Tufts University Friedman School of Nutrition Science and Policy  
NUTR 314 – Study Design in Nutrition Research  
Spring 2019

Class Time: Thursdays, January 17 to May 9, 9am–12pm

Class Location: Jaharis Room 156

Instructor: Adela Hruby, PhD, MPH  
adela.hruby@tufts.edu  
617-556-3087

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

Credits: 3 semester hour units

Course Description
Successful interventions, in research or 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 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

Diane McKay, PhD  
diane.mckay@tufts.edu

Nicola McKeown, PhD  
nicola.mckeown@tufts.edu

Sabrina Noel, PhD  
sabrina_noel@uml.edu

Tracey Smith, PhD, RD  
tracey.smith10.civ@mail.mil

Karen Switkowski, PhD, MPH  
karen_switkowski@harvardpilgrim.org

**Texts and Materials**

The textbook for this course is:


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 Canvas.

**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](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](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. 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.

Diversity Statement
We believe that the diversity of student experiences and perspectives is essential to the deepening of knowledge in this course. We consider it part of our responsibility as instructors to address the learning needs of all the students in this course. We will present materials that are respectful of diversity: race, color, ethnicity, gender, age, disability, religious beliefs, political preference, sexual orientation, gender identity, socioeconomic status, citizenship, language, or national origin, among other personal characteristics.

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

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<th>A range (90–&lt;93 = A-, 93+ = A, A+ given for superlative work)</th>
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<td>90–100</td>
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<td>80–89</td>
<td>B range (80–&lt;83 = B-, 83–&lt;87 = B, 87–&lt;90 = B+)</td>
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<td>70–79</td>
<td>C range (70–&lt;73 = C-, 73–&lt;77 = C, 77–&lt;80 = C+)</td>
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<td>60–69</td>
<td>D range (60–&lt;63 = D-, 63–&lt;67 = D, 67–&lt;70 = D+)</td>
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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 or electronically on Canvas on or before class start on the due date, except as noted. 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

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<tr>
<th>Category</th>
<th>Percentage</th>
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<td>Participation, 37%</td>
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<td>In-class (5%)</td>
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<td>3-2-1 Reflections (18%)</td>
<td>9 pts, 2 pts each</td>
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<td>Special topic presentation (7%)</td>
<td>7 pts</td>
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<td>Final project presentation (7%)</td>
<td>7 pts</td>
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<td>Grant Proposal Development, 17%</td>
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<td>Study Ideas (5%)</td>
<td>5 pts, 1 pt each</td>
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<td>Letter of Intent &amp; Funding Sources (6%)</td>
<td>6 pts</td>
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<td>Peer Reviews of Letters of Intent (6%)</td>
<td>2, 3 pts each</td>
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The Grant Proposal and its development 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:

**In-Class Participation**
Students are expected to participate in class lectures and discussions in constructive ways. 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 whole class discussions.

**3-2-1 Reflections**
“3-2-1”s are weekly opportunities to demonstrate that students are following with the readings and synthesizing text-based material. These are due on **Wednesdays before 9:00am** to receive credit (24 hours prior to class time).

**Special Topic Presentation and Discussion Lead**
Students will present and lead a discussion of a published, peer-reviewed article on a special topic in study design.

**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 must be provided.

**Letter of Intent and Funding Sources**
After students have narrowed their list of study questions following feedback from the instructor, they will develop a Letter of Intent (LOI) for a single study question which will become the basis of their grant proposal. Students are to identify potential funding sources for their LOI. 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. Students should be mindful of the feasibility of their study given the funding amounts.

**Peer Reviews of Letter of Intent**
Students will share their LOI with 2 classmates for constructive peer review.

**Grant Proposal Parts 1–4, Peer Reviews (Parts 1 and 3), 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. Peer reviews of at least 2 parts of the proposal will be required.

**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 17**

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 24**

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 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

**Week 3, January 31**

This session focuses on various study settings, such as the workplace, and discusses selection of outcomes and other measurements and monitoring, bias, etc. Students will hear from an expert interventionist. Students will share and discuss their study ideas.

*Health Topic:* Weight loss and exercise, workplace wellness

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
- Define "bias" and give examples of types of bias in various study designs and settings
Week 4, February 7
This session focuses on key components of intervention studies, identifying target populations, setting inclusion and exclusion criteria, and the limitations implicit in sample selection, and introduces via a pilot example “real world” grant application requirements. Students will learn from an expert investigator. Skill development will focus on rewriting research questions as specific aims.

Health Topic: Foods and nutrients

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
- Explain SMART, FINER, AND PICO criteria
- Be able to state a research question in the form of testable hypotheses and specific aims
- Learn how to develop the specific aims section of a grant proposal
- Become familiar with grant funding sources and applications/requirements

Week 5, February 14
This session focuses on non-experimental study designs, including cross-sectional, survey, and cohort studies. Students will also hear from an expert epidemiologist on cohort design, inception, and recruitment. Additional session foci include sample size and recruitment, and screening strategies. Students will practice identifying inherent limitations to their own research questions.

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
- Understand drivers of successful recruitment approaches
- Describe the factors needed to conduct sample size and power analyses

[February 20 – Last day to drop class without record of enrollment]

[February 21 – No class, Monday schedule due to President’s Day]

Week 6, February 28
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
• Practice giving and hearing feedback in the context of peer reviews

Week 7, March 7
This session focuses on special topics in study design, potentially including topics such as regression discontinuity, equivalency and non-inferiority trials, regression to the mean, cross-over trials, practical/pragmatic clinical trials, adaptive clinical trials, platform clinical trials, randomization schema (cluster-randomized, multi-site), comparative effectiveness trials, stepped-wedge designs, hybrid designs, and others. Students will each present on a topic.

Learning Objectives:
• Learn about evolving approaches and key statistical issues in designing and analyzing studies
• Describe several evolving approaches to intervention study design
• Build presentation and discussion skills

Week 8, March 14
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. Students will have the opportunity to review with their peer reviewers their specific aims, including how they incorporated feedback. 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: Mothers and children

Learning Objectives:
• Understand why multi-generational studies are important to our understanding of health and disease
• Discuss why focusing on child health may be critical for adult (lifelong) health
• 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 very long-term study management
• Learn how to develop the background/literature section of a grant proposal

[March 21 – No class, Spring Recess]

Week 9, March 28
This session focuses on a unique population, military personnel, and discusses how unique populations demand unique approaches in their engagement, as well as serve very specific organizational needs. Students will learn from an interventionist specializing in soldier health.
Health Topic: Health of military personnel

Learning Objectives:
- Discuss how researchers have to manage and meet the unique needs of special populations as well as specific organizational requirements
- Learn how to develop the methodological and statistical portions of a grant proposal

Week 10, April 4
This session focuses on health disparities and introduces aspects of community-based participatory research. Students will learn from a researcher specializing in health disparities.

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
- 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

Week 11, April 11
Extending discussions of CBPR and disparities, and also including community and schoolchild health, this session focuses on engaging with and working in the community in various ways, as well as qualitative research. Students will learn from an expert with a history of working in interventions targeting child physical activity and health, as well as, more recently, community-wide health.

Health Topic: Community health

Learning Objectives:
- Describe rewards and specific challenges of developing studies and programs involving children, and subsequently working with children and their parents, schools, etc.
- Elaborate on qualitative methods and differences between quantitative and qualitative methods
- 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 18 and 25
Students will share their proposals to date in presentations, having an opportunity to receive feedback and questions from their peers and the instructor.

Weeks 14 and 15, May 2 and May 9
No classes. Revise grant proposal; final proposal due by May 9
## Course Schedule

This schedule is subject to modification at the instructor’s discretion. Each week we focus on a selected set of study design and nutrition topics and build skills around specific aspects of study design and grant proposals.

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<tr>
<th>Date</th>
<th>Topic</th>
<th>Guest Lecturer/Topic</th>
<th>Class Preparation</th>
<th>Material Due</th>
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| 1/17 | Introductions  
Course overview  
Epidemiology review | — | Review notes and texts from prior courses in statistics and epidemiology | — |
| 1/24 | Ethics, informed consent  
Study idea generation | — | Text, Ch. 1, Foundations of Research Methods  
Text, Ch. 2, Ethics  
Supplemental resources:  
http://www.bmj.com/content/313/7070/1448.1  
• Belmont Report  
Watch a very short mini-documentary called "First Light": a "quick-take" on the bigger topic of native peoples of Maine, and attempts at truth and reconciliation by state authorities (http://upstanderproject.org/firstlight/). It is an example of, among many things, why establishing trust with some communities can be immensely difficult, and why it is so critical. It is also reveals the corrosive damage of systemic racism, and why the inclusion of minority groups in research is a part of federal grant reviews. | Online Human Subjects CITI Training & Certificate  
3-2-1 Reflection #1 on textbook chapters (not on movie) |
| 1/31 | Weight loss  
Outcomes and measures  
Funding  
NOTE ROOM CHANGE SACKLER 316 | Sai Das, PhD—  
Worksite Wellness Study  
[11:00 am] | Text, Ch. 5, Introduction to Measurement  
Text, Ch. 6, Scales, Tests, and Indexes  
Study Ideas |
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<tr>
<td>4</td>
<td>2/7</td>
<td>Foods and nutrients</td>
<td>Text, Ch. 8, Introduction to Design</td>
<td>3-2-1 Reflection #3</td>
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<td>Intervention studies in nutrition</td>
<td>Text, Ch. 9, Experimental Design</td>
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<td>Study settings and target populations</td>
<td>McKay D, et al. Chronic and acute effects of walnuts on antioxidant capacity and nutritional status in humans: a randomized, cross-over pilot study. <em>Nutr J.</em> 2010; 9:21. [Note the open-access peer reviews available online, which informed the pecan protocol, below.]</td>
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<td>Inclusion and exclusion criteria</td>
<td>Dr. McKay's Pecan Study Protocol</td>
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<td>5</td>
<td>2/14</td>
<td>Dietary patterns</td>
<td>Text, Ch. 7, Survey Research</td>
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<td>Cross-sectional and cohort studies</td>
<td>Text, Ch. 10, Quasi-Experimental Design</td>
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<td>Recruitment strategies</td>
<td><em>Journal articles TBD</em></td>
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<td>Pilots</td>
<td><em>Supplemental resources:</em></td>
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<td>• Developing and Writing Grant Proposals <a href="http://njms.rutgers.edu/research/orsp/DevelopingAndWritingGrantProposals.htm">http://njms.rutgers.edu/research/orsp/DevelopingAndWritingGrantProposals.htm</a></td>
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<td>• Guide for Writing a Funding Proposal <a href="http://learnerassociates.net/proposal/index.htm">http://learnerassociates.net/proposal/index.htm</a></td>
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<td>3-2-1 Reflection #4</td>
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<td>Letter of Intent and Funding Sources</td>
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<td>Email this to peer reviewers and upload to Canvas by 9am, Thursday, 2/14</td>
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<td>2/21</td>
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<td>No class (Monday schedule substitution)</td>
<td>2 Peer Reviews of Letter of Intent</td>
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<td>Guest Lecturer/Topic</td>
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<td>7</td>
<td>3/7</td>
<td>Student presentations on special topics in study design</td>
<td>Student presentations</td>
<td>Reading(s) for your special topic Skim other special topic readings Special Topic Presentation Grant Proposal Part 1—Specific Aims DRAFT ONLY email to peer reviewer by 9am; 48-hour turnaround</td>
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<td>3/21</td>
<td>No class (Spring Recess)</td>
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| 10   | 4/4                      | Health disparities  
Community-based participatory research                               | Sabrina Noel, PhD—  
Studies of health disparities  
[11:00 am]                                                                            | Text, Ch. 13, Research Communication  
*Journal articles TBD*                                                                | 3-2-1 Reflection #8  
Grant Proposal Part 3—Research Plan: Approach **DRAFT ONLY email to peer reviewer by 9am; 48-hour turnaround** |
| 11   | 4/11                     | Community-based participatory research  
Qualitative research  
Program evaluation                                                                 | Virginia Rall Chomitz, PhD—Chinatown  
[11:00 am]                                                                            | Text, Ch. 12, Inferential Analysis *Should be a repeat of prior statistics classes; skim unless unfamiliar.*  
Text, Ch. 3, Qualitative Approaches to Research  
Obesity; 2010; 18: Supplement 1.  
2014; 3:199-205.                                                                 | 3-2-1 Reflection #9  
Grant Proposal Part 3—Research Plan: Approach                                                                                     |
| 12   | 4/18                     | Student presentations                                                            | Student presentations                                                               | —                                                                                   | Presentation                                                                 |
| 13   | 4/25                     | Student presentations                                                            | Student presentations                                                               | —                                                                                   | Presentation                                                                 |
| 5/2–9| No class (reading/finals period)                                       | —                                                                                   | —                                                                                   | Grant Proposal Part 4—including Project Summary/Abstract, Narrative, Literature Cited, Inclusion of Women/Minorities, Inclusion of Children, and **Final Revision** of all previous sections; upload to Canvas by May 9, 12pm |