

GMS 6813: Applied Topics in Pragmatic Clinical Trials and Implementation Science

SEMESTER: Spring 2021

FORMAT: Hybrid: Both In-Person and Online, Synchronous (through Canvas)

LOCATION: In-Person Section: Communicore C1-09 (maximum number of students in-class = 9)

DAY/TIME: Mondays 3:00-4:55pm

CREDITS: 2

COURSE WEBSITE: Canvas GMS 6813

INSTRUCTOR:

Matthew J. Gurka, PhD

Clinical and Translational Research Building (CTRB) 2250

Phone: (352) 627-9088

Email: matthewgurka@ufl.edu

TEACHING ASSISTANT:

Gina T. Eubanks, MPH, CPH

Phone: (352) 627-9145

Email: gina7@ufl.edu

OFFICE HOURS: Dr. Gurka: Wednesdays 8:00-9:00pm (Zoom via Canvas) or by appointment

COURSE DESCRIPTION:

The focus of this course is on providing students with applied knowledge related to conducting pragmatic clinical trials and implementation studies. Pragmatic trials evaluate the effectiveness of interventions and treatments in typical community clinical care settings. Specifically, students in this course will focus on:

- Understanding research questions that can be answered through pragmatics trials design;
- Examining pragmatic trials design through current real-world examples;
- Identifying strategies to mediate common statistical challenges with conducting pragmatic trials; and
- Conducting pragmatic clinical trials and implementation science research.

Specific examples of pragmatic trials and implementation science studies will be addressed. Because students obtain specific methods training in other courses throughout the curriculum, the focus of this course is on critical appraisal of the appropriateness of the methods used relative to the study question and the implications of the study design for translating evidence into practice.

COURSE OBJECTIVES:

The primary goals of this course are to enhance students' knowledge about how to design and conduct pragmatic trials and implementation science research.

More specifically, students who successfully complete the course will be able to:

- Discuss the major concepts related to the design, implementation, interpretation and dissemination of pragmatic clinical trials and implementation science research,
- Identify the differences between typical clinical trials and pragmatic trials, from the types of research questions to the study design to the application of research findings,
- Develop strategies for mediating common statistical challenges with pragmatic clinical trials,
- Discuss some sentinel studies in pragmatic clinical trials and implementation science research,
- Describe the role of academic-health system partnerships in pragmatic trials and implementation science research,

- Identify the “users” of knowledge gained through pragmatic trials and implementation science research and develop strategies to disseminate research findings and apply knowledge gained to improve clinical care,
- Critically evaluate pragmatic clinical trials and implementation science studies for the appropriateness of the overall design, statistical methodology, and the potential application of knowledge gained.

COURSE TOPIC SCHEDULE:

Week	Dates	Topic	Sub-Topics	Evaluation Assignment
1	Jan 11	Introduction to Pragmatic Clinical Trials (PCTs) and Implementation Science	<ul style="list-style-type: none"> • PCTs vs. traditional trials vs. quality improvement • Comparative effectiveness research • Implementation Science 	Syllabus quiz due Jan 22 11:59pm
2	Jan 18	1/18 – Holiday (No Class)		
3	Jan 25	Dissemination and Implementation Overview	<ul style="list-style-type: none"> • Dissemination and implementation frameworks • D&I outcomes and strategies • Reporting to the scientific community 	
4	Feb 1	Building partnerships	<ul style="list-style-type: none"> • Stakeholder engagement • Embedded PCT’s • Dissemination to patients and health system leaders 	
5	Feb 8	PCT Design Considerations	<ul style="list-style-type: none"> • Randomization methods • Cluster randomized trials (CRTs) 	
6	Feb 15	PCT Design Considerations	<ul style="list-style-type: none"> • Concealment and blinding • Identification bias 	
7	Feb 22	<i>Group Presentations</i>		Group Presentations of Initial Study Proposals
8	Mar 1	PCT Alternative Designs	<ul style="list-style-type: none"> • CRT Variations • Hybrid designs • Stepped-wedge designs 	
9	Mar 8	Adaptive Designs and Interventions	<ul style="list-style-type: none"> • Adaptive designs • Adaptive interventions • SMART designs 	Design quiz due March 12 11:59pm
10	Mar 15	Adaptive Designs and Interventions (continued)	<ul style="list-style-type: none"> • Just in Time Adaptive Interventions • Micro-randomized trials 	
11	Mar 22*	Selecting Meaningful Outcomes (1)	<ul style="list-style-type: none"> • Meaningful outcomes • Electronic health records 	
12	Mar 29	Selecting Meaningful Outcomes (2)	<ul style="list-style-type: none"> • Patient reported outcomes • Outcomes from mobile technologies 	Outcomes quiz due April 2 11:59pm
13	Apr 5	Statistical challenges	<ul style="list-style-type: none"> • General analytic approaches • Analyzing multilevel data • Sample size/power analysis for PCT’s 	
14	Apr 12	Statistical challenges (continued)	<ul style="list-style-type: none"> • Missing data and intention-to-treat analyses • Residual confounding 	
15	Apr 19	<i>Final presentations of research projects</i>		Final research protocol due April 23 5:00pm

* March 22: no face-to-face class; class will be exclusively through Zoom (via Canvas)

COURSE REQUIREMENTS: Students are expected to actively engage in weekly lecture and discussions, complete readings posted to Canvas, and complete all assigned assessments. A computer with high-speed Internet connectivity, ability to read/review/edit Microsoft files, ability to read/review pdf files, and a working webcam and microphone are required to effectively complete all course components.

WEEKLY LECTURES/DISCUSSION: Students are expected to participate in weekly lectures. Lectures will average about one hour, followed by active discussion (that will include discussion of one or more assigned readings relevant to the weekly topic). A hybrid format will be utilized that will allow for in-person instruction/discussion but also allow for online participation. These two-hour classes will be held in a classroom with the technology to accommodate this hybrid format, allowing students in both settings to interact with one another via Zoom. A discussion forum will be available in Canvas each week to allow for follow-up discussion.

TEXTBOOKS/READING MATERIALS:

A selection of scientific publication(s) and article(s) will be assigned to read each week; readings will be chosen to highlight the content of that particular week and will be expected to be read before class to facilitate discussion. Students are responsible for any content from the assigned readings posted in Canvas. There is no required book for this course; however, we will borrow heavily from the “NIH Collaboratory Living Textbook of Pragmatic Clinical Trials” (<https://rethinkingclinicaltrials.org/>).

COURSE COMMUNICATIONS:

General course questions should be posted to the discussion board on Canvas. We will respond to discussion posts within 24 hours during the workweek (48 hours over the weekend). Private or grade related questions should be sent to us via the email function in Canvas. The e-learning canvas site follows the rules and regulations of FERPA. Using the email function in Canvas, select the instructor and any teaching assistants as recipients, and include the course mnemonic, GMS6813, in the subject line (to facilitate a more timely response).

ATTENDANCE:

Success in this course is dependent on your active participation and engagement throughout the course. Requirements for class attendance and make-up exams, assignments and other work in this course are consistent with university policies that can be found at <https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/>.

GRADING SCALE:

Total Points Earned	% of Total Points Earned	Letter Grade	Grade Point Equivalent
279 +	≥ 93	A	4.0
270-278	90-92	A-	3.67
261-269	87-89	B+	3.33
249-260	83-86	B	3.00
240-248	80-82	B-	2.67
231-239	77-79	C+	2.33
219-230	73-76	C	2.00
210-218	70-72	C-	1.67
201-209	67-69	D+	1.33
189-200	63-66	D	1.00
180-188	60-62	D-	0.67
< 180	< 60	E	0.00

For more detail on letter grades and related University of Florida policies, please see the Grades and Grading Policies at <http://gradcatalog.ufl.edu/content.php?catoid=6&navoid=1219#grades>.

MAKE-UP POLICY: Students are allowed to make up work only as the result of substantial illness or other unanticipated circumstances. In the event of such emergency, documentation will be required in conformance with University policy. Work missed for any other reason will earn a grade of zero.

GRADE COMPOSITION:

Students' final grades will be determined via a variety of assessments, specifically: weekly discussions, quizzes, team paper critiques, and the development of a PCT protocol.

Assessment Description	Points Possible	% of Grade
Weekly Lecture/Discussion Participation		
<ul style="list-style-type: none"> • Contribution to discussion of assigned weekly publication(s) in person or via Canvas online forum • Students are required to actively engage in <u>10 of the 12 non-presentation weeks of class</u>. Essentially, students will have the opportunity to earn 5 points on a weekly basis if they contribute at least one meaningful question or comment relevant to the topic/discussion. There will be the opportunity to discuss in class and/or through our discussion forum in Canvas 	50 pts (i.e. 5 pts weekly)	16.7%
Quizzes		
<ul style="list-style-type: none"> • There will be three quizzes throughout the semester <ul style="list-style-type: none"> ○ Syllabus quiz (20 points) ○ Quiz of knowledge of design issues (40 points) ○ Quiz of knowledge of outcomes (40 points) • Each quiz will be administered online via Canvas and will be comprised of 10 questions of various formats (true/false, multiple choice, short answer) to assess knowledge of important concepts related to PCT's. 	100 pts	33.3%
Group Study Proposal		
<ul style="list-style-type: none"> • The culminating project will be the development of a study proposal that describes the key components of a PCT. Numerous examples of PCT protocols can be found here: https://rethinkingclinicaltrials.org/data-and-resource-sharing/, which may be helpful (although this level of detail is not necessary). • Student groups (assigned early in the semester) will be expected to come up with a research question on their own that can be addressed by a PCT; students are encouraged to discuss with the instructor early if they need assistance with coming up with a research question. • Primary components of the study proposal will include: 1) the research question (including rationale); 2) the research design; 3) primary outcomes and general analysis plan; 3) potential "users" of the study findings; 4) and how the results may be applied to clinical care and implemented • No written proposal is required; evaluation will include the content (and display) in the presentation file (.PPT or .PDF) as well as the presentation itself (see below) • Detailed instructions and rubrics will be provided separately early in the semester <ul style="list-style-type: none"> ○ Oral presentation (10 minutes): draft background/rationale/objectives (mid-semester) <ul style="list-style-type: none"> ▪ This will provide the opportunity for student/instructor engagement on the chosen topic and refinement if necessary. ○ Oral presentation (15-minutes); end of the semester <ul style="list-style-type: none"> ▪ Students will be expected to create a powerpoint or equivalent file that summarizes their protocol and present to the class 	50 pts	16.7%
	100 pts	33.3%
Total Points Possible	300 pts	100%

UNIVERSITY OF FLORIDA POLICIES

UNIVERSITY POLICY ON ACCOMMODATION OF STUDENTS WITH DISABILITIES: Students requesting accommodation for disabilities must first register with the Dean of Students Office (<http://www.dso.ufl.edu/drc/>). The Dean of Students Office will provide documentation to the student who must then provide this documentation to the instructor when requesting accommodation. You must submit this documentation prior to submitting assignments or taking the quizzes or exams. Accommodations are not retroactive, therefore, students should contact the office as soon as possible in the term for which they are seeking accommodations.

UNIVERSITY POLICY ON ACADEMIC MISCONDUCT: Academic honesty and integrity are fundamental values of the University community. Students should be sure that they understand the UF Student Honor Code at <http://www.dso.ufl.edu/students.php>. You are expected and required to comply with the University's academic honesty policy (University of Florida Rules 6C1-4.017 Student Affairs: Academic Honesty Guidelines, available at <http://regulations.ufl.edu/chapter4/4017.pdf>). Cheating, plagiarism, and other forms of academic dishonesty will not be tolerated. Note that misrepresentation of the truth for academic gain (e.g., misrepresenting your personal circumstances to get special consideration) constitutes cheating under the University of Florida Academic Honesty Guidelines

NETIQUETTE – Communication Courtesy: All members of the class are expected to follow rules of common courtesy in all email messages, threaded discussions, and chats. The first instance of clearly rude and/or inappropriate behavior will result in a warning. The second instance will result in a deduction of five percentage points from your overall grade. The third instance will result in a drop of a letter grade (A to B, A- to B-, and so on). <http://teach.ufl.edu/wp-content/uploads/2012/08/NetiquetteGuideforOnlineCourses.pdf>

ONLINE FACULTY COURSE EVALUATION PROCESS: Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at <https://gatorevals.aa.ufl.edu/students/>. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <https://ufl.bluera.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>.

GETTING HELP:

For issues with technical difficulties for E-learning in Canvas, please contact the UF Help Desk at:

- learning-support@ufl.edu
- (352) 392-HELP - select option 2
- <https://lss.at.ufl.edu/help.shtml>

Any requests for make-ups due to technical issues must be accompanied by the ticket number received from LSS when the problem was reported to them. The ticket number will document the time and date of the problem. You must e-mail your instructor within 24 hours of the technical difficulty if you wish to request a make-up/extension. Other resources are available at <http://www.distance.ufl.edu/getting-help> for:

- Counseling and Wellness resources
- Disability resources
- Resources for handling student concerns and complaints
- Library Help Desk support

Should you have any complaints with your experience in this course please visit <http://www.distance.ufl.edu/student-complaints> to submit a complaint.