the report found that progestin was adversely associated with increased risk of postmenopausal breast cancer.³⁻⁵ These results changed the course of clinical postmenopausal management almost overnight. From 1988 through 1994, 44% of American women reported using hor-

mone therapy, but this was reduced to 4.7% by 2010, with ongoing recommendations against its use in 2017 by the US Preventive Services Task Force.⁶

Extending Existing Data

Going beyond what is known to discover what is not known remains a compelling force of research. Another classic example is discovery of the second vitamin. When the idea of accessory food factors was introduced to the scientific community, researchers eagerly devoted attention to ascertaining whether other important food factors existed and their sources and functions. From 1913 to 1916, research teams led by McCullum et al^{7,8} observed and isolated components from foods that they termed Fat Soluble A and Water Soluble B. Shortly thereafter, Fat Soluble A was partitioned into vitamins A, D, E, and K, and Water Soluble B developed into the long series of B vitamins.⁹ This search for accessory food factors was a highly productive extension of the earlier discovery of vitamin C.

A more current example is the study of glycemic index and glycemic load. While the relevance and practical application of these two factors in regards to development of insulin resistance or type 2 diabetes remains somewhat mixed,^{10,11} awareness of the potential role of these factors in impacting postprandial glucose/insulin response opened a new and compelling area for nutrition research.¹²⁻¹⁴ The epidemiologic relevance of a topic like this and its importance in setting the stage for next generation research are addressed more extensively in Chapters 5 and 7.

One of the trending topics of today centers on the growing awareness of biomarkers, which can help provide objective measures of nutrient intake and help to identify biological pathways and processes related to digestion, absorption, and metabolism. Chapters 16 and 21 are particularly relevant to this topic and offer insights into how best to cross-check diet intake with metabolic outcomes.

Also, with the increasing interest in precision medicine and now precision nutrition, nutrigenomics and the myriad of diet-gene interactions are likely to become even more important to the understanding of prevention and diet therapy to meet the

needs of the individual, including questions regarding weight control.¹⁵ Chapter 19 is devoted to this topic and raises many hypothesis-generating research questions.

Point-Counterpoint Comparisons

The point-counterpoint concept involves actions and reactions. A current example is the explosion of “functional foods,” including prebiotics and probiotics that have been developed by the food industry, presumably to conveniently meet nutrient needs of busy people without imposing the hassle of buying and preparing raw ingredients. Whether these foods and products prove helpful or harmful (perhaps due to extra calories, sugar, salt, or other factors) remains controversial,^{16,17} but the presence of these products continues to have a growing influence on the modern diet.¹⁸ The knowledge gap associated with their risk-benefit ratios—especially the gap based on age, sex, health status, and pharmacological influences—requires future study.

Responding to the Socioeconomic, Political, and Culturally Diverse Environment

The Special Supplemental Food Program for Women, Infants and Children (WIC) represents an outstanding response to the socioeconomic and political environment.¹⁹ Evaluation and documentation of the WIC program and innovative new approaches are among the prime reasons that the program has been so successful.²⁰ Increasing cultural diversity and the accompanying increase in rates of homelessness raise challenges related to economic opportunity and adequate nutrition for underserved pregnant women. Qualitative research on these and associated topics is addressed in Chapter 6. Applied research on these topics offers promise for ameliorating these difficult problems.²¹

Research Now

Nutrition research has never been more exciting or more challenging. The forces of research are ever influencing new studies and their findings. Regis-

tered Dietitian Nutritionists (RDNs) are encouraged to take an active role in designing studies, both basic science and clinical, to document the benefits of nutrition in prevention and treatment of disease. Applied translational research is especially valued; it takes results from bench to bedside and even curbside, offering timely community health benefits derived from well executed experimental and clinical designs. Chapters 11, 18, 29, and 30 are especially relevant in this area. This book offers a wealth of tools and techniques for designing nutrition research studies of your own. Here are a few of the basics to get you started.

Prepare the Research Protocol

A research protocol is essential to direct the study in a manner that ensures meaningful results. The research protocol includes (1) specific aims and hypotheses that pose focused and concisely stated research questions, (2) a comprehensive literature review, (3) the merit and potential value or innovations of the research, and (4) the appropriate research design to adequately test the questions. Research design includes the study methods, data collection, and decisive statistical analyses to be used to test the hypotheses. See Chapters 8 through 10.

Research proposals must conform to a funding agency’s requirements, as stated in its guidelines. Chapter 4 provides detailed guidance on securing funding. Many private and public agencies model their guidelines after those of the National Institutes of Health (NIH). Proposals are typically submitted electronically, requiring the authors to pay careful attention to all details, including the due date and time.

Conduct the Pilot Study to Produce Preliminary Data

A pilot study to generate preliminary results is essential in most NIH studies to demonstrate the feasibility and merit of the proposed study design and methodology. Testing instruments and validated methods permits researchers to make adjustments before launching the study, thereby assuring that data collection is efficient and accurate. All data collection needs justification. Providing preliminary data and demonstrating experience gained from the

pilot study are crucial to successful review and funding for the proposed project. See Chapters 2, 8, 9, 12, and 13.

Ensure Ethical Research

Institutional Review Board (IRB) approval is required prior to initiating all research studies. Researchers must follow ethical procedures in all aspects of the design and conduct of their research. Everything, ranging from the choice of topic, to the samples collected, to the interventions designed, to the data collected, to—perhaps most important of all—gaining informed consent, must be considered ethical as judged by IRB approval. Data analyses and reporting of data are likewise subject to scrutiny. Chapter 3 provides a more detailed discussion.

These investigations must meet ethical guidelines to protect the rights, privacy, and welfare of the individuals. The Declaration of Helsinki, drafted in 1964 by the World Medical Association, serves as the basis for the ethical guidelines that are now detailed regulations issued by governmental agencies, such as the NIH. The local IRB is required to review all investigations using human subjects to ensure ethical conduct and evaluate potential risks and benefits.

As part of informed consent, the investigator must explain to potential participants the nature of the study, including the possible risks and discomforts they may experience. Confidentiality of all data is mandated by all review boards. Specific elements to be included in the informed consent procedure, including written and verbal descriptions, are designated by the local IRB. See Chapters 3 and 9.

Validity, Accuracy, Reliability, and Precision

Qualities critical to all research are validity, accuracy, and precision. Use of validated instruments is essential to ensuring accuracy, reliability, and precision of the data and the results.²² The National Cancer Institute has developed a highly comprehensive Dietary Assessment Primer (<https://dietassessmentprimer.cancer.gov>) that provides de-

tailed definitions and examples of these and other aspects of nutrition research as follows:

- **Validity:** The degree to which a tool measures what it claims to measure.
- **Accuracy:** The degree of closeness of measurements of a quantity to that quantity's true value.
- **Precision:** The degree to which repeated measurements under unchanged conditions show the same results.

Sensitivity and Specificity

The choice of a single cut point to categorize individuals may not always be clear when the test yields a continuous scale of values. A cut point selected to maximize sensitivity will unavoidably cause the test to be less specific. The selection of an appropriate cut point is aided by use of graph plotting true-positive against false-positive ratios, known as the receiver operating characteristic (ROC) curve. The ROC curve graphically displays the reciprocal relationship between sensitivity and specificity for values of a test measured on a continuous scale, and it allows investigators to choose a cut-point that maximizes the performance of the test for the needed levels of sensitivity, specificity, or both. See Chapters 17, 25, 28, for more detailed explanations.

National Health and Nutrition Examination Survey (NHANES) I, II, and III provide countless examples of valid survey testing. The mean intakes of certain vitamins by age and gender are useful for determining areas of weakness in the population's diet and indicating possible policies to apply. Limitations in survey results often include low response rate and cross-sectional design.²³ Randomized clinical trials and longitudinal cohort studies are considered more robust, but these also have limitations that require further considerations. Chapters 8, 9, 12, 13, and 14 offer further discussion and insights regarding these issues.

Researchers must also use discretion in applying inferential statistical tests to data from survey research. Because survey studies are designed to be descriptive rather than analytic, formal tests of hypotheses are undertaken after the data are viewed,

and the test result is likely to be biased toward a spurious statistically significant result. Such inferential tests should be regarded as exploratory and useful in generating questions for future analytic studies. Chapters 21 and 25 offer further explanation of this topic.

ADVANCING YOUR OWN RESEARCH

The topics listed in this chapter represent only a few of the key aspects of nutrition research that are addressed in this book. The possibilities are endless, but the competitive nature of grant reviews and funding constraints often steer research proposals towards filling high priority knowledge gaps identified by the funding agencies.²⁴ A newly convened Dietary Guidelines for Americans Advisory Committee, with the assistance of the Nutrition Evidence Library, conducts systematic reviews of newly published nutrition research every 5 years as part of the process for developing the next edition of the Dietary Guidelines for Americans. Savvy researchers can begin with the end in mind by reviewing these priority areas and carefully developing testable hypotheses that will address them. Consider the population, intervention, comparator, and outcome (PICO) that form the criteria used in systematic reviews. Formulation of study questions, specific aims, and validated outcome measures that are consistent with these criteria can often make or break an investigator's chances of achieving a fundable score.

CONCLUSION

In this era, massive use of social media, blogs, tweets, and crowdsourcing to derive answers to countless questions has influenced public perception of what to believe and how to behave. The importance of evidence-based science to provide sound answers and guide public policy, including what to eat, is paramount. Take these tools and go for it!

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Index

Page numbers followed by *b*, *f*, or *t* refer to boxes, figures or tables.

- 3DPAR, 61*t*
- 10-undecanoate, 388*t*
- 23andMe, 394
- 45 Code of Federal Regulations part 46, 37
- 24-hour dietary recall
 - automated self-assessed, 254
 - interviewer administered, 251, 253–254
- α error, 469–471
- β error, 470
- ϕ coefficient, 499
- A**
- abstracts, 555
 - for podium presentations, 531
 - for poster presentations, 527, 528*f*
 - of research reports, 519, 520*f*
- Academy of Nutrition and Dietetics, 128*b*, 214, 431*b*, 513, 516, 523, 560, 566
 - Code of Ethics, 35
 - Council on Research, 574
 - Data Extraction Tool, 197
 - EBP adoption by, 193
 - Evidence Analysis Library, 128, 146, 193, 208, 573
 - Evidence Analysis Manual, 213*b*
 - evidence analysis roles in, 211*b*–212*b*
 - funding from, 55
 - on nutrigenetics, 397
 - Nutrition Research Network, 361, 572, 573, 575, 583
 - Quality Criteria Checklist, 197, 199, 200*f*–203*f*, 579
 - Quality Management Committee, 583
 - Research Ethics for the Registered Dietitian Nutritionist, 38*t*
 - research gaps assessed by, 128
 - Standards of Education, 576
- Academy of Nutrition and Dietetics Health Informatics Infrastructure (ANDHII), 573, 575
- Academy of Nutrition and Dietetics Informatics Infrastructure, 128*b*
- Academy of Nutrition and Dietetics Methodology for Conducting Systematic Reviews for the Evidence Analysis Library, 213*b*
- Acceptable Macronutrient Distribution Range (AMDR), 297, 302, 307
- Accreditation Council for Education in Nutrition and Dietetics (ACEND), 462, 564
- accuracy
 - computer-assisted interviews and, 241
 - defining, 5, 108
 - of dietary recall interviews, 169
 - of food records or diaries, 254
 - of interview responses, 459
 - of patient intakes, 580
 - proofreading for, 530*b*
 - quality improvement and, 148
 - of questionnaire data collection, 458
- ACEND. *See* Accreditation Council for Education in Nutrition and Dietetics
- acetaminophen, 342
- Adequate Intake (AI), 296–297, 302
 - limitations of, 306
- adherence
 - assessing, 144
 - of clinical nutrition study participants, 144–145
 - in community-based research, 602, 603
 - in dietary supplement research, 437
 - to grant proposals, 67
 - in metabolic studies, 144–145
 - to research plans or proposals, 67
- administration
 - ASA24 for, 253, 599
 - of dietary supplements, 436
 - of survey questionnaires, 240, 241
 - of 24-hour dietary recall, 251, 253–254
- Adult Cancer Control Module, 166
- Agency for Healthcare Research and Quality (AHRQ), 197, 213*b*, 439
- AGREE II. *See* Appraisal for Guidelines Research Evaluation
- AGRICOLA, 176*b*
- Agricultural Research Service (ARS), 160*t*, 162*t*, 169, 176*b*, 273, 274, 289
- Agriculture Handbook No. 8: The Composition of Foods: Raw, Processed, Prepared*, 272
- AHRQ. *See* Agency for Healthcare Research and Quality
- alanine, 386*t*
- alcohol
 - biomarkers and, 313
 - breast cancer and, 24
 - GWASs and, 388*t*–389*t*
- algorithms, 542
- alpha-linolenic acid, 387*t*
- alpha-tocopherol, 385*t*
- Alternative Healthy Eating Index, 313
- alternative hypothesis
 - defining, 484–485
 - sample size calculation and, 469–470
- AMDR. *See* Acceptable Macronutrient Distribution Range
- American College of Cardiology, 351
- American Diabetes Association Standards of Medical Care in Diabetes, 578
- American Dietetic Association, 456
- American Heart Association, 351
 - funding from, 55
- American Journal of Clinical Nutrition*, 516, 517*t*, 518, 560, 564
- American Journal of Public Health*, 517*t*

- American Oil Chemists' Society (AOCS), 147
 American Society for Nutritional Sciences Working Group, 155
 American Time Use Survey, 167
 amino acids
 assembly of, 382
 genetic variation and, 383
 GWASs and, 386*t*–387*t*
 in parenteral solutions, 497
 SNPs and, 383
 triplets coding, 381
 AMPM. *See* Automated Multiple-Pass Method
 AMRM Program. *See* Analytical Methods and Reference Materials Program
 analysis plans, ethics and, 46
 Analytical Methods and Reference Materials (AMRM) Program, 431
 analytic frameworks
 for evidence-based dietetics practice reviews, 194, 195*f*
 for economic analysis, 366, 368
 analytic methods, in economic analysis, 364–366, 364*t*
 analytic nutrition epidemiology
 biases in, 110–111
 cohort studies in, 114–116
 concepts in studies for, 107–112
 confounding in, 111–112
 cross-sectional studies in, 113
 effect modification and, 112
 exposures, 108
 goals of, 103–107
 nutrition exposure variable choices, 108–110
 overview of, 103
 poor exposure measurements and, 110
 research question in, 107–108
 study designs, 112–121
 ANDHII. *See* Academy of Nutrition and Dietetics Health Informatics Infrastructure
 antioxidants, 424*t*
 AOAC. *See* Association of Official Analytical Chemists
 AOCS. *See* American Oil Chemists' Society
 apolipoprotein E (APOE), 391*t*
 appetite
 biomarkers of, 339
 energy/food intake and, 339
 glucose and, 339–340
 insulin and, 341
 appetite questionnaires, 337–339
 appetite research
 applications of, 331–332, 332*b*
 cognitive factors in, 337
 environmental context and, 333–334
 measurement methodology in, 337–342
 neuroimaging in, 341–342
 participant deception in, 334–335
 participant recruitment for, 332–333
 satiety measurement, 337
 satiating measurement, 335–337
 statistical plan for, 335
 study design for, 335
 study length in, 333
 terminology for, 332
 Appraisal for Guidelines Research Evaluation (AGREE II), 208, 214*b*
 arachidonic acid, 387*t*
 area probability sampling, 179
 arginine, 386*t*
 ARIC. *See* Atherosclerosis Risk in Communities study
 array tables, 374
 ARS. *See* Agricultural Research Service
 arsenic metabolism, 388*t*
 ASA24. *See* Automated Self-Administered Recall System
 ascorbic acid, 18
 association
 case-control studies for examining, 116–118
 cohort studies for examining, 114–116
 continuous data, 502
 cross-sectional studies for examining, 113
 defining, 103–104
 discrete data, 499
 establishing, 103–105
 genome-wide studies of, 384
 measures of, 104, 104*b*
 observational study designs for examining, 113–118
 statistical procedures for estimating, 499, 502–507
 strength of, in binary variables, 499
 study designs for, 104–105
 Association of Official Analytical Chemists (AOAC), 147, 279
 dietary supplement standards by, 431
 Atherosclerosis Risk in Communities study (ARIC), 115
 Atlas.ti, 95*b*
 attack rate, 76
 attributable risk, 104
 Atwater, W.O., 272
 Atwater table, 272
 authors
 checklists for, 522
 conducting research, 559
 editor communication with, 561*b*
 ethics and, 48–49
 irresponsible authorship, 562–563
 journal choice of, 560, 561*b*
 manuscript preparation, 559–560
 manuscript submission, 561, 561*b*
 perspective on research, 558–563
 authorship. *See also* writers
 ethics and, 48–49
 irresponsible, 562–563
 Automated Multiple-Pass Method (AMPM), 169, 253, 599
 Automated Self-Administered Recall System (ASA24), 253, 599
- ## B
- bariatric surgery, 504*t*
 diabetes remission and, 501*b*–502*b*
 basal metabolic rate (BMR), 262
 BCBP. *See* bias-corrected best power method
 behavior. *See also* cognitive behavioral therapy; theory of reasoned action/planned behavior
 eating, 339–340
 food attitudes and, 173
 nutrition monitoring and assessment of, 162*t*–165*t*, 172–173
 youth, risky, 173
 behavioral processes, 414
 Behavioral Risk Factor Surveillance System (BRFSS), 155, 162*t*, 172–173, 176*b*
 behavior change theory
 key constructs, 407*t*
 using, 408–415
 behavior change theory-based research, 405

- choosing theory for, 407–408
 - guidelines for applying, 406–408
 - importance of, 406
 - Belmont Report, 37
 - benefits
 - discounting, 373–374
 - types of, 372
 - benefit stream, 366
 - Berkson bias, 110, 117
 - beta carotene, 109, 354*t*, 385*t*
 - betaine, 386*t*
 - Bethesda Statement on Open Access Publishing, 517
 - bias
 - in analytic nutrition epidemiology, 110–111
 - Berkson, 110, 117
 - in clinical nutrition studies, 147
 - in data analysis, 111
 - incidence-prevalence, 110
 - information, 110
 - measurement, 44
 - Neyman, 173
 - noncoverage, 43
 - nondifferential, 110
 - nonresponse, 43–44
 - other sources of, 44–45
 - recall, 390
 - sampling, 43, 178–179
 - selection, 21, 357, 390
 - treatment, 44
 - unintentional, 111
 - volunteers', 110
 - bias-corrected best power method (BCBP), 304, 308
 - big data, visualizing, 554–555
 - binary variables, 482
 - strength of association, 499
 - binge eating, 61*t*
 - biological measures, in nutrition assessment, 313–314
 - biological plausibility, 106
 - biological variability, QA and, 326
 - biomarkers, 3, 251, 258
 - alcohol and, 313
 - of appetite, 339
 - blood, 260, 314*b*, 316*t*
 - calibration of self-reported intake with, 320–322
 - defining, 311–312
 - dietary intake method validation with, 259–261
 - in dietary supplement research, 437, 438*t*, 439
 - of energy, 318–320
 - general considerations in using, 325–326
 - as general dietary indicators, 315–318, 315*t*
 - long-term, 314*b*
 - for macronutrient assessment, 315*t*
 - medium-term, 314*b*
 - metabolomics and, 322–323
 - microbiome and, 312
 - in nutrition assessment, 313–314
 - of nutrition for development, 323
 - of plant-based diets, 317*t*
 - plasma, 314*b*
 - of polyphenol intakes, 318
 - for protein, sodium, potassium and sugars intake, 320
 - quality assurance and, 326
 - recovery, 262
 - sample collection considerations, 323–325
 - short-term, 314*b*
 - smoking and, 313
 - urine, 261, 314*b*
 - Biomarkers of Nutrition for Development (BOND), 323
 - biospecimen data collection, 598–599
 - bladder cancer, 27
 - blinding, 111, 133
 - Block Questionnaires, 256
 - block substitutions, 383
 - blood biomarkers, 260, 314*b*
 - for nutrition assessment or dietary intake monitoring, 316*t*
 - blood collection, 314
 - practical considerations in, 323–324
 - blood pressure, 108, 115, 122, 140
 - obesity and, 112
 - salt intake and, 106, 114
 - BLS. *See* Bureau of Labor Statistics
 - BMI. *See* body mass index
 - BMR. *See* basal metabolic rate
 - body mass index (BMI), 61*t*, 492, 494*t*
 - BOND. *See* Biomarkers of Nutrition for Development
 - bone density testing, 520*f*
 - bone metabolism, 581
 - bone mineral managers, 581
 - Botanical Dietary Supplements Research Centers, 429
 - Bradford Hill criteria, 105–106, 105*b*
 - Branded Foods Products Database, 171, 274, 275*f*
 - BRCA1*. *See* breast cancer gene 1
 - BRCA2*. *See* breast cancer gene 2
 - breast cancer
 - alcohol-related, 24
 - diet and, 16
 - dietary fat and, 251, 258
 - osteoporosis and, 520*f*
 - progesterin hormone therapy and, 3
 - vitamin D and, 513
 - breast cancer gene 1 (*BRCA1*), 383
 - breast cancer gene 2 (*BRCA2*), 383
 - breastfeeding, 168, 297
 - BRFSS. *See* Behavioral Risk Factor Surveillance System
 - brief assessment tools, 258
 - British Medical Journal*, 564
 - Budapest Open Access initiative, 517
 - budgets
 - for clinical nutrition research, 139
 - in research strategy, 65–66, 66*b*
 - Bureau of Labor Statistics (BLS), 160*t*
 - Burnaby, British Columbia, 430*t*
- ## C
- cadmium, 385*t*
 - caffeine, 388*t*
 - genome studies and, 389*t*
 - calcium, 299*t*, 303*t*, 385*t*, 438*t*
 - estimating body, 313
 - foods rich in, 12
 - serum, 581
 - calibration equations, 321
 - calibration of self-reported intake, with
 - biomarkers, 320–322
 - Campbell Collaboration, 213*b*
 - cancer. *See also* National Cancer Institute
 - bladder, 27
 - breast, 3, 16, 24, 251, 258, 513, 520*f*
 - colon, 76*b*, 251
 - lung, 109
 - CAPI. *See* computer-assisted personal or telephone interviews

- carbon-13 (¹³C), 314
- CARDIA. *See* Coronary Artery Risk Development in Young Adults
- cardiovascular disease, 112, 582
- carotenoids, 276, 298, 316*t*, 438*t*
 - plasma levels of, 315
 - smoking and, 112
- carryover effect, 335, 336*b*
- case-comparison studies. *See* case-control studies
- case-control studies, 104
 - advantages and disadvantages of, 116
 - alternative designs, 117–118
 - analytic considerations in, 118
 - case selection, 26
 - control selection, 26–27
 - examining associations with, 116–118
 - exposure assessment, 27
 - features of, 25
 - finding types in, 118
 - of gene-diet interactions, 390
 - implementation issues, 116–117
 - nested, 390
 - sample size, 475–476
 - statistical analysis and interpretation, 27–28
 - uses of, 25
- case-referent studies. *See* case-control studies
- case reports, 81
- case series, 12–13, 81
- case studies, 90*b*, 461*b*, 597*b*
- Catalogue of Surveillance Systems, 81, 157, 176*b*
- CATCH. *See* Child and Adolescent Trial for Cardiovascular Health
- category scales, 338, 338*f*
- CATI. *See* computer-assisted personal or telephone interviews
- causation
 - criteria for, 105–107, 105*b*
 - defining, 105
 - establishing, 105–107
 - etiologic study designs for examining, 118–121
 - study designs for, 107
- CB. *See* US Census Bureau
- CBA. *See* cost-benefit analysis
- CBPR. *See* community-based participatory research
- CCK. *See* cholecystokinin
- CDC. *See* Centers for Disease Control and Prevention
- CEA. *See* cost-effectiveness analysis
- cell separation tubes, 314
- Center for Food Safety and Applied Nutrition, 176*b*
- Center for Nutrition Policy and Promotion, 176*b*
- Centers for Advancing Research on Botanical and Other Natural Products Program, 429, 430*t*
- Centers for Disease Control and Prevention (CDC), 38, 158*t*, 176*b*
 - Community Guide, 213*b*
 - economic analysis and, 376
 - food environment studies by, 174
 - Growth Standards, 157
 - laboratory quality assurance and standardization programs, 431
 - nutrition surveillance programs, 167, 168*b*
 - vital statistics reporting by, 82
- Centers on Advancing Natural Product Innovation and Technology, 429
- Centre for Reviews and Dissemination (CRD), 213*b*
- CGMPs. *See* Current Good Manufacturing Practices
- chance observations, 46
- checklists
 - author, 522
 - Critical Appraisal Skills Programme, 565
 - Quality Criteria Checklist, 197, 199, 200*f*–203*f*, 579
 - Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), 522
- Child and Adolescent Trial for Cardiovascular Health (CATCH), 120
- Child Growth Standards, 168*b*
- cholecystokinin (CCK), 333, 340
- choline, 276, 276*t*
- chromosomes, 381
- Chronic Kidney Disease-Mineral and Bone Disorder Clinical Practice Guidelines, 581
- CITI. *See* Collaborative Institutional Training Initiative Program
- citrate, 388*t*
- Classification of Laws Associated with School Students (CLASS), 166*t*
 - data set, 174
- ClinCalc, 478*b*
- Clinical and Laboratory Standards Institute, 431
- Clinical and Translational Science Awards (CTSA), 139
- Clinical Nutrition Management dietetic practice group, 583
- clinical nutrition managers (CNMs), 583
- clinical nutrition research, 126
 - bias in, 147
 - budgets for, 139
 - data analysis for, 148–149
 - data management in, 147–148
 - defining, 127
 - economic analysis and, 376
 - free-living, 135, 138
 - identifying needs for, 127–129
 - incentives in, 143
 - objectives of, 129, 130*f*
 - parallel randomized controlled trials for, 131–132, 131*f*
 - participant monitoring, 143–144
 - participant population selection for, 139–140
 - participant randomization, 142–143
 - participant recruitment, 141
 - participant retention and adherence, 144–145
 - participant screening, 141–142
 - potential problems, 147
 - quality improvement and, 147–148, 149*f*
 - Randomized controlled trials for, 131
 - resources for, 128*b*, 138–139
 - sample size, 140–141
 - study design for, 131–135, 138
 - study hypotheses and objectives, 129, 130*f*
 - study participants in, 139–145
 - survey methods in, 231
 - training for, 148
 - translation of results, 150
 - varying control in, 137*f*
- clinical practice guidelines, 207
- Clinical Practice Guidelines We Can Trust*, 214*b*
- clinical significance, 477
- Clinical Trial Planning Grant, 56*t*
- clinicaltrials.gov, 515
- closed-circuit calorimetry, 319
- closed-ended questions, 242, 243*b*
- cluster randomization, 133–134, 134*f*
 - for community-based research, 600, 602
- cluster sampling, 308
 - defining, 237*b*

- CNMs. *See* clinical nutrition managers
- Cochrane Collaboration, 565
- Cochrane Handbook, 199
- Cochrane Handbook for Systematic Reviews of Interventions*, 213*b*
- Cochrane Library, 565
- Code of Ethics, 35
- CODEX, 282, 284
- Codex Alimentarius, 272
- coding
 - of food names and descriptions, 282
 - for qualitative data analysis, 94–95
- cognitive behavioral therapy, 411
- cognitive factors, in appetite research, 337
- cognitive response tasks, 92
- cohort studies, 22–25, 104
 - advantages and disadvantages of, 114–115
 - examining associations with, 114–116
 - exposure status assessment, 24
 - features of, 24
 - finding types in, 115–116
 - of gene-diet interactions, 390
 - implementation issues, 115
 - outcome assessment, 24–25
 - participant selection for, 24
 - sample size, 476–477
 - statistical analysis and interpretation of, 25
 - use of, 22–23
- colinearity, defining, 232*b*
- Collaboration and Team Science: A Field Guide* (NIH), 221–222
- Collaborative Institutional Training Initiative (CITI) Program, 38*t*
- colon cancer
 - cumulative incidence, 76*b*
 - meat consumption and, 251
- Commission on Dietetic Registration
 - Code of Ethics, 35
 - Compensation and Benefits Survey for the Dietetics Profession, 369
- Committee on Diet and Health, 107
- Common Rule, 37, 41
- communication
 - between author and editor, 561*b*
 - through community presentations, 536–537
 - copyright control over, 562
 - ethics in, 47
 - graphs enhancing, 548
 - guidelines for, 48*b*
 - in multicenter research, 121
 - in multidisciplinary research, 223–224
 - of study findings, 150
- community-based participatory research (CBPR), 599
- community-based research, 592
 - adherence in, 602–603
 - cluster randomization for, 600, 602
 - community partner involvement in, 599–600, 602–603
 - qualitative aspects of, 596–597
 - quantitative aspects of, 597–599
 - recruitment in, 600
 - research design for, 593–594, 595*f*, 596, 602*f*
 - study results and community focus, 603
- community controls, 117
- community intervention impacts, 598
- community presentations, 536–537
- community trials, 594
- companion calibration studies, 109
- comparability, dietary, 259
- comparative studies, 461*b*
- Compensation and Benefits Survey for the Dietetics Profession, 369
- complex situations, sample size, 477
- compliance
 - efficacy and, 44
 - to study protocols, 17, 21
- Computer Access to Research on Dietary Supplements database, 425
- computer-assisted personal or telephone interviews (CAPI/CATI), 241
- computer graphics software, 546, 548
- conclusions
 - false-negative, 471
 - false-positive, 471
 - from statistical results, 469–470, 469*t*
- conclusion statements
 - Academy of Nutrition and Dietetics Evidence Analysis Library, 208
 - evidence-based dietetics practice, 206*f*, 207*f*
- confidence interval, 496–497
- confidentiality, 41–42
- confirmability, 97
- conflicts of interest, 49
- confounding, in analytic nutrition epidemiology studies, 111–112
- confounding variables
 - defining, 232*b*
 - unmeasured, 22
- Consolidated Standards of Reporting Trials (CONSORT), 46, 135, 136*f*, 214*b*, 522
- constraints
 - knowledge, 586
 - time, 587
- constructive criticism, 561
- constructs
 - in behavior change theory, 407*t*
 - examining relationships between, 408
 - of health belief model, 408–409
 - of social cognitive theory, 410–412
 - theoretical, 60, 62
 - theories and, 406
 - theory of reasoned action/planned behavior, 410
 - of transtheoretical model, 412–415, 416*b*
 - variables reflecting, 407
- Consumer Expenditure Survey, 160*t*, 167
- contemplation stage, 415
- content analysis, 94
- Continuing Survey of Food Intakes by Individuals (CSFII), 81, 169
- continuous data
 - associations in, 502
 - paired, 471–472
 - summary statistics describing, 492–493
- continuous variables, 482–483, 482*f*
- control conditions, 335, 336*b*
- controlled feeding studies, human, 320
- copper, 385*t*
- copy number variants, 383
- copyright, 562
- Coronary Artery Risk Development in Young Adults (CARDIA), 104, 112, 255
- coronary heart disease, 260
- correlation analysis, 408, 502–503, 505*f*, 506*b*
- correlation studies, 461*b*

- cost analysis, 368, 369
 applying, 371
 cost-benefit analysis (CBA), 364, 364*t*, 365
 applications of, 373
 sensitivity analysis and, 375
 cost-decision analysis, 364*t*
 cost-effectiveness analysis (CEA), 352, 362*b*, 363, 364, 364*t*
 applications of, 373
 of medical nutrition therapy 361
 outcomes, 371–372
 sensitivity analysis and, 375
 cost minimization analysis, 364*t*
 cost outcomes, 354–355
 costs
 assigning monetary value, 369–370
 discounting, 373–374
 gross, 369
 macrocosting, 369
 microcosting, 369
 opportunity, 361
 relating to outcomes, 374–375
 special considerations for, 370–371
 summarizing and reporting, 370
 types of, 368, 368*b*
 cost stream, 366
 cost-utility analysis, 364, 364*t*
 Council on Research, 211*b*, 574
 courtroom analogy, 486, 487*b*
 CPS. *See* Current Population Survey
 CRD. *See* Centre for Reviews and Dissemination
 C-reactive protein (CRP), 140, 354*t*
 credibility, 97
 criminal trials, hypothesis testing and, 487*b*
 Critical Appraisal Skills Programme checklists, 565
 critically ill children, 581
 crossover study design, 131–132, 132*f*, 336*b*
 cross-sectional studies, 13–14, 81, 104
 examining associations with, 113
 of gene-diet interactions, 390
 surveys, proportions, and continuous variables, 473–474
 CRP. *See* C-reactive protein
 CSFII. *See* Continuing Survey of Food Intakes by Individuals
 CTSA. *See* Clinical and Translational Science Awards
 cumulative incidence, 75–76, 76*b*
Cumulative Index to Nursing and Allied Health Literature, 525
 Current Good Manufacturing Practices (CGMPs), 423
 Current Population Survey (CPS), 160*t*, 166
 curve difference graphs, 553*f*
 cut-point approach to nutrient inadequacy
 estimation, 305–306
 CYP1A2 gene, 393
 cytochrome P450 1A2, 391*t*
- D**
- daidzein, 318
 DASH. *See* Dietary Approaches to Stop Hypertension
 data
 big, 554–555
 continuous, 471–472, 492–493, 502
 discrete, 492, 499
 extracting, 197, 199
 food environment and policy, 164*t*–167*t*, 174
 for nutrition monitoring, 156
 paired continuous, 471–472
 surveillance, 178–179
 data aggregation, 281
 data analysis
 bias in, 111
 in clinical nutrition research, 148–149
 coding for, 94–95
 data display for, 95–96
 for nutrition survey and surveillance data, 178
 qualitative, 93–96
 in research proposals, 61–62
 secondary, 177–180
 in survey research, 246–247
 weighted, 179
 databases. *See* food composition databases; specific databases
 data cleaning, 236, 236*b*
 data collection
 in case series, 12–13
 in community-based research, 598–599
 for foodservice management research, 447–448, 448*b*
 for nutrition and dietetics education research, 457–461
 for qualitative research, 88–93
 for randomized controlled trials, 20
 in research proposals, 61
 scale of measurement and, 481–482
 with surveys, 15–16
 in survey studies, 238–242
 data collection tools, evaluation measures, 61*t*
 data compilations, 279–281
 data compilers, 279–281
 data display, for qualitative data analysis, 95–96
 data distortion, 45–46
 data dredging, 45
 Data Extraction Tool (DET), 197, 199*f*
 DataFerrett, 176*b*, 178
 data interpretation, statistics in, 46–47
 data management, in clinical nutrition research, 147–148
 data quality, nutrition survey and surveillance data and, 179–180
 data sets
 confidentiality and, 41
 federal information sources on, 176*b*
 linking, 41
 data visualization techniques, 554–555
 decisional balance, 412, 414
 Declaration of Helsinki, 5, 36
 Dedoose, 95*b*
 degeneracy, 381
 Delphi process, 93, 449–450
 Delphi research design, 449*t*
 delta-6 desaturase activity, 387*t*
 demographic measurements, 81–82
 Department of Health and Human Services (HHS), 158*t*, 169, 230, 231, 289, 425
 Department of Housing and Urban Development, 166
 dependability, 97
 dependent samples, study design and statistical analysis, 483
 descriptive epidemiologic studies, 103
 terminology for, 75
 descriptive research designs, 11–16, 79–82
 for foodservice management, 449
 for nutrition and dietetics education research, 457
 descriptive studies, 74

- design effects, nutrition survey and surveillance data and, 179
- DET. *See* Data Extraction Tool
- Developing NICE Guidelines: the Manual*, 214*b*
- development
- biomarkers of nutrition for, 323
 - career, 572, 573*b*
 - of posters, 527, 529, 530*b*
- DEXA, 61*t*
- DFE. *See* dietary folate equivalent
- DGA. *See* Dietary Guidelines for Americans
- DGAC. *See* Dietary Guidelines Advisory Committee
- diabetes, 575, 578
- bariatric surgery and remission in, 501*b*–502*b*
 - GRS and, 393
 - prediabetes, 27, 577
 - type 2, 3, 140, 389, 393
- Diabetes Care*, 517*t*
- didactic programs in dietetics (DPDs), 397
- diet
- as exposure, 108
 - gene interactions with, 389–390, 391*t*–392*t*
 - genetic determinants of exposure and response to, 384, 385*t*–389*t*, 389
- Dietary Approaches to Stop Hypertension (DASH), 108, 258
- dietary assessment, 250, 380
- biomarkers and validating, 259–261
 - potential errors in methods of, 258–259
- Dietary Assessment Primer, 5, 255
- dietary comparability, 259
- dietary fiber, 109
- dietary folate equivalent (DFE), 298
- Dietary Guidelines Advisory Committee (DGAC), 234
- Dietary Guidelines for Americans (DGA), 6, 9, 145, 155*b*, 234, 279, 284
- Dietary Guidelines for Americans Advisory Committee, 6
- dietary indicators, biomarkers as, 315–318, 315*t*
- dietary inflammatory index (DII), 27
- dietary intake, 299–300
- assessing in individuals, 300–303
 - assessing in populations, 303–308
 - biomarkers and validating, 259–261
 - blood biomarkers for monitoring, 316*t*
 - calculating prevalence of adequacy/inadequacy, 304–305
 - community assessment of, 598–599
 - dietary supplement research and, 433
 - estimating distributions of, 303–304, 304*f*
 - probability approach to estimating, 305, 306
 - special populations and, 263
 - underreporting, 261–262
- dietary quality indexes, 231
- Dietary Reference Intakes (DRIs), 126, 171, 280, 294
- definitions for, 295*b*
 - dietary supplement labeling and, 423
 - establishing, 295–296
 - Estimated Average Requirement and, 296
 - framework of, 296–300
 - individual diet assessment using, 302–303
 - special considerations in, 297–299, 299*t*
 - validity and reproducibility of, 259
- Dietary Reference Values, dietary supplement labeling and, 423
- Dietary Screener Questionnaire, 166
- Dietary Supplement Health and Education Act of 1994, 422
- Dietary Supplement Ingredient Database (DSID), 162*t*, 171, 171*b*, 172
- dietary supplements. *See also* specific supplements
- administration of, 436
 - botanical centers of excellence and, 429
 - context of research in dietetics practice on, 428–429
 - databases for, 277
 - defining, 422, 423
 - documentation of use, 440–441
 - dosage determination for research on, 432
 - labels for, 298–299, 423–424, 424*t*
 - outcomes in research on, 437–439
 - product integrity resources for, 431
 - randomized controlled trials for, 427–428
 - research approaches for, 426–429, 426*f*
 - research design for, 432–439
 - research funding and priorities, 425–426
 - research methodology, 431–432
 - research programs for, 429, 430*b*
 - selection of, for studies, 435–436
 - training opportunities for, 441–442
 - use of, 424–425
- dietary validity, 259
- diet assessment and selection, in gene-diet interaction studies, 393
- Diet Assessment Primer Roadmap, 251, 252*f*
- dietetic practice groups (DPGs), 523
- Dietetics Outcome Registry, 575
- Dietetics Practice Based Research Network (DPBRN), 128*b*
- diet histories, 251, 255
- Diet History Questionnaire, 256
- Dieticians in Nutrition Support and Dietetic Practice Group, 525
- diet-quality indexes, 23
- diet-related inflammation, 27
- diet soda, 115
- digital animation, 539
- dihomo-gamma-linolenic acid, 387*t*
- DII. *See* dietary inflammatory index
- direct benefits, 372
- direct-to-consumer genetic testing, 394, 397
- discounting, of costs and benefits, 373–374
- discrete data, 492, 499
- discrete variables, 482–483, 482*f*
- disease frequency, 75–79
- distribution maps, 542, 552, 554*f*
- dithiocarbamates, 318
- Division of Cancer Prevention, 525
- DLW. *See* doubly labeled water
- DNA, 381, 382*f*
- mutations in, 383
- docosapentaenoic acid, 387*t*
- documentation
- of dietary supplement use, 440–441
 - for evidence-based dietetic practice reviews, 197
 - of effectiveness, research for, 581–582
- dose-response relationships, 106
- doubly labeled water (DLW), 260, 262, 319, 321
- DPBRN. *See* Dietetics Practice Based Research Network
- DPDs. *See* didactic programs in dietetics
- DPGs. *See* dietetic practice groups
- DRIs. *See* Dietary Reference Intakes
- drug development process, 427
- Drug Pricing Lab, 363
- DSID. *See* Dietary Supplement Ingredient Database

E

- EAL. *See* Evidence Analysis Library
- EAR. *See* Estimated Average Requirement
- Early Childhood Longitudinal Study, 167
- Eating and Activity in Teens (EAT), 63*f*
- eating behavior, 339–340
- EBDP. *See* evidence-based dietetics practice
- EBP. *See* evidence-based practice
- ecological frameworks, in nutrition research planning, 232, 233*b*, 234
- ecological research, 358
- ecological studies, 79–81
- economic analysis. *See also* cost-benefit analysis; cost-effectiveness analysis
- analytic frameworks for, 366, 368
 - analytic methods used in, 364–366, 364*t*
 - assigning monetary value in, 369–370
 - in clinical nutrition, 376
 - cost analysis for, 369
 - costs used in, 368*b*
 - cost types for, 368, 368*b*
 - ethics and, 375
 - frameworks for, 366, 368
 - interpreting and using results from, 375–376
 - in nutrition, 361, 363
 - objectives of, 366, 368
 - outcome determination, 371–374
 - of outcomes, 371–374
 - perspectives for, 367*b*
 - public health and, 376
 - steps of, 366, 368–376
 - study designs for, 372
- Economic Research Service (ERS), 167, 176*b*, 425
- editors, 212*b*
- EER. *See* Estimated Energy Requirement
- effectiveness studies, 357*b*
- effect modification, 112
- effect size, 407–408, 408*b*, 470
- efficacy, compliance and, 44
- efficacy studies, 357*b*
- EI. *See* energy intake
- eicosapentaenoic acid, 387*t*
- electronic health records, 584
- electronic presentations, of research, 537–539
- eligibility criteria, for evidence-based dietetic practice reviews, 196
- Elsevier, 518
- employee training, incentive program impacts on, 21
- end-stage renal disease (ESRD), 115
- energy
- biomarkers of, 318–320
 - EER, 297, 302, 307
 - estimating requirements, 146
 - measuring expenditure, 319
 - REE, 318–319
- energy intake (EI), 262, 263
- aberrant, 331
 - appetite and, 339
 - assessing, 307
 - evaluating, 302
- environmental context
- appetite research and, 333–334
 - food environment studies, 164*t*–167*t*, 174
- environmental exposures, 380
- somatic mutations from, 383
- environmental interventions, 411
- EPIC. *See* European Prospective Study of Diet and Cancer epidemiology. *See also* analytic nutrition epidemiology
- defining, 74
 - descriptive studies, 75, 103
 - genetic studies in, 384, 390
 - nutrition, 102
 - Reporting of Observational Studies in Epidemiology checklist for reporting, 522
- Epi Tools, 478*b*
- equipoise, 45
- errors
- α error, 469–471
 - β error, 470
 - in dietary assessment methods, 258–259
 - human, 35–36
 - hypothesis testing and, 486
 - measurement, 44, 106, 110, 261–262
 - noncoverage, 43
 - nonresponse, 43–44
 - other sources of, 44–45
 - random, 147, 321*b*
 - research, 35–36
 - sampling, 43
 - standard, 495–496, 496*f*
 - systematic, 321*b*
 - type I error, 394, 469–470, 486
 - type II error, 470, 486
- ERS. *See* Economic Research Service
- erythritol, 388*t*
- erythrocyte transaminase, 312
- ESRD. *See* end-stage renal disease
- Estimated Average Requirement (EAR), 296, 300–302
- Estimated Energy Requirement (EER), 297, 302, 307
- ethical research, 5
- ethics
- analysis plans and, 46
 - authorship and, 48–49
 - in communication, 47
 - defining, 34–35
 - in designing, conducting, and analyzing research, 42–45
 - economic analysis and, 375
 - equipoise and, 45
 - in presentation and interpretation of research, 45–47
 - in publication, 47
 - research in climate of, 49–50
 - in research involving humans, 36–42
- ethnography, 90*b*, 597*b*
- etiologic fraction, 104, 104*b*
- etiologic study designs, 118–121
- European Prospective Study of Diet and Cancer (EPIC), 260, 278
- Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease* (Institute of Medicine), 353
- evidence
- level of, 439
 - research progression towards, 427–428, 428*f*
 - summarizing, 199, 204, 205*t*, 206*f*
- Evidence Analysis Library (EAL), 128, 146, 193, 566, 573
- conclusion statements, 208
 - cost-effectiveness review by, 361, 362*b*–363*b*, 363
 - dissemination, 210
- Evidence Analysis Project Managers, 211*b*
- evidence analysis question, 194–196
- Evidence Analysis Work Groups, 211*b*
- evidence analysts, 212*b*

- evidence-based dietetics practice (EBDP)
 conclusion statement for, 206*f*, 207*f*
 conducting systematic reviews for, 193–199, 204, 207–208, 210
 evidence analysis question for, 194–196
 extracting data and critically appraising articles for, 197, 199
 gathering research for, 196–197
 grading evidence for, 204, 207
 study designs for, 203*t*–204*t*
 summarizing evidence, 199, 204, 205*t*, 206*f*
- evidence-based practice (EBP), 192, 576
 dissemination of results, 208, 210
 future research, 212–213
 guidelines for, 207–208
 practice question in, 584
 reasons for using, 193
 research cycle of, 351, 351*f*
 resources for systematic reviews and guideline development, 213, 213*b*–214*b*
 strengths and limitations of guidelines and reviews, 210, 212
- evidence mapping, 196
- exons, 381
- experiential processes, 414
- experimental design, 9, 16–21, 594, 595*f*
 for nutrition and dietetics education research, 457, 458*b*
- experimental study, 458*b*
- explanatory research, 461*b*
- Exploratory/Developmental Research Grant Award, 56*t*
- exposure
 assessing, in cohort, 24
 diet or nutrient as, 108
 genetics and diet, 384, 385*t*–389*t*, 389
 measurement of, 110
- exposure variables, 108–110
- external validity, 119, 357*b*
 in appetite assessment, 334, 334*b*
 in outcomes research, 355–357
- extracting data, 197, 199
- extreme case sampling, 91*b*
- F**
- FAB. *See* Food Attitudes and Behaviors Survey
- Facebook, 539
- factorial design, 21, 22, 132–133, 133*f*
- false-negative conclusion, 471
- false-positive conclusion, 471
- FAO. *See* Food and Agriculture Organization
- Farrell, Margaret, 539
- fatty acids, 387*t*
 blood concentration of, 316*t*
 food levels of, 318
 membrane phospholipids and, 317
trans, 118
- FDA. *See* Food and Drug Administration
- fecal collection, 325
- Federal Interagency Working Group for Food Security Measurement, 166
- Feed Early Enteral Diet Adequately for Maximum Effect protocol (FEED ME), 584
- fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPS), 19
- ferretin, 316*t*, 385*t*
- FFQs. *See* food frequency questionnaires
- Fiese, Barbara, 224
- figures, in research reports, 521–522, 523*f*
- Finding What Works in Health Care: Standards for Systematic Reviews*, 213*b*
- fisheries, 164*t*
- Fisheries of the United States survey, 173
- flavonoids, 276, 276*t*
- flowcharts, 542, 554*f*
- fluoride, 276, 276*t*
- fMRI. *See* functional magnetic resonance imaging
- FNDDS. *See* Food and Nutrient Database for Dietary Studies
- FNS. *See* Food and Nutrition Service
- focus groups, 11
 for foodservice management research, 450
 research design, 449*t*
- FODMAPS. *See* fermentable oligosaccharides, disaccharides, monosaccharides, and polyols
- folate, 108, 299*t*
 blood concentration, 316*t*
 quantification of, 314
- folate/folic acid, 299*t*, 303*t*, 438*t*
- folic acid, 107, 170*b*
- follow-up, 413*b*
- follow-up studies, 22–25
- Food4Me, 394
- food analysis, 278–279
- Food and Agriculture Organization (FAO), 80
 Codex Alimentarius, 272
- Food and Agriculture Organization/International Network of Food Data Systems (INFOODS), 273, 274, 289
- Food and Drug Administration (FDA), 56, 107, 170*b*
 Center for Food Safety and Applied Nutrition, 176*b*
 Current Good Manufacturing Practices and, 423
 nutrition monitoring by, 173
 Safety Reporting Portal, 432
 surrogate outcomes and, 353
 Total Diet Study, 170, 172, 273
- Food and Nutrient Database for Dietary Studies (FNDDS), 162*t*, 171, 171*b*, 172, 272, 274, 276
- Food and Nutrition Board, 126, 295
- Food and Nutrition Service (FNS), 160*t*, 176*b*
- Food Attitudes and Behaviors Survey (FAB), 173
- Food Availability Data System, 164*t*, 173
- Food Balance Sheets, 80
- food component variability, 286–287
- Food Composition and Methods Development Laboratory, 147
- food composition databases, 147, 258, 271, 298
 basis of data in, 284–285
 dietary supplement databases, 277
 features of, 281–285
 food component variability and, 286–287
 food groupings, 284
 food names and descriptions in, 282–284, 283*b*
 implications for RDNs, 287–288
 major US databases, 273–274
 missing values in, 285
 outlook for, 288–289
 special interest databases, 272, 274, 276–277, 276*t*
 users and uses of, 278
- food contaminant databases, 277–278
- Food Data System (FoodS), 272
- food environment studies, 164*t*–167*t*, 174
- food frequency questionnaires (FFQs), 23, 27, 109, 251, 255
 dietary validity and, 259

- item selection for, 256
- semiquantitative vs quantitative, 256
- food groupings, 284
- food-handling practices, 513
- food intake, appetite and, 339
- Food Label and Package Survey, 162*t*, 172
- food names and descriptions, 282–284
- food name synonyms, 283*b*
- Food Patterns Equivalents Database (FPED), 162*t*, 171, 171*b*, 172, 284
- food propensity questionnaire (FPQ), 258
- food records or diaries, 251, 254–255
- FoodDS. *See* Food Data System
- food safety, 446, 452*f*, 513–514
- Food Safety and Inspection Service, 280
- Food Safety Survey, 162*f*, 173
- foodservice management research, 445
 - areas of, 446, 447*f*
 - data collection for, 447–448, 448*b*
 - historical development of, 446
 - research design for, 449–451, 449*t*
 - research techniques in, 446–451
- Food Stamp program. *See* Supplemental Nutrition Assistance Program (SNAP)
- Food Surveys Research Group (FSRG), 171, 172, 176*b*
- foundations, funding from, 55–56
- FPED. *See* Food Patterns Equivalents Database
- FPQ. *See* food propensity questionnaire
- Framingham Nutrition Studies, 234
- fraud, 35–36
 - selective reporting, 46
- Fred Hutchinson Cancer Research Center
 - Questionnaire, 256
- free-living clinical nutrition studies, 135, 138
- freezers, for sample storage, 325–326
- FSRG. *See* Food Surveys Research Group
- functional foods, 4
- functional magnetic resonance imaging (fMRI), 341
- funding
 - identifying sources of, 55–56
 - obtaining, 53
 - online resources for, 69–70

G

- G6PD. *See* glucose-6-phosphate dehydrogenase
- gamma-linolenic acid, 387*t*
- gas analysis, 319
- gas chromatography (GC), 322
- gas chromatography-mass spectrometry (GC-MS), 314
- gastric emptying rate, 342
- GC. *See* gas chromatography
- GC-MS. *See* gas chromatography-mass spectrometry
- gel electrophoresis, 552
- gene-diet interactions
 - diet assessment and selection and, 393
 - personalized nutrition and, 394, 397
 - selection of genes to study for, 393–394
 - study design and, 389, 390–394
- genes, 381, 382*f*
 - diet interactions with, 389–390, 391*t*–392*t*
- genetic code, 381
- genetic risk score (GRS), 393
- genetic testing services, 394, 397
- genetic variation, 383–384
- genistein, 318
- genome, 381

- genome-wide association studies (GWASs), 384, 385*t*, 385*t*–389*t*
- germ-line mutations, 383
- Germplasm Resource Information Network (GRIN), 282
- ghrelin, 340
- GLIMPSE, 478*b*
- global food trends, 452*f*
- glomerular filtration rate, 115
- glucagon-like-peptide-1 (GLP-1), 340
- glucose, appetite and, 339–340
- glucose-6-phosphate dehydrogenase (G6PD), 391*t*
- glucose intolerance, 115
- glucosinolates, 276*t*
- glutamine, 386*t*
- gluten intolerance, 115
- glycine, 386*t*
- Goldberg cutoff, 262
- Gold open access, 518
- Government Accountability Office, 397
- governments, funding from, 56
- G*Power, 478*b*
- GRADE. *See* Grading of Recommendations, Assessment, Development and Evaluation
- GRADEpro, 214*b*
- Grading of Recommendations, Assessment, Development and Evaluation (GRADE), 208
- grant programs, 56, 56*t*
- grant proposals, 53
 - adhering to, 67
 - composing strong, 58–66
 - for evaluation New Moves, 61*t*
 - online resources for, 69–70
 - research strategy, 59–63
 - review process for, 56–58
 - revising unfunded, 67–68
 - specific aims in, 58–59
 - suggestions for writing, 68–69
 - typical budget, 66*b*
 - writing to advance science, 54
- graphical perception, 550–551, 551*b*
- graphs, 542
 - characteristics of, 548–549, 549*f*, 550*f*
 - computer software, 546, 548
 - consistency in, 550
 - curve difference graphs, 553*f*
 - in illustrations, 546–551
 - types of, 548, 552*f*
 - useful, 548
- GRIN. *See* Germplasm Resource Information Network
- gross costing, 369
- grounded theory, 90*b*, 597*b*
- group comparison, sample size, 472–474
- group interviews, 93
- group-randomized trials
 - advantages and disadvantages of, 119
 - examining causation with, 119–120
 - statistical issues in, 119–120
- GRS. *See* genetic risk score
- Guidelines for Checking Food Composition Data, 285
- Guidelines International Network: toward international standards for clinical practice guidelines, 214*b*
- gut distention, 342
- gut microbiota, 109, 312
 - fecal collection in studies of, 325
- gut motility, 342
- GWASs. *See* genome-wide association studies

H

- HACCP. *See* Hazard Analysis and Critical Control Point *Handbook for Guideline Development* (World Health Organization), 214b
- Harris-Benedict equation, 146
- Harvard Food Frequency Questionnaire, 256
- Harvard School of Public Health, 47
- Hawthorne effect, 111
- Hazard Analysis and Critical Control Point (HACCP), 446
- HBM. *See* health belief model
- HBSC. *See* Health Behavior in School Aged Children
- HDL-C. *See* high-density lipoprotein cholesterol
- Health and Diet Survey, 162t, 173
- health assessment methods, 599
- Health Behavior in School Aged Children (HBSC), 164t
- health belief model (HBM), 406, 407, 407t, 408–409
- Health Information Index, 176b
- Health Information National Trends Survey, 173
- Health Insurance Portability and Accountability Act (HIPAA), 41, 576–577
- Health Professions Education: A Bridge to Quality* (Institute of Medicine), 583
- Healthy Eating Index (HEI), 231, 258
- Healthy Eating Index-2015, 109
- Healthy People 2020, 9, 156b, 528
- HEI. *See* Healthy Eating Index
- heptadecanoic acid, 318
- Herb Research Foundation, 431b
- HHS. *See* Department of Health and Human Services
- high-density lipoprotein cholesterol (HDL-C), 353–354, 354f, 354t
- high-performance liquid chromatography (HPLC), 314, 318
- quality assurance and, 326
- HIPAA. *See* Health Insurance Portability and Accountability Act
- Hispanic Community Health Study/Study of Latinos, 320, 321
- histidine, 386t
- histograms, 490, 492f, 493f, 544f, 551
- Homescan, 164t
- homogenous sampling, 91b
- hormone therapy, 3
- HPLC. *See* high-performance liquid chromatography
- HuGENet™ Handbook of Systematic Reviews, 213b
- human error, 35–36
- human genetics, 381–383
- diet exposure and response and, 384, 385t–389t, 389
- Human Genome Project, 555
- Human Microbiome Project, 555
- Human Nutrition Research Information Management system, 425
- human subjects
- institutional review board role in protecting, 37–38
- training resources for protection of, 38t
- hunger, meal size and, 337
- hydrocinnamate, 388t
- hyperkalemia, 351
- HyperRESEARCH, 95b
- hypertension, 115, 140
- defining, 122
- hypoglycemia, 24
- hypothesis
- alternative, 469–470, 484–485
- defining, 10, 129, 130f
- examples for nutrition studies, 130f
- null, 469–470, 484–486
- primary, 129
- secondary, 129
- hypothesis testing
- assumption of normality, 487–488
- courtroom analogy, 486, 487b
- errors in, 486
- logic of, 486
- one-sided, 485–486
- statistical significance in, 497–498
- study design and statistical analysis, 484–486
- two-sided, 485–486
- I
- IBD. *See* inflammatory bowel disease
- Icahn School of Medicine, Mount Sinai, 430t
- IFPS. *See* Infant Feeding Practices Survey
- IJCME. *See* International Committee for Medical Journal Editors
- Illinois Transdisciplinary Obesity Program (I-TOPP), 224
- Illustrating Science: Standards for Publication*, 548, 550
- illustrations. *See also* research, illustrating results
- algorithms and flowcharts, 553–554
- distribution maps, 552
- graphs, 546–551
- histograms, 490, 492f, 493f, 544f, 551
- message conveyed through, 542–543
- photographs, 542, 552
- preparing for publication, 555–556
- purposes, 542
- tables, 543, 544f, 545–546, 545b
- visualizing big data, 554–555
- immunoassay, 318
- impact evaluation measures, 61t
- impact factor models, 598
- incentives
- in clinical nutrition studies, 143
- training impacts of, 21
- incidence
- calculating, 76b
- defining, 77b
- measurement of, 75–76
- incidence-prevalence bias, 110
- incidence rate, 75–76
- incidence ratio, 24
- inconsistent findings among nutrition studies, 121–122
- indels. *See* insertion-deletion variants
- independent groups
- with continuous data, 472–473
- proportions and sample size, 474
- three or more, 473
- independent samples, study design and statistical analysis, 483
- indirect benefits, 372
- indirect calorimetry, 318–319
- industry, funding from, 56
- Infant Feeding Practices Survey (IFPS), 164t
- inflammatory bowel disease (IBD), 12
- INFOODS. *See* International Network of Food Data Systems
- informatics, 361
- information bias, 110
- informed consent
- components of form for, 40b
- equipoise and, 45
- processes for, 38, 40–41

- in-house funds, 55
 - initial advisory meetings, 413*b*
 - insertion-deletion variants (indels), 383
 - Institute of Medicine
 - on clinical practice guidelines, 207
 - Food and Nutrition Board, 126, 295
 - Panel on Enhancing the Data Infrastructure in Support of Food and Nutrition Programs, Research, and Decision Making, 157
 - on patient-centered care, 583
 - surrogate outcomes report, 353
 - institutional funds, 55
 - institutional review board (IRB), 5, 36, 139, 577
 - application and approval process, 39*f*
 - information requested, 40*b*
 - role in protecting subjects, 37–38
 - insulin, appetite and, 341
 - insulin receptor substrate 1, 392*t*
 - insulin resistance, 3
 - insulin therapy, 24
 - intent-to-treat comparison, 21
 - Interagency Committee on Human Nutrition Research, 155
 - interdisciplinary research
 - challenges, 220–221
 - conducting, 221–225
 - defining, 219, 220*f*
 - INTERHEART study, 104
 - INTERMAP. *See* International Population Study on Macronutrients and Blood Pressure
 - internal validity, 357*b*
 - in appetite assessment, 334, 334*b*
 - in outcomes research, 355–357
 - International Association of Scientific, Technical, and Medical Publishers, 515
 - International Committee for Medical Journal Editors (IJCME), 48–49
 - public registry requirements, 129
 - International Committee of Medical Journal Editors, 560
 - International Food Information Council, 47, 431*b*
 - International Guidelines Library, 212, 214*b*
 - International Life Sciences Institute North America, Fortification Committee, 298
 - International Network of Food Data Systems (INFOODS), 273, 274, 289
 - International Nutrient Databank Directory* (NDBC Directory), 273
 - International Population Study on Macronutrients and Blood Pressure (INTERMAP), 114
 - International Scientific Institute (ISI), 516, 517*t*
 - International Study of Salt and Blood Pressure (INTERSALT), 113
 - interval measurement, 243
 - intervention development, 413*b*
 - interventions. *See also* nutritional intervention
 - community impacts of, 598
 - environmental, 411
 - flow from concept to evaluation of, 409*f*
 - lifestyle, 582
 - in randomized controlled trials, 18
 - in research proposals, 60–61
 - intervention studies, of gene-diet interactions, 392
 - interviews, 92
 - computer-assisted, 241
 - group, 93
 - for nutrition and dietetics education research, 459
 - structured, 11, 12
 - unstructured, 11
 - introns, 381
 - iodine deficiency, 279
 - iodized salt, 279
 - Iowa State University (ISU), 304, 308
 - IRB. *See* institutional review board
 - iron, 385*t*, 386*t*, 438*t*
 - irresponsible authorship, 562–563
 - irritable bowel syndrome, 19
 - ISI. *See* International Scientific Institute
 - isoflavones, 276, 276*t*, 318
 - isothiocyanates, 438*t*
 - ISU. *See* Iowa State University
 - I-TOPP. *See* Illinois Transdisciplinary Obesity Program
- ## J
- Joanna Briggs Institute, 213*b*
 - journal articles. *See also* research articles; research reports
 - abstracts, 519, 520*f*
 - for research dissemination, 515–519, 521–522
 - selecting journal, 515
 - Journal Citation Reports*, 516
 - Journal of Food Composition and Analysis*, 289
 - Journal of Foodservice Management and Education*, 560
 - Journal of Nutrition, The*, 516
 - Journal of Nutrition Education and Behavior*, 516
 - Journal of Parenteral and Enteral Nutrition*, 516, 517*t*
 - Journal of the Academy of Nutrition and Dietetics*, 210, 462, 516–517, 517*t*, 518, 560, 564, 565
 - Journal of the American Dietetic Association*, 446, 456
 - journals. *See also* specific journals
 - predatory, 561*b*
 - publication access, 517–518
 - selecting for research reports, 515–517
 - selection of, 517
 - writers choosing, 560, 561*b*
- ## K
- key messages, 514
 - Kidney Disease-Improving Global Outcomes, 581
 - kitchens, in foodservice, 452*f*
 - knowledge constraints, 586
 - knowledge dissemination, 513–514
 - Kouba, Joanne, 524
- ## L
- labor minutes per meal equivalent, 13
 - lactase, 391*t*
 - LanguaL, 282, 284
 - Latin square design, 335, 336*b*
 - LC. *See* liquid chromatography
 - LC-MS. *See* liquid chromatography-mass spectrometry
 - LD. *See* linkage disequilibrium
 - LD blocks, 383
 - LDL-C. *See* low-density lipoprotein cholesterol
 - lead, 388*t*
 - lead analysts, 211*b*
 - leadership tasks, 221
 - Learning Styles Inventory, 459
 - least publishable units (LPUs), 46, 47
 - leptin, 341
 - leucine, 386*t*

- leukocyte collection, 324
 - level of evidence, 439
 - level of statistical significance, 489
 - librarians, 212*b*
 - lifestyle interventions, 582
 - lignans, 317
 - Lind, James, 3
 - linear regression, 505, 506*b*, 507*b*
 - linkage disequilibrium (LD), 383
 - linolenic acid, 387*t*
 - lipidomics, 314
 - liquid chromatography (LC), 322
 - liquid chromatography-mass spectrometry (LC-MS), 314, 320
 - literature
 - critical evaluation of, 565
 - professional and research, 571–572, 572*b*, 579
 - reader's evaluation, 564–565
 - literature search, 584–585
 - for evidence-based dietetic practice reviews, 196
 - logic
 - of hypothesis testing, 486
 - of sample size calculations, 469–470
 - logistic regression methods, 499
 - long-term biomarkers, 314*b*
 - low-density lipoprotein cholesterol (LDL-C), 353–354, 354*f*, 354*t*
 - LPUs. *See* least publishable units
 - lung cancer, 109
 - lycopene, 388*t*
 - lysine, 386*t*, 387*t*
- ## M
- macrocosting, 369
 - macronutrient intake
 - assessing, 307, 315*t*
 - biomarkers for, 315*t*
 - magnesium, 299*t*, 301*f*, 386*t*, 438*t*
 - magnetic resonance imaging (MRI), 341, 342
 - mailed surveys, 241
 - Male Health Professionals Follow-Up Study, 256
 - manganese, 386*t*
 - mannose, 388*t*
 - manuscript body, research reports, 521
 - manuscript preparation, 559–560
 - manuscript submission, 561
 - mass spectrometry (MS), 314, 322. *See also* gas chromatography-mass spectrometry; liquid chromatography-mass spectrometry
 - matching samples, study design and statistical analysis, 483
 - mathematical modeling, 449*t*
 - for foodservice management research, 451
 - maximum variation sampling, 91*b*
 - MAXQDA, 95*b*
 - mean hemoglobin A1c, 503*b*, 504*t*
 - measurement errors, 44
 - in analytic nutrition epidemiology studies, 110
 - causation criteria and, 106
 - in dietary intake, 261–262
 - measurements
 - appetite research methodologies of, 337–342
 - of association, 104, 104*b*
 - bias from, 44
 - degrees of uncertainty, 495–496
 - demographic, 81–82
 - energy expenditure, 319
 - of incidence, 75–76
 - interval, 243
 - nutrition monitoring and, 157, 158*t*–159*t*, 166–169
 - of poor exposure, 110
 - of prevalence, 76–77
 - ratio, 243–244
 - replicating, 484, 485*f*
 - of respiratory gases, 319
 - satiation, 335–337
 - satiety, 337
 - scale of, 481–483, 482*f*
 - serial/repeat, 483–484, 485*f*
 - surveys and strategies for, 242–243
 - of vital statistics, 81–82
 - measures
 - of central location, 494
 - relative risk, 499
 - of variation, 494
 - Medicaid, 166, 373
 - medical nutrition therapy (MNT), 195
 - cost-effectiveness research on, 361
 - Medicare, 166, 373
 - Mediterranean-style diet (MedSD), 16, 108, 582
 - medium-term biomarkers, 314*b*
 - MEDLINE, 176*b*, 562
 - Medscape Drug Interaction Checker, 431*b*
 - MedSD. *See* Mediterranean-style diet
 - membrane phospholipids, fatty acid composition of, 317
 - Mental Measurement Yearbooks*, 459
 - MenuStat, 166*t*
 - MEQ. *See* mindful eating questionnaire
 - messages
 - illustrations conveying, 542–543
 - key, 514
 - messenger RNA (mRNA), 382
 - Meta-analysis of Observational Studies in Epidemiology (MOOSE), 46, 214*b*
 - metabolic phenotyping, 323
 - metabolic rate, basal, 262
 - metabolic studies, adherence in, 144–145
 - metabolic syndrome, 105, 115, 477
 - metabolism
 - bone, 581
 - oxidative, 318
 - metabolomics, 109, 312, 314
 - dietary biomarkers and, 322–323
 - Methodological standards for the conduct of new Cochrane Intervention Reviews, 213*b*
 - methylenetetrahydrofolate reductase (MTHFR), 391*t*
 - microbiome
 - biomarkers and, 312
 - fecal collection in studies of, 325
 - glucose intolerance and, 115
 - microcosting, 369
 - Mifflin-St Jeor equation, 146
 - mindful eating questionnaire (MEQ), 77–78
 - minerals, 385*t*–386*t*
 - Minnesota Nutrition Data System, 258
 - MNT. *See* medical nutrition therapy
 - modeling, 411
 - Modification of Diet in Renal Disease study, 115
 - MOOSE. *See* Meta-analysis of Observational Studies in Epidemiology
 - motivation, food records and, 254–255
 - MRI. *See* magnetic resonance imaging
 - mRNA. *See* messenger RNA

- MS. *See* mass spectrometry
- MTHFR. *See* methylenetetrahydrofolate reductase
- multicenter randomized controlled trials
 advantages of, 120
 disadvantages of, 121
 examining causation with, 120–121
- multidisciplinary research, 217
 challenges, 220–221
 communication in, 223–224
 conducting, 221–225
 decisions in, 223
 defining, 219, 220*f*
 impetus for, 219
 National Institutes of Health and, 219, 221–222
 personal characteristics enhancing, 223
 rewards of, 219–220
 strategies for, 223–225, 224*b*
- multiple comparisons, 489
- Multiple Risk Factor Intervention Trial, 115
- multistage probability sampling, 179, 308
- multivariate Cox proportional hazards regression, 115
- multivariate relationships, of diet and disease, 112
- MyPlate, 284, 300
- My Pyramid Equivalents Database, 172
- myristoleate, 387*t*
- N**
- narratives, 90*b*
- National Academy of Medicine, 280, 295
- National Academy of Sciences, 127
 nutrition monitoring symposium by, 155
- National Agricultural Library, 272, 274
- National Cancer Institute, 539
 Division of Cancer Prevention, 525
 National Data on Food Intakes, 176*b*
- National Cancer Institute (NCI), 5, 58
 on behavior theory-based research, 406
 brief assessment tool registry, 258
 dietary assessment instrument comparison by, 257*f*
 Dietary Assessment Primer, 255
 Dietary Screener Questionnaire, 166
 Diet Assessment Primer Roadmap, 251, 252*f*
 Diet History Questionnaire, 256
 Food Attitudes and Behaviors Survey, 173
 food environment studies by, 174
 intake distribution estimation method, 304, 308
 nutrition monitoring by, 173
- National Cancer Institute Measurement Error Webinar series, 128*b*
- National Center for Advancing Translational Research, 592
- National Center for Chronic Disease Prevention & Health Promotion, 176*b*
- National Center for Complementary and Integrative Health (NCCIH), 429, 430*b*, 431, 435
- National Center for Environmental Health, 176*b*
- National Center for Health Statistics (NCHS), 82, 158*t*, 169, 176*b*, 274, 277, 308
 National Health Survey by, 373
- National Collaborative on Childhood Obesity Research (NCCOR), 81, 157, 176*b*
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 37
- National Death Index, 166
- National Food and Nutrient Analysis Program, 170, 171, 278
- National Food Consumption Survey, 80
- National Forest Service, 164*t*
- National Health and Medical Research Council, 214*b*
- National Health and Nutrition Examination Survey (NHANES), 5, 10, 80, 81, 104, 113, 154, 156*b*, 157, 158*t*, 176*b*, 230
 24-hour recalls in, 253
 clustered design in, 179
 dietary supplement data from, 424
 Dietary Supplement Ingredient Database and, 172
 folate status data from, 170*b*
 food and nutrient intake assessment in, 274, 308
 linkages to other data, 166–167, 170
 obesity findings, 77
 What We Eat in America and, 169, 231
- National Health Care Surveys, 158*t*, 169
- National Health Interview Survey (NHIS), 158*t*, 166
 dietary supplement data from, 425
- National Health Survey, 373
- National Heart, Lung, and Blood Institute (NHLBI), 232, 234
- National Institute for Food and Agriculture, 219
- National Institute of Allergy and Infectious Diseases, 58
- National Institute of Child Health and Human Development, 323
- National Institute of Diabetes, Digestive and Kidney Diseases, 575
- National Institute of Standards and Technology, 326
 dietary supplement standards by, 431
- National Institutes of Health (NIH), 4, 18, 289
 funding from, 56, 56*t*
 as information source, 176*b*
 multidisciplinary and, 219, 221–222
 noncoverage errors prevention and, 43
 nutrition research and, 575
 Nutrition Research Task Force, 156
 Office of Dietary Supplements, 176*b*, 277, 425
 Office of Extramural Research Protecting Human Research Participants, 38*t*
 Office of Nutrition Research, 176*b*
 proposal review criteria, 57*b*
 research application sections, 58
 research strategy, 59–63
 specific aims, 58–59
 US National Library of Medicine and, 9
- National Kidney Foundation, 581
- National Marine Fisheries Service, 173, 176*b*
- National Nutrient Database for Standard Reference (SR), 171, 171*b*, 272–274
- National Nutrition Monitoring and Related Research Program (NNMRRP), 154, 230, 231
- National Nutrition Monitoring System, 251
- National Nutrition Research Agenda, 575
- National Nutrition Research Roadmap, 155–156
- National Research Council (NRC), 304
- National School Lunch Program, 169
- National Science Foundation, 56, 431
- National Survey of Family Growth (NSFG), 158*t*
- National Survey of Recreation and the Environment, 164*t*
- National Vital Registration System, 158*t*
- National Vital Statistics System, 82
- naturalistic settings, 92
- Natural Medicine database, 431*b*
- NCCIH. *See* National Center for Complementary and Integrative Health
- NCHS. *See* National Center for Health Statistics
- NCI. *See* National Cancer Institute

- NCORR. *See* National Collaborative on Childhood Obesity Research
- NCP. *See* Nutrition Care Process
- NDBC Directory. *See* International Nutrient Databank Directory
- NDL. *See* Nutrient Data Laboratory
- nested case-control studies, 390
- neural tube defects (NTDs), 107, 108, 170*b*
- neuroimaging, in appetite research, 341–342
- Newcastle-Ottawa Scale (NOS) for Assessing the Quality of Nonrandomized Studies in Meta-Analysis, 214*b*
- New England Journal of Medicine*, 517*t*
- New Moves obesity prevention program, 61*t*
- newsletters, research, written, 523, 525
- Neyman bias, 110
- NHANES. *See* National Health and Nutrition Examination Survey
- NHIS. *See* National Health Interview Survey
- NHL. *See* non-Hodgkin lymphoma
- NHLBI. *See* National Heart, Lung, and Blood Institute
- niacin, 299*t*
- Nielsen Homescan, 170, 174
- Nielson Scantrack, 164*t*
- NIH. *See* National Institutes of Health
- Ni-Hon-San study, 253
- nitrogen excretion, urinary, 319, 320
- NMS spectroscopy. *See* nuclear magnetic resonance spectroscopy
- NNMRRP. *See* National Nutrition Monitoring and Related Research Program
- nominal group process, 93
- nominal variables, 242–243, 482, 482*f*
- noncoverage errors, 43
- nondifferential bias, 110
- non-Hodgkin lymphoma (NHL), 26
- nonparametric statistical methods, 488–489
- nonprobability sampling, 596
- nonprofit organizations, funding from, 55
- nonresponse errors, 43–44
- normal curve, 301
- Norovirus GII.17, 76
- NRC. *See* National Research Council
- NRN. *See* Nutrition Research Network
- NSFG. *See* National Survey of Family Growth
- NTDs. *See* neural tube defects
- nuclear magnetic resonance spectroscopy (NMR spectroscopy), 322
- nucleotides, 381
- null hypothesis
- defining, 484–486
 - sample size calculation and, 469–470
- numeric variables, 482–483, 482*f*
- Nuremberg Code of 1947, 36
- Nurses' Health Study, 256
- nutrient biomarkers, 312
- Nutrient Content of the US Food Supply Series, 173
- nutrient contents, 424*t*
- Nutrient Data Laboratory (NDL), 170, 176*b*
- nutrient inadequacy
- cut-point approach to estimating, 305–306
 - estimating prevalence of, 304–305
 - probability approach to estimating, 305, 306
- nutrients, as exposure, 108
- nutrigenetics, 381, 397
- nutritional intervention, 145–147
- diet composition and, 147
 - energy requirements and, 146
 - implementation strategies for, 146
- nutrition and dietetics education research
- categories of, 457
 - data collection for, 457–461
 - future needs for, 461–462
 - levels of, 461
 - types of methods in explanatory, 461*b*
- nutrition assessment
- biological measures in, 313–314
 - blood biomarkers for, 316*t*
- Nutrition Care Process (NCP), 194
- outcomes research and, 359, 361
- Nutrition Data System-Research software, 599
- nutrition epidemiology, 102
- Nutrition Evidence Library, 6
- Nutrition Facts label, 173, 272, 280
- Nutrition Frontiers* newsletter, 525
- nutrition informatics, 361
- Nutrition Labeling Education Act, 274
- nutrition monitoring, 153
- components of, 157, 158*t*–167*t*, 166–174
 - food and nutrient consumption, 160*t*–161*t*, 169–170
 - food composition, nutrient, food patterns, and supplemental databases, 160*t*–163*t*, 170–172
 - food environment and policy data, 164*t*–167*t*, 174
 - food supply determinations, 164*t*–165*t*, 173–174
 - gaps in, 174
 - knowledge, attitudes, and behavioral assessments, 162*t*–165*t*, 172–173
 - nutrition and related health measurements, 157, 158*t*–159*t*, 166–169
 - overview and history in United States of, 154–156
 - resources for researchers, 174–177
 - secondary analysis of data from, 177–180
 - starting research studies with, 180–181
 - uses and value of data from, 156
- Nutrition Practice Guidelines, 193
- nutrition research
- biomarkers in, 323–326
 - ecological framework for planning, 232, 233*b*, 234
 - federal information sources on, 176*b*
 - forces driving, 3–6
- Nutrition Research Information, 575
- Nutrition Research Network (NRN), 361, 572, 573, 575, 583
- Nutrition Research Task Force, 156
- Nutrition Reviews*, 517*t*
- nutrition studies, 498
- inconsistent findings among, 121–122
- NVivo, 95*b*
- ## O
- obesity, 389
- cardiovascular disease and, 112
 - prevalence among children and adolescents, 77
 - statistics of, 493, 493*t*
- objectives
- of clinical nutrition research, 129, 130*f*
 - of economic analysis, 366, 368
 - research, 10
 - study, 129
- observational study designs
- advantages and disadvantages, 113*t*
 - cross-sectional studies, 113
 - of gene-diet interactions, 390, 392

for nutrition and dietetics education research, 457, 458*b*, 460–461

observations, 92

- chance, 46
- paired, 474–475

observation techniques, 448*b*, 461*b*

Observing Protein and Energy Nutrition (OPEN), 260

odds ratio, 104, 104*b*, 499

Office of Dietary Supplements (ODS), 176*b*, 277, 425, 431

Office of Extramural Research Protecting Human Research Participants, 38*t*

Office of Nutrition Research, 176*b*

oleic acid, 387*t*

OmniHeat Study, 145

one-sided hypothesis tests, 485–486

OPEN. *See* Observing Protein and Energy Nutrition

open-circuit calorimetry, 319

open-ended questions, 242, 243*b*

Open Epi, 478*b*

opportunity cost, 361

ordinal variables, 243, 244*f*, 482, 482*f*

organizational publications, research, written, 522–523, 524*f*

osteoporosis, 520*f*

outcome assessment, 413*b*

outcomes

- cost-effectiveness analysis, 371–372
- chain of, from weight management programs, 354, 356*f*
- cost, 354–355
- in dietary supplement research, 437–439
- economic analysis of, 371–374
- patient-centered, 352–353
- primary variables, 407
- relating costs to, with ratios, 374
- surrogate, 353–354, 353*f*, 355*f*

outcomes registry, 358

outcomes research

- in evidence-based practice research cycle, 351, 351*f*
- internal validity in, 355–357
- methods for, 355–359, 361
- nutrition care process and, 359, 361
- nutrition informatics and, 361
- planning and conducting, 360*b*
- prospective studies for, 24–25
- research questions for, 360*b*
- results of, 359
- study design for, 360*b*
- study implementation, 359
- types of outcomes, 352–355, 352*t*

outliers, 490, 491*f*

overmatching, 116

oxalic acid, 276

oxidative metabolism, 318

P

P value, 486

PABA. *See* para-aminobenzoic acid

PAH. *See* phenylalanine hydroxylase

paired continuous data, sample size for, 471–472

paired observations, sample size and proportions, 474–475

paired *t* test, 471–472

pairing samples, study design and statistical analysis, 483

palmitic acid, 387*t*

palmitoleic acid, 388*t*

Panel on Enhancing the Data Infrastructure in Support of Food and Nutrition Programs, Research, and Decision Making, 157

pantothenate, 385*t*

para-aminobenzoic acid (PABA), 325

parallel-arm study, 335, 336*b*

parallel randomized controlled trials, 131–132, 131*f*

parametric statistical tests, 489*t*

parental consent, 600, 600*b*

parenteral nutrition (PN), 24

partially controlled study designs, 22

participant deception, in appetite research, 334–335

participant monitoring, in clinical nutrition studies, 143–144

participant recruitment

- for appetite research, 332–333
- for clinical nutrition studies, 141
- for dietary supplement research, 434
- homogeneity in, 434

participant retention, in clinical nutrition studies, 144–145

participant sampling, in qualitative research, 89–92

participant screening, for clinical nutrition studies, 141–142

participant selection

- for case series studies, 12
- for clinical nutrition research, 139–140
- for cohort studies, 24
- for prospective studies, 24
- for qualitative research, 11
- for randomized controlled trials, 16–17
- for surveys, 14–15

participatory action research, 90*b*

partnerships, 413*b*

- for community presentations, 536

PASS sample size calculator, 478*b*

Pathway Genomics, 394

patient-centered care, research to improve quality of, 583–584

patient-centered outcomes, 352–353

Patient-Centered Outcomes Research Institute, 352

patient identifiers, 41, 42*b*

Patient Protection and Affordable Care Act of 2010, 352

pediatric intensive care (PICU), 581

Pediatric Nutrition Surveillance System (PedNSS), 158*t*, 167, 168

Pediatrics, 517*t*

PedNSS. *See* Pediatric Nutrition Surveillance System

peer review, 563, 564

Pennington Biomedical Research Center, 430*t*

pentadecanoic acid, 318

peptide YY, 340–341

perceived severity, 406, 408

perceived susceptibility, 408

period prevalence, 76

- defining, 77*b*

personal career development, 572, 573*b*

personalized nutrition, 394, 397

PET. *See* positron-emitting tomography

phenomenology, 90*b*, 597*b*

phenylalanine, 387*t*

phenylalanine hydroxylase (PAH), 391*t*

phenylketonuria, 390

PHI. *See* protected health information

Philadelphia Collaborative Violence Prevention Center, 539

phosphate, 312

phosphorus, 386*t*, 581

- photographs, 542, 552
- PICO. *See* population, intervention, comparator, and outcome
- PICU. *See* pediatric intensive care
- pilot studies, 4–5
- placebos, in dietary supplement research, 435, 436
- plagiarism, 36
- planned behavior, 407*t*
- planning
 - ecological frameworks for, 232, 233*b*, 234
 - for outcomes research, 360*b*
 - for survey research, 234–238
 - for webinars, 537–538, 538*b*
- plant-based diets, biomarkers of, 317*t*
- plasma biomarkers, 314*b*
- plasma carotenoids, 315, 316*t*
- plasma collection, 324
- plasma glucose, eating behavior and, 339–340
- plasma retinol, 313
- plotting data, in statistical analysis, 490, 491*f*, 492*f*
- PLP. *See* pyridoxal 5'-phosphate
- PN. *See* parenteral nutrition
- PNSS. *See* Pregnancy Nutrition Surveillance System
- podium presentations
 - abstracts for, 531
 - delivering, 534–535
 - oral components, 532, 534
 - preparing, 531–532
 - professional conference selection, 530–531
 - proposal and abstract submission, 531
 - slide organization, 533*b*
 - visual components, 532, 533*b*
- Poehlman, Eric, 34–35
- point prevalence, 76
 - defining, 77*b*
- policy briefs, 525
- polymorphisms, 383
- polyphenol intakes, 317
 - biomarkers of, 318
- polyphenols, 438*t*
- population, intervention, comparator, and outcome (PICO), 6, 194
- population attributable risk, 104
- population coverage, nutrition survey and surveillance data and, 178–179
- population sampling, survey design and, 237–238
- population values estimate
 - confidence interval, 496–497
 - measuring degrees of uncertainty, 495–496
 - standard error, 495–496
 - statistical analysis, 495–497
 - using samples, 495
- portion control, 580
- positron-emitting tomography (PET), 341
- poster development, 527, 529, 530*b*
- poster presentations, 526, 526*f*
 - abstract submission, 527, 528*f*
 - exhibit sessions, 529–530, 530*b*
 - preparing, 527, 528*f*, 529
 - software for, 527–529
- postprandial studies, 138
- potassium, 303*t*
 - biomarkers for, 320
 - blood pressure and, 108
- potency, 424*t*
- potentially excessive intakes, prevalence of, 306
- PP4H. *See* Proviso Partners for Health
- practice-based research, 128, 575, 582–583
 - disseminating, 585, 585*b*
- practice questions, 584
- Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2), 357, 358, 358*b*
- pragmatic trials, 357–358
- PRAMS. *See* Pregnancy Nutrition Surveillance System
- prebiotics, 4
- PRECEDE-PROCEED, 406
- PRECIS-2. *See* Pragmatic-Explanatory Continuum Indicator Summary 2
- precision, 5
- precontemplation stage, 414, 415
- predatory journal, 561*b*
- prediabetes, 27, 577
- predictive value, 78–79, 79*f*, 80*f*
- PREDIMED. *See* Prevencion con Dieta Mediterranea
- preexperimental designs, for foodservice management research, 450–451
- preexperimental research design, 449*t*
- Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA), 46, 197, 210
- Pregnancy Nutrition Surveillance System (PNSS), 104, 158*t*, 167
- Pregnancy Risk Assessment Monitoring System (PRAMS), 162*t*
- press releases, 525
- pretesting, 236, 245
- prevalence, 80*f*
 - of adequacy/inadequacy, 304–305
 - measurement of, 76–77
 - period, 76, 77*b*
 - point, 76, 77*b*
 - of potentially excessive intakes, 306
- Prevencion con Dieta Mediterranea (PREDIMED), 45, 121
- Prevention Research Centers, 176*b*
- primary hypothesis, 129
- primary outcome variables, 407
- PRISMA. *See* Preferred Reporting Items for Systematic Reviews and Meta-analyses
- privacy, 41–42
- proanthocyanidins, 276, 276*t*
- probability
 - confidence interval and, 496
 - interpreting statistical values of, 498
 - normal curve and, 301
 - nutrient inadequacy estimation using, 305, 306
 - P* value and, 486
 - sample size and, 469–471
 - statistical significance and, 498
 - type II error and, 470
- probability sampling, 15
 - area, 179
 - defining, 237*b*
 - multistage, 179, 308
- probiotics, 4
 - processes of change, 412, 414
- professional career development, 572, 573*b*
- professional conferences, 525
- professional literature
 - reading, 571–572
 - research method knowledge and, 579
 - tips for keeping up with, 572*b*
- professional organizations, funding from, 55
- progesterin, 3
- Project EAT survey, 61*t*

proline, 387*t*
 propensity scoring, 359
 proposal review process, 56–58
 prospective studies
 exposure status assessment, 24
 features of, 24
 outcome assessment, 24–25
 participant selection, 24
 registry, 358
 statistical analysis and interpretation, 25
 uses of, 22–23
 protected health information (PHI), 41, 577
 protein intake, biomarkers for, 320
 proteomics, 314
 Proviso Partners for Health (PP4H), 524
 publication. *See also* journals; research publications
 ethics in, 47
 formatting for, 555–556
 public health, economic analysis and, 376
Public Health Nutrition, 516, 517*t*
 public research registries, 46, 129
 PubMed, 176*b*
 purposeful sampling, 91*b*
 purposive sampling, 596
 pyridoxal 5'-phosphate (PLP), 312
 pyridoxal-phosphate, 385*t*

Q

QA. *See* quality assurance
 QALYs. *See* quality-adjusted life years
 QDA Miner, 95*b*
 QEWP, 61*t*
 QI. *See* quality improvement
 QUADAS-2, 214*b*
 qualifying statements, 244–245
 qualitative data analysis, 93–96
 qualitative research, 11–12
 community-based, 596–597
 data collection for, 89–93
 defining, 85
 evaluating, 96–97
 examples of approaches for, 87*b*
 limitations and concerns with, 97
 participant sampling in, 89–92
 quantitative research compared with, 85–86, 86*b*
 reasons to do, 87–89
 reporting, 96
 research designs for, 89, 90*b*
 sampling methods for, 90, 91*b*
 strategies for, 597*b*
 trustworthiness criteria for, 597
 quality-adjusted life years (QALYs), 365–366, 365*b*
 quality assurance (QA), in biomarker studies, 326
 Quality Criteria Checklist, 197, 199, 200*f*–203*f*, 579
 quality improvement (QI), 583–584
 in clinical nutrition research, 147–148, 149*f*
 procedures for, 149*f*
 projects for, 129
 Quality of Reports of Meta-Analyses of Randomized
 Controlled Trials (QUOROM), 210
 quantitative food frequency questionnaires, 256
 quantitative research, 84
 community-based, 597–599
 qualitative research compared with, 85–86, 86*b*
 quasi-experimental designs, 22, 449*t*, 594, 595*f*
 for foodservice management research, 451

questionnaires. *See also* food frequency questionnaires
 accuracy of data collection with, 458
 administration of, 240, 241
 appetite, 337–339
 Block, 256
 design for survey research, 239, 242–245
 Dietary Screener Questionnaire, 166
 food propensity questionnaire, 258
 mindful eating questionnaire, 77–78
 for nutrition and dietetics education research, 457–458
 self-administered, 241
 question ordering, 245
 Quirkos, 95*b*
 QUOROM. *See* Quality of Reports of Meta-Analyses of
 Randomized Controlled Trials

R

R (software), 179
 RACC. *See* reference amount customarily consumed
 RAE. *See* retinol activity equivalent
 RALES. *See* Randomized Aldactone Evaluation Study
 random assignment, 335, 336*b*
 random error, 147
 defining, 321*b*
 Randomized Aldactone Evaluation Study
 (RALES), 350–351, 356–357
 randomized controlled trials (RCTs), 413*b*
 assigning treatment groups, 18–20
 in clinical nutrition studies, 131
 data collection for, 20
 for dietary supplements, 427–428
 end points, 20
 examining causation with, 118–121
 factorial design, 21, 22
 features of, 16
 intervention or treatment selection, 18
 multicenter, 120–121
 parallel, 131–132, 131*f*
 participant selection, 16–17
 sample size, 20
 statistical analysis and interpretation, 21
 uses of, 16
 random sampling, defining, 237*b*
 rate of carbon dioxide production (VCO₂), 318
 rate of gastric emptying, 342
 rate of oxygen consumption (VO₂), 318
 ratio measurement, 243–244
 ratios, relating costs to outcomes with, 374
 RCTs. *See* randomized controlled trials
 RDA. *See* Recommended Dietary Allowance
 RDNs. *See* Registered Dietitian Nutritionists
 reactivity, food records and, 254
 readers
 critical evaluation of literature, 565
 keeping current, 565–566
 literature evaluation, 564–565
 Readiness for Interprofessional Scale, 459
 recall bias, 390
 receiver operating characteristic (ROC), 5
 reciprocal determinism, 410–412
 RECIST. *See* Response Evaluation Criteria in
 Solid Tumors
*Recommendations for the Conduct, Reporting,
 Editing and Publication of Scholarly Work
 in Medical Journals*, 559
 recommendation statements, 208, 208*f*

- Recommended Dietary Allowance (RDA), 296, 300–302
 recovery biomarkers, 262
 REE. *See* resting energy expenditure
 reference amount customarily consumed (RACC), 274
 refrigeration, for sample storage, 325–326
 Registered Dietitian Nutritionists (RDNs), 3, 9, 10, 278
 activities for career development, 572, 573*b*
 dietary intake assessment by, 300
 dietary supplement research and, 426
 food composition database implications for, 287–288
 formal education of, 456
 journal publications, 516
 research priorities and opportunities and, 572–576
 research uses to, 571
 reviews for, 566
 registry studies, 358
 regression analysis, 504–506, 506*b*
 linear, 505, 506*b*, 507*b*
 logistic, 499
 multivariate Cox proportional hazards, 115
 relationships
 between constructs, 408
 dose-response, 106
 estimating, 499, 502–507
 multivariate, 112
 among samples, 483–484
 of two continuous variables, 494–495
 relative risk, 24, 104, 104*b*, 105, 105*f*
 relative risk measure, 499
 reliability, 77–78, 245, 246*f*
 replicating measurements, 484, 485*f*
 reporting guidelines, 46
 reports. *See* research reports
 reproducibility, of DRIs, 259
 requirement distribution, 301*f*
 research
 advancing, 6
 aims of, 458*b*
 applying to practice, 576–577
 to change practice, 581
 cycle of, in practice, 577–579
 defining problem for, 584–585
 to document effectiveness, 581–582
 in ethical climate, 49–50
 illustrating results, 541–542
 message, 542–543
 purpose, 542
 importance in practice of, 571
 to improve quality of patient-centered care, 583–584
 knowledge constraints in, 586
 to observe and alter practice, 580
 overcoming barriers to quality in, 586–588
 priorities and opportunities in, 572–576
 in problem solving, 579–580
 progression towards evidence of, 427–428, 428*f*
 role in practice, 573
 selecting topic for, 9
 to solve practice problems, 582–583
 time and other constraints in, 587
 translational, 574, 592–593, 593*f*, 594*b*
 turning barrier into opportunities in, 587–588
 written
 newsletters, 523, 525
 organizational publications, 522–523, 524*f*
 policy briefs, 525
 press releases, 525
 research articles, 518
 research briefs, 522
 research designs
 for analytic nutrition epidemiology, 112–121
 for associations, 104–105
 for causation, 107
 for clinical nutrition studies, 131–135, 138
 for community-based research, 593–594, 595*f*, 596
 descriptive, 11–16, 79–82, 449, 457
 for dietary supplements, 432–439
 ethics and, 42–45
 for foodservice management research, 449–451, 449*t*
 for qualitative research, 89, 90*b*
 Research Dietetic Practice Group, 574
 research dissemination
 audiences for, 513
 community presentations for, 536–537
 electronic presentations for, 537–539
 journal articles, 515–519, 521–522
 novel approaches, 539
 plans for, 514–515
 podium presentations, 530–532, 533*b*, 534–535
 poster presentations, 526–527, 526*f*, 528*f*, 529–530
 professional conferences, 525
 purposes of, 513–514
 reports, 515
 roundtable presentations, 535–536, 535*b*
 web seminars, 537–539, 538*b*
 written, 512–525
 research error, 35–36
 Research Ethics for the Registered Dietitian Nutritionist, 38*t*
 research findings, 512–513
 Research Grant Program, 56*t*
 research ideas, developing as fundable research plan, 54–55
 research literature
 reading, 571–572
 research method knowledge and, 579
 tips for keeping up with, 572*b*
 research objectives, 10
 research plans
 adhering to, 67
 developing ideas to, 54–55
 Research Project Cooperative Agreement, 56*t*
 research proposals. *See also* grant proposals
 adhering to, 67
 composing strong, 58–66
 data analysis in, 61–62
 data collection in, 61
 interventions in, 60–61
 other project information, 63–65
 research strategy, 59–63
 revising unfunded, 67–68
 specific aims in, 58–59
 statistical analysis in, 62–63
 research protocols, preparing, 4
 research publications
 reader's perspective, 564–566, 565*b*
 reviewer's perspective, 563–564, 563*b*
 writer's perspective, 558–563
 research questions
 in analytic nutrition epidemiology, 107–108
 for nutrition monitoring and surveillance system studies, 180
 for outcomes research, 360*b*
 sources of, 128–129
 stating, 10–11

- study design and statistical analysis, 481
 - research reports, 515
 - abstracts, 519, 520*f*
 - author checklists, 522
 - journal selection, 515–517
 - manuscript body, 521
 - original, 518–519
 - publication access, 517–518
 - supplementary materials, 522
 - tables and figures, 521–522, 523*f*
 - titles, 519
 - research strategy
 - appendix materials, 65
 - approach, 59–62
 - budget, 65–66, 66*b*
 - innovation, 59
 - significance, 59
 - statistical analysis, 62–63
 - summary and future directions, 63
 - theoretical framework, 62, 63*f*
 - timeline, 62, 64*f*
 - research studies
 - designing, 9–11
 - preparing for, 9–10
 - registering in public registries, 46
 - Research to Reality, 539
 - respiratory gases, measuring, 319
 - respiratory quotient (RQ), 318–319
 - Response Evaluation Criteria in Solid Tumors (RECIST), 432
 - response rates, nutrition survey and surveillance data and, 178–179
 - resting energy expenditure (REE), 318–319
 - retinol, plasma levels of, 313
 - retinol activity equivalent (RAE), 298
 - reviewers
 - challenges of peer, 564
 - of research publications, 563–564, 563*b*
 - riboflavin, 303*t*
 - ribonucleic acid (RNA), 381–382
 - ribosomal RNA, 382
 - risk
 - attributable, 104
 - genetic risk score, 393
 - genetic testing services and, 397
 - relative, 24, 104, 104*b*, 105, 105*f*
 - youth behavior, 173
 - risk difference, 104
 - RNA. *See* ribonucleic acid
 - Robert Wood Johnson Foundation, 55
 - ROC. *See* receiver operating characteristic
 - roundtable presentations
 - delivery of, 535–536
 - preparation, 535
 - sample questions, 535, 535*b*
 - RQ. *See* respiratory quotient
- S**
- Safe Harbor method, 41, 42*b*
 - salt intake, blood pressure and, 106, 114
 - sample collection, biomarkers and considerations for, 323–325
 - samples
 - evaluating differences between, 500*t*, 503
 - matching, 483
 - population values estimate using, 495
 - relationships among, 483–484
 - sample size, 468–469
 - case-control studies, 475–476
 - clinical and statistical significance, 477
 - for clinical nutrition studies, 140–141
 - cohort studies, 476–477
 - complex situations, 477
 - in dietary supplement research, 434–435
 - group comparison with continuous data, 472–474
 - independent groups and proportions, 474
 - paired observations and proportions, 474–475
 - in randomized controlled trials, 20
 - restrictions of, 470
 - software and websites for determining, 477, 478*b*
 - for specific research situations, 471–477
 - sample size calculations
 - alternative hypothesis, 469–470
 - general procedure, 470–471
 - logic, 469–470
 - software and websites, 477, 478*b*
 - sample storage, 325–326
 - sample weights, nutrition survey and surveillance data and, 179
 - sampling
 - cluster, 237*b*, 308
 - multistage probability, 179, 308
 - nonprobability, 596
 - probability, 15, 179, 237*b*, 308
 - purposive, 596
 - for qualitative research, 89–92, 91*b*
 - random, 147, 237*b*
 - survey design and, 237–238
 - sampling bias, 43
 - nutrition survey and surveillance data and, 178–179
 - sampling errors, 43
 - SAS, 179
 - satiation measurement, 335–337
 - satiety measurement, 337
 - scale of measurement
 - study design and statistical analysis, 481–483
 - variables, 481–482, 482*f*
 - Scantrack, 174
 - scatterplots, 490, 491*f*
 - SCD. *See* Specific Carbohydrate Diet
 - School Breakfast Program, 169
 - School Health Policies and Practices Study (SHPPS), 164*t*, 174
 - School Nutrition Dietary Assessment (SNDA), 164*t*, 169, 174
 - Scientific Affairs and Research Staff, 211*b*
 - screeners, 258
 - SCT. *See* social cognitive theory
 - scurvy, 3
 - SD. *See* standard deviation
 - search plans, 196, 198*f*
 - secondary hypothesis, 129
 - SELECT. *See* Selenium and Vitamin E Cancer Prevention trial
 - selection bias, 21, 357, 390
 - selective reporting, 46
 - selective sampling, 91*b*
 - selenium, 313, 386*t*, 438*t*
 - Selenium and Vitamin E Cancer Prevention trial (SELECT), 131, 133
 - self-administered mailed or web-based surveys, 241
 - self-administered questionnaires, 241
 - self-changers, 413

- self-efficacy, 410, 412, 414
- self-reported intake reporting
 biomarker calibration of, 320–322
 for dietary supplement research, 437
- self-reporting, 448*b*
- SEM. *See* social ecological model
- semiquantitative food frequency questionnaires, 256
- sensitivity, 5–6, 78, 78*f*
- sensitivity analysis, 375
- serial/repeat measurements, 485*f*
 study design and statistical analysis, 483–484
- serum calcium, 581
- serum carotenoids, smoking and, 112
- serum phosphorus, 581
- Shape Up Somerville, 411, 413*b*
- short-term biomarkers, 314*b*
- SHPPS. *See* School Health Policies and Practices Study
- SIDs. *See* Special Interest Databases
- SIGN 50: A Guideline Developers Handbook*, 214*b*
- Simon Fraser University, 430*t*
- simulations
 for foodservice management research, 451
 research design, 449*t*
- single nucleotide polymorphisms (SNPs), 383, 384
- SIPP. *See* Survey of Income and Program Participation
- SKP. *See* Synergistic Theory and Research on Obesity and Nutrition Group Kids Program
- SLAITS. *See* State and Local Area Integrated Telephone Survey
- Small Grant Program, 56*t*
- Smart Visits, 575
- smoking
 biomarkers and, 313
 cessation of, 413
 serum carotenoids and, 112
- SNAP. *See* Supplemental Nutrition Assistance Program
- SNDA. *See* School Nutrition Dietary Assessment
- snowball sampling, 91*b*
- SNPs. *See* single nucleotide polymorphisms
- social cognitive theory (SCT), 407, 407*t*, 410–412, 413*b*
- social ecological model (SEM), 410–412
- social marketing, 406
- Social Security Administration, 166
- sodium
 biomarkers for, 320
 variability among brands, 286*f*
- software
 computer graphics, 546, 548
 to determine sample size, 477, 478*b*
 Nutrition Data System-Research, 599
 for poster presentations, 527–529
- somatic mutations, 383
- soybeans, isoflavones from, 318
- Special Interest Databases (SIDs), 272, 274, 276–277, 276*t*
- Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), 167, 168
- specific aims, 58–59
- Specific Carbohydrate Diet (SCD), 12, 81
- specificity, 5–6, 78, 78*f*
- spironolactone, 350–351
- SPSS Sample Power 3, 478*b*
- SR. *See* National Nutrient Database for Standard Reference
- SR-Legacy database, 171
- SSB. *See* sugar-sweetened beverage
- stacked bar graph, 552*f*
- stages of change, 412–415, 414*f*
- standard deviation (SD), 471
 population values estimate, 495–496, 496*f*
- standard error, 495–496, 496*f*
- standardized tests, 458–459
- Standards for the Reporting of Diagnostic Accuracy Studies (STARD), 214*b*
- STATA, 179
- State and Local Area Integrated Telephone Survey (SLAITS), 158*t*
- statistical analysis. *See also* summary statistics
 for appetite research, 335
 assumption of normality, 487–488
 bariatric surgery and diabetes remission, 501*b*–502*b*
 for case-control studies, 27–28
 clinical study example, 491*b*
 of cohort studies, 25
 of differences between groups, 307–308
 evidence-based dietetic practice reviews and, 204
 elements of, 481–490
 evaluating differences between samples or groups, 500*t*, 503
 general process of, 490–498
 hypothesis testing, 484–486
 intake distribution estimation with, 303–304, 304*f*
 more than two groups, 489
 nonparametric methods, 488–489, 489*t*
 pairing matching samples, 483
 plotting data, 490, 491*f*, 492*f*
 for prospective studies, 25
 for randomized controlled trials, 21
 relationships among samples, 483–484
 replicating measurements, 484, 485*f*
 in research proposals, 62–63
 research question, 481
 scale of measurement, 481–483
 serial/repeat measurements, 483–484, 485*f*
 small groups and, 307
 to summarize data, 490–495
 transformations, 488, 488*f*
 unrestrained testing, 489–490
- statistical applications
 fundamentals, 480–481
 population values estimate, 495–497
 tool kit for procedures, 498–499, 502–507
- statistical power, estimating, 238
- statistical procedures
 comparing differences between groups, 498–499
 estimating relationships or associations, 499, 502–507
- statistical results, conclusions from, 469–470, 469*t*
- statistical significance
 assessing, 497–498
 data dredging and, 45
 hypothesis testing, 497–498
 probability values interpretation, 498
 sample size and, 141, 477
- statistics, in data interpretation, 46–47
- stearic acid, 388*t*
- stearidonic acid, 388*t*
- stepped-wedge study design, 134–145, 145*f*
- STICU. *See* surgical/trauma intensive care unit
- stop codons, 381
- stratified randomization, 142
- Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), 214*b*, 522
- structured interviews, 11, 12
- Student Leadership Practices Inventory, 459
- studies. *See* specific studies

study designs, 360b. *See also* research designs
 for analytic nutrition epidemiology, 112–121
 for appetite research, 335
 for association, 104–105
 for causation studies, 107, 118–121
 for clinical nutrition research, 131–135, 138
 crossover, 131–132, 132*f*, 336*b*
 dependent samples and, 483
 for evidence-based dietetic practice
 reviews, 203*t*–204*t*
 for economic analysis, 372
 elements of, 481–490
 etiologic, 118–121
 experimental, 16–21
 for gene-diet interactions, 389, 390–394
 hypothesis testing, 484–486
 independent samples, 483
 nonparametric methods, 488–489, 489*t*
 observational, 113–118, 390, 392, 457, 458*b*, 460–461
 for outcomes research, 360*b*
 pairing matching samples, 483
 partially controlled, 22
 relationships among samples, 483–484
 replicating measurements, 484, 485*f*
 research question, 481
 scale of measurement, 481–483
 serial/repeat measurements, 483–484
 stepped-wedge, 134–145, 145*f*
 terminology for, 336*b*
 transformations, 488, 488*f*
 study diaries, for dietary supplement research, 437
 study objectives, 129
 study power, gene-diet interactions and, 392–393
 study protocols, compliance to, 17, 21
 SUDAAN, 179
 sugars intake, biomarkers for, 320
 sugar-sweetened beverage (SSB), 20
 summarizing costs, 370
 summarizing evidence, 199, 204, 205*t*, 206*f*
 summary statistics
 continuous data described by, 492–493
 discrete data described by, 492
 measure of central location, 494
 measure of variation, 494
 shape of distribution, 494
 two continuous variables relationship, 494–495
 Supplemental Nutrition Assistance Program
 (SNAP), 167, 597
 Supplemental Nutrition Assistance Program (SNAP)
 Policy Database, 166*t*, 174
 Supplement Facts panels, 277
Support Line newsletter, 525
 surgery
 bariatric, 504*t*
 diabetes remission and bariatric, 501*b*–502*b*
 types of bariatric, 492, 493*f*
 surgical/trauma intensive care unit (STICU), 584
 surrogate outcomes, 353–354, 353*f*, 355*f*
 surveillance research, 358–359
 surveillance systems, 81, 167, 168, 168*b*
 gaps in, 174
 secondary analysis of data from, 177–180
 starting research studies with, 180–181
 survey design
 process of, 234–237, 235*f*
 statistical considerations, 237–238
 Survey of Income and Program Participation (SIPP), 160*t*

survey research, 230
 applications of, 231–232
 data analysis considerations in, 246–247
 data collection methods, 238–242
 design of, 449*t*
 for foodservice management research, 450
 planning, 234–238
 questionnaire design, 239, 242–245
 surveys, 13–16. *See also* specific surveys
 categories of questions, 242, 243*b*
 cross-sectional studies with, 473–474
 data collection, 15–16
 federal information sources on, 176*b*
 layout of, 245–246
 mailed, 241
 participant selection, 14–15
 pretesting and revising, 236, 245
 protocol design, 242
 questionnaire administration, 240
 question ordering in, 245
 self-administered, 241
 uses of, 14
 variables and measurement strategies for, 242–243
 web-based, 241
 Susan G Komen Foundation, 55
 sustainability, in foodservice, 452*f*
 symbolic interaction, 90*b*
 Synergistic Theory and Research on Obesity and
 Nutrition Group (STRONG) Kids Program
 (SKIP), 224
 synonyms, 283, 283*b*
 systematic error, defining, 321*b*

T

T2D. *See* type 2 diabetes
 tables, 542, 544*f*
 array, 374
 Atwater, 272
 categories, 543, 546*t*
 creating clear, 545*b*
 reading, 543, 545
 in research reports, 521–522, 523*f*
 strategies to make, 545–546, 547*f*
 TDS. *See* Total Diet Study
 technology
 for data collection, 448*b*
 in foodservice, 452*f*
 termination, 381
 test meals, 335–337
 Tests in Print, 459
 text mining, 222
 theoretical constructs, 60, 62
 theoretical framework, 62, 63*f*
 theoretical sampling, 91*b*
 Theory of Reasoned Action, 407*t*
 theory of reasoned action/planned behavior
 (TRA/TPB), 407, 407*t*, 410
 Thomson Scientific's International Scientific Institute
 (ISI) Web of Knowledge, 516
 time constraints, 587
 timeline, 62, 64*f*
 time-series analysis, 461*b*
 tissue collection, practical considerations in, 323–324
 tocopherols, 316*t*
 Tolerable Upper Intake Level (UL), 297, 302
Topics in Clinical Nutrition, 516

Total Diet Study (TDS), 162*t*, 170, 172, 273
 training
 for clinical nutrition research, 148
 incentive programs and, 21
 for protection of human subjects, 38*t*
 transcription, 94
 Transdisciplinary Obesity Prevention Program—
 Undergraduate, 224
 transdisciplinary research
 challenges, 220–221
 conducting, 221–225
 defining, 219, 220*f*
 impetus for, 219
 leadership in, 221
trans fatty acid, 388*t*
trans fatty acid intake, 118
 transferability, 97
 transfer RNA, 382
 transformations, study design and statistical
 analysis, 488, 488*f*
 translational research, 574
 community-based research and, 592
 spectrum of, 593, 593*f*, 594*b*
 transtheoretical model (TTM), 407, 407*t*, 412–415, 414*f*,
 416*b*
 TRA/TPB. *See* theory of reasoned action/
 planned behavior
 treatment biases, 44
 Trials of Hypertension Prevention study, 115
 triglyceride concentrations, 140
 triplets, 381
 true effect, 470
 true experimental research design, 449*t*
 TTM. *See* transtheoretical model
 two-sided hypothesis tests, 485–486
 two-sided test, 472, 472*t*
 type 2 diabetes (T2D), 3, 140, 389
 GRS and, 393
 type I error, 394, 469–470, 486
 type II error, 470, 486
 tyrosine, 387*t*

U

UCSF sample size calculator, 478*b*
 UEM. *See* Universal Eating Monitor
 UL. *See* Tolerable Upper Intake Level
 ultrasound, 342
 underreporting, 261–263
 unintentional bias, 111
 United Nations, Food and Agriculture Organization, 80,
 272
 United States. *See also* specific agencies and departments
 fisheries of, 173
 nutrition monitoring in, 154–156
 United States Pharmacopeia (USP), 423, 431*b*
 dietary supplement standards by, 431
 unitizing, 94
 Universal Eating Monitor (UEM), 339
 Universal Product Codes, 284
 University of California, Santa Cruz, 430*t*
 University of Illinois, Chicago, 430*t*
 University of Texas Southwestern Medical Center, 430*t*
 unrestrained statistical testing, 489–490
 unstructured interviews, 11
 urinary excretion
 isoflavones, 318

 nitrogen, 319, 320
 urine biomarkers, 261, 314*b*
 urine collection, 324–325
 US Census Bureau, 160*t*, 166, 176*b*, 178
 US Department of Agriculture (USDA), 56, 176*b*, 231
 Branded Foods Products Database, 171, 274, 275*f*
 Economic Research Service, 167, 425
 Food and Nutrition Service, 168–169
 Food Composition and Methods Development
 Laboratory, 147
 food composition databases, 147, 258, 272
 Food Safety and Inspection Service, 280
 food supply estimates published by, 173
 National Food and Nutrient Analysis Program, 170,
 171, 278
 National Nutrition Monitoring System, 251
 Nutrient Content of the US Food Supply Series, 173
 Nutrient Data Laboratory, 170
 US Department of Education, Early Childhood
 Longitudinal Study, 167
 US Food and Drug Administration, 515
 US National Library of Medicine, 9
 USP. *See* United States Pharmacopeia
 US Preventive Services Task Force, 3
 US Public Health Service, 363
 US Renal Data System registry, 115
 usual intake, 108

V

validation, of surrogate outcomes, 353, 353*f*
 validity, 5, 77–78, 108, 245, 246*f*
 dietary, 259
 of DRIs, 259
 external, 119, 334, 334*b*, 355–357, 357*b*
 internal, 334, 334*b*, 357*b*
 valine, 387*t*
 variability
 biological, 326
 food component, 286–287
 QA and, 326
 variables
 binary, 499
 categorical, 482, 482*f*
 confounding, 22, 232*b*
 discrete vs continuous, 482–483, 482*f*
 exposure, 108–110
 interval measurement of, 243
 nominal, 242–243, 482, 482*f*
 ordinal, 243, 244*f*, 482, 482*f*
 primary outcome, 407
 ratio measurement of, 243–244
 scale of measurement and, 481–482, 482*f*
 surveys and measurement strategies for, 242–243
 VAS. *See* visual analogue scale
 VCO₂. *See* rate of carbon dioxide production
 video, for research dissemination, 514–515
 virtual crosswalk, 539
 visual analogue scale (VAS), 338
 visualization, 554–555
Vital and Health Statistics series, 373
 vital statistics measurements, 81–82
 vitamin A, 299*t*, 385*t*, 438*t*
 vitamin B-5, 385*t*
 vitamin B-6, 312, 385*t*, 438*t*
 vitamin B-12, 385*t*, 438*t*
 blood concentration, 316*t*

vitamin C, 3, 18, 313, 317, 438*t*
 quantification of, 314
 vitamin D, 276, 297, 298, 385*t*, 438*t*, 513
 blood concentration, 316*t*
 vitamin E, 299*t*, 385*t*, 438*t*
 vitamin K, 276
 vitamins, 385*t*
 VO₂. *See* rate of oxygen consumption
 volunteers' bias, 110

W

web-based surveys, 241
 webQDA, 95*b*
 web seminars (webinars)
 delivery, 538
 editing after, 538
 planning, 537–538, 538*b*
 trouble-shooting, 538–539
 websites, to determine sample size, 477, 478*b*
 weight and height prestudy, 504*f*
 weight control behaviors, 61*t*
 weighted analysis, 179
 weight loss medication, 477
 weight management programs, outcomes chain
 from, 354, 356*f*
 WesVar, 179
 What We Eat in America (WWEIA), 160*t*, 169, 172, 231,
 308
 WHI. *See* Women's Health Initiative
 whole-body chamber, 319
 whole-room calorimetry, 319
 Willett Food Frequency Questionnaire, 256
 Women's Health Initiative (WHI), 3, 16, 320, 321
 World Health Organization, 208, 271
 Child Growth Standards, 168*b*
 economic analysis and, 376
 Global Infobase, 80
 Handbook for Guideline Development, 214*b*
 World Medical Association, 5, 36
 writers
 checklists for, 522
 conducting research, 559
 editor communication with, 561*b*
 ethics and, 48–49
 irresponsible authorship, 562–563
 journal choice of, 560, 561*b*
 manuscript preparation, 559–560
 manuscript submission, 561, 561*b*
 perspective on research, 558–563
 WWEIA. *See* What We Eat in America

Y

Youth Risk Behavior Survey (YRBS), 162*t*, 173
 YouTube, 539
 YRBS. *See* Youth Risk Behavior Survey

Z

zinc, 303*t*, 386*t*, 438*t*