



**MEDS-360 From Bench to Bedside Research--  
Research Approaches to Biomedical Problems**

**Units: 2 units**

**Spring 2024 – Wednesdays 4-5:50 pm**

**Location:** DMC 258

**Instructor:**

**Michael Menchine MD MPH**

**(Course Director)**

Executive Vice Chair

Associate Professor of Clinical Emergency Medicine

Keck School of Medicine of the University of Southern California

Senior Clinical Fellow

Schaeffer Center for Health Policy and Economics

Los Angeles County + USC Medical Center

**Office:** GH 1011, Los Angeles CA 90089

**Office Hours:** A Mondays 3-4 and by appointment

**Contact Info:** [mmenchin@gmail.com](mailto:mmenchin@gmail.com) (preferred) or  
menchine@usc.edu

**Teaching Assistants:**

None

## **Course Description**

The goals of this course are to gain an understanding of research methods commonly used in clinical method and to enhance the ability to critically appraise medical literature. These skills are vital as students progress in their medical education and training. Student will learn foundational concepts in research design and explore of various clinical research approaches. The course will be conducted in a 'journal club' style. Each week students will be assigned a published manuscript to review that exemplifies the concepts to be discussed in that session ranging from retrospective chart reviews through community-based cluster randomized trials. We will explore specific errors and biases intrinsic to particular study designs. Ultimately students will develop familiarity with the study designs, be able to quickly identify and be able to articulate general strengths and weaknesses of specific research designs and apply that knowledge to the critical interpretation of individual clinical research papers.

### **Core concepts covered:**

*At the end of this course, students should have a working understanding of the following:*

#### Observational Study Design

- 1) Case Report Concepts
- 2) Ecologic Studies
- 3) Case-Control Design
- 4) Cross-Sectional
- 5) Observational Cohort

#### Experimental Design

- 1) Randomized Clinical Trial
- 2) Cross Over Design
- 3) Cluster Randomized
- 4) Factorial Design

#### Meta-Analysis

#### Common Challenges with Clinical Research Designs

- 1) Selection bias
- 2) Incorporation Bias
- 3) Confounding and Omitted Variables Bias
- 4) Spectrum Bias
- 5) Failure of Randomization

<b>Learning Objective</b>	<b>Assignment/Assessment</b>
By the end of this course, students should be able to:	This learning objective skill is measured by:
1. Understand Key study design types and key concepts necessary to critically appraise medical literature	Graded midterm quiz / final exam
2. Identify specific study designs present in individual research reports	Homework and case-based class discussion
3. Succinctly present a journal article highlighting the design and most likely source of error or bias	In-class presentation to the group
4. Detail common research terms and abbreviations	Midterm quiz and final exam
5. Understand the research approaches required for FDA approval of a medication or drug	Homework and Case based discussion

### **Course Notes**

This is a journal club / seminar style course. Every week student will be assigned a specific published clinical research article to review that aligns with that weeks course objectives. Students will be provided with prompts that will guide homework assignments to be completed prior to the in-person session. These homework assignments and prompt will serve as the basis for the discussion of topics. Attendance points cannot be made up except in rare emergency (in which a make-up assignment must be submitted).

There will be a midterm quiz and a take-home final exam in addition to weekly homework. The quiz and exam will consist of multiple choice and short answer questions.

### **Technological Proficiency and Hardware/Software Required**

This course requires use of blackboard and Microsoft word. During (unexpected) remote teaching, the Zoom video-conferencing platform will be required with a working webcam.

Please submit exams to blackboard with Microsoft word or PDF files.

### **Required Readings and Supplementary Materials**

Required readings and supplementary materials will be available on blackboard via links or as attachments. There is no required textbook for the course. Journal articles, news articles, media clips, TED talks, book excerpts, case scenarios, and educational videos will be used as preparatory material and should be reviewed prior to each class.

**Grading Breakdown** *\*\*approximate breakdown which may change depending on course schedule\*\**

<b>Assessment Tool (assignments)</b>	<b>Points</b>	<b>Approximate % of Grade</b>
Class Participation (x14) 14 classes, 2 point per class	28	14%
Midterm Quiz	30	15%
In-Class Presentation	20	10%
Homework (x12) 12 assignments, 8 points per assignment	84	42%
Final Exam	38	19%
<b>TOTAL</b>	<b>200</b>	<b>100%</b>

**Description of Assessments:**

Class participation will be assessed by attendance, engagement in class discussion prompting group discussion with prepared questions, as well as demonstration of preparedness/knowledge of the daily class topics and discussions.

The midterm quiz will be multiple choice and short answer essay responses (take-home and open book) that cover topics discussed in class. Readings will apply to the quiz topics but will not be directly examined.

The homework assignment should be prepared prior to the start of class.

The final exam will be multiple choice and short answer responses demonstrating understanding of the course material and covers content from the entire semester.

**Grading Scale**

Course final grades will be determined using the following scale

A	93-100
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	59 and below

**Assignment Submission Policy**

Assignments are always due at the beginning of class. Assignments should be submitted through blackboard.

**Grading Timeline**

Students will be graded on their assignments within 1 to 1.5 weeks after submission. Grades for individual assignments will be posted on Blackboard.

### **Additional Policies and Information about Homework for Readings**

Examination topics will be on the material covered since the last quiz and may change accordingly. The midterm quiz and final exam are on broad concepts and are **open note**.

Three points will be deducted if no discussion questions are included. Late assignments will be given partial credit (one point deducted per week late, maximum of 8 points deducted resulting in a minimum grade of 6 total points)

If a student is unable to complete any of the work assigned, it is the responsibility of the student to contact the instructor/course director to discuss what alternate assignments can be done to make-up the assignment. Attendance points will be lost if there is not advanced notice for an excused absence or in the RARE case of significant emergency/illness. Students must contact the instructor in advance or as soon as possible in the event of an emergency.

All work must be completed by the deadline. Assignments will lose one point for each week that it is late (for a maximum of 8 points deducted or minimum grade of 7 total points).

Attendance and discussion posts CANNOT be made up except with advanced notice for excused absences or in the RARE event of an emergency. A make-up assignment submission is required in these rare cases.

### **Course Schedule: A Weekly Breakdown**

\*\*\*Subject to change \*\*\* The midterm quiz will be on the material covered since the beginning of class and may change accordingly. The midterm quiz and final exam are on broad concepts and are **open note**.

**Week 1: From Eminence-Based to Evidence Based Medicine – Why Clinical Research is the Driving Force Behind Medical Progress**

**Week 2: Randomized Clinical Trials – The Holy Grail for Clinical Research?**

**Week 3: Relative Risk and The Number Needed to Treat – Presenting Trial Research Results**

**Week 4: Cluster Randomized Trials – Moving into the Community**

**Week 5: The Retrospective Chart Review – Pearls and Pitfalls**

**Week 6: The Ecologic Fallacy and why we do it anyway**

**Week 7: Case-Control Studies**

**Week 8: Selection Bias, Units of analysis and other fun with Observational Cohort Studies**

**Week 9: Dose Response Relationships: Finding Causation in Observation**

**Week 10: Tests of Diagnostic Tests: Sensitivity, Specificity and Incorporation Bias**

**Week 11: Natural Experiments in Medicine: Interrupted Time Series Analysis**

**Week 12: Meta Analysis – Adding it all together (or garbage in, garbage out?)**

**Week 13: FDA Approval Process: Early Stage Trials (Phase 1)**

**Week 14: FDA Approval Process Part 2: Phase 2 and 3 Clinical Trials**

**Week 15: Wrapping Up: Course Review and Final Examination Prep**

## **Statement on Academic Conduct and Support Systems**

### **Academic Conduct:**

Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in SCampus in Part B, Section 11, “Behavior Violating University Standards” [policy.usc.edu/scampus-part-b](http://policy.usc.edu/scampus-part-b). Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on [Research and Scholarship Misconduct](#).

### **Students and Disability Accommodations:**

USC welcomes students with disabilities into all of the University’s educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at [osas.usc.edu](http://osas.usc.edu). You may contact OSAS at (213) 740-0776 or via email at [osasfrontdesk@usc.edu](mailto:osasfrontdesk@usc.edu).

### **Support Systems:**

*Counseling and Mental Health - (213) 740-9355 – 24/7 on call*  
[sites.google.com/usc.edu/counseling-mental-health](http://sites.google.com/usc.edu/counseling-mental-health)

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

*988 Suicide and Crisis Lifeline - 988 for both calls and text messages – 24/7 on call*  
[988lifeline.org](http://988lifeline.org)

The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

*Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL) – 24/7 on call*  
[sites.google.com/usc.edu/rsvpclientservices/home](https://sites.google.com/usc.edu/rsvpclientservices/home)

Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

*Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086*  
[eeotix.usc.edu](https://eeotix.usc.edu)

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

*Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298*  
[usc-advocate.symplicity.com/care\\_report](https://usc-advocate.symplicity.com/care_report)

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

*The Office of Student Accessibility Services (OSAS) - (213) 740-0776*  
[osas.usc.edu](https://osas.usc.edu)

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

*USC Campus Support and Intervention - (213) 740-0411*  
[campussupport.usc.edu](https://campussupport.usc.edu)

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

*Diversity, Equity and Inclusion - (213) 740-2101*  
[diversity.usc.edu](https://diversity.usc.edu)

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

*USC Emergency - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call*  
[emergency.usc.edu](https://emergency.usc.edu)

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

*USC Department of Public Safety - UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call*  
[dps.usc.edu](https://dps.usc.edu)

Non-emergency assistance or information.

*Office of the Ombuds - (213) 821-9556 (UPC) / (323-442-0382 (HSC)*  
[ombuds.usc.edu](https://ombuds.usc.edu)

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

*Occupational Therapy Faculty Practice - (323) 442-2850 or [otfp@med.usc.edu](mailto:otfp@med.usc.edu)*  
[chan.usc.edu/patient-care/faculty-practice](https://chan.usc.edu/patient-care/faculty-practice)

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.