



American Society for Nutrition
Excellence in Nutrition Research and Practice

Best Practices for Human Nutrition RCTs
An Online Course from the American Society for Nutrition
July 13, 2021 and July 20, 2021
12:00 PM – 5:00 PM ET

July 13, 2021 All times Eastern Daylight Time

12:00 PM	Welcome and Introductions to Day 1 ASN Leadership Connie Weaver, Weaver and Associates Consulting, LLC
12:10 PM	Session 1: Designing and Conducting Human Nutrition RCTs Cheryl Anderson, UC San Diego, Moderator
12:15 PM	Design and Conduct of a Randomized, Crossover, Controlled Feeding Study: Example from the Soy vs Animal Protein Study +/- Soy Derived Isoflavones Alice Lichtenstein, Tufts University
12:30 PM	Design and Conduct of a Randomized, Crossover, Controlled Feeding Study: Example from the Carbohydrates and Related Biomarkers (CARB) Study Johanna Lampe, Fred Hutchinson Cancer Research Center
12:45 PM	Translation of Findings from the DASH Feeding Study: Design and Conduct of PREMIER, a Behavioral Intervention Trial Lawrence Appel, Johns Hopkins University
1:00 PM	Session 1 Panel Discussion Lawrence Appel, Johns Hopkins University Brenda Davy, Virginia Tech University Johanna Lampe, Fred Hutchinson Cancer Research Center Alice Lichtenstein, Tufts University
1:20 PM	Break
1:50 PM	Session 2: Documentation and Regulation for Human Nutrition RCTs Connie Weaver, Weaver and Associates Consulting, LLC, Moderator
1:50 PM	Importance of Documentation Connie Weaver, Weaver and Associates Consulting, LLC
2:05 PM	Documentation of Dietary Interventions in a Controlled Feeding Study and a Tolerance Study DeAnn Liska, Texas A&M AgriLife
2:20 PM	Regulatory OVERSIGHT in Clinical Trials: WHI & WHIMS Linda Snetselaar, University of Iowa
2:35 PM	Development of SOPs and Staff Training in Clinical Trials: OWLE Sue Shapses, Rutgers University
2:50 PM	Session 2 Panel Discussion Rick Mattes, Purdue University DeAnn Liska, Texas A&M AgriLife Linda Snetselaar, University of Iowa Sue Shapses, Rutgers University
3:15 PM	Day 1 Highlights Cheryl Anderson, UC San Diego
3:20 PM	Break
3:45 PM	Breakout Sessions

July 20, 2021 All times Eastern Daylight Time

12:00 PM	Welcome and Introductions to Day 2 Penny Kris-Etherton, Pennsylvania State University
12:05 PM	Session 3: Laboratory Management and Statistical Analysis Plans for Clinical Nutrition Studies Part 1 Kristina Petersen, Texas Tech University, Moderator
12:05 PM	Elements and Purpose of a Statistical Analysis Plan Kristina Petersen, Texas Tech University
12:35 PM	Preparing a Statistical Analysis Plan George McCabe, Purdue University
1:05 PM	Session 3 Panel Discussion Kathryn Barger, Tufts University Joshua Miller, Rutgers University Kevin Maki, Indiana University George McCabe, Purdue University Connie Weaver, Weaver & Associates, LLC
1:30 PM	Break
2:00 PM	Session 4: Laboratory Management and Statistical Analysis Plans for Clinical Nutrition Studies Part 2 Kevin Maki, Indiana University, Moderator
2:05 PM	Laboratory Considerations Joshua Miller, Rutgers University
2:35 PM	Completing Statistical Analyses and Reporting Results Kathryn Barger, Tufts University
3:05 PM	Data Management Planning and Execution Kevin Maki, Indiana University
3:35 PM	Session 4 Panel Discussion Kathryn Barger, Tufts University Joshua Miller, Rutgers University Kevin Maki, Indiana University George McCabe, Purdue University Connie Weaver, Weaver & Associates, LLC
4:00 PM	Day 2 Highlights Kevin Maki, Indiana University
4:05 PM	Break
4:15 PM	Breakout Sessions