

**Department of Health Outcomes and Policy**  
**College of Medicine**  
**University of Florida**

***GMS 6852: Community Engaged Research for Clinical Effectiveness  
and Implementation Science Studies***  
***Spring 2017***

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<b>Class Meetings:</b>	Every Monday, Jan. 9 – Mar. 13 – Periods 7-9 (1:55 pm – 4:55 pm)
<b>Class Location:</b>	HPNP Room G-110
<b>Credit Hours:</b>	2 credits
<b>Prerequisite:</b>	None
<b>Course Director:</b>	Ryan P. Theis, Ph.D.
<b>Office Hours:</b>	Tuesdays, 2 – 4 pm
<b>Office:</b>	CTRB, Room 2252
<b>Email:</b>	rtheis@ufl.edu
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### **COURSE DESCRIPTION**

The focus of this course is on providing students with applied knowledge related to conducting clinical effectiveness and implementation science studies that involve communities as collaborators in the research process. Communities are broadly defined and can include: physicians, policymakers, state agencies, and patients and their families, among others. Students in this course will focus on:

- Examining the development of patient-centered, clinical effectiveness studies that engage communities;
- Identifying strategies to form partnerships with communities to address gaps in knowledge around evidence-based interventions; and
- Examining strategies to incorporate patient and other stakeholder preferences and outcomes in clinical effectiveness studies.

Specific examples of community-engaged approaches will be discussed. Because students obtain 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 involve communities and key stakeholders in clinical effectiveness and implementation science research.

Students who successfully complete the course will be able to:

- Discuss the major concepts related to engaging communities in the design, implementation, interpretation and dissemination of research;

- Identify the benefits and barriers to involving community collaborations in clinical effectiveness and implementation science studies, as well as strategies for overcoming key barriers;
- Develop strategies for engaging communities in identifying study topics of importance to them and beginning the process of protocol development;
- Discuss some sentinel studies in clinical effectiveness and implementation science research, their study designs, and strategies for involving community collaborations to build upon and improve those designs;
- Describe the role of stakeholders and how to involve them in clinical effectiveness research, including the role of practice-based research networks;
- Critically evaluate clinical effectiveness studies that have incorporated community engagement by assessing the strengths and limitations of the study design as well as involvement of stakeholders in the study design and selection of outcomes.

### **COURSE PROCEDURE**

Class time will be used for presentations and class discussion. Most classes will begin with presentation of a major topic, followed by class discussion. The course will be enhanced by students' active involvement in the course. Each class session will have assigned readings that must be completed prior to class. Students are expected to come to each class prepared and to actively and constructively participate in class discussions centered around the required readings.

### **STUDENT COURSE REQUIREMENTS**

The following will be used to assess students' progress in achieving the course objectives:

1. **Reaction Papers.** Short reports, no more than 2 pages, on the assigned readings will be required at the beginning of the class in which they are discussed. These reports are designed to help focus students' reading and to prepare for class discussions. If the student arrives late to class, the assignment is considered late. Assignments may be brought to class or emailed to the instructor prior to the start of class. Reaction papers will be required for Weeks 2 through 7 (six papers total).
2. **Attendance and Participation.** Each student is expected to be an active and regular participant in class discussions. Students should come to class prepared to discuss the strengths and weaknesses of the assigned readings as well as how the readings apply to their own research interests. In addition, each student will select one week (from Weeks 3, 4, 5, 6, or 7) to lead class discussion on a peer-reviewed paper of their choosing relevant to the week's topic. This paper will be in addition to the assigned readings for that week and must be selected at least one week prior to the class.
3. **Protocol/Engaging Communities in Research.** Students will identify a specific focus area for community engagement in translational research related to their research interests. Each student will develop strategies that could be used to engage communities in identifying research questions and in protocol development. The research approach should include refining the research questions, developing the study design, identifying key measures, and identifying measurement issues. Each student will: (1) write a brief summary of their proposal (5 pages); and (2) present their proposal to the rest of the class, followed by class discussion (30 minutes, including discussion). Format and content requirements of the written summary and presentation will be provided by Week 3.

## EVALUATION AND GRADING:

Grades will be based on the written reaction papers (30%); attendance and participation in class discussions (30% - for Weeks 1-7; 6% as discussion lead; 4% all other days); and the final written protocol (10%) and presentation (30%). All deadlines must be met. Any assignment turned in late will receive a 10 percentage point reduction in the final grade. The following grading system will be used: A (95% or higher), A- (90-94%), B+ (87%-89%), B (83%-86%), B- (80-82%), C+ (77%-79%), C (73%-76%), C- (70-72%), D+ (67-69%), D (63%-66%), D- (60-62%), and E ( $\leq$ 59%). Information on UF grading policies can be found at: <https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>.

## TEXTBOOKS AND READINGS:

**Olsen, L. and McGinnis, J.M. (2010).** *Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Practice-Based Approaches*. Washington, D.C.: Institute of Medicine. Free PDF available for download at: <https://www.nap.edu/catalog/12197/>

**U.S. Department of Health and Human Services (2011).** *Principles of Community Engagement (PCE) - Second Edition*. NIH Publication No. 11-7782. Free PDF available for download at: [https://www.atsdr.cdc.gov/communityengagement/pdf/PCE\\_Report\\_508\\_FINAL.pdf](https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf)

Supplementary readings will be assigned and may be expanded beyond what is outlined in the syllabus.

Belone, L. et al. (2016). "Community-Based Participatory Research Conceptual Model: Community Partner Consultation and Face Validity." *Qualitative Health Research* 26(1): 117-135.

Bergman, D.A., and Beck, A. (2011). "Moving from Research to Large-Scale Change in Child Health Care." *Academic Pediatrics* 11: 360-368.

Boote, J., Baird, W., and Beecroft, C. (2010). "Public involvement at the design state of primary health research: A narrative review of case examples." *Health Policy* 95: 10-23.

Cox, S., Ross, K., Townsend, A., Avar, D., and Woodgate, R. (2011). "From Stakeholders to Shareholders: Engaging Consumers in Health Research." *Health Law Review* 19(3): 63-71.

Hoffman, A., Montgomery, R., Aubry, W., and Tunis, S.R. (2010). "How Best to Engage Patients, Doctors, and Other Stakeholders in Designing Comparative Effectiveness Studies." *Health Affairs* 29(10): 1834-1841.

Israel, B.A., Schulz, A.J., Parker, E.A., and Becker, A.B. (1998). "Review of Community-Based Research: Assessing Partnership Approaches to Improve Public Health." *Annual Review of Public Health* 19: 173-202.

Maar, M., et al. (2015). "I-RREACH: an engagement and assessment tool for improving implementation readiness of researchers, organizations and communities in complex interventions." *Implementation Science* 10:64.

Minkler, M., and Salvatore, A.L. (2012). "Participatory Approaches for Study Design and Analysis in Dissemination and Implementation Research". In *Dissemination and Implementation Research in Health* (Brownson, R.C., Colditz, G.A., and Proctor, E.K., eds.). New York, NY: Oxford University Press.

Mullins, C.D., Abdulhalim, A.M., and Lavalley, D.C. (2012). "Continuous Patient Engagement in Comparative Effectiveness Research." *JAMA* 307(15): 1587-1588.

Mullins, C.D., Vandigo, J., Zheng, Z., and Wicks, P. (2014). "Patient-Centeredness in the Design of Clinical Trials". *Value in Health* 17: 471-475.

Strunin, L., et al. (2013). "Preventing Cancer: A Community-Based Program for Youths in Public Housing." *Journal of Adolescent Health* 52: S83-S88.

Wallerstein, N, and Duran, B. (2010). "Community-Based Participatory Research Contributions to Intervention Research: The Intersection of Science and Practice to Improve Health Equity." *American Journal of Public Health* 100: S40-S46.

## Resources

Patient Centered Outcomes Research Institute (PCORI)

- Review the website, funding announcements, currently funded projects: <http://www.pcori.org>
- The PCORI Methodology Report (2013): <http://www.pcori.org/assets/2013/11/PCORI-Methodology-Report.pdf>

Agency for Health Care Research and Quality (AHRQ). AHRQ Funding Opportunity Announcement (FOA) Guidance. <http://www.ahrq.gov/funding/policies/foaguidance/index.html>

National Science Foundation (NSF). Smart and Connected Health.  
[http://www.nsf.gov/funding/pgm\\_summ.jsp?pims\\_id=504739](http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=504739)

## **PROTOCOL/ENGAGING COMMUNITIES IN RESEARCH**

You are a faculty member at a major university. You are interested in engaging the community in health outcomes research and are planning to submit a pilot proposal on engaging the population in the identification of the topic and study design. The following is a list of questions to consider as you develop your project.

1. Where are you planning to submit this proposal? Identify the specific mechanism.
2. Who are your stakeholders in general and why are they important to the study?
3. How will you identify specific stakeholders to contribute to your study development?
4. How will you be introduced to stakeholders?
5. How will you formulate research questions?
6. What study designs fit with your research questions but also are acceptable to your stakeholders?
7. What is the setting of your study (locations) and why is this important given the purpose and aims of your study?
8. How will you identify appropriate patient-centered outcomes in collaboration with stakeholders?

**TOPICAL OVERVIEW \***

<b>Day</b>	<b>Major Topic</b>	<b>Sub-Topics</b>	<b>Required Readings</b>
Week 1 Jan. 9	Introduction to Clinical Effectiveness Research Paradigms and Community Engagement	<ul style="list-style-type: none"><li>• Review of definitions of clinical effectiveness research</li><li>• The role of various types of communities in clinical effectiveness research</li></ul>	Olsen & McGinnis, 2010 – Summary, Chapter. 1; Hoffman et al., 2010; Bergman & Beck, 2011
Week 2 Jan. 23	Principles of Community Engagement	<ul style="list-style-type: none"><li>• Review of principles</li><li>• Managing organizational support</li><li>• Challenges and evaluation</li></ul>	PCE, 2nd edition, 2011 Chapters 1, 2, 4, 5; Cox et al., 2011;
Week 3 Jan. 30	Engagement in Clinical Research Designs	<ul style="list-style-type: none"><li>• Policy mandates</li><li>• Patient engagement to improve implementation and dissemination</li></ul>	Olsen & McGinnis, 2010 – Chapter 6 Mullins et al., 2012 & 2014; Boote et al., 2010
Week 4 Feb. 6	Engagement in Community Research	<ul style="list-style-type: none"><li>• Identifying and involving community stakeholders</li><li>• Community organizing and coalitions</li></ul>	PCE, 2 <sup>nd</sup> edition, 2011 – Chapter 6, 7 Israel et al., 1998; Strunin et al., 2013
Week 5 Feb. 13	Community-Based Participatory Research in Implementation Science	<ul style="list-style-type: none"><li>• Ethical and methodological challenges</li><li>• Engaging stakeholders in study design and analysis</li></ul>	Wallerstein & Duran, 2010; Belone et al., 2016; Minkler & Salvatore, 2012; Maar et al., 2015
Week 6 Feb. 20	Introduction to Major National Initiatives Related to Community-Engagement	<ul style="list-style-type: none"><li>• The Patient Centered Outcomes Research Institute</li><li>• Agency for Health Care Research and Quality</li><li>• National Science Foundation</li></ul>	See syllabus resources for weblinks
Week 7 Feb. 27	Future Directions for Clinical Effectiveness Research and Engaging Communities	<ul style="list-style-type: none"><li>• Identifying gaps in research and future priority areas</li><li>• One Florida Clinical Research Consortium</li></ul>	Olsen & McGinnis, 2010 – Ch. 5, 7;
Week 8 Mar. 13	Student Presentations		-

\* **NOTE:** Jan. 16 is a holiday (Martin Luther King, Jr.'s birthday). March 6 is the first day of Spring Break. There will be no class on these days.

## **COURSE POLICIES**

### **Class Decorum**

Please: (1) be on time, (2) respect others' points of view, (3) listen quietly when others are speaking, and (4) turn off cell phones, alarms, and other such distractions.

### **Returned Assignments**

Keep copies of all assignments that you submit and of all grades until you receive official notification of your final course grade.

### **Attendance Policy**

Class attendance is mandatory. Excused absences follow the criteria of the UF Graduate Catalog (e.g., illness, serious family emergency, military obligations, religious holidays), and should be communicated to the instructor prior to the missed class day when possible. The UF Graduate Catalog is available at <http://gradcatalog.ufl.edu/>. Students should read the assigned readings prior to the class meetings, and be prepared to discuss the material. Regardless of attendance, students are responsible for all material presented in class and meeting the scheduled due dates for class assignments.

### **Policy on Make-Up Work**

Students are allowed to make up work only as the result of 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.

### **Special Needs**

Students requiring accommodations for special needs or disabilities must first register with the Dean of Students' Office (352-392-8565, [www.dso.ufl.edu/drc/](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 faculty member when requesting accommodation. The College is committed to providing reasonable accommodations to assist students in their coursework.

### **Academic Honesty**

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>). The Honor Code states: "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty and integrity." 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.

### **Course Evaluations**

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results/>.