

GMS 6812: Health Outcomes Research in Cancer
Department of Health Outcomes and Biomedical Informatics
College of Medicine
University of Florida

Semester: Fall 2021

Time: Tuesdays, Period 4 - 6 (10:40 AM - 1:40 PM)

Location: HMEB 423

Credits: 3

Instructors: Georges E. Khalil, MPH, PhD CTRB; gkhalil@ufl.edu

Office Hours: TBD

COURSE DESCRIPTION

Understanding and measuring outcomes of health care has become increasingly important with a continued and growing focus on comparative effectiveness research, patient reported outcomes, quality of care and value-based purchasing for health care. This course is designed to focus on assessing cancer-related health outcomes particularly within the context of delivering high quality cancer care. Outcomes research is broad and includes clinical endpoints such as toxic effects of drugs, clinical progression of disease and others. But it also includes functioning, health related quality of life (HRQOL), and patient reported outcomes. Examining outcomes across the cancer care continuum is critical and includes addressing outcomes associated with preventive care, treatment phases, survivorship, palliative and end-of-life care.

This course provides a framework for assessing cancer-related outcomes and for applying this framework to clinical and community-based research. Because outcomes research is rooted across the cancer continuum from prevention to end of life care, this continuum will be included in the discussions of outcomes measure. In addition, cancer-related outcomes are measured in controlled clinical environments but also in real-world clinical and community settings. Therefore, the course will also address measurement challenges in pragmatic and community based settings. As part of this course, students will be required to develop a proposal addressing a critical issue in cancer care with a focus on identifying key outcomes, how they were selected, how the data will be collected, and how the measures will be assessed.

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 xxx Measurement and Health Outcomes and/or permission of instructor.

COURSE OBJECTIVES

The primary goals of this course are to enhance students': (1) cancer outcomes research; (2) ability to critically evaluate the cancer care continuum and outcomes that may be used; and (3) experience in designing a proposal with an emphasis on the identification and analysis of cancer-

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

1. Describe the different stages in the continuum of cancer care and prevention;
2. Describe conceptual models used to conduct health outcomes assessment in cancer;
3. Demonstrate familiarity with the range of measures that are used to assess cancer health outcomes and explain the strengths and limitations of those measures;
4. Evaluate the applicability of different outcomes assessment instruments in the different stages of the cancer care continuum;
5. Identify methodological challenges associated with assessing cancer care outcomes across the continuum of care and strategies for overcoming those challenges;
6. Compare and contrast measurement issues and methodological approaches for assessing health outcomes for pediatric versus adult cancer patients; and
7. Critically evaluate specific cancer health outcomes assessment studies for their potential to inform clinical practice, cancer population science, and health care policy.

COURSE EVALUATION

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/>.

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 cancer outcomes measurement proposal 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 class session.

TESTS

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

REACTION PAPERS (SEE ADDITIONAL INFORMATION AT THE END OF THE SYLLABUS)

Students will write weekly reaction papers to review the readings of the week and present their reactions and thoughts concerning the readings. These papers must also include any implications for future research and practice.

TERM PAPER/PROPOSAL DEVELOPMENT (SEE ADDITIONAL INFORMATION AT THE END OF THE SYLLABUS)

As described in the course introduction, students will develop a study proposal to assess cancer-related outcomes. The proposal can focus on any stage in the cancer care continuum, any population of interest, and any cancer-related health issue. The proposal will contain the following sections: Specific Aims, Research Strategy, Approach, Expected Results, Implications for Future Research and Practice, and References. Please see additional information and instructions at the end of the syllabus. You will also find these in Canvas.

INTERIM AND FINAL PRESENTATION GUIDELINES:

You are expected to provide an interim and a final presentation of your proposal. 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) at least 4 business days 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.

READING ASSIGNMENTS

You must read the assigned readings prior to each class session, prepare the weekly reaction paper, 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 particularly important. Discuss implications of that reading for your scientific work. All students are expected to participate in each class discussion. In some cases, an out-of-class discussion activity will be assigned. In the week following the lecture for which it is assigned, you are to read the article or watch the video provided and post your reactions on the course discussion board on Canvas.

EVALUATION AND GRADING

Grades will be based on: Attendance and Participation in Discussions (10%); Interim Presentation (20%); Reaction Papers (15%), Study Proposal (35%), 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

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 all 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>

CLASS DECORUM

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

CANVAS

Course information, readings, and grades are available on Canvas at <http://lss.at.ufl.edu/>. You must have a Gatorlink account to log on. *You are expected to check the web site on a regular basis (i.e., at least one day prior to each class meeting).*

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>

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 for work only as a 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 & 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

This course does not include a textbook.

ONLINE COURSE EVALUATIONS

Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online 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>.

SCHEDULE OF TOPICS AND READINGS

Class 1. 08/23: Understanding the Cancer Care Continuum and Cancer Prevention

- a. Taplin SH, Anhang Price R, Edwards HM, Foster MK, Breslau ES, Chollette V, Prabhu Das I, Clauser SB, Fennell ML, Zapka J. Introduction: understanding and influencing multilevel factors across the cancer care continuum. *Journal of the National Cancer Institute Monographs*. 2012 May 1;2012(44):2-10.
- b. Bode AM, Dong Z. Cancer prevention research—then and now. *Nature Reviews Cancer*. 2009 Jul;9(7):508-16.
- c. Schüz J, Espina C. The eleventh hour to enforce rigorous primary cancer prevention. *Molecular Oncology*. 2021 Mar 1;15(3):741-3.

Class 2. 08/30: Cost Outcomes in Cancer

- a. Cadham CJ, Cao P, Jayasekera J, Taylor KL, Levy DT, Jeon J, Elkin EB, Foley KL, Joseph A, Kong CY, Minnix JA. Cost-Effectiveness of Smoking Cessation Interventions in the Lung Cancer Screening Setting: A Simulation Study. *JNCI: Journal of the National Cancer Institute*. 2021 Jan 23;00(0): djab002. doi: 10.1093/jnci/djab002
- b. McLeod M. Colorectal Cancer Screening: How Health Gains and Cost-Effectiveness Vary by Ethnic Group, the Impact on Health Inequalities, and the Optimal Age Range to Screen. *Cancer Epidemiol Biomarkers Prev*. 2017 Sep;26(9):1391-1400. doi: 10.1158/1055-9965.EPI-17-0150.
- c. Slatore CG, Au DH, Hollingworth W. Cost-effectiveness of a smoking cessation program implemented at the time of surgery for lung cancer. *Journal of Thoracic Oncology*. 2009 Apr 1;4(4):499-504.

Class 3. 09/06: Patient Centered Communication for Cancer Treatment and Prevention

- a. Hong YA, Hossain MM, Chou WY. Digital interventions to facilitate patient-provider communication in cancer care: A systematic review. *Psycho-Oncology*. 2020 Apr;29(4):591-603.
- b. Gilligan T. Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline. *Journal of Clinical Oncology*. September 11, 2017. DOI: 10.1200/JCO.2017.75.2311. PMID: 28892432.
- c. Ketcher D, Bidelman A, Le LQ, Otto AK, Lester DK, Amtmann-Beuttner KK, Gonzalez BD, Wright KL, Vadaparampil ST, Reblin M, Lau EK. Partnering patients, caregivers, and basic scientists: an engagement model that fosters patient-and family-centered research culture. *Translational Research*. 2021 Jan 1; 227:64-74.

- d. White-Means SI and Osmani AR. Racial and Ethnic Disparities in Patient-Provider Communication with Breast Cancer Patients: Evidence From 2011 MEPS and Experiences with Cancer Supplement. *Inquiry*. 2017 Jan 1; 54:46958017727104. doi: 10.1177/0046958017727104.

Class 4. 09/13: Patient-reported Outcomes

- a. Ong WL, Schouwenburg MG, Van Bommel AC, Stowell C, Allison KH, Benn KE, Browne JP, Cooter RD, Delaney GP, Duhoux FP, Ganz PA. A standard set of value-based patient-centered outcomes for breast cancer: the International Consortium for Health Outcomes Measurement (ICHOM) initiative. *JAMA oncology*. 2017 May 1;3(5):677-85.
- b. Kaat AJ et al. Physical function metric over measure: An illustration with the Patient-Reported Outcomes Measurement Information System (PROMIS) and the Functional Assessment of Cancer Therapy (FACT). *Cancer*. 2017 Sep 8. doi: 10.1002/cncr.30981.
- c. Duman-Lubberding S et al. Durable usage of patient-reported outcome measures in clinical practice to monitor health-related quality of life in head and neck cancer patients. *Support Care Cancer*. 2017 Jul 12. doi: 10.1007/s00520-017-3808-3.
- d. Jefford M. Patient-reported outcomes in cancer survivors: a population-wide cross-sectional study. *Support Care Cancer*. 2017 Apr 22. doi: 10.1007/s00520-017-3725-5.
- e. Schandl A, Johar A, Anandavadivelan P, Vikström K, Mälberg K, Lagergren P. Patient-Reported Outcomes 1 Year after Oesophageal Cancer Surgery. *Acta oncologica*. 2020 Jun 2;59(6):613-9. doi: 10.1080/0284186X.2020.1741677
- f. Oliver A, Greenberg CC. Measuring outcomes in oncology treatment: the importance of patient-centered outcomes. *Surgical Clinics of North America*. 2009 Feb 1;89(1):17-25.

Class 5. 09/20: Outcomes of Integrative Cancer Therapies

- a. Jones E, Nissen L, McCarthy A, Steadman K, Windsor C. Exploring the use of complementary and alternative medicine in cancer patients. *Integrative cancer therapies*. 2019 May;18:1534735419846986.
- b. Narayanan S, Francisco R, Lopez G, Chaoul MA, Cohen L. Role of yoga across the cancer care continuum: From diagnosis through survivorship. *JCOM*. 2019 Sep;26(5).
- c. Ngo-Huang A, Parker NH, Bruera E, Lee RE, Simpson R, O'Connor DP, Petzel MQ, Fontillas RC, Schadler K, Xiao L, Wang X. Home-based exercise prehabilitation during preoperative treatment for pancreatic cancer is associated with improvement in physical function and quality of life. *Integrative cancer therapies*. 2019 Dec;18:1534735419894061.
- d. Kubo A, Kurtovich E, McGinnis M, Aghaee S, Altschuler A, Quesenberry Jr C, Kolevska T, Avins AL. A randomized controlled trial of mHealth mindfulness intervention for cancer patients and informal cancer caregivers: a feasibility study within an integrated health care delivery system. *Integrative cancer therapies*. 2019 May;18:1534735419850634.
- e. Sagar SM. How do we evaluate outcome in an integrative oncology program?. *Current Oncology*. 2008 Aug;15(s2):78-82.

Class 6. 09/27: Behavioral Outcomes of Cancer Treatment and Prevention

- a. McTiernan A, Friedenreich CM, Katzmarzyk PT, Powell KE, Macko R, Buchner D, Pescatello LS, Bloodgood B, Tennant B, Vaux-Bjerke A, George SM. Physical activity in cancer prevention and survival: a systematic review. *Medicine and science in sports and exercise*. 2019 Jun;51(6):1252.
- b. Greenwald P, Clifford CK, Milner JA. Diet and cancer prevention. *European journal of cancer*. 2001 May 1;37(8):948-65.

- c. Cinciripini PM, Karam-Hage M, Kyriotakis G, Robinson JD, Rabius V, Beneventi D, Minnix JA, Blalock JA. Association of a comprehensive smoking cessation program with smoking abstinence among patients with cancer. *JAMA network open*. 2019 Sep 4;2(9):e1912251-.
- d. Elder JP, Haughton J, Perez LG, Martínez ME, De la Torre CL, Slymen DJ, Arredondo EM. Promoting cancer screening among churchgoing latinas: fe en acción/faith in action. *Health education research*. 2017 Apr 1;32(2):163-73.

Class 7. 10/04: Psychosocial Outcomes of Cancer Treatment and Prevention

- a. Parker PA, Peterson SK, Shen Y, Bedrosian I, Black DM, Thompson AM, Nelson JC, DeSnyder SM, Cook RL, Hunt KK, Volk RJ. Prospective study of psychosocial outcomes of having contralateral prophylactic mastectomy among women with nonhereditary breast cancer. *Journal of Clinical Oncology*. 2018 Sep 1;36(25):2630.
- b. Kowitt SD, Ellis KR, Carlisle V, Bhushan NL, Black KZ, Brodar K, Cranley NM, Davis KL, Eng E, Martin MY, McGuirt J. Peer support opportunities across the cancer care continuum: a systematic scoping review of recent peer-reviewed literature. *Supportive Care in Cancer*. 2019 Jan;27(1):97-108.
- c. Mina DS, Au D, Brunet J, Jones J, Tomlinson G, Taback N, Field D, Berlingeri A, Bradley H, Howell D. Effects of the community-based Wellspring Cancer Exercise Program on functional and psychosocial outcomes in cancer survivors. *Current Oncology*. 2017 Oct;24(5):284-94.
- d. Reese JB, Handorf E, Haythornthwaite JA. Sexual quality of life, body image distress, and psychosocial outcomes in colorectal cancer: a longitudinal study. *Supportive Care in Cancer*. 2018 Oct;26(10):3431-40.

Class 8. 10/11: Student-led interim activities for the preparation of study proposals.

Discussion will focus on presentation topics and the selection of outcome measures. To aid in preparation of their final presentations, students will receive in-class feedback on their presentation topics, content, and delivery.

Class 9. 10/18: Outcomes of Entertainment and Technology in Cancer Care and Prevention

- a. Davis SW, Oakley-Girvan I. mHealth education applications along the cancer continuum. *Journal of Cancer Education*. 2015 Jun;30(2):388-94.
- b. Kato PM, Cole SW, Bradlyn AS, Pollock BH. A video game improves behavioral outcomes in adolescents and young adults with cancer: a randomized trial. *Pediatrics*. 2008 Aug 1;122(2):e305-17.
- c. Li WH, Chung JO, Ho EK. The effectiveness of therapeutic play, using virtual reality computer games, in promoting the psychological well-being of children hospitalised with cancer. *Journal of clinical nursing*. 2011 Aug;20(15-16):2135-43.
- d. Hoffman AS, Lowenstein LM, Kamath GR, Houston AJ, Leal VB, Linder SK, Jibaja-Weiss ML, Raju GS, Volk RJ. An entertainment-education colorectal cancer screening decision aid for African American patients: a randomized controlled trial. *Cancer*. 2017;123(8):1401-8.

Class 10. 10/25: Measuring Health Disparities in Cancer

- a. Zavala VA, Bracci PM, Carethers JM, Carvajal-Carmona L, Coggins NB, Cruz-Correa MR, Davis M, de Smith AJ, Dutil J, Figueiredo JC, Fox R. Cancer health disparities in racial/ethnic minorities in the United States. *British journal of cancer*. 2021 Jan;124(2):315-32.
- b. Griggs J, Maingi S, Blinder V, Denduluri N, Khorana AA, Norton L, Francisco M, Wollins DS, Rowland JH. American Society of Clinical Oncology position statement: strategies for reducing cancer health disparities among sexual and gender minority populations. *Obstetrical & Gynecological Survey*. 2017 Oct 1;72(10):598-9.

- c. Paskett E. et al. Multilevel Interventions To Address Health Disparities Show Promise In Improving Population Health. *Health Aff (Millwood)*. 2016 Aug 1;35(8):1429-34. doi: 10.1377/hlthaff.2015.1360.
- d. Smith SA. Persons Who Failed to Obtain Colorectal Cancer Screening Despite Participation in an Evidence-Based Intervention. *J Community Health*. 2017 Feb;42(1):30-34. doi: 10.1007/s10900-016-0221-7
- e. Burgard SA, Chen PV. Challenges of health measurement in studies of health disparities. *Social Science & Medicine*. 2014 Apr 1;106:143-50.
- f. Halbert CH, Jefferson MS, Danielson C, Froeliger B, Giordano A, Thaxton JE. An observational study and randomized trial of stress reactivity in cancer disparities. *Health Psychology*. 2020 Sep;39(9):745.

Class 11. 11/01: Cancer Outcomes: Adverse Events

- a. Lipitz-Snyderman A Pfister D, Classen D, Atoria CL, Killen A, Epstein AS, Anderson C, Fortier E, Weingart SN. Preventable and mitigable adverse events in cancer care: Measuring risk and harm across the continuum. *Cancer*. 2017 Aug 17. doi: 10.1002/cncr.30916.
- b. Basch E et al. Feasibility of Patient Reporting of Symptomatic Adverse Events via the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) in a Chemoradiotherapy Cooperative Group Multicenter Clinical Trial. *Int J Radiat Oncol Biol Phys*. 2017 Jun 1;98(2):409-418. doi: 10.1016/j.ijrobp.2017.02.002. Epub 2017 Feb 10.
- c. Lipitz-Snyderman A. et al. Performance of a Trigger Tool for Identifying Adverse Events in Oncology. DOI: 10.1200/JOP.2016.016634 *Journal of Oncology Practice* 13, no. 3 (March 2017) e223-e230. PMID: 28095173
- d. Basch E, Reeve BB, Mitchell SA, Clauser SB, Minasian LM, Dueck AC, Mendoza TR, Hay J, Atkinson TM, Abernethy AP, Bruner DW. Development of the National Cancer Institute's patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE). *Journal of the National Cancer Institute*. 2014 Sep 1;106(9):dju244.
- e. Dueck AC, Mendoza TR, Mitchell SA, Reeve BB, Castro KM, Rogak LJ, Atkinson TM, Bennett AV, Denicoff AM, O'Mara AM, Li Y. Validity and reliability of the US National Cancer Institute's patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE). *JAMA oncology*. 2015 Nov 1;1(8):1051-9.

Class 12. 11/08: Outcomes for Special Populations with Cancer

- a. Kommann VNN et al. The First Year After Colorectal Surgery in the Elderly. *Ann Coloproctol*. 2017 Aug;33(4):134-138. doi: 10.3393/ac.2017.33.4.134. Epub 2017 Aug 31.
- b. Rocque GB et al. Healthcare utilization, Medicare spending, and sources of patient distress identified during implementation of a lay navigation program for older patients with breast cancer. *Breast Cancer Res Treat*. 2017 Sep 12. doi: 10.1007/s10549-017-4498-8.
- c. Ehrhardt MJ, et al. Neurocognitive, psychosocial, and quality-of-life outcomes in adult survivors of childhood non-Hodgkin lymphoma. *Cancer*. 2017 Sep 15. doi: 10.1002/cncr.31019.
- d. Reeve BB, Potosky AL, Smith AW, Han PK, Hays RD, Davis WW, Arora NK, Haffer SC, Clauser SB. Impact of cancer on health-related quality of life of older Americans. *JNCI: Journal of the National Cancer Institute*. 2009 Jun 16;101(12):860-8.

Class 13. 11/15: Student-led interim activities for the preparation of study proposals.

Discussion will focus on presentation topics and the revision of outcome measures. To aid in preparation of their final presentations, students will receive in-class feedback on their presentation topics, content, and delivery.

Class 14. 11/22: Presentations of Proposals

Class 15. 11/29: Presentations of Proposals

**Resources to prepare for the 7-page abbreviated proposal, Use ½ margins and Arial 11 font.
You may refer to the NIH R01 Instructions in this website:**

<http://grants1.nih.gov/grants/funding/424/index.htm>

- 1) **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.

Key questions in the Specific Aims page: What is the critical cancer prevention, clinical, palliative care or end-of-life care issue, the setting and the patient population? What is the gap in knowledge? What evidence-based intervention for this issue will be the focus of your study? What are the key outcomes that will be measured to address the critical issue? Why have you selected these outcomes? What **impact** would this study have on improving patient outcomes (clinical, health related quality of life)? Costs? Clinician and patient satisfaction and engagement? What are your 2 or 3 aims, and what are the hypotheses to test?

- 2) **Research Strategy (4-6 pages):** Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. Identify the gap in knowledge. State how scientific knowledge or practice will be advanced. Describe the effect of previous studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field.
 - a. **Significance:** Describe in more detail the issue and the evidence base selecting the issue. Describe in more detail why the outcomes you have chosen are critical. Select and describe an appropriate conceptual framework to guide your study aims and hypotheses, study design, choice of outcomes and interpretation of findings.
 - b. **Innovation:** Explain how the application challenges and seeks to shift current research, prevention, clinical practice, community practice, and/or cancer-care 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
 - c. **Approach:** Describe the research design, conceptual or clinical framework, outcomes selected (include their reliability and validity, applicability to your population and topic) procedures (include how you will collect the data, barriers to data collection and how you will overcome these barriers), and analyses. Describe

any new methods and their advantage over existing methods. Describe any novel concepts, outcome measures, approaches, tools, or technologies for the proposed studies. 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. The following outline can be helpful:

- i. Description of the study setting
 - ii. Description of the study population
 - iii. Study design
 - iv. Sample size considerations
 - v. Specification of study variables – be specific here about how you are specifying each of the selected outcome variables and the rationale for selecting them, their reliability and validity, applicability to the topic
 - vi. Intervention approach or explanation of observational approach
 - vii. Data collection plan – be very specific about how you will collect your outcome information
 - viii. Data analysis plan – be specific about the
- d. Strengths and limitations of the approach – be very specific here about how you will address potential barriers to collecting your outcomes of interest.
 - e. Dissemination plans

3) Data safety and monitoring plans (1/2 page)

4) Literature cited (no page limit; use AMA or APA guidelines)