

SURG 200: Emergency Medicine Research I Spring 2016 (3 credits)

Class meeting times: Tuesdays and Thursdays 4:25-5:40 PM (Rowell Room 110) Laboratory: One 4-hour shift per week (Emergency department)

Faculty

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Curriculum Overview

This course is for pre-health professional students interested in learning clinical research skills. The class focuses on teaching the foundations of human subjects research, and is combined with a related "clinical research laboratory" experience. The first semester involves students in active projects while it defines research, introduces the ethics of clinical research and considers research design, basic analysis, recruitment, and informed consent process. Integral to the course is the four-hour weekly clinical research lab, working with investigators in the emergency department (ED) as Student Research Associates (SRAs). Students obtain handson experience evaluating patients and collecting data in the ED during rotating shifts arranged around individual student schedules.

Course Goals

Upon completion of the course, the student will be able to:

- 1. screen patients for eligibility for EMRAP studies
- 2. practice the principles and regulations involving patient and data confidentiality
- 3. demonstrate the art of patient care, humanism, and professionalism
- 4. gather and record data for EMRAP studies
- 5. gain informed consent from a prospective study subject
- 6. transfer blood from a syringe to blood collection tubes

Students will accomplish these goals by doing the following (under the supervision of a senior RA and attending physician): functioning as part of a research team; screening and recruiting potential study subjects; and contributing to the process of clinical research data collection

Textbook (optional): Designing Clinical Research, by Stephen B. Hulley *et al* Lippincott Williams & Wilkins; Fourth Edition (2013) Text available at the UVM Bookstore

Clinical Research Laboratory

The lab provides students with a patient-oriented clinical experience by participation in hands-on clinical research in the hospital setting under direct supervision of on-duty attending physicians. Students are trained to serve as Student Research Associates (SRAs) as part of the Emergency Medicine Research Associate Program. As SRAs, students interact with patients and their providers, observing the practice of emergency medicine and learning some of the methodology of clinical research. All of the research projects in the program are aimed at improving patient outcomes. As such, SRAs participate daily in the innovation of emergency medical practice and actively work to improve patient care at FAHC.

Research Meetings

Discussions of all ongoing research studies will be held periodically during class time, and may include principal investigators. The goal of these meetings will be to update everyone on the state of affairs for all on-going projects.

Additional Course Requirements and Material

All required material is available on the Research Associate Program's UVM Blackboard site or the shared drive (available in the ED). During orientation to the program, SRAs will receive a research manual outlining the responsibilities of the Student Research Associate position at

UVM Medical Center. The manual will also include summaries of the research projects, with key references providing background information for each of our clinical studies. The following is a sample of ongoing projects and is subject to change during the course of the semester:

- 1. Activation of Coagulation and Inflammation in Trauma (ACIT)
- 2.a. Luoxis Sepsis
- 2.b. Luoxis Trauma
- 2.c. Luoxis Traumatic Brain Injury
- 3. Post-Arrest Therapeutic Hypothermia with a Cervical Cooling Collar (PATH-C)
- 4. Mobile Assessment after Trauma Pilot (MAAT-P)
- 5. Temperature Evaluation by MRI-Thermometry during Cervical Cooling (TEMP-C)

Grading

Student performance will be evaluated in three ways:

50% Attendance and participation, including quizzes on readings, projects, performance on ED recruitment and screening, and other topics as assigned in class.

25% Midterm examination

25% Final examination

Lecture Attendance

All lectures are mandatory and absences are detrimental to the student's participation grade. In the case of an absence, the student is required to meet with the instructor and develop a plan to make up the material and missed time. Any student having more than one absence may be considered ineligible for course completion.

For most of the semester, there will be weekly quizzes. Quizzes will typically be announced, but students should always be up-to-date on basic study information, including inclusion and exclusion criteria, purpose and procedures for each study.

Occasionally, because of last minute changes in guest speakers' schedules, the order of classes may change. Students will receive as much advance notice as possible, both in class and on BlackBoard.

Students are expected to refrain from the use of computers in the classroom. Texting during class is not allowed and cell phones should be silenced.

Laboratory Attendance (Emergency Department)

Students are responsible for attending their scheduled shifts as Students Research Associates or for finding coverage. *There are no excuses ever for absence from a scheduled ED shift.* We consider the Research Associate position to be a critical part of patient care provided by the FAHC Emergency Department, and much like a surgeon or cardiologist, you are expected to be present when needed in the clinical setting. Points will be deducted from the student's participation score for any absences. In the case of an absence, students are required to contact the instructor and will also be required to make-up the shift. Any student having more than one absence may be considered ineligible for course completion.

Examinations

Written midterm and final examinations focus on current projects and research methods.

UVM Medical Center

Hospital Credentials and Access

To work at the UVM Medical Center, you need to fulfill certain requirements, listed below. These requirements maintain a safe environment for patients, healthcare providers, researchers and others. The items in **bold** are steps you need to take. Program staff will request the other (non-bolded) items for you. You must do all of these before you can function as an SRA.

☐ Complete UVM tutorial on human subjects research	
☐ Provide identifying data (complete name, major, last 4 digits of SSN, date of birth, i	IRE
tutorial completion, student ID number and cell number).	
■ Receive a UVM Medical Center account with user ID (M number)	
☐ Complete UVM Medical Center eLearn modules after you get your M number	
☐ Complete UVM Medical Center Non-Employee Confidentiality Agreement and	
Cusomer Feedback Policy	
After you complete the eLearn modules:	
☐ Pick up Medical Center ID badge at UHC	
■ Receive access to PRISM (hospital electronic health record system)	
■ Receive proximity card for ED (will be distributed in class or ED)	
☐ Complete UVM bloodborne pathogens tutorial	
■ Receive access to REDCAP database	

eLearn Modules (formerly FAHC Mandatories) completion will be worth a quiz grade of 10 points.

If you run into computer problems, first call hospital IS Security at (802) 847-1414. If they are unable to help you or tell you it may take a few days to correct whatever might be wrong, then contact Mike at mokeefe@uvm.edu right away.

You should receive (or have received) an email which contains your M# (your UVM Medical Center user ID) and temporary password. Once you have gotten your temporary password, you will need to change it before your account is activated. To do this, go to https://elearn.fletcherallen.org. In the field "User name," enter your M# (make sure to include the letter "M" so that it looks like "M123456"). You will be prompted to change the temporary password you were given. Type in a new password in the two fields for that information. Make sure the new password has at least 3 of the following: 1) a capital letter, 2) a lowercase letter, 3) a number and 4) a symbol. Then click "OK" and it should say your password was successfully changed.

Once your password has been changed, log in again to the FAHC system through the same link: https://elearn.fletcherallen.org

Enter your user name (M#) and new password. Once on the eLearn page, look to the right of the screen and choose "Click here to access your learning materials," then click on "Mandatories 2015." Complete all of the learning modules (there should be 15 of them). Each module consists of a reading and a quiz at the end. You must get an 80% on each quiz to pass each tutorial. These grades do not count as grades for the course, but you need to pass them to get your FAHC credential. You have several opportunities to do so.

Once you have completed the tutorials, click the "Training Records" tab on the top left of your screen and choose "Records/Transcript." This will give you a complete list of all the tutorials that you have completed. Make sure they are all completed and then click on the link at the bottom of the page "Print Records/Transcript Report." On the new screen, click on "Select learning modules/programs." Click on the link that is a double downward arrow (but looks like the letter W), then click OK. Change the field for "Summarized Report" to "Yes" and click "Print Preview." Save the information in a Word document named "eLearn [yourlast name] 2015spring" and send it to EmergencyMedicine@uvm.edu.

Hospital Dress Code

PURPOSE: The appearance of employees working in a health care environment impacts the perception of quality service and care for our patients and the community we serve. Care is enhanced when patients, families, visitors and staff feel a sense of trust and confidence in the care and the services being provided by staff at the hospital. The professional appearance of staff is key in promoting trust, comfort, and confidence while providing care and service in a safe environment

General Guidelines for Appearance:

- A. Student Research Associates (and RAs) are to be clean and well-groomed at all times.
- B. Clothes are to be clean and in good condition (not frayed, ripped or with holes).
- Discretion should be used in the selection of clothing to ensure that safety and professional appearance are not compromised. Clothing must cover torso and have wide shoulder straps (no spaghetti straps). **Blue Denim** is not allowed.
- C. Safety, noise control and OSHA standards should prevail in the selection of shoes. Soft-soled shoes are preferred. **Open-toed shoes and sandals are not permitted** where they present a safety hazard or in patient care areas.
- D. Name badges are part of each employee's required attire and should be visible and worn above the waist. Name badges are not to be compromised in a manner that prevents clear display of name or picture ID.
- E. Hair shall be clean and neat with styles that are appropriate to business attire and be of a color that occurs naturally. For example, hair colors such as pink, purple, blue, green are not allowed. Long hair (below the shoulders) should be pulled back and secured when providing direct patient care. Moustaches and beards must be neat and trimmed and not interfere with personal protective equipment (PPE).

- F. Fingernails should be clean, conservative in length, and neatly manicured. Because of infection risks, only short, natural fingernails (nail tip may be no longer than a quarter of an inch in length) are allowed when providing patient care or when working with patient care products (i.e., housekeeping, pharmacy). No artificial nails/gels, nail jewelry, sparking ornaments or chipped nail polish are allowed.
- G. Jewelry is to be simple and appropriate to business attire. All jewelry must meet safety standards. Because performing adequate hand hygiene is difficult if jewelry is worn, a limited number of rings should be worn when providing patient care. Visible body piercing is not permitted except for in the ears only and this is limited to 2 earrings per ear.
- H. Colognes and perfumes should not be used in patient care areas due to patients' allergies and reactions. Colognes and perfumes should be used sparingly and not be offensive.
- I. Tattoos must be covered where possible.
- J. Clothing guidelines:
 - 1. Clothing should not be tight fitting and should be appropriate to perform work and in a length not to exceed 4" above the knee.
 - 2. Professional attire, as appropriate, for the care setting.
 - 3. Ornamental hosiery is not appropriate (e.g., lace, rhinestones, bows, etc.).
 - 4. Shorts, skorts, tank tops, T-shirts, tube tops, sweatshirts/pants, running suits, and shirts with commercial slogans or pictures are not acceptable attire. (Unobtrusive small logos such as those found on dresses and shirts, UVM Medical Center logos and other logos of this nature are acceptable).

Badges

You are required to wear your hospital ID badge in the hospital during your shifts. You will also get a proximity card that will give you access to the ED, which is otherwise locked to the general public. You will receive an email when your badge is ready to be made. You will have to go to the 5th floor of UHC (up elevator A) to find the badge office and a photo ID will be made for you when you arrive.

*If you lose your badge or prox card you must email mokeefe@uvm.edu right away so that it can be deactivated

ED Scheduling

Each ED shift is four hours long, starting at (using the 24 hour clock) 1000, 1400, 1800 or 2200. You will be expected to complete one shift each week. You will receive separate information regarding how to indicate which shifts you prefer in the Emergency Department.

Trauma Physiology Laboratory

As of summer 2014, EMRAP has a laboratory in the rear of the ED. The door code is 47502. This room is where: we process blood, the on-duty RA is stationed, both blank and completed forms are stored, you may store your belongings during your shift and other activities take place. Since it is a laboratory, you cannot eat or drink there. When you have questions, this is where you will find the RA who is on duty. Take care to keep it neat and clean.

Emergencies and Other Unusual Situations

Although an Emergency Department by its very nature deals with the unexpected, it has its own rhythm and the staff deals on a regular basis with things that would alarm or frighten others. Occasionally, though, events occur that are truly unique or at least unexpected. In general, if you encounter a situation where you are unsure of what to do or feel uncomfortable, you should contact the RA on duty. If you are unable to reach the RA, contact one of the program staff. Specific examples of what to do in certain situations are listed below:

Event	Steps to Take
Fire or fire alarm	Follow hospital procedures on your red card
Administrator or inspector asks	Contact the RA on duty – do not give out confidential
you about any study or study subject	information without checking first
Violence	Protect yourself by leaving the area quickly and notifying the charge nurse or security
Emotional distress from death or serious illness of a patient	Contact Dr. Freeman or Mike O'Keefe or a staff member
Potential study subject or family	Explain that when the patient is not in a condition to
member confronts you about not	understand the consent discussion, we draw blood for the
getting consent for blood	purpose of research at the same time it is drawn for patient
samples	care purposes and approach the patient later. No data is used
	or blood processed until we gain consent from the patient.
	This is specifically approved by the institutional ethics board.
	A staff member or trauma surgeon will attempt to gain
	consent from the patient the morning after admission. If a
	patient or family members ask about blood being drawn, you
	can let them know it is for the trauma team. If they have any
	questions about this protocol, they should contact Dr. Kalev
	Freeman.

UVM Bloodborne Pathogens training

This is UVM-specific training that needs to be completed even though you already completed similar training for the hospital. Fortunately, this one is quick. Go to this link: http://esf.uvm.edu/courses/, sign in with your UVM NetID and password and then select only the "Safety Around Blood Borne Pathogens" tutorial. This module will be similar to the hospital's with a quiz at the end. Be sure you have a few uninterrupted minutes for the tutorial because you cannot stop in the middle and go back to where you stopped. It has to be done in one sitting. When you reach the question, "Are you at risk?" answer yes. At the end of the tutorial, where you are asked to enter your supervisor's email address, enter mokeefe@uvm.edu.

UVM Administrative Policies

Student Learning Accommodations: If you have a formal accommodation plan developed in conjunction with UVM's ACCESS Office or would like to discuss the supports that you need in order to learn well in this class, please contact emsresearch@uvm.edu at the beginning of the semester. Adaptations and instructional support are available through consultation with the instructor(s) and the ACCESS Office.

ACCESS Office: www.uvm.edu/~access/

UVM's policy on disability certification and support: www.uvm.edu/~uvmppg/ppg/student/disability.pdf

Religious Holidays: Students have the right to practice the religion of their choice. If you need to miss class to observe a religious holiday, please submit the dates of your absence in writing by the end of the second full week of class. You will be permitted to make up work within a mutually agreed-upon time.

Academic Integrity: The policy addresses plagiarism, fabrication, collusion, and cheating. www.uvm.edu/policies/student/acadintegrity.pdf

Grade Appeals: If you would like to contest a grade, please follow the procedures outlined in: www.uvm.edu/~uvmppg/ppg/student/gradeappeals.pdf

Grading: For information on grading and GPA calculation, please go to www.uvm.edu/academics/catalogue and click on Policies for an A-Z listing.

Code of Student Rights and Responsibilities:

www.uvm.edu/~uvmppg/ppg/student/studentcode.pdf

FERPA Rights Disclosure: The purpose of this policy is to communicate the rights of students regarding access to, and privacy of, their student educational records as provided for in the Family Education Rights and Privacy Act (FERPA) of 1974. http://uvm.edu/~uvmppg/ppg/student/ferpa.pdf

Final Exam Policy: The university final exam policy outlines expectations during the final exam period, explaining timing and process:

http://catalogue.uvm.edu/undergraduate/academicinfo/examsandgrading/

University of Vermont

SURG 200: Emergency Medicine Research I Schedule: Spring 2016

Revised 1/19/16

NOTE: In lieu of a lab the first week, the first class meets from 4:25 p.m. to 7:00 p.m. Pizza will be provided.

Day	Date	Торіс
Tu	1/19/16	Orientation to Projects and Procedures
Th	1/21/16	Course Introduction & Emergency Department Tour
Tu	1/26/16	Introduction to Emergency Medicine
Th	1/28/16	Introduction to EMS
Tu	2/2/16	Research Ethics I
Th	2/4/16	Research Ethics II -Vulnerable Subjects
Tu	2/9/16	Screening Procedures and Professionalism
Th	2/11/16	Informed Consent
Tu	2/16/16	Informed Consent Workshop
Th	2/18/16	Applying to School of Medicine or Allied Health
Tu	2/23/16	Study Design I: Cohort, Cross-Sectional, Case Control, Observational
Th	2/25/16	The Research Question: FINER Criteria
Tu	3/1/15	Town Meeting Day Recess
Th	3/3/16	Truth, Noise and Bias
		Spring Recess
Tu	3/15/16	Reading an Article Critically
Th	3/17/16	Study Design II: Randomized Controlled Trials, Studies of Medical Tests, Sensitivity, Specificity
Tu	3/22/16	Midterm Exam
Th	3/24/16	Statistical Methods I: Power, Sample Size, Clinical vs. Statistical Significance, Confidence Intervals
Tu	3/29/16	Vascular Biology
Th	3/31/16	Statistical Methods II: Graphical Presentation of Data, Introduction to ROC Curves
Tu	4/5/16	Journal Club
Th	4/7/16	Insulin - Example of Clinical Research
Tu	4/12/16	Humanism
Th	4/14/16	Prehospital Care Topic
Tu	4/19/16	Research Update, Part 1
Th	4/21/16	Trauma Physiology - Head Injury/Concussion
Tu	4/26/16	Clinical Topic
Th	4/28/16	Clinical Topic
Tu	5/3/16	Research Update, Part 2
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Please note: as a student in SURG 200, you will be working in the hospital under Dr. Freeman's medical license. The hospital and UVM ethics board both require that all students engaged in human subjects research work complete our curriculum. Everything is mandatory. Nothing is optional. If you are unable to attend lecture or a scheduled laboratory shift, you must notify program staff.