


Course Syllabus

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Course information

This is an on-line class taught, starting on Tuesday, January 21, 2020 and ending on Friday, May 8, 2020.

Your instructor

Your instructor is Steve Simon in the Department of Biomedical and Health Informatics. My phone number is 816-235-6617 and my email is  simons@umkc.edu (<mailto:simons@umkc.edu>). My office is M5-117, located on the fifth floor of the School of Medicine building in the suite of offices for Biomedical and Health Informatics.

Catalog information

Course Title: Clinical Research Methodology

Credit Hours: 3 credit hours

Prerequisites: none

Course Attributes: graduate research training

Course Format: Lecture, Discussion, and individual activities

Course Instructional Mode : OA (Online Asynchronous class instruction); material posted on Canvas course site will support all course activities.

Course Description

This course trains the student on the fundamentals of research design, planning, and implementation and provides a broad overview of clinical research in terms of definition, methodology, conduct, and applications. The course will explore basic elements of clinical research including the hierarchy of clinical research design and the conduct of clinical research.

Course Topics

- Conceiving the research question;
- Study designs;
- Questionnaire construction;

- Research methodology;
- Research ethics;
- Human subjects requirements;
- The role of statistical analysis in clinical research;
- Research proposal preparation; and
- Research based on analysis of secondary data.

Introduction

Clinical research has always been critical for the discovery of new knowledge and the development of new medications and treatments. Now, clinical research carries an increasingly important role as it contributes to critical issues facing our health care system. These issues include such things as the identification of social and individual factors that influence clinical outcomes, determination of optimal treatment regimens, and methods to optimize outcomes and efficiencies in clinical care. This clinical research methods course is designed to provide the foundation for people who plan to contribute to research that has the potential to have a significant impact on health care.

Note: Many thanks go to Dr. Mary Gerkoich, who provided an excellent structure and format to this class that I will be following closely.

Course Objectives

The course will provide students with the foundation for understanding and contributing to clinical research on a variety of topics. The course will cover a range of topics that are essential components of good clinical research projects. It will serve as a foundation for subsequent course work for students who are obtaining a Master's or PhD degree and those obtaining the Graduate Certificate in Clinical Research. The overall objective of the course is to give students the information and skills to be active participants in the ongoing efforts to conduct research with the goal of providing improved treatments and outcomes for patients as well as to be more knowledgeable consumers of health care-related material.

Student Learning Objectives

At the end of this course, students will be able to:

1. Evaluate existing clinical research literature and identify issues and topics for future research.
2. Develop research questions/hypotheses to address clinical research topics.
3. Determine an appropriate research design to address a clinical research issue.
4. Develop methods and materials to conduct clinical research.

5. Understand issues related to managing data sets.
6. Select appropriate analysis methods in order to test research questions/hypotheses.
7. Write a proposal for a research project to address a clinical research issue.
8. Make a presentation of a research proposal including the background to justify the research questions/hypotheses as well as the methods planned for collecting and analyzing the research data.

Course Requirements

Students are responsible for reading all assignments from the text, Canvas material, internet materials, and instructor provided resources before the class period in which they are to be discussed. Each student will complete Human Subjects training, assignments, a research proposal, and an oral presentation of the research proposal that will include poster material.

Course Framework

There is a long tradition of methodology and techniques as applied to research on various health topics from drug development trials to clinical outcomes. Understanding the methods required to conduct valid research is critical as clinical research projects play an increasingly significant role in the evolution of health care. Results from clinical research studies contribute not only to the development of new drugs and treatments but also to the determination of the best treatments for health care providers to offer patients. The readings, discussions, and projects in this course are all presented within the framework of current health care practices and issues. The material covered in this course can be viewed in the context of topics covered every day by the media.

Class structure

In general, each class session will consist of a mixture of recorded material available on Canvas as preparation for the session, individual assignments, and discussion/activities that are related to the topic and are completed either individually, within pairs, or within small groups of students. The lecture material is designed to supplement the information assigned from the textbook and other sources.

Required Materials

The required textbook for this class is:

Gliner JA, Morgan GA, Leech NL. Research Methods in Applied Settings: An Integrated Approach to Design and Analysis. 3rd ed. New York: Routledge, Taylor & Francis Group; 2017.

This textbook is available for purchase through the UMKC Health Sciences bookstore and online sources, and can be rented through online resources (e.g., Amazon).

Recommended Materials

Supplemental material for the class has been obtained from the following books:

Julius Sim and Chris Wright. Research in Health Care: Concepts, Designs and Methods. Cheltenham, United Kingdom: Nelson Thornes Ltd. 2000. (reprinted in 2002)

Stephen B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah G. Grady, and Thomas B. Newman. Designing Clinical Research, 3rd ed. Philadelphia, Pennsylvania: Lippincott Williams & Wilkins publishing.

Leslie G. Portney and Mary P. Watkins. Foundations of Clinical Research: Applications to Practice, 3rd ed. Upper Saddle River, New Jersey: Pearson Prentice Hall.

Students SHOULD NOT purchase the supplementary materials.

Resources

Students are encouraged to routinely check news and professional web sites in order to keep up with current information related to clinical research topics. Examples of these sites include:

[The New England Journal of Medicine](http://content.nejm.org/) ↗ [\(http://content.nejm.org/\)](http://content.nejm.org/)

[National Institutes of Health News & Events](http://www.nih.gov/news/index.html) ↗ [\(http://www.nih.gov/news/index.html\)](http://www.nih.gov/news/index.html)

[Kaiser Health News](http://www.kaiserhealthnews.org/) ↗ [\(http://www.kaiserhealthnews.org/\)](http://www.kaiserhealthnews.org/)

[The Commonwealth Fund](http://www.commonwealthfund.org/) ↗ [\(http://www.commonwealthfund.org/\)](http://www.commonwealthfund.org/)

Students are also encouraged to regularly read national newspapers and print media (e.g., New York Times, Washington Post, and/or listen to national new sources (e.g., NPR) for relevant stories.

Course Evaluation

Completion of the confidential course evaluation at the end of the semester is available for the course and strongly encouraged. You will receive information about completing the evaluation from the Department office towards the end of the semester.

Assignments

Schedule

The detailed listing of topics, assignments, and deadlines is shown in the Course Overview document in the "Course Content" section of the course Canvas site.

A calendar showing all dates for submissions (assessment items, assignments, final project oral presentation, and final project written proposal) is shown in the Calendar document in the "Course Content" section of the course Canvas site.

Evaluation Criteria

Participation via discussion boards, 3 points each, with a one point deduction for late submissions.

Literature review, 50 points, due at the end of the seventh week of classes (March 6, 2020).

Research methods section, 100 points, due on the last day of the semester (May 8, 2020).

Other work may be assigned, but will not count for a very large percentage of your grade.

Please note that some of the videos may refer to assignments that were required in a previous semester, but which are not being assigned this semester. In particular, there is no oral presentation and no poster presentation required for this class.

Grading criteria

The student's grade for the class will be based on the percentage of possible points the student has earned (rounded up to the next percentage point). A letter grade will be assigned based on the following scale:

94 to 100, A

90 to 93, A-

86 to 89, B+

83 to 85, B

80 to 82, B-

76 to 79, C+

73 to 76, C

70 to 73, C-

66 to 69, D+

63 to 65, D

60 to 62, D-

under 60, F

If a student feels that he/she has been unfairly graded, information on the appeal process can be found in the [academic regulations information](https://catalog.umkc.edu/colleges-schools/law/academic-rules-regulations-for-juris-doctor-degree-program/appeal-of-grades/appeal-of-grades.pdf) [_ \(https://catalog.umkc.edu/colleges-schools/law/academic-rules-regulations-for-juris-doctor-degree-program/appeal-of-grades/appeal-of-grades.pdf\)](https://catalog.umkc.edu/colleges-schools/law/academic-rules-regulations-for-juris-doctor-degree-program/appeal-of-grades/appeal-of-grades.pdf).

Submission format

Unless otherwise noted, all material that is submitted to Dr. Simon must be submitted via the course Canvas site and should be .pdf format. If you have difficulty producing pdf format files, alternate formats may be acceptable, but please clear this in advance. All files sent to Dr. Simon must include the student's name in the filename.

Canvas Discussions

During the semester, you will be expected to participate in online discussions through the course Canvas site. Online discussion forums will provided the basis for discussions and activities that normally take place during an on-campus class period. Your engagement in the discussions will be reflected in the points you earn for participation. The minimum expectation is that you will respond to the topic, using the information you have read and/or the material presented in the recordings. Full participation in the discussion topics will be demonstrated by responses you make to the entries made by other students as well as the content of your own posting, and making these contributions in a timely manner (first posting must be made by Sunday midnight following the posting of the forums. A vital discussion board should include responses between students that expand on the original posting. Think of this as the interchange that occurs when we are all in the same room.

When a discussion topic is posted, please add your contribution by replying to the original topic. When you are responding to another student's posting, use the reply function.


I will regularly assign a student to be the participation leader in a specific discussion forum. The leader is expected to respond to each posting, adding to the discussion as appropriate and findings links between individual postings in a way that adds value to the overall discussion. The quality of what you do when you are the participation leader will be factored into the participation part of the course evaluation.

Discussion forums

All students are expected to complete the readings prior to class and be prepared for discussion. A portion of the course grade will be based on discussion board participation. It is VERY IMPORTANT to keep these discussions contemporaneous. Please post your discussion comments by the due date.

Literature review and methods section

All MSB students will complete either a thesis or capstone project as part of their program completion and all PhD students will complete a doctoral dissertation. Completing a thesis is a requirement for students in the genomics emphasis area and an option for all other MSB students. Because of the value department faculty place on the student's ability to plan and propose a research project, the major project of this course will be a presentation of a literature review and a methods section for a research project on a specific topic that is of interest to you. This may or may not be the topic you choose for your thesis, capstone, or dissertation. The goal is for this research proposal to provide an experience that is relevant to the preparation of proposals such as a thesis or dissertation proposal or a proposal to obtain research funding.

Your work should conform strictly to the standards that UMKC has provided for [formatting Theses and Dissertations](http://sgs.umkc.edu/wp-content/uploads/2014/03/UMKC-Guide-to-Formatting-Theses-and-Dissertations)  ([http://sgs.umkc.edu/wp-content/uploads/2014/03/UMKC-Guide-to-Formatting-Theses-and-](http://sgs.umkc.edu/wp-content/uploads/2014/03/UMKC-Guide-to-Formatting-Theses-and-Dissertations)

[Dissertations.pdf](#)). Some of the pages in the UMKC guidelines may not be known at this time, such as who is on your review committee, but do the best you can and use a stock phrase such as "to be determined later" as needed.

Policies

Canvas

Lecture material will be posted as videos and Powerpoint handouts, including speaker notes, will be available for download. Students should do the required reading prior to viewing the videos to get the maximum benefit.

Additional materials will be made available in electronic format on the Canvas website. Announcements and schedule updates will also be posted on the website.

Many materials on the Canvas website can be read and/or printed with a standard web browser. Other items require Adobe Acrobat Reader to view.

Acrobat Reader may be downloaded for FREE from the [Adobe website](http://www.adobe.com/products/acrobat/readstep2.html) [Ⓔ](http://www.adobe.com/products/acrobat/readstep2.html) (<http://www.adobe.com/products/acrobat/readstep2.html>).

E-mail

You will be required to use a UMKC e-mail account for correspondence in this class. The instructor will not be responsible for the receipt of e-mails that are sent to locations other than those ending with "umkc.edu."

Any files that are submitted to an instructor via email MUST include the student's name in the filename.

Discussion Board Guidelines - General Information

The purpose of the discussion board forum is to engage students in applying the concepts of this course in an exchange of ideas and opinions that is open, honest, and that stimulates transference of ideas to your own area of expertise and interest. Discussion board conversations also serve to build a sense of community among students in the class for the purpose of examining how the concepts we are studying are relevant to our own experiences. In the best tradition of the value of learning from each other, the following guidelines should guide us all as we participate in these discussions:

Participants should listen ☐ to others respectfully. Remember that when communicating via the computer screen, you do not have the benefit of voice intonation, facial expressions, body language or gestures to interpret the meaning behind the words. The same words spoken orally in different manners can mean different things. Remember this and give the person the benefit of the doubt when interpreting discussion board posts. Take your responsibilities seriously and offer meaningful feedback.

Disagreements should focus on ideas and concepts, not the individual posting to the discussion board. If you disagree with what another student has written, strive to critique ideas in a respectful and

constructive manner. When a disagreement occurs, attempt to understand other person's perspectives rather than to simply criticize them. Treat other students with the same respect and courtesy that promotes the same thoughtful and fair treatment that is supportive of face to face discussions.

Intervene politely if someone is being disrespectful or unfair to others. If you find something on the Discussion Board that strikes you as unacceptable in either tone or content, gently share your concern with the poster AND be sure to let the course instructor know about it as soon as possible. Usually this kind of thing is the result of some kind of accident or misunderstanding, and I will make sure that it gets cleared up as soon as possible.

Keep the content of posts relevant to the topic. While the tone of your posts may be informal and genial, the discussion board is not a chat room. If necessary for personal messages, please use Mail or other forms of direct contact.

Use language, spelling and grammar that are appropriate to an educational setting. Avoid use of overly technical or discipline specific language, slang or Internet shorthand, and remember to proofread work prior to posting it for the class to read. Strive for proper spelling and grammar. Use complete sentences. Do not "shout" (i.e., type in capital letters).

Read and Reply. Note that your replies to others are just as important as the expression of your own initial thoughts about the topic. Take time to read what others have written and to give them relevant feedback when appropriate. Even if you have completed the requirements for posting in a given week, go back and see what others have written since you were last there.

Please be sure to bring any problems or suggestions regarding effective and courteous use of the discussion board to the attention of the course director.

Statement on Expectations Regarding Student Conduct

In order to maintain a proper learning environment within the class, it is important for all students enrolled in this course to treat both the faculty and their peers with courtesy, civility and respect. Conduct for which students are subject to sanctions includes academic dishonesty, such as cheating, plagiarism, or sabotage.

Students whose behavior is deemed disruptive by their instructor may be told to leave the classroom for the remainder of the session. Zero participation points will be earned for any weekly discussion activities when a student is told to leave the discussion.

Please refer to the [UM System standard of conduct](http://www.umsystem.edu/ums/rules/collected_rules/programs/ch200/200.010_standard_of_conduct)

(http://www.umsystem.edu/ums/rules/collected_rules/programs/ch200/200.010_standard_of_conduct) for more information.

Academic honesty

The Board of Curators of the University of Missouri recognizes that academic honesty is essential for the intellectual life of the University. Faculty members have a special obligation to expect high standards of academic honesty in all student work. Students have a special obligation to adhere to such standards. Academic dishonesty, including cheating, plagiarism or sabotage, is adjudicated through the University of Missouri Student Conduct Code and Rules of Procedures in Student Conduct Matters.

Conduct for which students are subject to sanctions includes academic dishonesty, such as cheating, plagiarism, or sabotage. In the event misconduct is confirmed, the students will receive 0 points on the exam or assignment. If academic dishonesty is admitted or confirmed by evidence the faculty are required to report the incident to the Assistant Dean for Graduate Studies, who will meet with the faculty member and student to review the event and then determine whether it should be further referred to the Dean of the School of Graduate Studies.

Students enrolled in this course assume an obligation to behave in a manner compatible with the University's function as an educational institution as described in the University Collected Rules and Regulations Chapter 200 Student Conduct, section 200.010 Standard of Conduct. Conduct for which students are subject to sanctions includes academic dishonesty, such as cheating, plagiarism, or sabotage. Conduct for which students are subject to sanctions are outlined as follows:

The term cheating includes but is not limited to: (i) use of any unauthorized assistance in taking quizzes, tests, or examinations; (ii) dependence upon the aid of sources beyond those authorized by the instructor in writing papers, preparing reports, solving problems, or carrying out other assignments; (iii) acquisition or possession without permission of tests or other academic material belonging to a member of the University faculty or staff; or (iv) knowingly providing any unauthorized assistance to another student on quizzes, tests, or examinations.

The term plagiarism includes, but is not limited to: (i) use by paraphrase or direct quotation of the published or unpublished work of another person without fully and properly crediting the author with footnotes, citations or bibliographical reference; (ii) unacknowledged use of materials prepared by another person or agency engaged in the selling of term papers or other academic materials; or (iii) unacknowledged use of original work/material that has been produced through collaboration with others without release in writing from collaborators. In addition, the Department of Biomedical and Health Informatics includes self-plagiarism in their expanded definition.

Self-plagiarism is reuse of an existing paper that has been submitted for credit in a different course without prior discussion and consent of the course director.

The term sabotage includes, but is not limited to, the unauthorized interference with, modification of, or destruction of the work or intellectual property of another member of the University community.

To ensure academic integrity and prevent plagiarism, UMKC has purchased the Internet-based Turn It In. This site allows faculty and students to submit papers online to examine a paper's originality. The site compares submitted papers with several proprietary algorithm databases to check for plagiarism. The course director reserves the right to have student assignments reviewed on Turnitin.com in this course.

Submissions will have all identifying student information (name, student ID number etc.) removed from the submission to ensure that student's rights are protected.

Academic Inquiry, Course Discussion and Privacy: University of Missouri System Executive Order No. 38 lays out principles regarding the sanctity of classroom discussions at the university. The policy is described fully in Section 200.015 of the Collected Rules and Regulations. In this class, students may make audio or video recordings of course activity unless specifically prohibited by the faculty member. However, the redistribution of any audio or video recordings of statements or comments from the course to individuals who are not students in the course is prohibited without the express permission of the faculty member and of any students who are recorded, including those recordings prepared by an instructor. Students found to have violated this policy are subject to discipline in accordance with provisions of Section 200.020 of the Collected Rules and Regulations of the University of Missouri pertaining to student conduct matters.

Attendance Policy

Students are expected to attend and participate in classes. Advance notice of attendance policies of academic units and individual instructors should be given, and such notice should be in writing. Students should notify instructors of excused absences in advance, where possible. Students who have an excused absence are expected to make arrangements with instructors for alternative or make-up work. Such arrangements should be made in advance of the absence, where possible. Instructors should accommodate excused absences to the extent that an accommodation can be made that does not unreasonably interfere with the learning objectives of the course or unduly burden the instructor. Attendance policies shall be applied in a non-discriminatory manner.

Discrimination

The course faculty is committed to creating and maintaining a supportive learning environment. If at any time you find yourself in an environment that does not support learning, it is best to first contact the course faculty. If faculty members are unable to resolve the situation for you, you may contact: the Chair of the Department, the Associate Dean for Student Affairs, Dr. Brenda Rogers, SOM Rm M4-207, [✉ rogersbr@umkc.edu \(mailto:rogersbr@umkc.edu\)](mailto:rogersbr@umkc.edu), (816) 235-1782; Sam Turner, Office of Diversity & Community Partnership, SOM Rm.M1-109, (816) 235-1780.

Discrimination Grievance Procedures for Students: Discrimination Grievance Procedures for Students can be found [here](#) [↗]

http://www.umsystem.edu/ums/rules/collected_rules/grievance/ch390/grievance_390.010.

English Proficiency Statement

Students who encounter difficulty in their courses because of the English proficiency of their instructors should speak directly with their instructors. If additional assistance is needed, students may contact the UMKC Help Line at 816-235-2222 for assistance.

Grade Appeal Policy

Students are responsible for meeting the standards of academic performance established for each course in which they are enrolled. The establishment of the criteria for grades and the evaluation of student academic performance are the responsibilities of the instructor.

The University [grade appeal procedure](https://www.umkc.edu/provost/Policy-Library/documents/tzt_Grade%20Appeal%20Policy.pdf) [_ \(https://www.umkc.edu/provost/Policy-Library/documents/tzt_Grade%20Appeal%20Policy.pdf\)](https://www.umkc.edu/provost/Policy-Library/documents/tzt_Grade%20Appeal%20Policy.pdf) is available only for the review of allegedly capricious grading and not for review of the instructor's evaluation of the student's academic performance. Capricious grading, as that term is used here, comprises any of the following:

- The assignment of a grade to a particular student on some basis other than the performance in the course;
- The assignment of a grade to a particular student according to more exacting or demanding standards than were applied to other students in the course; (Note: Additional or different grading criteria may be applied to graduate students enrolled for graduate credit in 300- and 400-level courses.)
- The assignment of a grade by a substantial departure from the instructor's previously announced standards.

Students who have concerns about this course should first consult with the specific instructor with whom there is a problem. If the issues are not satisfactorily resolved the student should contact the course director.

In the event a student would like to appeal a course grade they must follow the School of Medicine procedure for grade appeal for graduate courses, which is outlined in the student handbook or can be found at the [School of Medicine Graduate Council web page](http://med.umkc.edu/councils/graduate/documents/) [_ \(http://med.umkc.edu/councils/graduate/documents/\)](http://med.umkc.edu/councils/graduate/documents/).

Resources

Academic Calendar: Students are encouraged to review important add, drop or withdraw dates: <https://www.umkc.edu/calendar/> [_ \(https://www.umkc.edu/calendar/\)](https://www.umkc.edu/calendar/)

Campus Safety: [Inclement weather, mass notification, and emergency response guide](http://www.umkc.edu/umkcalert/) [_ \(http://www.umkc.edu/umkcalert/\)](http://www.umkc.edu/umkcalert/).

Counseling and Health Services Available at UMKC: UMKC students may experience many challenges in their lives while attending college – stress, depression, suicidality, trauma, relationship issues, health concerns, etc. As your professor I care about your success and well-being, and want to make you aware of some helpful resources on campus. The [UMKC Counseling Center](http://www.umkc.edu/counselingcenter/) [_ \(www.umkc.edu/counselingcenter/\)](http://www.umkc.edu/counselingcenter/), located at 4825 Troost in Room 206, offers a wide range of

supportive services to students. Appointments can be made by calling 816.235.1635. [UMKC Student Health and Wellness](http://info.umkc.edu/studenthealth/) [\(http://info.umkc.edu/studenthealth/\)](http://info.umkc.edu/studenthealth/), located at 4825 Troost in Room 115, offers a full range of health care and promotion services. Appointments can be scheduled online or by calling 816.235.6133. The [MindBody Connection](http://www.umkc.edu/mindbody/) [\(www.umkc.edu/mindbody\)](http://www.umkc.edu/mindbody/) is located in the Atterbury Student Success Center in Room 112 and offers a variety of stress-reduction services.

Disability Support Services: To obtain disability related accommodations and/or auxiliary aids, students with disabilities must contact the Office of Services for Students with Disabilities (OSSD) as soon as possible. To contact OSSD, call (816) 235-5696 or visit their website. Once verified, OSSD will notify the course instructor and outline the accommodation and/or auxiliary aids to be provided. UMKC has a [web page](http://www.umkc.edu/disability/) [\(http://www.umkc.edu/disability/\)](http://www.umkc.edu/disability/) with more information about disability services.

Severe Weather Policy: Cancellation of classes will be posted on the front page of the [University's website](http://www.umkc.edu) [\(www.umkc.edu\)](http://www.umkc.edu) as well as through the UMKC Alert message system.

Statement of Human Rights: The Board of Curators and UMKC are committed to the policy of equal opportunity, regardless of race, color, religion, sex, sexual orientation, national origin, age, disability and status as a Vietnam era veteran. Commitment to the policy is mentored by the [Division of Diversity Equity](https://info.umkc.edu/diversity/) [\(https://info.umkc.edu/diversity/\)](https://info.umkc.edu/diversity/), but it is the responsibility of the entire university community to provide equal opportunity through relevant practices, initiatives and programs.

Title IX: Under the University of Missouri's Title IX policy, discrimination, violence and harassment based on sex, gender, and gender identity are subject to the same kinds of accountability and support applied to offenses based on other protected characteristics such as race, color, ethnic or national origin, sexual orientation, religion, age, ancestry, disability, military status, and veteran status. If you or someone you know has been harassed or assaulted, you can find the appropriate resources by visiting [UMKC's Title IX Office webpage](http://info.umkc.edu/title9/) [\(http://info.umkc.edu/title9/\)](http://info.umkc.edu/title9/) or contacting UMKC's Title IX Coordinator, Mikah K. Thompson (816.235.6910 or thompsonmikah@umkc.edu [\(mailto:thompsonmikah@umkc.edu\)](mailto:thompsonmikah@umkc.edu)). Additionally, you can file a complaint using [UMKC's online discrimination complaint form](http://info.umkc.edu/title9/reporting/report-online/) [\(http://info.umkc.edu/title9/reporting/report-online/\)](http://info.umkc.edu/title9/reporting/report-online/).

While most UMKC employees are required to report any known or suspected violation of Title IX, students may seek confidential guidance from the following campus locations: UMKC Counseling Service Volker Campus 4825 Troost Ave, Suite 206 Kansas City, MO 64110 Phone – (816) 235-1635 UMKC Counseling Service Health Sciences Campus Health Sciences Building 1418 2464 Charlotte Kansas City, MO 64108 Phone – (816) 235-1635 (open Tuesdays, 1-5pm) Student Health and Wellness 4825 Troost Ave., Suite 115 Kansas City, MO 64110 Phone - (816) 235-6133





Week 1: Course Overview and Introductions; Introduction to Clinical Research Methods

Please note that I plan to make minor changes to the objectives, readings, homework assignments, and discussion questions. This list is current through week 1, and will be updated as the course progresses.

Learning objectives

1. To demonstrate an understanding of the course structure and expectations
2. To define clinical research
3. To distinguish between qualitative and quantitative research and identify when each type of research is called for.

Required reading

1. Gliner, Morgan, and Leech, Chapter 1
2. Conroy. Where do research ideas come from? Available in [html format](http://www.pmean.com/99/ideas.html)  (<http://www.pmean.com/99/ideas.html>).
3. Locklear. Patient Reported Outcomes. Available in [html format](http://rethinkingclinicaltrials.org/resources/patient-reported-outcomes-3/)  (<http://rethinkingclinicaltrials.org/resources/patient-reported-outcomes-3/>). (Recommended, not required)
4. Deshpande. Patient-reported outcomes: A new era in clinical research. Available in [html format](http://www.picronline.org/article.asp?issn=2229-3485;year=2011;volume=2;issue=4;spage=137;epage=144;aualast=Deshpande)  (<http://www.picronline.org/article.asp?issn=2229-3485;year=2011;volume=2;issue=4;spage=137;epage=144;aualast=Deshpande>) and [pdf format](http://www.picronline.org/article.asp?issn=2229-3485;year=2011;volume=2;issue=4;spage=137;epage=144;aualast=Deshpande;type=2)  (<http://www.picronline.org/article.asp?issn=2229-3485;year=2011;volume=2;issue=4;spage=137;epage=144;aualast=Deshpande;type=2>). (Recommended, not required)

Assignment

1. Complete and send in Syllabus Quiz. Quiz must be submitted by midnight, Friday, January 25, 2019 to be eligible to receive full credit.
2. Prepare for next week's session.

Discussion questions

Please submit your posts by Friday, January 25, 2019 and comment on at least one other post by the following Wednesday.










1. Briefly describe your background and explain why are you interested in this course?
2. Find a research paper that is relevant to your work or area of study. This must be a paper with full free text available. Post the abstract of this article and a link to the full text. Review the dichotomies


discussed in Chapter 1 and classify the paper into one of the two levels in each dichotomy, or classify it as a mixture of both levels of the dichotomies. If you are unsure about any classification, be honest about your uncertainty.













3. Review at least one paper posted by another student and comment on their classifications.












Remaining weeks of class to be announced.



Course Summary:

Date	Details
Fri Feb 15, 2019	 <u>D01-01. Introduce yourself</u> https://umkc.instructure.com/courses/66239/assignments/298124 due by 11:59pm
	 <u>D01-02. Find a peer-reviewed paper and comment on the dichotomies</u> https://umkc.instructure.com/courses/66239/assignments/298123 due by 11:59pm
	 <u>D01-EC. Find a methodology paper related to this week's lecture</u> https://umkc.instructure.com/courses/66239/assignments/298122 due by 11:59pm
	 <u>Q01. Syllabus quiz</u> https://umkc.instructure.com/courses/66239/assignments/298090 due by 11:59pm
	 <u>Q03. Quiz for week 3</u> https://umkc.instructure.com/courses/66239/assignments/298091 due by 11:59pm
Fri Feb 22, 2019	 <u>D01-03. Comment on another student's paper</u> https://umkc.instructure.com/courses/66239/assignments/298093 due by 11:59pm
Fri Mar 1, 2019	 <u>D02-01. Comment on one of the readings for this week.</u> https://umkc.instructure.com/courses/66239/assignments/298121 due by 11:59pm
	 <u>D02-02. Find a published guideline on research ethics and comment on it</u> https://umkc.instructure.com/courses/66239/assignments/298120 due by 11:59pm
	 <u>D02-EC. Find a paper related to the responsible conduct of research and comment on it</u> https://umkc.instructure.com/courses/66239/assignments/298119 due by 11:59pm

Date	Details
Fri Mar 8, 2019	 <u>D03-01. Find a peer-reviewed paper and comment on its literature review</u> https://umkc.instructure.com/courses/66239/assignments/298117 due by 11:59pm
	 <u>D03-02. How will you organize your literature review?</u> https://umkc.instructure.com/courses/66239/assignments/298116 due by 11:59pm
	 <u>D04-01. Comment on one of the recommended readings for this week.</u> https://umkc.instructure.com/courses/66239/assignments/298114 due by 11:59pm
	 <u>P03. Complete the required IRB training</u> https://umkc.instructure.com/courses/66239/assignments/298125 due by 11:59pm
	 <u>Q02. Quiz for week 2</u> https://umkc.instructure.com/courses/66239/assignments/298092 due by 11:59pm
	 <u>Q03. Quiz on literature reviews</u> https://umkc.instructure.com/courses/66239/assignments/298129 due by 11:59pm
Fri Mar 15, 2019	 <u>Q04. Quiz on randomization</u> https://umkc.instructure.com/courses/66239/assignments/298130 due by 11:59pm
	 <u>D05-01. Comment on one of the recommended readings for this week.</u> https://umkc.instructure.com/courses/66239/assignments/298112 due by 11:59pm
	 <u>D05-02. Summarize a quality improvement study.</u> https://umkc.instructure.com/courses/66239/assignments/298111 due by 11:59pm
Fri Mar 22, 2019	 <u>Q05. Quiz on quasi-experiments</u> https://umkc.instructure.com/courses/66239/assignments/298131 due by 11:59pm
	 <u>D06-01. Comment on one of the recommended readings for this week.</u> https://umkc.instructure.com/courses/66239/assignments/298109 due by 11:59pm
	 <u>D06-02. Why was randomization not used?</u> https://umkc.instructure.com/courses/66239/assignments/298108 due by 11:59pm

Date	Details
	 Q06. Quiz on observational studies https://umkc.instructure.com/courses/66239/assignments/298132 due by 11:59pm
Fri Apr 5, 2019	 P07. Literature review https://umkc.instructure.com/courses/66239/assignments/298126 due by 11:59pm
	 D08-01. Comment on one of the recommended readings for this week. https://umkc.instructure.com/courses/66239/assignments/298105 due by 11:59pm
Fri Apr 12, 2019	 D08-02. Find and discuss an example of purposeful, purposive, quota, or snowball sampling https://umkc.instructure.com/courses/66239/assignments/298104 due by 11:59pm
	 Q08. Quiz on sampling methods https://umkc.instructure.com/courses/66239/assignments/298133 due by 11:59pm
	 D09-01. One minute feedback https://umkc.instructure.com/courses/66239/assignments/298106 due by 11:59pm
Fri Apr 19, 2019	 D09-02. Find a validity/reliability example and comment on it. https://umkc.instructure.com/courses/66239/assignments/298103 due by 11:59pm
	 Q09. Quiz on reliability and validity https://umkc.instructure.com/courses/66239/assignments/298134 due by 11:59pm
	 D10-01. Review these resources on case report forms and list the best suggestion. https://umkc.instructure.com/courses/66239/assignments/298100 due by 11:59pm
Fri Apr 26, 2019	 D10-02. Describe your sample and data collection method https://umkc.instructure.com/courses/66239/assignments/298099 due by 11:59pm
	 D10-EC. Find a paper on data collection methods and comment on it. https://umkc.instructure.com/courses/66239/assignments/298098 due by 11:59pm
	 Q10. Quiz on data collection https://umkc.instructure.com/courses/66239/assignments/298135 due by 11:59pm

Date	Details
Fri May 3, 2019	 <u>D11-01. Discussion, Week 11, One minute feedback</u> https://umkc.instructure.com/courses/66239/assignments/298097
Fri May 10, 2019	 <u>D12-01. Discussion, Week 12, One minute feedback</u> https://umkc.instructure.com/courses/66239/assignments/298096
Fri May 24, 2019	 <u>D13-01. Discussion, Week 13, One minute feedback</u> https://umkc.instructure.com/courses/66239/assignments/298095
	 <u>D13-EC. Extra credit (2 points), Advice for next year</u> https://umkc.instructure.com/courses/66239/assignments/298094
	 <u>P13. Introduction, Literature Review, and Methods</u> https://umkc.instructure.com/courses/66239/assignments/298127
	 <u>D02-03. What is your research problem?</u> https://umkc.instructure.com/courses/66239/assignments/298118
	 <u>D03-EC. Find a paper outlining how to write a literature review</u> https://umkc.instructure.com/courses/66239/assignments/298115
	 <u>D04-EC. Extra credit discussion (1 point)</u> https://umkc.instructure.com/courses/66239/assignments/298113
	 <u>D05-EC. Extra credit discussion (1 point)</u> https://umkc.instructure.com/courses/66239/assignments/298110
	 <u>D06-EC. Extra credit discussion (1 point)</u> https://umkc.instructure.com/courses/66239/assignments/298107
	 <u>D08-EC. Find a paper on sampling methods and comment on it.</u> https://umkc.instructure.com/courses/66239/assignments/298101

Date	Details
	 <u>D09-EC. Find a paper on reliability or validity and comment on it.</u> https://umkc.instructure.com/courses/66239/assignments/298102
	 <u>P14. Suggestions for next year</u> https://umkc.instructure.com/courses/66239/assignments/298128