Brothers, Sheila

From: Farrell, Herman
Sent: Wednesday, February 21, 2018 7:56 AM
To: Brothers, Sheila; McCormick, Katherine
Cc: Kellum, Rebecca; Knudsen, Hannah
Subject: MS - Medical Sciences

The SAASC convened on Friday, February 16, 2018 to consider a proposal from the College of Medicine involving a change in the MS – Medical Sciences program. The change involves the formal recognition of the Clinical and Translational Science (CTS) concentration.

Attendance: Dan Morey, David Hulse, Dan Howe, Fred Danner, Kevin Donohue, Brad Hubbard, Brad Kerns, Rebecca Kellum, Herman Farrell (Chair).

Procedure:

Rebecca Kellum served as the facilitator of the proposal. She corresponded with Dr. Hannah Knudsen, the contact person for the proposal.

Discussion:

As noted in the proposal: "The CTS concentration seeks to provide rigorous research training to students pursuing research that involves the translation of basic science into clinical applications, the testing of clinical interventions in human subjects, and efforts to move clinical innovations into routine medical practice." Typically, the CTS students have already completed a formal professional degree (MD, DMD, PharmD).

Dr. Kellum described the essential elements of the proposal. Proposed changes include: the waiver of two basic science courses for students who have already completed equivalent coursework in their basic biomedical sciences training; the required completion of 3 courses that teach students the core research methodologies of research science, team science, grant writing skills and fundamentals in biostatistics; the required completion of a course that addresses ethical issues in conducting CTS research with human subjects; and the required completion of a seminar on clinical and translational science.

Vote:

A motion was made and seconded that the SAASC approve the proposal from the College of Medicine involving a change in the MS – Medical Sciences program.

The committee voted 9 in favor, 0 opposed.

Herman Daniel Farrell III
Chellgren Endowed Professor
Associate Professor - Playwriting
University of Kentucky

CHANGE MASTERS DEGREE PROGRAM FORM

1. GENERAL INFORMATION

College:	Medicine	Department:	
Current Major Name:	Medical Sciences	*Proposed Major Name:*	*Medical Sciences*
Current Degree Title:	Master of Science	*Proposed Degree Title:*	*Master of Science*
Formal Option(s):	Plan A & Plan B	*Proposed Formal Option(s):*	*Clinical & Translational Science- this would be an added concentration*
Specialty Fields w/in Formal Option:	N/A	*Proposed Specialty Fields w/in Formal Options*:	
Date of Contact with Associate Provost for Academic Administration[1]:			
Bulletin (yr & pgs):		CIP Code[1]:	Today's Date: 11/6/2017
Accrediting Agency (if applicable):			
Requested Effective Date:	☒ Semester following approval.	OR	☐ Specific Date[2]:
Dept. Contact Person:	Bridget Szczapinski	Phone: 218-6745	Email: bsz222@uky.edu

2. CHANGE(S) IN PROGRAM REQUIREMENTS

		Current	*Proposed*
1.	Number of transfer credits allowed	9	*9*
	(Maximum is Graduate School limit of 9 hours or 25% of course work)		
2.	Residence requirement (if applicable)		
3.	Language(s) and/or skill(s) required		
4.	Termination criteria		
5.	Plan A Degree Plan requirements[3] (thesis)	24 + 6 research hours	*24+6 research hours*
6.	Plan B Degree Plan requirements[3] (non-thesis)	27 + 3 research hours	*27 + 3 research hours*
7.	Distribution of course levels required	one-half at 600+ level & two thirds in organized courses	*one-half at 600+ level & two thirds in organized courses*
	(At least one-half must be at 600+ level & two-thirds must be in organized courses.)		
8.	Required courses (if applicable)	IBS 602, IBS 606, Tox 600, MI 772 or similar seminar course	*IBS 602 and IBS 606 waived due to content being previously covered in applicant's professional school. BSC 731 and BSC 732 to be required. BSC 534*

[1] Prior to filling out this form, you MUST contact the Associate Provost for Academic Administration (APAA). If you do not know the CIP code, the APAA can provide you with that during the contact.

[2] Program changes are typically made effective for the semester following approval. No changes will be made effective until all approvals are received.

[3] If there is only one plan for the degree, plans involving a thesis (or the equivalent in studio work, etc.) should be discussed under Plan A and those not involving a thesis should be discussed under Plan B.

			and BSC 733 to be substituted for Tox 600 and seminar course; BSC 625 or similar biostatistics course to be required
9.	Required distribution of courses within program (if applicable)		
10.	Final examination requirements	Presentation/Defense of thesis or final research project, as applicable for Plan A or B	*Presentation/Defense of thesis or final research project, as applicable for Plan A or B*
11.	Explain whether the proposed changes to the program (as described in sections 1 to 10) involve courses offered by another department/program. Routing Signature Log must include approval by faculty of additional department(s).		
	BSC 534 and BSC 733 will be involved as formal substitution options to meet the ethics (TOX 600) and seminar course (MI 772) requirements in the MSMS program, respectively. Students in the CTS concentration will be required to take BSC 731 and BSC 732. Students will also be required to take BSC 625 or an equivalent biostatistics course (e.g., STA 580).		
12.	List any other requirements not covered above?		
13.	Please explain the rationale for changes. If the rationale involves accreditation requirements, please include specific references to those requirements.		
	This proposal is to formally recognize the Clinical and Translational Science (CTS) concentration as a pathway option for CTS students who are interested in earning their MS in Medical Sciences (MSMS) degree. The CTS concentration seeks to provide rigorous research training to students pursuing research that involves the translation of basic science into clinical applications, the testing of clinical interventions in human subjects, and efforts to move clinical innovations into routine medical practice. Students accepted into the MSMS-CTS program typically consist of fellows or residents who have completed a formal professional degree program (e.g., MD, DMD, PharmD) with a rigorous basic biomedical sciences training that is identical or closely approximates the two basic science core courses, IBS 602 and IBS 606, in the MSMS program. Therefore, it is proposed that the two MSMS basic science core courses, IBS 602 and IBS 606, be waived. However, any CTS applicant who has not completed equivalent coursework will be required to enroll in and pass IBS 602 and IBS 606. All MSMS-CTS students will be required to complete BSC 731 (Methods and Technologies in Clinical and Translational Science), BSC 732 (Interdisciplinary Protocol Development), and BSC 625 (Fundamentals for Biostatistics in Clinical & Translational Research). The rationale for these courses is that 1) CTS students need to learn the core research methodologies of CTS science, which is covered in BSC 731, 2) team science and grant writing are key skills for CTS researchers, and these topics are covered in BSC 732, and 3) data from human subjects research typically involves a variety of statistical techniques, which are covered in BSC 625. A course that addresses similar statistical skills (e.g., STA 580) may be completed in place of BSC 625. Because students in the CTS concentration are focused on research with human subjects, all CTS students will be required to complete BSC 534, a course specifically designed to address ethical issues in conducting CTS research with human subjects. The rationale for requiring BSC 534 in place of TOX 600 is that TOX 600 is focused on bench research that does not involve human subjects.		

	In place of MI 772, all CTS students will be required to take BSC 731 which is a seminar course on clinical and translational science. It is aligned with the learning objectives of this program, and is more relevant to the research training needs of CTS students than MI 772. CTS students who have completed a professional degree program (e.g., MD, DMD, PharmD) will not be required to submit any entrance exam scores (e.g., GRE, MCAT, DAT). Note: The CTS program is housed in the Department of Behavioral Science. The requirements described above are aligned with the learning objectives of the CTS concentration. CTS students will then be required to complete the requisite number of hours and successfully pass a master's final exam to complete their MSMS degree.

CHANGE MASTERS DEGREE PROGRAM FORM

Signature Routing Log

General Information:

Proposal Name: _____

Proposal Contact Person Name: _____ Phone: _____ Email: _____

INSTRUCTIONS:

Identify the groups or individuals reviewing the proposal; note the date of approval; offer a contact person for each entry; and obtain signature of person authorized to report approval.

Internal College Approvals and Course Cross-listing Approvals:

Reviewing Group	Date Approved	Contact Person (name/phone/email)	Signature
Basic Science Sub-Committee (COM)	3-30-17	Tom Rosenau / 859 / 257-5286	
Curriculum Committee	4-17-17	Chris Feddock / 859 / 257-5286	
		/ /	
Faculty Council	4-17-17	Gregory Tudor / /	
		/ /	

External-to-College Approvals:

Council	Date Approved	Signature	Approval of Revision[4]
Undergraduate Council			
Graduate Council	9/21/17	Roshan Nikou	
Health Care Colleges Council			
Senate Council Approval		University Senate Approval	

Comments:

_____

[4] Councils use this space to indicate approval of revisions made subsequent to that council's approval, if deemed necessary by the revising council.

Brothers, Sheila

From: Knudsen, Hannah
Sent: Monday, November 20, 2017 8:44 AM
To: Pearson, RaeAnne M
Cc: Brothers, Sheila; Office of Strategic Planning and Institutional Effectiveness
Subject: Re: Proposed Change to MS Medical Sciences

From: "Pearson, RaeAnne M" <raeanne.pearson@uky.edu>
Date: Friday, November 17, 2017 at 5:21 PM
To: Hannah Knudsen <hkknud2@uky.edu>
Cc: "Brothers, Sheila" <sbrothers@uky.edu>, Office of Strategic Planning and Institutional Effectiveness <OSPIE@uky.edu>
Subject: RE: Proposed Change to MS Medical Sciences

Dear Dr. Knudsen,

Your change proposal was forwarded to our office by Sheila Brother at the University Senate Office. Our office reviews all new program proposals and curriculum changes for adherance to SACSCOC's Substantive Change Policy. Regarding the proposed program change(s) to **Medical Sciences, MS(26.0102/Previously: 26.9999.03)** my email will serve 2 purposes: 1.) Next steps for SACSCOC, and 2.) Verification and notification that you have contacted OSPIE—a Senate requirement for proposal approval.

1. **Next steps for SACSCOC:** None required
2. **Verification that OSPIE has reviewed the proposal:** Based on the proposal documentation presented and Substantive Change Checklist, the proposed program changes (refer to list below) are not substantive changes as defined by the University or SACSCOC, the university's regional accreditor. Therefore, no additional information is required by the Office of Strategic Planning & Institutional Effectiveness at this time. The proposed program change(s) may move forward in accordance with college and university-level approval processes.

List of Proposed Change(s):

· Revisions to the course requiements for the Clinical & Translational Sciences Concentration

Should you have questions or concerns about UK's substantive change policy and its procedures, please do not hesitate contacting me.

RaeAnne Pearson, PhD
Office of Strategic Planning & Institutional Effectiveness
University of Kentucky
Phone: 859-218-4009
Fax: 859-323-8688
Visit the Institutional Effectiveness Website: http://www.uky.edu/ie

BSC 731: Methods & Technologies in Clinical and Translational Science
Spring 2017, Thursdays, 5:00pm-7:30pm
Medical Behavioral Science Building, Room 104

Course Directors

J. Matthew Webster, Ph.D. (webster@uky.edu)
Carl G. Leukefeld, Ph.D. (cleukef@uky.edu)
Course directors are available by appointment.

Course Assistant

Katherine Marks, Ph.D. (katie.marks@uky.edu)

Clinical and translational science (C&TS) has emerged as an approach strongly endorsed by the National Institutes of Health to increase the impact of research on human health. C&TS retains some design elements of traditional human biomedical and behavioral research, but it also challenges the overarching tradition of single-discipline research that is conducted under tightly controlled conditions. For example, while the core methodologies of C&TS research may be similar to conventional research (e.g., random assignment and double-blind placebo experimental designs), research designs may have to adapt to the realities of conducting research in "real world" clinical settings where conditions cannot be as rigorously controlled as they would be in the laboratory. C&TS is critical to the movement of interventions from efficacy to effectiveness research. C&TS may also integrate multiple methodological approaches in its research with human subjects, drawing upon techniques used in the behavioral and social sciences, such as qualitative, survey, and experimental methods.

While C&TS may be informed by basic "bench" research and examine the effectiveness of specific innovations (e.g., procedure, treatment, or technology) in real-world clinical settings, it also considers questions about the implementation of clinical innovations, particularly the changes necessary for making an innovation a part of routine care that can be sustained over time. C&TS is not only focused on the efficacy and effectiveness of clinical innovations, but it is also concerned with translating those innovations into everyday practice. It may address the interface of clinical innovations with individual users (e.g., medical personnel), with recipients of the innovation (e.g., patients), with organizational systems of care (e.g., hospitals, outpatient clinics), and with the broader environment of healthcare (e.g., regulatory systems, public policy, and financing of health care).

Perspectives from multiple disciplines are often integrated into the formation of research questions and the development of research designs, thereby transcending the perspective of any single discipline. Such inter- and trans-disciplinary research requires researchers to learn to communicate in scientific languages beyond their own fields and to consider new conceptual and theoretical approaches that may be tested and refined through C&TS research.

Core Principles of the Course

C&TS transcends the boundaries of traditional disciplines by integrating concepts and theories from multiple perspectives. C&TS is supported through creativity, intellectual curiosity, and openness to new points of view. The course directors assume that students in this course

are either actively engaged in human subjects research or intend to be involved in such research in the near future. This course has been designed around a key principle that practical knowledge about how to conduct C&TS should be our primary focus. A second key principle is that this course is *student-centered*, meaning that it emphasizes the involvement of students in applying the concepts of C&TS to their own research interests. Students are encouraged to explore and develop their research through written course activities. While the course instructors recognize that many students work with mentors on existing projects, it is expected that students make progress toward their development as independent scientists through their written assignments. These written activities are intended to promote the creative application of research concepts to students' areas of interest while fostering practical knowledge that is supportive of students' own research agendas. The diverse interests and experiences of students and faculty offer opportunities to learn from each other.

Course Objectives

Students will learn the core methodologies of clinical and translational science through classroom experiences, readings, and written portfolio activities that challenge them to apply methodological concepts to their own areas of research interest. The specific objectives of this course are:

1. To compare clinical and translational science (C&TS) to conventional bio-behavioral and bio-medical research designs.

2. To learn how to formulate C&TS research questions and aims.

3. To build skills in conducting and writing literature reviews.

4. To understand and appreciate a variety of types of research methods and technologies that may be applied in C&TS.

5. To apply C&TS methods and technologies to diverse areas of research, with a focus on aligning appropriate research methodologies based on the research questions of interest.

6. To enhance interdisciplinary communication and collaboration skills.

Course Materials

Course materials include book chapters, journal articles, and portfolio activities. There are two required books for the course, both of which are available from online sellers, such as Amazon (http://www.amazon.com) or Barnes & Noble (http://www.barnesandnoble.com).

1) ***Designing Clinical Research*, 4th edition**, edited by Stephen Hulley, Steven Cummings, Warren Browner, and Deborah Grady (2013). In addition to the paperback version, Amazon offers this book in a Kindle edition while Barnes & Noble sells it for the Nook.
2) ***How to Read a Paper*, 5th edition** by Trisha Greenhalgh (2014). In addition to the paperback version, Amazon offers this book in a Kindle edition.

Other course materials and assignments are housed on a BSC 731 course site, which is located within UK's online learning management system known as Canvas. You will need to regularly

access the BSC 731 Canvas site. To log in, visit **https://uk.instructure.com.** You will be prompted to enter your Link Blue user id (after "MC\" or "AD\") and your Link Blue password. Once you are logged in, you simply select BSC 731-001 to enter the course website. The course website serves four critical functions:

1) Providing access to non-textbook readings for downloading (via the Modules tab)
2) Submitting all assignments (via the Assignments tab)
3) Receiving feedback on your assignments from the course instructors
4) Seeing due dates for assignments (via the Calendar)

Course Activities

Learning will be facilitated through a combination of readings, written activities, and group discussions in the classroom. These activities include:

1) Core readings that provide an overview of methodologies (the "tools of the trade") and, to a lesser extent, research examples (concrete examples of "research in action"). The reading load for this course is ambitious, but it is intended to provide the resources to help you to design a strong research project. Core readings include chapters from the required textbooks as well as articles that are posted in the weekly "Modules" on Canvas. It is expected that you will have completed the core readings before class meets. For some topics, we have included additional references that may be helpful, but these are not required readings.

2) A portfolio of writing activities that challenge students to integrate the concepts from the readings into their own research interests. These activities are intended to stimulate critical thinking while allowing you to practice different facets of research design. Most are brief writing activities (1-3 pages), but somewhat longer writing activities will encourage you to apply the research methodologies to your own areas of interest. The portfolio activities are structured to support the development of the Research Design Project (see page 18). Please note that, in some cases, your research questions might not be well matched with the research method or technology focus of a particular writing assignment. Adapting your research questions or applying a different, but related, research question from your field of interest might be necessary at times.

Each assignment is posted within Canvas (simply click the "Assignments" button. These portfolio activities will often be the basis for in-class discussions, so it is expected that you will have completed each activity before class. Written assignments are to be uploaded to the course's Canvas site before 5pm on the day class meets. The course instructors will subsequently provide you with feedback on your written assignments through comments directly posted within Canvas.

3) Leading an in-class discussion. This is a vital skill to develop. Each student will be responsible for guiding the discussion through the core readings for one of the following weeks of class: 5, 6, 7, 10, 11, 12, 13, and 14. Students will need indicate their preference (first and second choices) for which week they will guide the readings discussion. The list of topics is posted within Canvas in the Discussion section. In the left column, click "Discussions" to respond with your top two choices of topics by **Thursday, February 2**. Assignments will be made on a first come, first serve basis, based on responses within this Discussion thread. If you do not reply to the Discussion by February 2, the course instructors will assign a topic to you. See the section on page 19, *Guide to Serving as an In-Class Discussion Leader,* for more information about how to prepare for this assignment.

4) In-class discussions that consider important concepts related to C&TS methods, how students might apply C&TS research methods to their own interests, and key "lessons learned" from research experiences (e.g., how decisions about research design were made and how challenges during the research process were addressed). This course is intended to be an interactive experience for both students and the course directors, so participation in discussions is expected. Didactic lectures will be kept to a minimum. Because of the significant value of these discussions in relation to the learning objectives of the course, generally absences will not be excused.

5) A research design project using one of the methodologies covered in the course. This more in-depth research design will be based on each student's research interest using a research methodology that is consistent with C&TS. It is expected that this project will be distinct from your mentor's current or proposed research. This expectation is consistent with the course's objective of promoting your growth toward becoming an independent scientist. In addition, your research design project should be a proposed project that would recruit human subjects (i.e., would require institutional review board (IRB) approval to implement the study). You will submit an initial draft of your research design project on **April 20** for the peer review experience (described below) and then the final draft on **May 4**.

6) A peer review experience during the process of developing a research design project, which includes reading and constructively critiquing other students' work. This activity will provide students with feedback about their own research design while also giving them the experience of preparing constructive feedback for other students.

Grading for the Course

Points will be accumulated based on completion of the required elements of the course at an acceptable level of quality based on scholarly completion of the activities. In general, it is the course directors' grading philosophy to allocate the full point value as long as reasonable effort has been directed towards a given activity. Sloppy or incomplete work, however, will be penalized at the discretion of the course directors. Late submissions of written activities will result in a 10% point penalty per day. Absence from a class meeting will result in the forfeiture of the points associated with that class meeting.

Maximum point values for course activities are as follows:
Attendance and participation: 14 class meetings @ 10 points each = 140 points
Serving as an In-class Discussion Leader: 30 points
Portfolio Activities: 11 portfolio activities (weeks 2 through 13) @ 25 points each and 2 portfolio activities (weeks 14 and 15) @ 40 points each = 355 points
Final Research Design Project: 75 points

Based on your accumulation of points, your grade will be calculated according to the following criteria:

A: 540 – 600 points	D: 360 – 419 points
B: 480 – 539 points	F: 359 points or less
C: 420 – 479 points	

DETAILED OUTLINE OF TOPICS, READINGS, AND ACTIVITIES FOR THE COURSE

WEEK 1, JANUARY 19th: Introduction to the Course

WEEK 2, JANUARY 26th: Approaches to Defining Clinical and Translational Science

READINGS

Core Readings

- Perspectives from NIH on C&TS
    - Rosenblum, D., & Alving, B. (2011). The role of the Clinical and Translational Science Awards program in improving the quality and efficiency of clinical research. *Chest, 140,* 764-767.
- What is translational science?
    - Woolf, S. H. (2008). The meaning of translational research and why it matters. *JAMA, 299,* 211-213.
    - Westfall, J.M., Mold, J., & Fagnan, L. (2007). Practice-based research: "Blue highways" on the NIH roadmap. *JAMA, 297,* 403-406.
    - Roberts, S. F., Fischhoff, M. A., Sakowski, S. A., & Feldman, E. L. (2012). Transforming science into medicine: How clinician-scientists can build bridges across research's "valley of death". *Academic Medicine, 87,* 266-270.

Additional References

- Zerhouni, E. A. (2005). Translational and clinical science—Time for a new vision. *New England Journal of Medicine, 353,* 1621-1623.
- Contopoulos-Ioannidis, D. G., Ntzani, E. E., & Ioannidis, J. P. A. (2003). Translation of highly promising basic science research into clinical applications. *The American Journal of Medicine, 114,* 477-484.
- Sung, N. S., Crowley, W. F., Genel, M., et al. (2003). Central challenges facing the national clinical research enterprise. *JAMA, 289,* 1278-1287.

WEEK 2 PORTFOLIO ACTIVITY (25 Points)

Part A: Readings Synopsis

Synthesize the key arguments made in the core readings about C&TS by writing a couple of paragraphs that answer the question: What are the types of problems or weaknesses in the traditional model of research that clinical and translational science (C&TS) attempts to address? Then, in a paragraph or less, write your own definition of C&TS. As you develop your own definition, draw on the readings as well as any relevant research experiences that you may have had.

Part B: C&TS Research Example
Identify a research article that you think is an example of C&TS that is relevant to your own research interests. Provide an electronic copy of the article and write a one to two paragraphs about why that research article represents an example of C&TS (i.e. what distinguishes it from traditional biomedical research).

WEEK 3, FEBRUARY 2nd: Developing Research Questions and Literature Searches

READINGS

Core Readings

- Research questions
  - Cummings, S. R., Browner, W. S., & Hulley, S. B. (2013). Conceiving the research question. Pp. 14-22. in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
- Specific aims
  - Yang, O. (2005). Specific aims. Pp. 27-32 in *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application*. New York: Kluwer Academic/Plenum Publishers.
- Searching the literature
  - Greenhalgh, T. (2014). Searching the literature. Pp. 15-27 in *How to Read a Paper: The Basics of Evidence-Based Medicine (5th edition)*. Oxford: Wiley-Blackwell.

WEEK 3 PORTFOLIO ACTIVITY (25 Points)

Part A: Research Question, Specific Aims, and Your Research Interests
Based on your research interests, write a clear and concise research question, and develop at least three specific aims related to that research question. (Note: You are free to revise or change your research question and aims as the course progresses. Having a strong research question and aims will be important for activities later in the course.) Then, prepare a ***5-MINUTE*** *PowerPoint presentation for the class (4 slides) that provides a title slide, a very brief description of the background of your research interest (no more than 2 slides) and a final slide with your research question and specific aims. The 5-minute limit will be very strictly adhered to.*

Part B: Using Web-Based Technologies to Identify Relevant Research
*Using the research question written for Part A or a new research question, conduct a web-based literature search of journal articles. Identify at least 10 articles that address your research question. (You'll be using these articles later for a literature review activity, so make them count!) For your portfolio, provide the citation and abstract from each article. Then use UK's E-Journal website (*https://libraries.uky.edu/record.php?lir_id=215*) to ascertain whether each article is available online; for each citation, indicate whether the article is accessible online. There are several databases for searching for relevant research. In your literature search, you might consider the following databases and tutorials as well as the sources described by Greenhalgh:*

DATABASES

- PubMed http://www.ncbi.nlm.nih.gov/pubmed
- Web of Science (Thomson Reuters) http://apps.webofknowledge.com
- Google Scholar http://scholar.google.com

TUTORIALS

- PubMed tutorial http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/index.html
- Web of Science tutorials http://scientific.thomson.com/support/recorded-training/wok/

Sometimes the links to articles within these databases make it appear that UK does not have access to the electronic journal, when in fact, you can access the full-text via UK's E-journals website: https://libraries.uky.edu/record.php?lir_id=215. When you are off-campus, you may be asked to provide your LinkBlue id and password before you can access the full-text article.

WEEK 4, FEBRUARY 9th: Methods and Technologies for Reviewing the Literature

READINGS

Core Readings

- Reading a research article
  - Greenhalgh, T. (2014). Getting your bearings: What is this paper about? Pp. 28-44 in *How to Read a Paper: The Basics of Evidence-Based Medicine (5th edition).* Oxford: Wiley-Blackwell.
  - Greenhalgh, T. (2014). Assessing methodological quality. Pp. 45-59 in *How to Read a Paper: The Basics of Evidence-Based Medicine (5th edition).* Oxford: Wiley-Blackwell.
- Writing a literature review
  - Martin, P.A. (1997). Writing a useful literature review for a quantitative research project. *Applied Nursing Research, 10(3),* 159-162.

Additional References

- Huth, E. J. (1990). The research paper. Pp. 59-68 in *How to Write and Publish Papers in the Medical Sciences.* Baltimore: Williams & Wilkins.
- Huth, E. J. (1990). Critical argument and the structure of scientific papers. Pp. 55-58 in *How to Write and Publish Papers in the Medical Sciences.* Baltimore: Williams & Wilkins.
- Browner, W.S. (2006). "Introduction." Pp. 21-26 in *Publishing and Presenting Clinical Research*. Philadelphia, PA: Lippincott, Williams, & Wilkins.

WEEK 4 PORTFOLIO ACTIVITY (25 Points)

Part A: Critical Reading of Relevant Research

Select one of the articles that you identified in last week's literature search and briefly answer the three questions posed by Greenhalgh in Chapter 3 ("Getting Your Bearings"). Then use the questions that Greenhalgh presents in Chapter 4 ("Assessing Methodological Quality) as a guide in your assessment of the quality of the article. Write a brief assessment of whether you think the article was original, the appropriateness of the design, and whether reasonable steps were taken to reduce systematic bias.

Part B: Literature Review Autopsy
Choose a research article of interest (e.g. the article from Part A or an alternate) and write a brief analysis (1 paragraph) of the quality of its literature review in the manuscript's Introduction. Start by thinking about "what" was accomplished in each major paragraph of the literature review (i.e. the arguments they made in each paragraph). For example, did the authors establish the significance of the study? Did they make a case for a "gap" in the literature that their study will fill? In your analysis, summarize what the authors did well and what could have improved in their literature review. By the end of the article's literature review, were you persuaded that the study addressed an important issue? Why or why not?

Part C: Writing a Literature Review
Using your research question, write a brief literature review (1-2 pages) that explains why a research study based on your question is needed. This brief literature review might include: the health significance of the research question(s), what is currently known about the subject of your research question, and what the key gaps are in the existing literature. Use the articles identified in your last week's literature search (and any additional sources that are necessary for making your arguments) as the basis for this review.

WEEK 5, FEBRUARY 16th:
Human Subjects, Defining a Population, and Selecting a Site

READINGS

Core Readings

- Defining the study population
    - Hulley, S. B., Newman, T. B., & Cummings, S. R. (2013). Choosing the study subjects: Specification, sampling, and recruitment. Pp. 23-31 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
- Conducting ethical research and protecting human subjects
    - Lo, B., & Grady, D. G. (2013). Addressing ethical issues. Pp. 209-222 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
- Choosing research sites and gaining access
    - Gaglio, B., Nelson, C. C., & King, D. (2006). The role of rapport: Lessons learned from conducting research in a primary care setting. *Qualitative Health Research, 16,* 723-734.

Additional Reference

- Carey, T.S., Kinsinger, L., Keyserling, T., & Harris, R. (1996). Research in the community: Recruiting and retaining practices. *Journal of Community Health, 21,* 315-327.

WEEK 5 PORTFOLIO ACTIVITY (25 Points)

Part A: Defining a Study Population
Based on your research question(s) and specific aims from Week 3, write a description of the study population for your proposed study. More specifically, develop a bulleted list of inclusion and exclusion criteria that you would use to determine whether individuals are eligible to participate in this study. NOTE: You can continue to use the question(s) and aims from previous

portfolio entries, edit/modify earlier question(s) and aims, or create new question(s)/aims. Please copy and paste your question(s) and aims into the beginning of your description of the study population.

Part B: Selecting and Accessing Research Sites
Thinking about your research question and aims, write a description of the type of site(s) in which you could conduct your research. Discuss how this research question is innovative and adds new knowledge. Consider the following questions: What barriers to gaining access to that site(s) might you face, and how might you overcome them? For example, who would you need to involve so you could gain access to the site? What steps will you need to take to establish rapport with individuals at the site?

Part C: Conducting Ethical Research
Thinking about your research question and the study eligibility criteria that you have developed, write a brief response (1 paragraph) to the following questions: What are some of the ethical challenges that you might face if you were conducting a study based on your research question? What might you need to consider in designing the study to protect your research subjects from harm? Describe how the risk-to-benefit ratio is sufficient to justify the proposed research.

WEEK 6, FEBRUARY 23rd: Qualitative Research Methods and Technologies

READINGS

Core Readings

- Basics of qualitative research
    - Greenhalgh, T. (2014). Papers that go beyond the numbers (qualitative research). Pp. 164-177 in *How to Read a Paper: The Basics of Evidence-Based Medicine (5th edition).* Oxford: Wiley-Blackwell.
    - Giacomini, M. K., & Cook, D. J. (2000). Users' guides to the medical literature, XXIII: Qualitative research in health care (part A). *JAMA*, 284, 357-362.
    - Britten, N. (1995). Qualitative research: Qualitative interviews in medical research. *British Medical Journal,* 311, 251-253.
    - Pope, C., Ziebland, S., & Mays, N. (2000). Analysing qualitative data. *British Medical Journal,* 320(7227), 114–116.
- **Choose <u>one</u> of the following examples of qualitative research**
    - Verbeek-Heida, P. M., & Mathot, E. F. (2006). Better safe than sorry—why patients prefer to stop using selective serotonin reuptake inhibitor (SSRI) antidepressants but are afraid to do so: Results from a qualitative study. *Chronic Illness, 2,* 133-142.
    - Cranney, M., Warren, E., Barton, S., Gardner, K., & Walley, T. (2001). Why do GPs not implement evidence-based guidelines? A descriptive study. *Family Practice, 18,* 359-363.
    - Butler, C. C., Rollnick, S., Pill, R., Maggs-Rapport, F., & Stott, N. (1998). Understanding the culture of prescribing: Qualitative study of general practitioners' and patients' perceptions of antibiotics for sore throats. *British Medical Journal, 317,* 637-642.

WEEK 6 PORTFOLIO ACTIVITY (25 Points)

Brief Qualitative Research Design
Using your research question and one (or more) of your specific aims, write a 1-2 page description of a research project that uses qualitative research methods. Think about (1) who you would recruit and how you would recruit them, (2) the types of qualitative questions that you would ask, and (3) how you would analyze the data. Also consider both the advantages and disadvantages of using this type of research methodology for addressing your research question.

WEEK 7: MARCH 2nd: Survey Research Methods and Technologies

READINGS

Core Readings

- Basics of survey research
    - Greenhalgh, T. (2010). Papers that report questionnaire research. Pp. 178-189 in *How to Read a Paper: The Basics of Evidence-Based Medicine (5th edition).* Oxford: Wiley-Blackwell.
    - Cummings, S. R., Kohn, M. A., & Hulley, S. B. (2013). Designing questionnaires, interviews, and online surveys. Pp. 223-236 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
    - Aday, L. (1989). Defining and clarifying the survey variables. Pp. 36-50 in *Designing and Conducting Health Surveys*. San Francisco: Jossey-Bass.

Additional Reference

- Dillman, D. A. (2007). Writing questions. Pp. 32-78 in *Mail and Internet Surveys: The Tailored Design Method* (2nd ed.). Hoboken, NJ: John Wiley & Sons.
- Hulley, S. B., Newman, T. B., & Cummings, S. R. (2013). Planning the measurements: Precision, accuracy, and validity. Pp. 32-42 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.

WEEK 7 PORTFOLIO ACTIVITY (25 Points)

Part A: Analyzing a Survey Research Paper
Select a research article of interest (e.g., in your research area or related to your research question) that uses a survey as its source of data. Write a brief analysis of the quality of that research article using Greenhalgh's 10 questions in Chapter 13.

Part B: Analyzing an Existing Scale of Survey Items
Select an important construct based on your Specific Aims or a research question of interest to you. Search the literature for an existing multi-item scale that measures that construct. Identify at least 2 research studies that have used that scale. In your portfolio entry, address the following two issues. First, describe the validity and reliability of the questionnaire based on the research studies. Second, write a brief critique of the quality of the items in terms of the issues raised in Cummings (chapter 15) in the sections on "Wording," "Setting the Time Frame," and "Avoid Pitfalls." To what extent do the items meet these standards?

WEEK 8, MARCH 9th:
Sampling and Data Collection

READINGS

Core Readings

- Calculating sample size
    - Browner, W.S., Newman, T.B., & Hulley, S.B. (2013). Getting ready to estimate sample size: Hypotheses and underlying principles. Pp. 43-54 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
    - Browner, W.S., Newman, T.B., & Hulley, S.B. (2013). Estimating sample size and power: Applications and examples. Pp. 55-83 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.

Additional Resource

- Videos about using REDCap for web-based surveys and data entry are available at https://projectredcap.org/resources/videos/. Access to these videos is open to the public without establishing an account through UK's CCTS. To use REDCap for a project, visit http://www.ccts.uky.edu/ccts/redcap-research-informatics-tool for more information about obtaining an account.

WEEK 8 PORTFOLIO ACTIVITY (25 Points)

Brief Survey Research Design

Using your research question and one (or more) of your specific aims, write a 1-2 page description of how you would design a survey research project. In this description, given your estimated sample size, you should discuss: 1) what mode of survey administration you would use (e.g., paper, Internet, telephone), 2) how you would identify potential participants, 3) how you would achieve an acceptable response rate, and 4) to whom your findings might generalize. Then define the key constructs that you will be measuring with your survey items. Then develop a survey with at least 10 items; be sure to include some items from the literature (include the sources as references in your write-up) while developing some items on your own. Be sure to apply the concepts from the readings when constructing questions and organizing the survey. Bring these documents to class. This is particularly important this week because we will be splitting into pairs to administer and evaluate each other's surveys.

WEEK 9, MARCH 16th:
SPRING BREAK (No Class)

WEEK 10, MARCH 23rd:
Observational Studies: Cohort and Case-Control Designs

READINGS

Core Readings

- Cohort studies
    - Hulley, S. B., Cummings, S.R., & Newman, T.B. (2013). Designing cross-sectional and cohort studies. Pp. 85-96 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
- Case-control studies
    - Newman, T.B., Browner, W.S., Cummings, S.R., & Hulley, S.B. (2013). Designing case-control studies. Pp. 97-116 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
- Reporting observational research
    - von Elm, E., Altman, D. G., Egger, M., Pocock, S. J., Gotzsche, P. C., Vandenbrouke, J. P., for the STROBE initiative. (2007). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. *Lancet,* 370, 1453-1457.
    - STROBE Checklist (PDF)

Additional Reference

- Grimes, D.A., & Schulz, K.F. (2002). Cohort studies: Marching towards outcomes. *Lancet*, 359, 341-345.
- Grimes, D.A., & Schulz, K.F. (2005). Compared to what? Finding controls for case-control studies. *Lancet*, 365, 1429-1433.
- Vandenbrouke, J. P., von Elm, E., Altman, D. G., Gotzsche, P. C., Mulrow, C. D., Pocock, S. J., Poole, C., Schlesselman, J. J., & Egger, M. for the STROBE initiative. (2007). Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and elaboration. *Epidemiology,* 18, 805-835.
- Case-control example: Chambers, C. D., Hernandez-Diaz, S., Van Marter, L. J., Werler, M. M., Louik, C., Jones, K. L., & Mitchell, A. A. (2006). Selective Serotonin-Reuptake Inhibitors and risk of persistent pulmonary hypertension of the newborn. *The New England Journal of Medicine, 354,* 579-587
- Cohort study example: Satizabal, C. L., Beiser, A. S., Chouraki, V., Chene, G., Dufouil, C., & Seshadri, S. (2016). Incidence of dementia over three decades in the Framingham Heart Study. *The New England Journal of Medicine, 374,* 523-532.

WEEK 10 PORTFOLIO ACTIVITY (25 Points)

Cohort and Case-Control Studies

Identify two research articles in your areas of interest (e.g., in your research area or related to your research question), one that uses a case-control design and one that uses a cohort design. For each article, summarize the primary research questions and discuss the strengths and weaknesses of each design. How could the design of each study be improved? Bring the articles and your write-up to class.

WEEK 11, MARCH 30th:
Overview of Experimental Design & Technologies

READINGS

Core Readings

- Overview of experimental research designs
    - Cummings, S.R., Grady, D., & Hulley, S.B. (2013). Designing a randomized blinded trial. Pp. 137-150 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.
    - Grady, D., Cummings, S.R., & Hulley, S.B. (2013). Alternative trial designs and implementation issues. Pp. 151-170 in Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (Eds.), *Designing Clinical Research*. Philadelphia: Lippincott, Williams, & Wilkins.

Additional References

- Reading randomized trials
    - Greenhalgh, T. (2014). Papers that report trials of drug treatments and other simple interventions. Pp. 78-89 in *How to Read a Paper: The Basics of Evidence-Based Medicine (5th edition).* Oxford: Wiley-Blackwell.
    - Greenhalgh, T. (2014). Papers that report trials of complex interventions. Pp. 90-98 in *How to Read a Paper: The Basics of Evidence-Based Medicine (5th edition).* Oxford: Wiley-Blackwell.

WEEK 11 PORTFOLIO ACTIVITY (25 Points)

Part A: Choosing Between Types of Experimental Designs

This week's readings present multiple options for designing experiments, including between-groups designs, factorial designs, and crossover designs. Based on your research question and specific aims, select two of these types of designs and briefly describe how you would design a study using these two methodologies. Then provide a justification for which design is the better fit for your research question.

Part B: Outcome Measurement

Based on the design that you chose for Part A, describe your primary outcome measure. What is the measure that you will use for your primary outcome? Why is this the best way to measure your primary outcome (i.e., why is it superior to other measures)? How often will you assess this outcome during the experiment (i.e., total number of assessments and time between assessments)?

WEEK 12, April 6th:
Experimental Design: Practical Clinical Trials, Sample Size, and Choosing a Control Condition

READINGS

Core Readings

- Practical clinical trials
    - Tunis, S.R., Stryer, D.B., & Clancy, C.M. (2003). Practical clinical trials: Increasing the value of clinical research for decision-making in clinical and health policy. *JAMA, 290,* 1624-1632.
    - Glasgow, R.E., Magid, D.J., Beck, A., Ritzwoller, D., & Estabrooks, P.A. (2005). Practical clinical trials for translating research to practice. *Medical Care, 43,* 551-557.
- Sample size
    - Schulz, K. F., & Grimes, D.A. (2005). Sample size calculations in randomised trials: Mandatory and mystical. *Lancet, 365,* 1348-1353.
- Considerations related to the control condition
    - Schwartz, C.E., Chesney, M.A., Irvine, M.J., Keefe, F.J. (1997). The control group dilemma in clinical research: Applications for psychosocial and behavioral medicine trials. *Psychosomatic Medicine, 59,* 363-371.

Additional Reference

- Clark, P.I., & Leaverton, P.E. (1994). Scientific and ethical issues in the use of placebo controls in clinical trials. *Annual Review of Public Health, 15,* 19-38.

WEEK 12 PORTFOLIO ACTIVITY (25 Points)

Part A: Designing "Practical Clinical Trials"

Briefly summarize how practical clinical trials (PCTs) differ from conventional experimental research and how PCTs fit within the rubric of "Clinical and Translational Science." Then identify a research article in your area of interest that is an example of a PCT and discuss briefly why this research article is representative of PCTs. Bring your write-up and the article to class.

Part B: Choosing a Control Condition

Next week, you'll be writing about how you would design a research project that uses an experimental methodology. For Part B, describe the control condition that you are proposing for that next Research Design Write-up. Discuss the logic of your choice of this control condition as it relates to the reading about control conditions (Schwartz et al.).

WEEK 13, APRIL 13th:
Experimental Design & Technologies:
Randomization, Blinding, Data Collection, and Reporting Results

READINGS

Core Readings

- Randomization
  - Schulz, K.F., & Grimes, D.A. (2002). Generation of allocations sequences in randomised trials: Chance, not choice. *Lancet, 359,* 515-519.
  - Schulz, K.F., & Grimes, D.A. (2002). Unequal group sizes in randomised trials: Guarding against guessing. *Lancet, 359,* 966-970.
- Blinding and Allocation Concealment
  - Schulz, K.F., & Grimes, D.A. (2002). Blinding in randomised trials: Hiding who got what. *Lancet, 359,* 696-700.
  - Schulz, K.F., & Grimes, D.A. (2002). Allocation concealment in randomised trials: Defending against deciphering. *Lancet, 359,* 614-618.
- Baseline Assessment and Other Data Collection
  - Friedman, L.M., Furberg, C.D., & DeMets, D.L. (1998). Baseline assessment. Pp. 130-139 in *Fundamentals of Clinical Trials* (3rd ed.). New York: Springer.
- CONSORT reporting
  - CONSORT 2010 Flow Diagram
  - CONSORT 2010 checklist
  - Schulz, K. F., Altman, D. G., Moher, D., for the CONSORT Group. (2010). CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *Journal of Clinical Epidemiology, 63,* 834-840.

Additional References

- Friedman, L.M., Furberg, C.D., & DeMets, D.L. (1998). The randomization process. Pp. 61-81 in *Fundamentals of Clinical Trials* (3rd ed.). New York: Springer.
- Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gotzsche, P. C., Devereaux, P. J., Elbourne, D., Egger, M., & Altman, D. (2010). CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *Journal of Clinical Epidemiology.* e1-e37.
- Publication checklist from *Nature*. (PDF file)

WEEK 13 PORTFOLIO ACTIVITY (25 Points)

Brief Experimental Research Design

Using your research question and one (or more) of your specific aims, write a 1-2 page description of how you would design a research project that uses an experimental design. Present a primary hypothesis for the study. Discuss how you would recruit potential participants and the inclusion and exclusion criteria that you would apply. Also, outline how you would approach randomization and blinding, particularly how you would ensure that the blind is maintained. Present the key features of the experimental and the control conditions.

WEEK 14: APRIL 20th:
Patient-Oriented Research and Study Implementation

READINGS

Core Readings

- Patient-oriented research
    - Washington, A.E., & Lipstein, S.H. (2011) The Patient-Centered Research Institute—Promoting better information, decisions, and health. *New England Journal of Medicine, e31,* 1-3.
    - Selby, J.V., & Lipstein, S.H. (2014). PCORI at 3 years—Progress, lessons, and plans. *New England Journal of Medicine, 370,* 592-594.
    - Howie, L., Hirsch, B., Locklear, T., & Abernathy, A.P. (2014). Assessing the value of patient-generated data to comparative effectiveness research. *Health Affairs, 33,* 1220-1228.
    - The PCORI Methodology Report, Appendix A: Methodology Standards. http://www.pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf
- Translating clinical research to implementation in real-world medical settings
    - Donovan, J., Mills, N., Smith, M., Brindle, L., Jacoby, A., Peters, T., Frankel, S., Neal, D., & Hamdy, F., for the Protect Study Group. (2002). Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. *British Medical Journal, 325,* 766-770.
    - Fussell, H.E., Kunkel, L.E., Lewy, C.S., McFarland, B.H., & McCarty, D. (2008). Using a standardized patient walk-through to improve implementation of clinical trials. *Journal of Substance Abuse Treatment, 35,* 470-475.
    - Roy-Byrne, P.P., Sherbourne, C.D., Craske, M.G., Stein, M.B., Katon, W., Sullivan, G., Means-Christensen, A., & Bystritsky, A. (2004). Moving treatment research from clinical research to the real world. *Focus: The Journal of Lifelong Learning in Psychiatry, 2,* 410-415.

WEEK 14 PORTFOLIO ACTIVITY (40 Points)

Part A: Planning for Implementation

This week's readings focus on patient-centered outcome research (PCOR) and challenges faced by researchers when implementing clinical trials in "real world" settings. Return to your portfolio activity from last week and discuss (1) how you might make your research design more patient-centered and (2) the potential challenges that you may face if you were to implement your research in a non-academic setting. What might you do to plan ahead to avoid these kinds of challenges and pitfalls?

Part B: First Draft of the Final Research Design Project

See page 18 of the syllabus for a detailed description of the Final Research Design Project.

WEEK 15, APRIL 27th:
Peer Reviews of the Research Design Projects

READINGS

Core Readings

- Understanding the peer review process—please review this NIH website http://grants.nih.gov/grants/peer_review_process.htm
- Writing an NIH style review: (1) NIH reviewer orientation; (2) NIH scoring system and procedure; and (3) Recommendations for writing NIDA reviews (good advice about preparing a professional review)

WEEK 15 PORTFOLIO ACTIVITY (40 Points)

Written Peer Reviews for Two Research Design Projects
Each student will review initial research design projects of two other students and provide a written and oral presentation of each review. Each review should include a brief summary of the key elements of the research project for the class discussion and an overall assessment of impact of the hypothesized results.

In each review, focus on these three sections of an NIH critique: (1) Significance, (2) Innovation, and (3) Approach. Identify strengths and weaknesses in these three areas. Contrary to the style of NIH critiques, offer suggestions for resolving weaknesses if you have ideas about how to improve the research design. (See "Recommendations for Writing NIDA Reviews" and the Enhanced Review Criteria in the "Side by Side Comparison" pdf.). Numerical scoring is not required.

Be ready to summarize your critiques during class.

WEEK 16, MAY 4th:
Deadline for Course Requirements (No Class)

Final Draft of the Research Design Project (75 Points)
See page 18 of the syllabus for a detailed description of the Final Research Design Project. Please submit your Final Draft of the Research Design Project on Canvas by 5:00pm on Thursday, May 4th.

RESEARCH DESIGN PROJECT (First and Final Drafts)

This course requires the development of a research project using one of the following research methodologies to address a research question that is consistent with C&TS: qualitative research, survey research, cohort or case-control studies, or experimental research. It is expected that this project will be distinct from your mentor's current or proposed research. This expectation is consistent with the course's objective of promoting your growth toward becoming an independent scientist. In addition, your research design project should be a proposed project that would recruit human subjects (i.e., would require institutional review board (IRB) approval to implement the study).

The process of designing this research project will occur in three phases:
Phase 1: Initial Draft of the Research Design
Phase 2: Peer Review of the Initial Draft
Phase 3: Revision and Submission of the Final Draft of the Research Design

This Initial and Final Drafts of the Research Design Project will be similar in format to a small NIH grant (for example, an R21) and should include the following content, within a ***7-page limit****:*

1. *A* ***one-page*** *Specific Aim(s)/Research Question(s)*
2. *A* ***six-page*** *(maximum) Research Plan including the following sections:*
   a) Significance: A brief literature review that provides the context for your research question (only provide the key background information that will allow the peer reviewers and preceptors to understand the significance of this research). Describe how the project addresses an important problem or critical barrier to progress in the field. State how scientific knowledge, technical capability and/or clinical practice will be improved. Indicate how the project will change the concepts, methods, technologies, treatments, services or preventative interventions that drive the field.
   b) Innovation: Describe how the application challenges and seeks to shift current research or clinical practice paradigms by using novel concepts, approaches or methods, instrumentation or interventions.
   c) The details of how the research will be conducted, including:
   - *Methodology/Design*
   - *Subjects (inclusion/exclusion; sample size; recruitment strategies; randomization if applicable) and Site(s) for this research*
   - *Research Site and Implementation Considerations*
   - *Experimental vs. control condition if a clinical trial*
   - *Data Collection (measures, timing of assessments)*
   - *Plans for data analysis*
   - *Ethical concerns and how they will be addressed*

   d) References

GUIDE TO SERVING AS CLASS DISCUSSION LEADER

During the semester, each student will lead a class discussion. The information below provides structure to help you prepare for being a class discussion leader and for all students to use to contribute to class discussions. Please e-mail the course instructors with questions.

Discussion Leader Responsibilities: Each student will be responsible for leading the discussion for one course topic. For the topic that you lead, you should:

1. Review the assigned readings before class, and be ready to synthesize the main points from the readings.

2. Facilitate the class discussion.

Resources about Leading a Discussion: Leading a discussion is very different from presenting a didactic lecture or a PowerPoint presentation. As Class Discussion Leader, your role is to provide direction for the discussion but not to dominate the discussion. By posing questions and encouraging follow-up questions based on the discussion, the class as a whole will gain a deeper understanding about the topic. Research has shown that discussion-based formats are more effective in promoting student learning than didactic lectures, which is why this course relies heavily upon in-class discussions rather than PowerPoint presentations.

If you have not led a discussion before, you can learn more about how to prepare for and then effectively lead a discussion here: https://teachingcommons.stanford.edu/resources/teaching/small-groups-and-discussions/how-lead-discussion

Additional details can be found here: https://teachingcommons.stanford.edu/resources/teaching-resources/teaching-strategies/how-lead-discussion/discussion-leading-guidelines

POLICY ON PLAGIARISM AND ACADEMIC FRAUD

Plagiarism and academic fraud are strictly prohibited. Students who are deemed to have engaged in plagiarism or academic fraud will automatically receive a final grade of "F" in the course. As a student, you are responsible for knowing how the University of Kentucky defines plagiarism and academic fraud and are responsible for monitoring your own behavior.

For your information, the following is reprinted from the current **University Senate regulations:**

6.3.1 PLAGIARISM
All academic work, written or otherwise, submitted by students to their instructors or other academic supervisors, is expected to be the result of their own thought, research, or self-expression. In cases where students feel unsure about a question of plagiarism involving their work, they are obliged to consult their instructors on the matter before submission.

When students submit work purporting to be their own, but which in any way borrows ideas, organization, wording or anything else from another source without appropriate acknowledgment of the fact, the students are guilty of plagiarism.

Plagiarism includes reproducing someone else's work, whether it be published article, chapter of a book, a paper from a friend or some file, or whatever. Plagiarism also includes the practice of employing or allowing another person to alter or revise the work which a student submits as his/her own, whoever that other person may be. Students may discuss assignments among themselves or with an instructor or tutor, but when the actual work is done, it must be done by the student, and the student alone.

When a student's assignment involves research in outside sources or information, the student must carefully acknowledge exactly what, where and how he/she has employed them. If the words of someone else are used, the student must put quotation marks around the passage in question and add an appropriate indication of its origin. Making simple changes while leaving the organization, content and phraseology intact is plagiaristic. However, nothing in these Rules shall apply to those ideas which are so generally and freely circulated as to be a part of the public domain.

6.3.2 CHEATING
Cheating is defined by its general usage. It includes, but is not limited to, the wrongfully giving, taking, or presenting any information or material by a student with the intent of aiding himself/herself or another on any academic work which is considered in any way in the determination of the final grade. The fact that a student could not have benefited from an action is not by itself proof that the action does not constitute cheating. Any question of definition shall be referred to the University Appeals Board.

BAD WEATHER POLICY

Any decisions regarding the cancellation of classes, delayed opening or early cancellation of classes due to bad weather will be made by the University's Vice President for University Relations. Up-to-date information in made available through several sources which you may access directly: 1) the UK INFOLINE at 257-5684; 2) UK Home Page at www.uky.edu; and 3) UK Alerts (to sign up, go to http://www.uky.edu/EM/UKAlert/)

BSC 732: Interdisciplinary Protocol Development (3 Credits)
Department of Behavioral Science
University of Kentucky College of Medicine
Spring, 2017

Course Meetings

Monday, 4:45 pm – 7:15 pm
104 Medical Behavioral Science Building (MBSB)
University of Kentucky College of Medicine

Course Instructors	Office	Telephone	Email
Michael Andrykowski, Ph.D.	133 MBSB	323-6657	mandry@uky.edu
Brady Reynolds, Ph.D.	105 MBSB	323-1457	brady.reynolds@uky.edu

- Both instructors are available outside of class time (during regular business hours) for consultation. Please contact either course instructor to arrange an individual appointment, if needed, to discuss issues or questions related to the course.

Course Description

Interdisciplinary research holds the potential to increase the pace of scientific discovery and speed the translation of knowledge into biobehavioral interventions designed to improve health and well-being. Although there are many descriptions of interdisciplinary research (IDR), the National Academy of Sciences (2005) has adopted the following definition: "…a mode of research by teams or individuals that integrates information, data, techniques, tools, perspectives, concepts, and/or theories from two or more disciplines or bodies of specialized knowledge to advance fundamental understanding or to solve problems whose solutions are beyond the score of a single discipline or area of research practice." Interdisciplinary research is often referred to as "team science" and these terms can be used interchangeably.

Whether it is called interdisciplinary research or team science, this mode of inquiry offers new opportunities and challenges for science and efforts to reduce morbidity and mortality. In many ways IDR is at the core of clinical and translational science (C&TS) and subscribes to a similar, if not overlapping, set of beliefs and values. Like C&TS, IDR transcends the boundaries of traditional disciplines and integrates concepts and theories from multiple and diverse perspectives, and its vitality is generated by creativity, intellectual curiosity, and openness to new perspectives.

It is assumed that students enrolled in this course are currently actively engaged in research and have an existing strong relationship with an appropriate research mentor.

Course Objectives

This course will introduce students to the processes involved in the development and implementation of interdisciplinary research. Students will be introduced to key aspects of the leadership, communication and teamwork involved in interdisciplinary research. Students will also be introduced to the structure and functioning of the NIH and the NIH grant application and review process. Finally, students will apply their knowledge regarding the research methods and technologies of clinical and translational science to develop an NIH-format research grant application that addresses a research topic in their own area of interest.

At the conclusion of the course, students will be able to:

1. Understand and appreciate the key roles of communication, leadership and teamwork in interdisciplinary clinical and translational research.

2. Apply knowledge regarding the responsible conduct of research, statistical analyses, and clinical and translational science methods and technologies to the development of an interdisciplinary NIH-format grant research grant application.

3. Understand the general organization of the NIH and the NIH grant application and review process

Course Prerequisites

This course is intended for advanced graduate or professional students pursuing focused research training in one of the degree or certificate programs available in clinical and translational science. It is expected students will have completed the course in Methods and Technologies in Clinical & Translational Science (BSC 731) prior to this course.

Course Materials

Course materials include a required text, selected book chapters and journal articles, and online team science training modules.

Required Text:

There is one required text for the course:

Gerin, W. & Kapelewski, C. (2011). *Writing the NIH grant proposal: A step-by-step guide (2nd ed)*. Sage: Thousand Oaks, CA.

This required text is available for purchase at Amazon.com as well as other online booksellers.

Book chapters and journal articles:

Copies of all selected book chapters and journal articles that comprise the weekly readings will be made available to students through DropBox. When accessing required book chapters and journal articles through DropBox, please make an electronic copy of these chapters and articles for your use. Do not move the chapters and articles from DropBox as this will make these items unavailable to other students.

Of course, some of the book chapters and journal articles may also be available through the UK library and UK's Electronic journals website.

Online Team Science training modules:

A collection of online Team Science training modules have been developed by the Northwestern University program in Clinical and Translational Science program (NUCATS). These modules are available online at http://teamscience.net/. To access these modules, students will need to go to this web address and register online to use the website to access the modules. Additional instructions for accessing the online modules will be provided at the appropriate time during the semester. Viewing of these online modules is recommended but not required.

Course Activities

Course activities are intended to promote an awareness of the process involved in the design and conduct of interdisciplinary research as well as foster the creative application of research technologies and methods to students' individual areas of research interest. A key premise of the course is the diverse interests and experiences of students and faculty participating in the course offer opportunities to learn from each other.

Learning will be facilitated through a combination of core readings, classroom discussions, online team science video modules, and written assignments. These activities include:

1) **Core readings** will provide information regarding interdisciplinary research skills, specific topical areas, and grant development. Core readings are intended to foster the development of interdisciplinary research skills and the translation of those skills into the development of an interdisciplinary research grant application. It is expected students will have completed all assigned weekly readings before the class meeting for that week.

2) **Class discussions** will center around assigned core readings, online team science training modules, weekly written assignments, and didactic presentations by course instructors. This course is intended to be an interactive experience for students. Therefore class attendance and participation in class discussion is strongly encouraged. To engage effectively in class discussion, it is important that students have completed all weekly assignments prior to class meetings.

3) **Online Team Science Video Training Modules** will provide information regarding the nature of team science and the issues that commonly confront individuals engaged in interdisciplinary, team science. You will be asked to register at the team science website (http://teamscience.net/) which will enable you to watch and listen to a set of video modules. Viewing of these modules is recommended but not required.

4) **Written assignments** will be of two types: weekly assignments and a final interdisciplinary research grant application due at the conclusion of the semester.

   Weekly assignments:

   Weekly assignments are intended to stimulate critical thinking and reflection as well as lead the student through a step-by-step process, which will ultimately culminate in the creation of the final research grant application. Specific instructions for each weekly written assignment will be provided in class and will also be available via DropBox. Again, when using DropBox to access instructions for the weekly assignments, students are asked to make an electronic copy of any materials related to the weekly assignments for their use. Do not move copies of these materials from DropBox.

   The weekly assignments will provide a basis for in-class discussions, so it is expected the written assignment for each week will be completed before class and turned in before class. In most instances, written assignments will be reviewed by the course instructors and returned to students with feedback and comments prior to the next class. All weekly assignments can be revised and resubmitted once to improve their quality (and potentially their grade) and make them a more effective preparation for the final research grant application. See details under "Course Grading" below.

   All weekly assignments should be deposited in the Dropbox by 3 PM on the day the assignment is due. This will enable the course instructors to review assignments prior to class that evening.

   When submitting assignments, they should be labeled with both your last name and the assignment number. For example: Jones_Assignment_#1 A revised assignment should then be labelled: Jones_Assignment_#1_Revised

Interdisciplinary Research Grant Application:

The course is designed to culminate in the submission of an interdisciplinary research grant application based on a research area of the student's choice.

While the interdisciplinary research grant application will be based on a research area of the student's choice, several requirements must be met:

(1) The final interdisciplinary research grant application *must be written using the NIH format appropriate for either an R01 (investigator initiated research), R03 (small grant) or R21 (exploratory research) mechanism*, as appropriate. Complete information regarding the required NIH formats for the R01, R03, and R21 grant mechanisms are available at the NIH.gov website.

(2) The final interdisciplinary research grant *application must be based on a research project involving human subject participation*. The final interdisciplinary research grant application must not be based upon animal research.

(3) The final interdisciplinary research grant application *must be a new project* for which the student will serve as the principal investigator.

(4) The research described in the final interdisciplinary research grant application *must have a definite interdisciplinary research component*.

Additional more specific information regarding the final interdisciplinary research grant application assignment will be provided later in the semester.

The final interdisciplinary research grant application should be submitted as a single, complete, continuous, electronic document to the course directors by 5:00 PM eastern time on Monday, May 1, 2017.

Class Attendance

Class attendance and participation in class discussion are vital and critical components of the course. Consequently, attendance at each class accompanied by appropriate class participation is rewarded by adding 10 points toward the student's final grade for each class attended. To earn 10 points for attending class, a student must be present for at least one half of the scheduled class time (1/2 of 2.5 hours = 1 hour 15 minutes)

Course Grading

Final course grades will be determined on the basis of points accumulated through completion of course activities. Course activities include weekly class attendance and participation, weekly assignments, and a final interdisciplinary research grant application. All weekly assignments (except late assignments) can be revised and resubmitted once in order to receive maximum credit for that assignment. Resubmitted weekly assignments must be submitted within two weeks of their original due date. Late submissions of weekly assignments will result in a 5 point deduction. Submission of a weekly assignment more than 48 hours after its initial due date (i.e., after 3 PM on a Wednesday) will result in awarding of 0 points for the assignment.

Maximum point values for course activities:

- Class attendance and participation: 13 classes @ 10 points each = 130 possible points (18%)
- Weekly written assignments: 12 assignments in total = 280 possible points (39%)
- Final research grant application: 1 application @ 300 possible points (43%)

Based on accumulation of points, final course grades will be calculated as follows:

A: 639 – 710 points
B: 568 – 638 points
C: 497 – 567 points
F: 496 points or less

Policy on Academic Accommodations Due to Disability

If you have a documented disability that requires academic accommodations, please arrange an appointment with a course director as soon as possible. In order to receive accommodations in this course, you must provide a Letter of Accommodation from the University of Kentucky Disability Resource Center (Director: Jacob Karnes, telephone: 257-2754, email address jkarnes@email.uky.edu) for coordination of campus disability services available to students with disabilities.

Policy on Plagiarism and Academic Fraud

Plagiarism and academic fraud are strictly prohibited. Any instances of plagiarism and academic fraud will be dealt with strictly. Students who are deemed to have engaged in plagiarism or academic fraud will automatically receive a final grade of "F" in the course. As a student, you are responsible for knowing how the University of Kentucky defines plagiarism and academic fraud and are responsible for monitoring your own behavior.

For your information, the following is reprinted from current **University regulations:**

6.3.1 PLAGIARISM

All academic work, written or otherwise, submitted by students to their instructors or other academic supervisors, is expected to be the result of their own thought, research, or self-expression. In cases where students feel unsure about a question of plagiarism involving their work, they are obliged to consult their instructors on the matter before submission.

When students submit work purporting to be their own, but which in any way borrows ideas, organization, wording or anything else from another source without appropriate acknowledgment of the fact, the students are guilty of plagiarism.

Plagiarism includes reproducing someone else's work, whether it be published article, chapter of a book, a paper from a friend or some file, or whatever. Plagiarism also includes the practice of employing or allowing another person to alter or revise the work which a student submits as his/her own, whoever that other person may be. Students may discuss assignments among themselves or with an instructor or tutor, but when the actual work is done, it must be done by the student, and the student alone.

When a student's assignment involves research in outside sources or information, the student must carefully acknowledge exactly what, where and how he/she has employed them. If the words of someone else are used, the student must put quotation marks around the passage in question and add an appropriate indication of its origin. Making simple changes while leaving the organization, content and phraseology intact is plagiaristic. However, nothing in these Rules shall apply to those ideas, which are so generally and freely circulated as to be a part of the public domain.

6.3.2 CHEATING

Cheating is defined by its general usage. It includes, but is not limited to, wrongfully giving, taking, or presenting any information or material by a student with the intent of aiding himself/herself or another on any academic work which is considered in any way in the determination of the final grade. Any question of definition shall be referred to the University Appeals Board.

Bad Weather Policy

Any decisions regarding the cancellation of classes, delayed opening or early cancellation of classes due to bad weather will be made by the University's Vice President for University Relations. Up-to-date information is made available through several sources which you may access directly:

1) the UK INFOLINE at 257-5684
2) UK TV (check your local TV guide for channel number) or WUKY-FM at 91.3
3) UK Home Page at www.uky.edu

Fall, 2016

Detailed Schedule of Classes and Topics and Reading and Written Assignments

January 16 **Martin Luther King holiday (no class)**

January 23 **Week 1: Course Introduction *(Reynolds & Andrykowski)***

Required Readings:

- None

Written Assignment Due:

- None

January 30 **Week 2: Identifying the Research Question and Constructing Specific Aims *(Reynolds)***

Required Readings:

- Gerin & Kapelewski (2011). Chapter #5 (pps. 61-79), *Writing the Application, Part I: The Scientific Content*
- Yang, O. (2012). Planning the Aims and Overcoming Writer's Block (Chapter 6; pps. 15-18) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Yang, O. (2012). Specific aims. (Chapter 9; pps. 31-34) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Cummings, S.R., Browner, W.S., & Hulley, S.B. (2013). Conceiving the research question and developing the study plan (Chapter 2; pps. 14-22) In Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. *Designing Clinical Research* (4th edition): Lippincott, Williams & Wilkins: Philadelphia, PA.

Written Assignment #1 Due: (20 points)

- #01a: Identify your primary research question(s)
- #01b: Identify 2-3 specific aims
- #01c: State hypotheses associated with your specific aims

February 6 Week 3: Identifying an Appropriate Funding Opportunity *(Andrykowski)*

Required Readings:

- Gerin & Kapelewski (2011). Chapter #1 (pps. 1-6), *The National Institutes of Health and Biomedical Funding*
- Gerin & Kapelewski (2011). Chapter #3 (pps. 15-40), *Types of Award Mechanisms*
- Gerin & Kapelewski (2011). Chapter #4 (pps. 47-57), *Preparation and Preliminary Steps*

Written Assignment #2 Due: (20 points)

- #02a: Conduct an NIH Reporter Search on your research question
- #02b: Identify an appropriate NIH program announcement, institute, and funding mechanism for your research question

February 13 Week 4: Framing the Significance and Innovation of Your Research *(Reynolds)*

Required Readings:

- Yang, O. (2012). Research Strategy: Significance (Chapter 10; pps. 35-39) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Yang, O. (2012). Research Strategy: Innovation (Chapter 11; pps. 41-42) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Gerin & Kapelewski (2011). Chapter #5 (pps. 79-87), *Writing the Application, Part I: The Scientific Content*

Written Assignment #3 Due: (25 points)

#03 Outline the significance and innovation of your research

February 20 Week 5: Choosing and Describing Research Methods – Part I *(Reynolds)*

Required Readings:

- Gerin & Kapelewski (2011). Chapter #5 (pps. 90-110), *Writing the Application, Part I: The Scientific Content*
- Yang, O. (2012). Research Strategy: Approach (Chapter 10; pps. 43-49) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Bordage, G., & Dawson, B. (2003). Experimental study design and grant writing in eight steps and 28 questions. *Academic Medicine, 37,* 376-385.

Written Assignment #4 Due (25 points)

- #4: Prepare an elaborated outline of your Research Design and Methods

February 27 **Week 6: Pulling it Together: Specific Aims, Significance, Innovation *(Andrykowski)***

Required Readings:

- Gerin & Kapelewski (2011). Chapter #9 (pps. 221-241), *The Grant Review and Award Process*
- Yang, O. (2012). Organization and writing style (Chapter 7; pps. 19-24) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Ries & Leukefeld (1995). Writing to Be Competitive (Chapter 13, pps. 193-204). *Applying For Research Funding: Getting Started and Getting Funded.* Thousand Oaks, CA: Sage Publications.
  .

Written Assignment #5 Due: (35 points)

- #05a: Prepare a fully developed Specific Aims page, along with fully developed Significance and Innovation sections
- #05b: Choose a title for your application

March 6 **Week 7: Identifying and Presenting Preliminary Studies *(Reynolds)***

Required Readings:

- Gerin & Kapelewski (2011). Chapter #4 (p. 57), Preparation and Preliminary Steps
- Gerin & Kapelewski (2011). Chapter #5 (pps. 87-90), Writing the Application, Part I: The Scientific Content
- Yang, O. (2005). Preliminary results. (pps. 37-41) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application*. New York: Kluwer Academic/Plenum Publishers.

Written Assignment #6 Due (20 points)

- #6a: Identify potential preliminary studies and describe their relevance to your research
- #6b: Prepare the public health relevance statement for your application

March 13 **UK Main Campus Spring Break (No Class)**

March 20 Week 8: Choosing and Describing Research Methods – Part II (Reynolds)

Required Readings:

- Von Elm, E., Altman, D.G., Egger, M., Pocock, S.J., Gotzsche, P.C., Vandenbrouke,J.P., for the STROBE Initiative (2014). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. International Journal of Surgery, 12, 1495-1499.
- Chan, A-W., Tetzlaff, J.M., Altman, D.G., Laupacis, A., Gotzsche, P.D., Krieza-Jeric, K., et al. (2013). SPIRIT 2013 statement: Defining standard protocol items for clinical trials. Annals of Internal Medicine, 158, 200-207.
- Gerin & Kapelewski (2011). Chapter #5 (p. 74), The Abstract
- Yang, O. (2012). Figures and tables (Chapter 8; pps. 25-30) Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed). New York: Springer.
- Schulz, K.F., Altman, D.G., Moher, D., for the CONSORT Group (2011). CONSORT 2010 statement: Updated guidelines for reporting parallel group randomized trials. International Journal of Surgery, 9, 672-677. (Recommended only; not required)

Written Assignment #7 Due (35 points)

- #7a: Prepare a fully developed version of your Approach section
- #7b: Prepare the abstract for your application

March 27 Week 9: Team Science: Leadership, Collaboration, and Communication *(Andrykowski)*

Required Readings:

- Gerin & Kapelewski (2011). Chapter #2 (pps. 7-13), *Mentoring and Collaborative Relationships*.
- Bennett, Gadlin & Levine-Finley (2010). Preparing yourself for team science. *Collaboration & Team Science: A Field Guide* (pps. 5-13).
- Bennett, Gadlin & Levine-Finley (2010). Building a research team. *Collaboration & Team Science: A Field Guide* (pps. 15-19).
- Bennett, Gadlin & Levine-Finley (2010). Developing a shared vision. *Collaboration & Team Science: A Field Guide* (pps. 25-27).
- Bennett, Gadlin & Levine-Finley (2010). Communicating about science. *Collaboration & Team Science: A Field Guide* (pps. 29-33).
- Bennett, Gadlin & Levine-Finley (2010). Handling conflict. *Collaboration & Team Science: A Field Guide* (pps. 39-44).
- Bennett, Gadlin & Levine-Finley (2010). Strengthening team dynamics. *Collaboration & Team Science: A Field Guide* (pps. 45-49).

Recommended Team Science Video Modules

- Managing a Team: Leadership (130 through 144) (24:40 total viewing)
- Managing a Team: Communication (106 through 116, 119 through 123) (30:10 total viewing time)

Written Assignment #8 Due: (20 points)

- #08a: Identify and assess the strengths and weaknesses of your leadership style
- #08b: Identify and assess the strengths and weaknesses of your collaborative style
- #08c: Identify and discuss the strengths and weaknesses of your communication style
- #08d: Describe a situation where your style created a difficulty in a research setting

April 3 **Week 10: Team Science: Team Building and Teamwork *(Reynolds)***

Required Readings:

- Gerin & Kapelewski (2011). Chapter #4 (pps. 58-59), *Preparation and Preliminary Steps*
- Bennett, Gadlin & Levine-Finley (2010). Fostering trust. *Collaboration & Team Science: A Field Guide* (pps. 21-24).
- Bennett, Gadlin & Levine-Finley (2010). Sharing recognition and credit. *Collaboration & Team Science: A Field Guide* (pps. 35-38).
- Yang, O. (2012). Collaborators and Consultants (Chapter 15; pps. 57-58) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer
- Whitfield, J. (2008). Group theory. *Nature, 455*, 720-723.
- Miller, K. (2008). Successful collaborations: Social scientists who study science have noticed a trend. *Biomedical Computation Review*, 7-15.

Recommended Team Science Video Modules

- Managing a Team: Conflict/Conflict Resolution: Videos (#'s 145 through 155) (Total time: 21:25)
- Assembling a Team: Team Building: Videos (#' (Total time: 17:38)
- Assembling a Team: Team Building: Animations and Activities (#'s 40, 103, 105)

Written Assignment #9 Due (20 points)

- #9a: Identify appropriate collaborators and describe their roles
- #9b: Prepare your NIH biosketch

April 10 **Week 11: Additional Grant Sections and Procedural Processes – Part I: Budget *(Andrykowski)***

Required Readings:

- Gerin & Kapelewski (2011). Chapter #7 (pps. 151-184), *Writing the Application, Part III:*

Written Assignment #10 Due: (20 points)

- #10a: Prepare a detailed budget for your research
- #10b: Prepare a detailed budget justification

April 17 **Week 12: Additional Grant Sections and Procedural Processes – Part II: Human Subject Considerations *(Andrykowski)***

Required Readings:

- Gerin & Kapelewski (2011). Chapter #6 (pps. 111-144), *Writing the Application, Part II: Human and Animal Concerns*
- Gerin & Kapelewski (2011). Chapter #7 (pps. 188-189), *The Targeted/Planned Enrollment Form*
- Yang, O. (2005). Use of Appendices (pps. 55-57). *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application*. New York: Kluwer Academic/Plenum Publishers.
- Yang, O. (2012). Administrative Sections and Submission Process (Chapter 17; pps. 63-68) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Yang, O. (2012). Use of Appendices (Chapter 14; p. 55) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.

Written Assignment #11 Due: (20 points)

- #11: Prepare the human subjects research section of your grant

April 24 **Week 13: Peer Review *(Andrykowski)***

Required Readings:

- Gerin & Kapelewski (2011). Chapter #9 (pps. 226-237), *The Grant Review and Award Process*
- Yang, O. (2012). Scoring Process (Chapter 18; pps. 69-75) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Yang, O. (2012). Resubmitting an Application (Chapter 19; pps. 77-81) *Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application (2nd Ed)*. New York: Springer.
- Bourne, P. E., & Korngreen, A. (2006). Ten simple rules for reviewers. *PLoS Computational Biology, 2*, e110-e111.

Written Assignment #12 Due: (20 points)

- #12: Prepare a written NIH-style review of a peers' Specific Aims, Significance, Innovation, and Approach sections

May 1 **Final Interdisciplinary Research Grant Application Due at 5:00 PM (Eastern Time)**

Please submit an electronic copy of your final Interdisciplinary research grant application to the course instructors. This should be submitted as a continuous, single, electronic document. It can be submitted by email directly to the course instructors or can be deposited in the course Dropbox.

Be sure to consult and follow the detailed instructions provided regarding preparation of the final interdisciplinary research grant application. These are available in the course DropBox.