

Department of Health Outcomes and Biomedical Informatics
College of Medicine
University of Florida
Spring 2024

Class Meetings: Every Thursday (3:00 pm to 4:55 pm)

Class Location: Zoom

Zoom Meeting ID: 914 2017 5207

Zoom Link: <https://ufl.zoom.us/j/91420175207>

Credit Hours: 2 credits

Course Directors:

Betsy Shenkman, PhD – eshenkman@ufl.edu – DSIT 7003 – Office hours by appointment

Ryan Theis, PhD – rtheis@ufl.edu – DSIT 7110 – Office hours by appointment

COURSE DESCRIPTION

The focus of this course is on providing students with applied knowledge related to conducting pragmatic clinical trials, comparative effectiveness research 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 and their application in different pragmatic clinical trials, comparative effectiveness research and implementation science studies 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, comparative effectiveness research 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, comparative effectiveness research 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 3, 7, or 13) to lead class discussion on a peer-reviewed paper of their choosing relevant to stakeholder engagement in clinical effectiveness and implementation science. The paper must have been published in the last 5 years. The student must email the selected paper to eshenkman@ufl.edu and rtheis@ufl.edu at least one week prior to the class.
3. **Group activity.** Readings for Week 11 include peer-reviewed articles detailing clinical effectiveness or implementation science studies that do not incorporate stakeholder engagement. During the Week 11 class, students will split into groups of three or more, with each group taking one of the assigned articles. Groups will discuss how they might incorporate engagement methods to improve the study described in their assigned article, and will then present their ideas to the class.
4. **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, 9, 12, 13; 4% per week); the Discussion Lead assignment (5%); the Group Activity (5%); 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 in the UF Graduate Catalog at:

<https://gradcatalog.ufl.edu/graduate/regulations/>

READINGS

- 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, Katsovich L, et al. (2020). "Stakeholder Engagement in Pragmatic Clinical Trials: Emphasizing Relationships to Improve Pain Management Delivery and Outcomes." *Pain Med* 21(Suppl 2):S13-S20. doi: 10.1093/pm/pnaa333. PMID: 33313726; PMCID: PMC7824996.
- 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.
- Davies-Teye BB, Medeiros M, Chauhan C, Baquet CR, Mullins CD. (2021). Pragmatic patient engagement in designing pragmatic oncology clinical trials. *Future Oncol* 17(28):3691-3704. doi: 10.2217/fon-2021-0556.
- Frank L, Forsythe L, Ellis L, Schrandt S, et al. (2015). Conceptual and practical foundations of patient engagement in research at the Patient-Centered Outcomes Research Institute. *Qual Life Res* 24(5):1033-1041. doi: 10.1007/s11136-014-0893-3.
- Gesell SB, Halladay JR, Mettam LH, Sissine ME, Staplefoote-Boynnton BL, Duncan PW. (2020). Using REDCap to track stakeholder engagement: A time-saving tool for PCORI-funded studies. *J Clin Transl Sci* 4(2):108-114. doi: 10.1017/cts.2019.444.
- Gould GS, Bovill M, Pollock L, Bonevski B, et al. (2019). Feasibility and acceptability of Indigenous Counselling and Nicotine (ICAN) QUIT in Pregnancy multicomponent implementation intervention and study design for Australian Indigenous pregnant women: A pilot cluster randomised step-wedge trial. *Addict Behav* 90: 176-190. doi: 10.1016/j.addbeh.2018.10.036.
- Hamilton AB, Brunner J, Cain C, Chuang E, et al. (2017). Engaging multi-level stakeholders in an implementation trial of evidence-based quality improvement in VA women's health primary care. *Trans Behav Med* 7(3): 478-485. doi: 10.1007/s13142-017-0501-5.
- Hentschel A, Hsiao CJ, Chen LY, Wright L, et al. (2021). Perspectives of Pregnant and Breastfeeding Women on Participating in Longitudinal Mother-Baby Studies Involving Electronic Health Records: Qualitative Study. *JMIR Pediatr Parent* 5;4(1):e23842. doi: 10.2196/23842.
- 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.

Joseph J, Pajewski NM, Dolor RJ, Sellers MA, et al. (2023). PREVENTABLE Trial Research Group. Pragmatic evaluation of events and benefits of lipid lowering in older adults (PREVENTABLE): Trial design and rationale. *J Am Geriatr Soc* 71(6):1701-1713. doi: 10.1111/jgs.18312.

Mardian A, Perez L, Pun T, Cheung M, et al. (2022). Engagement in Prescription Opioid Tapering Research: the EMPOWER Study and a Coproduction Model of Success. *J Gen Intern Med* 37(Suppl 1):113-117. doi: 10.1007/s11606-021-07085-w.

Minkler M, Salvatore AL, Chang C. (2017). Participatory Approaches for Study Design and Analysis in Dissemination and Implementation Research. In RC Brownson, GA Colditz, and EK Proctor (eds.), *Dissemination and Implementation Science Research in Health: Translating Science to Practice* (pp. 175-190). Oxford University Press. doi: 10.1093/oso/9780190683214.003.0011

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

Page-Reeves J, Regino L, McGrew HC, Tellez M, et al. (2017). Collaboration and Outside-the-Box Thinking to Overcome Training-Related Challenges for Including Patient Stakeholders as Data Collectors in a Patient-Engaged Research Project. *Journal of Patient Experience* 5(2): 88-91. doi: 10.1177/2374373517729506.

Poger JM, Mayer V, Duru OK, et al. (2020). Network Engagement in Action: Stakeholder Engagement Activities to Enhance Patient-centeredness of Research. *Med Care* 58 Suppl 6 Suppl 1(Suppl 6 1): S66-S74. doi: 10.1097/MLR.0000000000001264.

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. (2019). A taxonomy of impacts on clinical and translational research from community stakeholder engagement. *Health Expect* 22(4):731-742. doi: 10.1111/hex.12937.

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, Stanford JC, Goodman JR, Duke LL, Shenkman EA. (2017). Defining 'quality' from the patient's perspective: Findings from focus groups with Medicaid beneficiaries and implications for public reporting. *Health Expectations* 20(3): 395-406.

Theis RP, Blackburn K, Lipori G, Harle CA, Alvarado MM, Carek PJ, Zemon N, Howard A, Salloum RG, Shenkman EA. (2021). "Implementation context for addressing social needs in a learning health system: a qualitative study." *Journal of Clinical and Translational Science* 5(e201): 1-11.

Unertl KM, Fair AM, Favours JS, Dolor RJ, et al. (2018). Clinicians' perspectives on and interest in participating in a clinical data research network across the Southeastern United States. *BMC Health Serv Res* 18(1):568. doi: 10.1186/s12913-018-3399-9.

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

Duke University

- Researcher's Guide to Community-Engaged Research:
https://guides.mclibrary.duke.edu/CENR_researchers/home

Patient Centered Outcomes Research Institute (PCORI)

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

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>
- Accelerating Change and Transformation in Organizations and Networks III (ACTION III):
<https://www.ahrq.gov/research/findings/factsheets/translating/action3/index.html>

National Institutes of Health (NIH)

- All of Us Research Program: <https://allofus.nih.gov/>
- All of Us Program Partners – Communications and Engagement:
<https://allofus.nih.gov/about/program-partners/communications-and-engagement>

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. 14. 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 15, submitted to the instructor by email no later than 5 pm on April 18. 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	Topic	Sub-topics	Required readings
Week 1 Jan. 11	Introduction to Stakeholder Engagement	-Implementation science -Improvement science -Comparative effectiveness -Pragmatic clinical trials -PCORI	Ahmed et al., 2015 Bastian et al., 2020 Frank et al., 2015 Mullins et al., 2012
Week 2 Jan. 18	Principles and Methods of Stakeholder Engagement	-Defining stakeholders -Identifying stakeholders -Approaches to engagement	Hoffman et al., 2010 Minkler et al., 2017 Walsh et al., 2021 See syllabus resources for web-links (Duke University)
Week 3 Jan. 25	Applying Community Engagement to Research 1 and Discussion Leads	Student-led discussion -How can your work be community-engaged? -2 student discussion leads	-

Day	Topic	Sub-topics	Required readings
Week 4 Feb. 1	Patient Engagement: Approaches and Studies	-Patient engagement -Practical and ethical challenges	Boote et al., 2010 Davies-Teye et al., 2021 Page-Reeves et al., 2017 Theis et al., 2017
Week 5 Feb. 8	Independent Study (no class)	-Work on paper outlines that are due next week	-
Week 6 Feb. 15	Provider Engagement: Approaches and Studies	-Clinician engagement -System leader engagement -Multi-level engagement	Hamilton et al., 2017 Mardian et al., 2022 Tapp et al., 2014 Unertl et al. 2018
Week 7 Feb. 22	Student discussion leads	-4 student discussion leads	-
Week 8 Feb. 29	Engagement in Implementation Science Research	-Meet the Citizen Scientists -UF engagement resources -Use case: Epic Healthy Planet -Use case: Postpartum Care	Hentschel et al. 2021 Theis et al., 2021
Week 9 March 7	Evaluating Engagement	-Tracking engagement -Taxonomy of impacts	Gesell et al., 2020 Hoekstra et al., 2018 Stallings et al., 2019
Week 10 March 14	Spring Break (no class)	-	-
Week 11 March 21	Applying Community Engagement to Research 2	Student-led discussion -Group activity: How to add engagement to a published study	Gould et al., 2019 Joseph et al., 2023
Week 12 March 28	Engagement in Learning Health Systems	-LHS researcher competencies -Community engagement in research networks -OneFlorida CRC	Poger et al., 2020 Shenkman et al., 2018 Warren et al., 2018
Week 13 April 4	Student discussion leads	-4 student discussion leads	-
Week 14 April 11	Independent Study (no class)	-Work on final papers	-
Week 15 April 18	Independent Study (no class)	-Final papers due	-

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/>.

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/).

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 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/>.

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/>