GMS 6853: Implementation Science in the Learning Health System

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

Semester: Spring 2022
Time: Mondays, 12:50 pm to 3:50 pm (P. 6-8)
Location: Zoom videoconference
Credits: 3
Instructor: Ryan Theis, Ph.D.; (352) 294-5973; rtheis@ufl.edu

COURSE DESCRIPTION

Quality improvement and implementation of evidence-based practices are critical for addressing gaps in the delivery and effectiveness of health care. Translating research into practice is a complex process that involves engagement from multiple stakeholders (including clinicians, patients and families, and communities), which facilitates the adoption of evidence-based interventions into health care and community settings and contributes to the sustainability of interventions. Implementation science seeks to: (1) understand the barriers and facilitators that influence successful implementation of effective interventions, (2) design strategies to foster the adoption of best practices, and (3) enhance the extent to which intervention research is generalizable, representative, and ultimately scalable. Combined with implementation science, more rigorous dissemination efforts, beyond traditional academic venues, are needed to increase outreach into real-world settings.

This course provides a framework for examining improvement and implementation science and its application to clinical and community-based research. Because improvement and implementation science are rooted in real world clinical and community settings, the focus of the course is twofold:

- First, the course focuses on **examining different study designs in improvement and implementation science**, and the strengths and limitations of different approaches.
- Second, the course provides **real world experience** for the students by pairing them with a researcher and a topic expert to design an improvement and implementation science approach and dissemination activities that address a real-world clinical or community concern.

To meet these objectives, students will to develop an implementation science proposal that addresses a real world clinical or community issue, in consultation with a researcher and a topic expert. Topic experts may include a collaborating clinician, community agency/group representative, technical expert, or Citizen Scientist. Students already conducting research that could benefit from improvement and implementation science may choose to select their own topics and collaborators. Students may also select topics through the Clinical and Translational Science Institute (CTSI) Learning Health System-Implementation Science (LHS-IS) Program, the Quality Improvement Project Registry (QIPR), and other UF Health initiatives. The engagement

of researchers is essential to ensure that the appropriate scientific expertise is available to guide the development of the proposal. The engagement of topic experts is essential to ensure that the proposal effectively addresses critical health or community issues facing our patients.

During the course, the students will develop their projects in consultation with their selected researcher and topic expert and engage in didactic videoconference discussion sessions. At the end of the semester, students will present their projects to the class. Study collaborators, members of the CTSI leadership team, UF Health, and Faculty Group Practice will be invited to attend and provide feedback on the final presentations.

STUDENT CONSULTATIONS WITH TOPIC EXPERTS

For their semester proposal assignment, students are encouraged to select researchers and topic experts with whom they already have an established working relationship. This allows students to build upon their own graduate thesis or dissertation work, or the work of their mentors and advisors, and develop an implementation science strategy that has the potential to enhance existing projects. For students who do not have their own topics, resources will be provided in the first two weeks of the course for identifying potential implementation science topics that are important to UF Health Clinicians, Citizen Scientists, and researchers.

Students will complete a graded consultation assignment, which involves a videoconference consultation with their topic expert, and includes a PowerPoint presentation and interview guide that will be used during the consultation, and meeting notes that will be submitted after the consultation. To assist students in understanding what to expect from this collaboration, the following guidelines are provided.

1) Students will prepare a PowerPoint presentation to discuss with the topic expert that describes the purpose, aims and suggested interventions to promote the uptake of evidence-based best practices. The PowerPoint presentation is due March 14 and comprises 10% of your grade.
2) The student will develop an interview guide to solicit feedback from the topic expert about: (a) adaptations that should be considered before the protocol could be implemented in a clinical or community setting, (b) barriers that may be encountered, and (c) strategies that could facilitate implementation. The interview guide is due March 14 and comprises 10% of your grade.
3) Students are expected to spend 1-2 hours total during the semester (scheduled at a time most convenient for the topic expert) to present the proposal to the topic expert, conduct the interview, and obtain feedback. Week 9 has been set aside for the consultation, although students may conduct the consultation prior to this with permission from the instructor.
4) Students will prepare meeting notes (2 to 3 pages) from their consultations, which are due on March 28 and comprise 5% of your grade.
5) For any papers or presentations that are developed from this work, the topic expert should be included as one of the authors.

The decision of which type of topic expert to collaborate with depends on the specifics of the proposed project. For projects that address implementation of a clinical intervention, a clinician collaborator specializing in the appropriate field is recommended. Projects that involve a high level of interaction with patients or community members will benefit most from collaboration with a Citizen Scientist. Projects that address community-level interventions will benefit from collaboration with a leader or representative from a community agency or organization. Projects that propose a technical implementation strategy (e.g., new EHR functionality) will benefit from collaboration with an expert specializing in the specified technology.

AUDIENCE

The course is designed for advanced masters-level and doctoral-level students in health outcomes, biomedical informatics, medicine, public health, and other health professions, as well as advanced students in public policy, sociology, psychology or other social sciences with plans for a career in health research. Prerequisites are GMS 6851 (*Fundamentals of Dissemination and Implementation Research*) and permission of the instructor.

COURSE GOALS

The primary goals of this course are to enhance students': (1) knowledge of improvement and implementation science; (2) ability to critically evaluate studies focused on improvement and implementation science; and (3) real-world experience in designing an implementation science study. More specifically, students who successfully complete the course will be able to:

1. Discuss the theoretical underpinnings of improvement and implementation science,

2. Explain barriers and facilitators to implementation and dissemination of research findings and methods to address those barriers,

3. Describe the major categories of study designs that are used in conducting improvement and implementation science and strategies for engaging key stakeholders, and including clinicians and policymakers, in the research process,

4. Describe the importance of contextual factors and assessing multiple outcomes when designing improvement and implementation science studies, and

5. Critically evaluate improvement and implementation science studies by assessing the strengths and limitations of the study design and measures selected for informing health care decision-making in real world settings.

COURSE EVALUATION

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. 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/. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/.

METHODS OF INSTRUCTION

We will operate as an advanced graduate seminar, with students taking an active role in initiating and leading discussions and presenting their implementation science study progress. Attendance and active participation in all class discussions is required, and will be evaluated as part of the student's grade for the course. Students must read the required readings prior to each discussion session.

Discussion sessions and presentations will take place during scheduled class times (Mondays, 12:50 pm – 3:50 pm) using Zoom. There is no in-person component to this course. Several lectures have been recorded and uploaded to the course Canvas site; students are expected to view these lectures prior to the discussion session for which they are assigned. Some weeks include live lectures from the instructor and guest lecturers.

Reading Assignments and Class Discussions

You must read the assigned readings prior to each discussion session and be prepared to discuss your reactions, thoughts, analysis, comments and questions on the main issues raised in the readings. Share what strikes you as new, unexpected, or significant. Discuss implications of that reading for your scientific work. All students are expected to participate in each discussion session. Participation in discussion is worth 20% of your grade.

Discussion Lead

As 10% of your final grade, each student will be assigned two readings throughout the semester to lead during class discussion. You will have the opportunity to lead discussion on peer-reviewed journal articles assigned in Week 2 through Week 8, Week 10, and Week 11. To receive full credit for your discussion lead assignment, you must participate as a discussion lead on at least two of these weeks during the semester (leading discussion on no more than one paper each week).

Tests

No exams will be given in this graduate-level seminar course.

Term Paper / Proposal Development

As described in the course introduction, students will develop a written implementation science proposal in collaboration with a researcher and a topic expert. The proposal is worth 25% of your grade and will contain the following sections:

1) Specific aims
2) Research strategy, including: (a) significance, (b) innovation, and (c) approach
3) Practical and ethical considerations, including: (a) human subjects consideration; (b) data sharing and dissemination plans; and (c) data safety and monitoring plans

See detailed guidelines for proposal development at the end of the syllabus.

Final Presentation guidelines

The final presentations will occur the last two weeks of class (April 11 and April 18), and are worth 20% of your grade. You should prepare a well-designed set of slides in a PowerPoint file, which you will use during your presentations and will email to the entire class and the attendees (according to an attendee list that will be provided to you) by the Friday before your presentation. Design each visual carefully to illustrate the main points. Remember the rules for clear, easy to understand, and interesting slides: No more than 8 words per line, and no more than 8 lines on a slide; prevalent use of diagrams, charts, etc. to illustrate points; minimize the number of word-only slides; and aim for about one slide per minute.

You are expected to work with the researcher and topic expert with whom you are collaborating to develop your presentation, and also invite them to attend your presentation. It is not expected that your collaborators attend the presentations if their other professional commitments do not permit their attendance.

EVALUATION AND GRADING

Grades will be based on attendance and participation in discussions (20%); discussion lead assignment (10%), consultation assignment (25%), implementation science proposal (25%), and final presentation (20%). All deadlines must be met. Any assignment turned in after the deadline will receive one grade below what it would have earned had it been submitted on time. Grades will be assigned as follows:

Letter Grade	Grade Points	Grade Percentage
A	4.0	95-100
A-	3.67	90-94
B+	3.33	87-89
B	3.0	83-86
B-	2.67	80-82
C+	2.33	77-79
C	2.0	73-76
C-	1.67	70-72
D+	1.33	67-69
D	1.0	63-66
D-	.67	60-62
E	0	59 and below

For additional grading policy information, you may visit the undergraduate catalog web page at: https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx.

COURSE POLICIES AND RESOURCES

Students are expected to adhere to the following course policies.

Class Attendance

Class attendance is required. 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. University of Florida rules require attendance during the first two course sessions, and students must attend both course sessions of student presentations for this class. Missing more than three scheduled sessions will result in a failure. Regardless of attendance, students are responsible for all material presented in class and meeting the scheduled due dates for class assignments. Finally, students must read the assigned readings *prior to* the class meetings, and be prepared to discuss the material. For more information, please visit: https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx

CANVAS

Course information, readings, lectures, and grades are available on Canvas at http://lss.at.ufl.edu/. You must have a Gatorlink account to log on. *You will access the web site on a weekly basis to access readings, and to view assigned lecture videos (during weeks when videos are assigned).*

Getting Help

For issues with technical difficulties for E-learning in Canvas, please contact the UF Help Desk at: learning-support@ufl.edu or by calling (352) 392-HELP - select option 2. Additional information is available at: https://lss.at.ufl.edu/help.shtml

Online Participation

This course follows an online format in which students and the instructor attend weekly discussion sessions remotely using videoconference technology (e.g., Zoom). At the beginning of the semester, the instructor will provide information for accessing weekly discussions via videoconference. The videoconference technology also includes functions that allow students to conduct their consultations and make their final presentations remotely.

Class Decorum

Please be on time and respect others' points of view. For in-person sessions and all presentations, please listen quietly when others are speaking, and turn off cell phones, alarms, and other such distractions.

Diversity Statement

I consider this classroom to be a place where you will be treated with respect, and I welcome individuals of all ages, backgrounds, beliefs, ethnicities, genders, gender identities, gender expressions, national origins, religious affiliations, sexual orientations, ability – and other visible and nonvisible differences. All members of this class are expected to contribute to a respectful, welcoming and inclusive environment for every other member of the class.

Returned Assignments

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

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.

Accommodations for Students with Disabilities

Students requiring accommodations must first register with the Dean of Students' Office. 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.

Counseling and Mental Health Services

Please visit the UF counseling center website for information regarding appointments: https://counseling.ufl.edu/ or call (352)392-1575

UF Police Department

For Campus Police, please call the UF Police Department at (352)392-1111
For **all** emergencies and medical assistance, please call 911.

TEXTBOOK

Brownson, R.C., Colditz, G.A. & Proctor, E.K. (Eds). *Dissemination and Implementation Research in Health: Translating Science to Practice*, 2nd Edition. New York: Oxford University Press, 2017.

SCHEDULE OF TOPICS AND READINGS

Week 1 – Introductions, Course Overview, and Assignments
Introductory session – Jan. 10

Resources for identifying project topics and local clinical and research collaborators will be discussed during the Week 1 session. Students will also receive their discussion lead assignments for the semester. A guide/rubric for leading discussions will be available on the Canvas site.

Martin Luther King Jr. Day
No session – Jan. 17

Week 2 – Introduction to Improvement and Implementation Science
Discussion session – Jan. 24

Readings:

- Chapter 1: Colditz, GA & Emmons, KM. The promise and challenges of dissemination and implementation research.
- Chapter 2: Rabin, B.A. & Brownson, R.C. Terminology for dissemination and implementation research.
- Chambers DA, Feero WG, Khoury MJ. Convergence of Implementation Science, Precision Medicine and the Learning Health Care System: A new Model for Biomedical Research. JAMA. 2016 May 10;315(18):1941-2. doi: 10.1001/jama.2016.3867.PMID: 27163980
- Kilbourne AM, Goodrich DE, Miake-Lye I, Braganza MZ, Bowersox NW. Quality Enhancement Research Initiative Implementation Roadmap: Toward Sustainability of Evidence-based Practices in a Learning Health System. Medical Care. 2019; 57(10)-Suppl 3: S286-S293.
- Shojania KG, Grimshaw JM. Evidence-Based Quality Improvement: The State of the Science. Health Affairs. 2005; 24(1): 138-150. doi: 10.1377/hlthaff.24.1.138.

Week 3 - Research Design in Dissemination and Implementation Research
Discussion session – Jan. 31

Readings:

- Chapter 13: Landsverk, J. et al. Design and analysis in dissemination and implementation research.
- Balasubramanian BA, Heurtin-Roberts S, Krasny S, Rohweder CL, Fair K, Olmos-Ochoa TT, Stange KC, Gorin SS; MOHR Study Group. Factors Related to Implementation and Reach of a Pragmatic Multisite Trial: The My Own HealthReport (MOHR) Study. J Am Board Fam Med. 2017 May-Jun;30(3):337-349. doi: 10.3122/jabfm.2017.03.160151.
- Liang S, Kegler MC, Cotter M, et al. Integrating evidence-based practices for increasing cancer screenings in safety net health systems: a multiple case study using the Consolidated Framework for Implementation Research. *Implementation Science : IS*. 2016;11:109. doi:10.1186/s13012-016-0477-4.
- Zatzick DF, Russo J, Darnell D, et al. An effectiveness-implementation hybrid trial study protocol targeting posttraumatic stress disorder and comorbidity. *Implementation Science : IS*. 2016;11:58. doi:10.1186/s13012-016-0424-4.
- Zgierska AE, Robinson JM, Lennon RP, et al. Increasing system-wide implementation of opioid prescribing guidelines in primary care: findings from a non-randomized stepped-wedge quality improvement project. *BMC Family Practice*. 2020; 21:245.

Week 4 – Qualitative and Mixed Methods in Implementation Science
Discussion session – Feb. 7

Proposal topics and collaborators must be selected by the beginning of class in Week 4. Time will be set aside during class for you to present your topic idea and collaborators and receive initial feedback from the instructor and fellow students.

Readings:

- Chapter 20: Palinkas, LA and Rhoades Cooper, B. Mixed Methods Evaluation in Dissemination and Implementation Science
- National Cancer Institute. 2018. *Qualitative Methods in Implementation Science*. https://cancercontrol.cancer.gov/IS/docs/NCI-DCCPS-ImplementationScience-WhitePaper.pdf
- Hamilton AB, Cohen AN, Glover DL, et al. Implementation of Evidence-Based Employment Services in Specialty Mental Health. *Health Services Research*. 2013; 48(6), Part II: 2224-2244.
- Shaw RJ, Kaufman MA, Bosworth HB, et al. Organizational factors associated with readiness to implement and translate a primary care based telemedicine behavioral program to improve blood pressure control: the HTN-IMPROVE study. *Implementation Science: IS*. 2013;8:106. doi:10.1186/1748-5908-8-106.
- Warner G, Kervin E, Pesut B, et al. How do inner and outer settings affect implementation of a community-based innovation for older adults with serious illness: a qualitative study. *BMC Health Services Research*. 2021; 21:42. doi: 10.1186/s12913-020-06031-6.

Week 5 – Measurement Approaches for Dissemination and Implementation Research
Discussion Session – Feb. 14

Readings:

- Chapter 14: Lewis, C.C., Proctor, E.K. & Brownson, R.C. Measurement issues in dissemination and implementation research.
- Chapter 16: Allen, J.D. et al. Fidelity and its relationship to implementation effectiveness, adaptation and dissemination.
- Chapter 18: Green, L.W. & Nasser, M. Furthering dissemination and implementation research: The need for more attention to external validity.
- Serhal E, Arena A, Sockalingham S, et al. Adapting the Consolidated Framework for Implementation Research to Create Organizational Readiness and Implementation Tools for Project ECHO. *J Contin Educ Heath Prof*. 2018; 38(2): 145-151.

Week 6 – Implementation Strategies
Discussion session – Feb. 21

Readings:

- Chapter 15: Kirchner, J.E., Waltz, T.J., Powell, B.J., Smith, J.L., & Proctor E.K. Implementation Strategies.
- Salbach NM, MacKay-Lyons M, Solomon P, et al. The role of theory to develop and evaluate a toolkit to increase clinical measurement and interpretation of walking speed and distance in adults post-stroke. *Disability and Rehabilitation*. 2021; DOI: 10.1080/09638288.2020.1867653.
- Waltz TJ, Powell BJ, Fernandez ME, et al. Choosing implementation strategies to address contextual barriers: diversity in recommendations and future directions. *Implementation Science*. 2019; 14(1): 42.

Week 7 –— Special Topic: Developing Tools to Improve Provider Communication
Discussion session – Feb. 28
Guest lecture: Karen Coker and Tyler Nesbit

Readings:

- Burgess DJ, Beach MC, Saha S. Mindfulness practice: A promising approach to reducing the effects of clinician implicit bias on patients. *Patient Education and Counseling*. 2017; 100(2): 372-376. doi: 10.1016/j.pec.2016.09.005
- Hong YA, Hossain MM, Chou WS. Digital interventions to facilitate patient-provider communication in cancer care: A systematic review. *Psycho-oncology*. 2020; 29: 591-603. doi: 10.1002/pon.5310
- Quigley DD, Qureshi N, Slaughter ME, et al. Provider and Coach Perspectives on Implementing Shadow Coaching to Improve Provider-Patient Interactions. *Journal of Evaluation in Clinical Practice*. 2021; 27(6): 1381-1389. doi: 10.1111/jep/13575

Spring Break
No session – March 7

Week 8 – **Evaluation Approaches for Dissemination and Implementation Research**
Discussion session – March 14

Readings:

- Chapter 19: Gaglio, B. & Glasgow, R.E. Evaluation approaches for dissemination and implementation research.
- RE-AIM Model: D'Angelo H, Ramsey AT, Rolland B, et al. Pragmatic Application of the RE-AIM Framework to Evaluate the Implementation of Tobacco Cessation Programs Within NCI-Designated Cancer Centers. *Frontiers in Public Health*. 2020; 8: 221. doi: 10.3389/fpubh.2020.00221
- PRECIS Model: Glasgow RE, Gaglio B, Bennett G, et al. Applying the PRECIS Criteria to Describe Three Effectiveness Trials of Weight Loss in Obese Patients with Comorbid Conditions. *Health Services Research*. 2012; 47(3, Part 1).
- Implementation Outcomes Framework: Torres LM, Camarena AE, Martin A, Shah R. Examining Implementation Outcomes of Sit Down and Play, a Primary Care-Based Intervention, in a Large Urban Primary Care Clinic. *Maternal and Child Health Journal*. 2021; 25: 1744-1756.

Consultation Powerpoint slides and interview guide are due by 1 pm on Monday, March 14.

Week 9 – Student independent study and consultations with researchers/topic experts
No session – March 21

There will be no discussion session in Week 9. Students will make arrangements for a videoconference with their topic expert collaborators, make their presentations to topic experts, and conduct their interviews. Consultation meeting notes are due on Week 10.

Week 10 – Systems Science Approaches
Discussion session – March 28
Guest lecture: Biswadeep Dhar, ABD

Readings:

- Chapter 10: Luke DA, Morshed AB, McKay VR, Combs TB. Systems Science Methods in Dissemination and Implementation Research
- Glegg SMN, Jenkins E, Kothari A. How the study of networks informs knowledge translation and implementation: a scoping review. *Implementation Science*. 2019; 14: 34. doi: 10.1186/s13012-019-0879-1
- Weiner BJ, Lewis MA, Clauser SB, Stitzenberg KB. In Search of Synergy: Strategies for Combining Interventions at Multiple Levels. *JNCI Monographs*. 2012; 44: 34-41. doi: 10.1093/jncimonographs/lgs001

Consultation meeting notes are due by 1 pm on Monday, March 28.

Week 11 – Special Topics: COVID-19, Provider Capacity, De-Implementation
Discussion session – April 4

Readings:

- Berlin A, Lovas M, Truong T, et al. Implementation and Outcomes of Virtual Care Across a Tertiary Cancer Center During COVID-19. *JAMA Oncology*. 2021; doi: 10.1001/jamaoncol.2020.6982.
- Leeman J, Calancie L, Hartman MA, et al. What strategies are used to build practitioners' capacity to implement community-based interventions and are they effective?: a systematic review. *Implementation Science.* 2015;10:80. doi:10.1186/s13012-015-0272-7.
- Montini T, Graham ID. "Entrenched practices and other biases": unpacking the historical, economic, professional, and social resistance to de-implementation. *Implementation Science*. 2015;10:24. doi:10.1186/s13012-015-0211-7.

Week 12 – Final Student Presentations, Day 1
Presentations – April 11

Final presentations will be detailed – 25 minutes, plus 5 minutes for questions for each student. Presentations will follow the main topics described in the students' written proposals, focusing on aims, research strategy, and practical/ethical considerations.

Week 13 – Final Student Presentations, Day 2
Presentations – April 18

Final presentations will be detailed – 25 minutes, plus 5 minutes for questions for each student. Presentations will follow the main topics described in the students' written proposals, focusing on aims, research strategy, and practical/ethical considerations.

Final written proposals due (via email to the instructor) by 1 pm, Monday April 25.

IMPLEMENTATION SCIENCE PROPOSAL GUIDELINES

Specific Aims (1 page)

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Be sure to list the very *specific* few research questions or hypotheses to be tested in the proposed study.

As appropriate to your topic, ensure that your aims page addresses the following questions: (1) What is the critical clinical issue, the setting and the patient population? (2) What evidence-based intervention for this issue will be the focus of your study? (3) What factors have contributed to the failure and/or success of implementing the intervention in clinical settings? (4) What **impact** would the successful implementation of this intervention have on patient outcomes (clinical, health related quality of life)? Costs? Clinician satisfaction and engagement?

Research Strategy (5 pages)

Significance

Briefly sketch the background leading to the present application or intervention, including its evidence base. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of your proposed research by relating the specific aims to broad, longer-term objectives. State how scientific knowledge or practice will be advanced if the aims of your study are achieved, including the effect that your work may have on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field. Describe anticipated barriers to implementation in *your* practice setting, and discuss evidence-based strategies to address these barriers.

Innovation

Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

Approach

Describe the research design, conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methods and their advantage over existing methods. Discuss how threats to validity are addressed by the design. Discuss potential

difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Ensure that your approach section addresses each of the following: (a) description of the study setting; (b) description of the study population; (c) implementation science design; (d) sample size considerations; (e) specification of study variables; (f) intervention strategies in the clinical setting; (g) data collection plan; (h) data analysis plan; and (i) strengths and limitations of the approach.

Practical and Ethical Considerations (1 page)

Human subjects consideration
Describe considerations that should be made for protecting the safety and privacy of your study participants. If the study has an approved IRB protocol, include information from your IRB approval. Address the inclusion of women, children, and minorities.

Data and safety monitoring
Describe how you will establish appropriate oversight and monitoring of the conduct of your study to ensure the safety of participants and the validity and integrity of data collected. This should include a system for ensuring the security of data collected and used in your study.

Data sharing and dissemination plans
If you have established academic, clinical, or community partners with whom your data will be shared, describe your process for data sharing. Describe how you will disseminate findings from your study to clinical or community partners, patient stakeholders, and the academic and scientific communities.

Literature Cited (no page limit; does not count toward page limit)

Use AMA or APA guidelines for in-text citations and the reference listing. Ensure that the reference listing is accurate and consistent.

Format
Proposals should be 7 pages, single-spaced, with ½ inch margins and 11-point Arial font.

NIH R01 Instructions
For more information on developing written proposals, see the NIH R01 instructions at:
http://grants1.nih.gov/grants/funding/424/index.htm