

**Department of Health Outcomes and Biomedical Informatics**

**College of Medicine**

**University of Florida**

**GMS 6852: Collaborative Clinical and Health Research Methods  
and Implementation Science Studies**

***Spring 2022***

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**Class Meetings:** Every Tuesday, January 11 – April 19 – Period 7 (1:55 pm – 3:50 pm for the first class and 2:30pm - 3:50pm for every class thereafter)

**Class Location:** Zoom

**Zoom Meeting ID:** 927 1274 6422 (January 11th)

985 2396 6863 (January 18th - April 19th)

**Zoom Password:** N/A

**Zoom Link:**

<https://ufl.zoom.us/j/92712746422> (Links to an external site.) (January 11th)

<https://ufl.zoom.us/j/98523966863> (Links to an external site.) (January 18th - April 19th)

**Credit Hours:** 2 credits

**Prerequisite:** GMS 6851

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**Course Director:** Betsy Shenkman, PhD

**Office Hours:** Tuesdays from 4 to 4:45 pm immediately following class or by appointment

**Office:** CTRB 2247 (2004 Mowry Road)

**Email:** eshenkman@ufl.edu

**Phone:** 352-294-5975

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**Course Description**

The focus of this course is on providing students with applied knowledge related to conducting pragmatic clinical trials 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, pragmatic clinical trials and implementation science 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 research.

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 engaging communities and 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 pragmatic clinical trials 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 pragmatic clinical trials 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 pragmatic clinical trials 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 research;
- Critically evaluate pragmatic clinical trials and other clinical research 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 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. **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.
2. **Discussion lead.** In addition, each student will select one week (from Weeks 12, 14 or 15) 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. The student must email the selected paper to [eshenkman@ufl.edu](mailto:eshenkman@ufl.edu) at least one week prior to the class.
3. **Review or commentary paper.** Students will identify a specific topic in community engagement and translational science that is related to their research interests. During the semester, students will research and write a paper that addresses their topic. This may be a scoping review, a systematic review, or a commentary paper, which will be submitted for publication in a peer-reviewed journal of the student's choice. The paper should follow the content, style, and formatting guidelines of the selected journal.

## Evaluation and Grading:

Grades will be based on the attendance and participation in class discussions (40% - for Weeks 1, 2, 3, 4, 6, 7, 8, 10; 5% per week); the Discussion Lead assignment (10%); the final paper outline (20%); and the final paper (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> (Links to an external site.).

## Textbooks and Readings:

**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) (Links to an external site.)

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

Ahmed, S.M., et al. (2015). "Towards Building a Bridge between Community Engagement in Research (CEnR) and Comparative Effectiveness Research (CER). *Clin Trans Sci* 8: 160-165.

Bastian LA, Cohen SP, Katsoyich L, Becker WC, Brummett BR, Burgess DJ, Crunkhorn AE, Denneson LM, Frank JW, Goertz C, Ilfeld B, Kanzler KE, Krishnaswamy A, LaChappelle K, Martino S, Mattocks K, McGeary CA, Reznik TE, Rhon DI, Salsbury SA, Seal KH, Semiatin AM, Shin MH, Simon CB, Teyhen DS, Zamora K, Kerns RD; NIH-DOD-VA Pain Management Collaboratory. Stakeholder Engagement in Pragmatic Clinical Trials: Emphasizing Relationships to Improve Pain Management Delivery and Outcomes. *Pain Med*. 2020 Dec 12;21(Suppl 2):S13-S20. doi: 10.1093/pm/pnaa333. PMID: 33313726; PMCID: PMC7824996.

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., Avard, D., et al. (2011). "From Stakeholders to Shareholders: Engaging Consumers in Health Research." *Health Law Review* 19(3): 63-71.

Das LT, Kaushal R, Garrison K, Carrillo V, Grinspan Z, Theis R, Shenkman E, Abramson E. Drivers of preventable high health care utilization: a qualitative study of patient, physician and health system leader perspectives. *J Health Serv Res Policy*. 2020 Oct;25(4):220-228. doi: 10.1177/1355819619873685. Epub 2019 Sep 10. PMID: 31505976.

Gesell SB, Halladay JR, Mettam LH, Sissine ME, Staplefoote-Boynton BL, Duncan PW. Using REDCap to track stakeholder engagement: A time-saving tool for PCORI-funded studies. *J Clin Transl Sci*. 2020 Feb 6;4(2):108-114. doi: 10.1017/cts.2019.444. PMID: 32313700; PMCID: PMC7159814.

Hoekstra, F., Martin Ginis, K.A., Allan, V., Kothari, A, et al. (2018). "Evaluating the impact of a network of research partnerships: a longitudinal multiple case study protocol." *Health Research Policy and Systems* 16:107.

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.

McNulty M, Smith JD, Villamar J, Burnett-Zeigler I, Vermeer W, Benbow N, Gallo C, Wilensky U, Hjorth A, Mustanski B, Schneider J, Brown CH. Implementation Research Methodologies for Achieving Scientific Equity and Health Equity. *Ethn Dis*. 2019 Feb 21;29(Suppl 1):83-92. doi: 10.18865/ed.29.S1.83. PMID: 30906154; PMCID: PMC6428169.

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.

Poger JM, Mayer V, Duru OK, Nauman B, Holderness H, Warren N, Vasquez C, Bibi S, Rasmussen-Torvik LJ, Hosseinian Z, Shi L, Wallace J, Goytia CN, Horowitz CR, Kraschnewski JL. Network Engagement in Action: Stakeholder Engagement Activities to Enhance Patient-centeredness of Research. *Med Care*. 2020 Jun;58 Suppl 6 Suppl 1(Suppl 6 1):S66-S74. doi: 10.1097/MLR.0000000000001264. PMID: 32412955; PMCID: PMC7398633.

Shenkman, E., Hurt, M., Hogan, W., Carrasquillo, O., et al. (2018). OneFlorida Clinical Research Consortium: Linking a Clinical and Translational Science Institute With a Community-Based Distributive Medical Education Model. *Academic Medicine* 93(3): 451-455.

Stallings SC, Boyer AP, Joosten YA, Novak LL, Richmond A, Vaughn YC, Wilkins CH. A taxonomy of impacts on clinical and translational research from community stakeholder engagement. *Health Expect*. 2019 Aug;22(4):731-742. doi: 10.1111/hex.12937. Epub 2019 Jul 18. PMID: 31321849; PMCID: PMC6737764.

Tapp, H., Kuhn, L., Alkhazraji, T., Steuerwald, M., et al. (2014). Adapting community based participatory research (CBPR) methods to the implementation of an asthma shared decision making intervention in ambulatory practices. *Journal of Asthma* 51(4): 380-390.

Theis RP, Malik AM, Thompson LA, Shenkman EA, Pbert L, Salloum RG. Considerations of Privacy and Confidentiality in Developing a Clinical Support Tool for Adolescent Tobacco Prevention: Qualitative Study. *JMIR Form Res*. 2019 Apr 28;3(2):e12406. doi: 10.2196/12406. PMID: 31066687; PMCID: PMC6528437.

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.

Warren, N.T., Gaudino, J.A., Likumahuwa-Ackman, S., Dickerson, K., et al. (2018). "Building Meaningful Patient Engagement in Research: Case Study from ADVANCE Clinical Data Research Network." *Medical Care* 56 (10,S1): S58-S63.

## Resources

### Patient Centered Outcomes Research Institute (PCORI)

- Review the website, funding announcements, currently funded projects: <http://www.pcori.org> (Links to an external site.)
- The PCORI Methodology Report (2017): <http://www.pcori.org/sites/default/files/PCORI-Methodology-Report.pdf> (Links to an external site.)

### Agency for Health Care Research and Quality (AHRQ)

- AHRQ Activities Using CBPR to Address Health Care Disparities: <https://www.ahrq.gov/research/findings/factsheets/minority/cbprbrief/index.html> (Links to an external site.)
- Accelerating Change and Transformation in Organizations and Networks III (ACTION III): <https://www.ahrq.gov/research/findings/factsheets/translating/action3/index.html> (Links to an external site.)

### National Institutes of Health (NIH)

- All of Us Research Program: <https://allofus.nih.gov/> (Links to an external site.)
- All of Us Program Partners – Communications and Engagement: <https://allofus.nih.gov/about/program-partners/communications-and-engagement> (Links to an external site.)

## **Review/Commentary Paper**

The final paper may be a scoping review, systematic review, or commentary (between 2,000 and 5,000 words), which students will submit to a peer-reviewed journal of their choice after receiving their final grades.

- An outline of the paper will be due in Week 6, submitted to the instructor by email no later than 5 pm on Feb. 17. There will be no class meeting the week before to give you time to work on this. This written assignment will include: (1) at least a two-page clear description of the working title, topic choice, and rationale (two page minimum

does not include references); (2) the target peer-reviewed journal; (3) a conceptual framework based on concepts of community-engaged research discussed in this course; (4) a brief review of methodology (with supporting references); (5) an outline of the major paper sections (with drafted text); (6) at least twenty references, and (7) any additional preparatory notes, including potential challenges and how you will address them.

- The final paper will be due in Week 13, submitted to the instructor by email no later than 5 pm on April 7. There will be no class meeting that day. The final paper should be organized into a narrative rather than a series of facts or bullets. It should be proofread with correct grammar and spelling. Citation style and paper formatting should correspond with the selected target journal. The manuscript should be ready to be submitted to the selected journal and include all necessary components per journal instructions (e.g., abstract, introduction, discussion, references). This manuscript should be the student's own original work and not previously submitted for credit or publication.

### Topic Overview \*

Day	Major Topic	Sub-Topics	Required Readings
Week 1 Jan. 11	Introduction: The Role of Community in Pragmatic Clinical Trials, Clinical Effectiveness and Implementation Studies	•Community-engaged research (CEnR) Engaging communities in Pragmatic Clinical Trials, comparative effectiveness research (CER) and D&I	Ahmed et al., 2015 Hoffman et al., 2010 Bergman & Beck, 2011 Bastian et al., 2020
Week 2 Jan. 18	Principles of Community Engagement	Review of principles of community engagement	PCE, 2nd edition, 2011 (Chapters 1, 2)
Week 3 Jan. 25		Community engaged research study examples	PCE, 2nd edition, 2011 (Chapters 3) Das et al. 2019 Theis et al., 2019



Week 4 Feb. 1	Engagement in Clinical Research Designs	Policy mandates Patient/consumer engagement and public involvement	Mullins et al., 2012 & 2014 Boote et al., 2010; Cox et al., 2011; Stallings et al., 2019
Week 5 Feb. 8	Independent Study (Work on paper outlines that are due next week)	-	-
Week 6 Feb. 15	Engagement in Community Research	Identifying and involving community stakeholders Capacity, challenges Community organizing and coalitions	PCE, 2 <sup>nd</sup> edition, 2011 (Chapters 4, 5, 6);
Week 7 Feb. 22	Community-Engaged Research in Implementation Science	Ethical and methodological challenges Engaging stakeholders in study design and analysis	Wallerstein & Duran, 2010 Belone et al., 2016; Tapp et al., 2014 Poger et al., 2020
Week 8 March 1	Introduction to Major National Initiatives Related to Pragmatic Clinical Trials and Implementation Science Studies	<ul style="list-style-type: none"> <li>• PCORI</li> <li>• AHRQ</li> <li>• NIH</li> </ul>	See syllabus resources for links
Week 9 March 8	No Class Spring Break Week		



Week 10 March 15	Future Directions – Community Partnership Networks	Community engagement in research networks One Florida Clinical Research Consortium	Warren et al., 2018 Hoekstra et al., 2018 Shenkman et al., 2018
Week 11 March 22	Discussion with Citizen Scientists	Role of Citizen Scientists in Study Topic Identification, Study Design and Implementation-	
Week 12 March 29	Student Led Discussion		
Week 13 April 5	Independent Study Final papers due (no class)		
Week 14 April 12	Student Led Discussion		
Week 15 April 19	Student Led Discussion Final Class		

### **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. For those attending via Zoom, please have all windows closed out so that your full attention is on the class and discussion.

## **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/> ([Links to an external site.](#)). 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/) ([Links to an external site.](#))). 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> ([Links to an external site.](#))). 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 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 is available

at <https://gatorevals.aa.ufl.edu/students/> (Links to an external site.). 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/> (Links to an external site.). Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/> (Links to an external site.).