Tufts University Friedman School of Nutrition Science and Policy
NUTR 314 – Study Design in Nutrition Research
Spring 2017

Class Meetings: Thursdays, January 19 to May 11, 9am–12pm, Room TBD

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Office hours: By appointment, HNRCA, 711 Washington Street, 901C

Credits: 1 credit

Course Description

Successful interventions, in research or for programs, rely on intentional design that begins with a hypothesis that can be developed into a conceptual model and translated into an intervention. This course describes this process, from conception, through design, to execution and implementation. Students are guided through generating hypotheses and introduced to specific principles of designing feasible studies—including intervention and observational studies—that address these hypotheses. Students will learn how having a critical understanding of research-based approaches can inform programmatic intervention and evaluation. Guest lectures will present real-world examples that illustrate this process. Students will gain experience in identifying appropriate funding sources and developing proposals that meet the interests and missions of potential funders. Students will also present their proposals, and review and critique the work of their classmates.

Prerequisites

At least one semester of introductory epidemiology, one semester of statistics, one semester of nutrition, and some familiarity with dietary assessment.

Course Objectives

Students will:

- Become familiar with the characteristics, language and logic of quantitative and qualitative study designs and methods
- Master principles of study design, specifically intervention, and select observational designs (cross-sectional and cohort)
- Articulate ethical issues in research, including the policies and practices used to protect research subjects, specifically human participants
- Identify and state a hypothesis and research question
- Conduct “due diligence” on hypotheses, in particular searching the literature and databases, and keeping up with the literature
- Design a research study or programmatic intervention that is ethical, efficient, feasible, likely to produce valid results, and able to answer the question(s) posed
- Identify funding mechanisms and draft a grant proposal
- Be able to recognize and assess quality and rigor in evaluating proposals for interventions and studies

Guest Lecturers

Virginia Rall Chomitz, PhD	virginia.chomitz@tufts.edu
Sai Das, PhD	sai.das@tufts.edu
Hassan Dashti, PhD, RD	hassan.dashti@mgh.harvard.edu
Christina Economos, PhD *[tentative]*	christina.economos@tufts.edu
Diane McKay, PhD	diane.mckay@tufts.edu
Nicola McKeown, PhD	nicola.mckeown@tufts.edu
Sabrina Noel, PhD	sabrina_noel@uml.edu
Jennifer Sacheck, PhD	jennifer.sacheck@tufts.edu
Karen Switkowski, PhD, MPH	karen_switkowski@harvardpilgrim.org

Texts and Materials

The textbook for this course is:

> William Trochim, James P Donnelly, Kanika Arora. *Research Methods: The Essential Knowledge Base*. 2nd Edition. Cengage Learning, 2015. (ISBN-13: 9781133954774. ISBN-10: 1133954774)

In addition to the textbook, selected journal articles related to each class topic will be required. Students will also be expected to identify and familiarize themselves with published literature relevant to their study design projects. The textbook is on reserve in the Hirsh Health Sciences Library, but students are encouraged to obtain their own copy. The required journal articles and other material will be made available on Trunk.

Academic Conduct

Each student is responsible for upholding the highest standards of academic integrity, as specified in the Friedman School's Policies and Procedures manual (http://nutrition.tufts.edu/documents-and-forms/policies-and-procedures-students) and Tufts University policies (http://students.tufts.edu/student-affairs/student-life-policies/academic-integrity-policy). It is the responsibility of each student to understand and comply with these standards, as violations will be sanctioned by penalties ranging from failure on an assignment and the course to dismissal from the school. Assignments are to be completed independently (without solicitation of help from other individuals in person or online), unless otherwise indicated. In certain cases, assignments may be assessed for plagiarism using tools such as TurnItIn. A significant part of appropriate academic conduct is proper citation of ideas that are not your own. Assignments must include appropriate citations. For this course, APA will be the required citation format for all assignments. There are great resources for APA formatting available here: https://owl.english.purdue.edu/owl/resource/560/01/. It will be helpful for you to become familiar with using Endnote, Zotero, or another automated citation formatting software. If citing sources—including the why, what, and how—is new to you, please bring it up with the instructor. Finally, if you know you have writing weaknesses, please seek help early from Tuft's writing tutors.

Classroom Conduct and Laptop Policy

Students are expected to attend all sessions, to have read the assigned materials before coming to class, and to participate in class exercises and discussions. We will discuss the in-class laptop use policy during the first session.

Accommodation of Disabilities

Tufts University is committed to providing equal access and support to all students through the provision of reasonable accommodations so that each student may access their curricula and achieve their personal and academic potential. If you have a disability that requires reasonable accommodations please contact the Friedman School Assistant Dean of Student Affairs at 617-636-6719 to make arrangements for determination of appropriate accommodations. Please be aware that accommodations cannot be enacted retroactively, making timeliness a critical aspect for their provision.

Grading

Letter grades are assigned for individual assignments and overall based on points, as follows:

<80	C+ and lower (failing)
≥80–<83	B-
≥83–<87	B
≥87–<90	B+
≥90–<93	A-
≥93–<97	A
≥97	A+ (outstanding)

Students who are unable to complete the course for any reason must contact the instructor as soon as possible to discuss grading (e.g., withdrawal before add/drop deadline [W], incomplete [I], or failure) and/or remediation. Students will have one calendar year from the start of the course to complete the course requirements, otherwise an "I" or "W" grade will remain on the transcript. Students who receive a grade of less than a B in a course may repeat the course in order to attempt to earn a better grade. If a student re-takes a course and passes it, he/she receives credit for the course; both grades are included on the student transcript, and in the computation of the GPA. See the *Policies and Procedures Handbook* for additional information.

Assignments and Submission Instructions

Written assignments should be submitted in hard copy *and* electronically on Trunk on or before class start on the due date. Assignments received after the due date will not be accepted or graded unless an extension is approved *in advance*. Students who are unable to complete an assignment on time for any reason should notify the instructor in person or by email prior to the deadline, with a brief explanation for why an extension is needed.

Contributing to the course grade are the following categories and assignments

Participation, 30%	In-class Article review and discussion lead Final project presentation
Grant Proposal Development, 35%	Study Ideas Funding Sources Letters of Intent (2) Peer Review of Letters of Intent (2) Screening Questionnaire
Grant Proposal, 35%	Background Hypothesis and Specific Aims Methodological and Statistical Approaches Final Revision

Assignments are generally designed to be iterative, with built-in opportunities for improvement. These and the grading criteria will be discussed in detail in class. In brief, they include the following:

Participation
Students are expected to participate in class lectures and discussions in constructive ways. To do that, students must complete the required reading and homework before each class. It is recognized that students have different levels of comfort in participating. Thus, various opportunities will be available for contributing to the class learning environment from small group work to all class discussions.

Article Review and Discussion Lead
Students will present and lead a discussion of a published, peer-reviewed article on a nutrition-related topic, including a review of the grant proposal (if available), the study protocol, and related information (e.g., prior papers on the study, study web sites, etc.).

Study Ideas
Students are to identify a tentative list of 5 study questions/research hypotheses that they are interested in developing further as a part of their grant proposal project. Brief statements of the underlying rationale for each question are to be provided.

Funding Sources
Students are to identify potential funding sources for each of the 2 study questions. Sources may include NIH, foundations (e.g., Robert Wood Johnson, Gates, Clinton), local agencies, pilot mechanisms, etc. Alongside naming the potential source, relevant RFPs, guidelines, or other documentation related to proposal submission requirements are to be provided, as well as why a given source is a good fit for the study question(s). Students should be mindful of the feasibility of their study given the funding amounts.

Letters of Intent (2)
After students have narrowed their list of study questions to 2 (from the 5 above) following feedback from the instructor, they will develop a Letter of Intent (LOI) for each study question.

Peer Review of Letters of Intent (2)
Students will share their 2 LOIs with 2 classmates (1 LOI each) for constructive peer review.

Screening Questionnaire
Students will develop a screening questionnaire appropriate to their chosen research topic and specific aims, based on their inclusion/exclusion criteria.

Grant Proposal Parts 1–4 and Presentation
Over the latter half of the semester, students will develop grant proposal incrementally, be provided with feedback, and ultimately submit full, revised proposals based on new/changing knowledge and feedback. The research proposal should reflect the student's ability to critically review scientific literature, understand how the proposed research fits into the existing body of evidence, design a methodologically and ethically sound study. The proposed study must involve new recruitment and data collection, or be an ancillary study that uses existing study resources, yet requires new data collection, validation, or assays. Students will practice writing and presentation skills.

Course Topics and Learning Objectives

See the **Course Schedule** for a weekly overview of topics, lecturers, skill building, class preparation (e.g., readings), and assignments due.

Week 1, January 19
This session provides an overview of course concepts and introduces the major approaches of study design. We will review principles of epidemiology and conduct a self-assessment of existing knowledge. Students will explore the many ways research questions can be answered.

Learning Objectives:
- Understand the overall objectives and general structure of NUTR 314
- Describe and classify the basic types of study designs
- Identify study designs used in sample manuscripts and potential alternate study designs, and rationale behind choosing one approach or another
- Describe the general steps involved in developing a study and how the principles of effective study design inform the development of intelligent programmatic interventions

Week 2, January 26
This session has three main topics: ethics and informed consent; research question formation; and due diligence and background. Students will learn about IRB processes, learn how researchers identify gaps in the literature, and begin to formulate their own research questions.

Learning Objectives:
- Describe underlying principles of ethical considerations for studies involving human subjects
- Summarize the important concepts of informed consent and the components of a well-designed informed consent form
- Understand how researchers and program managers are able to identify gaps in the evidence and needs
- Use databases and other online sources to conduct literature reviews
- Discuss the characteristics of well-formed research/intervention questions and hypotheses
- Explain FINER and PICO criteria

Week 3, February 2
This session focuses on key components of intervention studies, discusses selection of outcomes and other measurements and monitoring, and introduces via a pilot example “real world” grant application requirements. Students will learn from an expert investigator.

Health Topic: Foods and nutrients

Learning Objectives:
- Discuss characteristics of intervention studies, including randomization, controls, blinding, etc., as well as their advantages and disadvantages, uses and rationale
- Discuss different types of measures, endpoints, and outcomes, issues surrounding surrogate endpoints, and using measures to assess adherence, including concepts of validity and reliability, and precision and accuracy
- Give examples of sources of error and methods of assessing error
- Be able to state a research question in the form of a testable hypothesis
- Explain SMART criteria
- Become familiar with grant funding sources and applications/requirements

Week 4, February 9
This session focuses on various study settings and identifying target populations, setting inclusion and exclusion criteria, and the limitations implicit in sample selection. Skill development will focus on rewriting research questions as specific aims. Students will hear from an expert interventionist.

Health Topic: Weight loss and exercise

Learning Objectives:
- Learn to determine appropriate study populations for an intervention or observational study
- Give examples of different types of sampling strategies, including advantages and disadvantages/
- Give examples of different types of participant selection criteria, with advantages and disadvantages
- Define "bias" and give examples of types of bias in various study designs and settings
- Learn to restate research questions as hypotheses and specific aims

Week 5, February 16
This session focuses on non-experimental study designs, including cross-sectional, survey, and cohort studies. Additional session foci expand on last week's participant orientation, with discussion of sample size and recruitment, and screening strategies. Students will practice identifying screening criteria and inherent limitations for their own research questions. Students will also hear from an expert epidemiologist on cohort design, inception, and recruitment.

Health Topic: Dietary patterns

Learning Objectives:
- Be able to discuss dietary patterns and give examples of why and how we study them
- Describe and give examples of select observational study designs, their strengths and weakness, and their appropriateness within specific settings
- Describe the factors needed to conduct sample size and power analyses
- Identify appropriate screening strategies for a given study
- Understand drivers of successful recruitment approaches
- Learn to design an effective, short screening questionnaire

Week 6, March 2
This session extends prior sessions on cohort and intervention studies and adherence and outcome assessment by exploring in greater detail two complex topics: protocol development and data collection methods and tools. Students will learn from a PhD, RD who is a sleep researcher. In addition, students will share the peer review of their LOIs and spend time discussing the feedback with their peer reviewers. Students will also review in class their grant application guidelines and requirements, and grant proposal assignments will be reviewed.

Health Topic: Sleep

Learning Objectives:
- Discuss interrelationships between sleep, diet, and overall health
- List uses of protocols and ways of ensuring adherence to protocols
- Describe key elements in the design of data collection instruments, advantages and disadvantages

- Describe logistic and other considerations for collection and management of different types of data

Week 7, March 9
This session focuses on community-based participatory research (CBPR)/interventions and will additionally include discussion of program evaluation. Students will learn from a researcher specializing in CBPR approaches. Students will also have in-class time to work on and ask questions about the background portions of their grant proposals, using examples of actual background sections.

Health Topic: Community-based participatory research and interventions

Learning Objectives:
- Describe the history, principles, and process considerations associated with community engagement in research and CBPR
- Describe key considerations of planning community studies/interventions
- List examples and key characteristics of this type of research that make it especially challenging and rewarding
- Describe key elements of program evaluations and stages of evaluation
- Learn how to develop the background/literature section of a grant proposal

Week 8, March 16
This session focuses on health disparities, qualitative research methods, and iterates aspects of CBPR introduced in the previous week. Students will learn from a researcher specializing in health disparities. Students will also have in-class time to work on and ask questions about the specific aims portions of their grant proposals, using examples of actual aims sections.

Health Topic: Health disparities

Learning Objectives:
- Discuss socioeconomic, cultural, and historical reasons for health disparities
- Give examples of disease and mortality disparities in the US
- Elaborate on qualitative methods and differences between quantitative and qualitative methods
- Learn how to construct a script for an interview or semi-structured interview
- Learn how to develop the specific aims section of a grant proposal

Week 9, March 30
Extending discussions of CBPR and disparities, and introducing child health, this session focuses on focuses on challenges in behavior tracking and modification, and in working with children. Students will learn from an expert working in interventions targeting child physical activity and health. Students will also have in-class time to work on and ask questions about the methodological and statistical portions of their grant proposals, using examples of actual methodologies sections.

Health Topic: Child health

Learning Objectives:
- Discuss why focusing on child health may be critical for adult (lifelong) health

- Describe rewards and specific challenges of developing studies and programs involving children, and subsequently working with children and their parents, schools, etc.
- Learn how to develop the methodological and statistical portions of a grant proposal

Week 10, April 6
This session focuses on studies of mothers and children, their importance and complexity, and on the practical topics of protocol-driven study execution and study management. Students will hear from an experienced project manager-turned-investigator about the day-to-day of running a long-term study.

Health Topic: Mothers and children

Learning Objectives:
- Understand why multi-generational studies are important to our understanding of health and disease
- Describe some of the complexities of working with mothers and their children over the very long-term (i.e., gestation through adolescence)
- Understand the central role of protocols, and how deviations from protocols subject outcomes to bias
- Recognize the complexity of study management and day-to-day operations
- List several “best practices” of study management

Week 11, April 13
This session takes students beyond the research itself, pushing them to consider the bigger picture of the effects of research on the world around us, and how to meet “real world” challenges by scaling science for broader impact. Students will learn from a leader in the field of nutrition research whose work is (well-)known as “Child Obesity 180”.

Health Topic: Child health

Learning Objectives:
- Describe known (intended and unintended) implications of research, how it impacts people, communities, businesses, government, etc., beyond the proverbial ivory tower
- Describe how research can move from an academic pursuit into an agent of change
- Discuss strategies to scaling science and implementing research-derived initiatives in ever broader settings

Weeks 12 and 13, April 20 and 27
Student presentations

Weeks 14–15, May 4–11
No classes. Feedback and revisions of grant proposal; final proposal due by May 11

Course Schedule

This schedule is subject to modification at the instructor's discretion. Each week we focus on a given nutrition-related health topic, review why and how it has been studied, including a presentation of a specific article and related materials, enjoy a guest lecture about study design and execution on that topic, review related study design components, and build skills around specific aspects of study design and grant proposals.

	Date	Health and Study Design Topics	Guest Lecturer/Topic	Class Preparation	Material Due
1	1/19	Introductions, epidemiology review	—	Review notes and texts from prior courses in statistics and epidemiology	—
2	1/26	Ethics, informed consent	—	Text, Ch. 1, Foundations of Research Methods Text, Ch. 2, Ethics *Supplemental resources:* Nuremburg Code: http://ohsr.od.nih.gov/nuremberg.php3 Belmont Report: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm	Online Human Subjects CITI Training & Certificate
3	2/2	Foods and nutrients, intervention studies in nutrition, outcomes and measures, funding	Diane McKay, PhD—Small-scale and short-term interventions	Text, Ch. 5, Introduction to Measurement Text, Ch. 6, Scales, Tests, and Indexes McKay, *et al*. Chronic and acute effects of walnuts on antioxidant capacity and nutritional status in humans: a randomized, cross-over pilot study. *Nutr J*. 2010; 9:21. *[Note the open-access peer reviews available online, which informed the pecan protocol, below.]* Dr. McKay's Pecan Study Protocol	Study Ideas

4	2/9	Weight loss and exercise, study setting and target populations, inclusion and exclusion criteria	Sai Das, PhD—Worksite Wellness Study	Text, Ch. 8, Introduction to Design Text, Ch. 9, Experimental Design Salinardi, *et al*. Lifestyle intervention reduces body weight and improves cardiometabolic risk factors in worksites. *Am J Clin Nutr*. 2013; 97: 667–76. *Supplemental resources:* • Developing and Writing Grant Proposals http://njms.rutgers.edu/research/orsp/DevelopingAndWritingGrantProposals.htm • Guide for Writing a Funding Proposal http://learnerassociates.net/proposal/index.htm	Funding Sources
5	2/16	Dietary patterns, cross-sectional and cohort studies, recruitment and screening, pilots	Nicola McKeown, PhD—ADAPT	Text, Ch. 7, Survey Research Text, Ch. 10, Quasi-Experimental Design *Journal article TBD*	Letters of Intent
	2/23	*No class (Monday class substitution)*			
6	3/2	Sleep, recruitment, and protocols	Hassan Dashti, PhD, RD—SHIFT	Text, Ch. 4, Sampling *Journal article TBD*	Peer Reviews of Letters of Intent
7	3/9	Community-based participatory research, program evaluation	Virginia Rall Chomitz, PhD—Chinatown	Text, Ch. 3, Qualitative Approaches to Research *Journal article TBD*	Screening Questionnaire
8	3/16	Health disparities, community research, qualitative research	Sabrina Noel, PhD—Studies of health disparities	*Journal article TBD*	Grant Proposal Part 1—Background
	3/23	*No class (Spring Break)*			

9	3/30	Child health, behavioral interventions, school-based programs	Jennifer Sacheck, PhD—FLEX	Text, Ch. 11, Introduction to Data Analysis *[Should be a repeat of prior statistics classes; skim unless unfamiliar.]* Wright, *et al*. Study protocol: the Fueling Learning through Exercise (FLEX) study – a randomized controlled trial of the impact of school-based physical activity programs on children's physical activity, cognitive function, and academic achievement. *BMC Public Health*. 2016; 16:1078.	Grant Proposal Part 2—Hypothesis and Specific Aims
10	4/6	Studying mothers and children, study protocols, execution, management of long-term studies, participant retention	Karen Switkowski, PhD, MPH—Project Viva	Text, Ch. 12, Inferential Analysis *[Should be a repeat of prior statistics classes; skim unless unfamiliar.]* Oken, *et al*. Cohort Profile: Project Viva. *Int J Epidemiol*. 2015; 37–48.	Grant Proposal Part 3—Methodological and Statistical Approaches
11	4/13	Studying children, implications and impact of research: moving beyond the study, scaling science	Christina Economos, PhD—Child Obesity 180 *[tentative]*	Text, Ch. 13, Research Communication *Journal article TBD*	—
12	4/20	Student presentations	—	—	Presentation
13	4/27	Student presentations	—	—	Presentation
	5/4–11	Feedback and revisions	—	—	Grant Proposal Part 4—Final Revision (by May 11)