Georgia Institute of Technology
Department of Biomedical Engineering
&
Emory University
Department of Emergency Medicine

Clinical Observational Design Experience
(CODE I – BME 4813)

Orientation Manual

Fall 2013

NOTE: THIS COURSE IS A WORK IN PROGRESS. ALL STUDENT RESEARCH ASSOCIATES ARE ENCOURAGED TO SUBMIT CONTRIBUTIONS AND SUGGESTIONS (E.G., IDEAS, OPINIONS, ANECDOTES, ETC.). PLEASE SEND THEM TO DR. ACKERMAN OR SUBMIT THEM TO THE TAS.

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We encourage you to address any questions that arise with the course TAs or via e-mail:

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Introduction

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This guide provides a basic overview of this course. It outlines procedures concerning data collection, patient encounters and interactions with staff. Tidbits of wisdom from prior course participants have been included to help you.is course has a wide variety of goals.

This is a course where you are expected to learn by doing. The course has relatively little structure in order to adapt to unanticipated changes in our clinical settings. Experience has shown that significant changes in the course have been needed as the semester progresses – be prepared to adapt. Dr. Ackerman, the TAs, and research staff will try their best to assist you and provide information and guidance, but ultimately you will have to chart the course that lets you take best advantage of this exposure to a clinical environment.

The Cardinal Rules

Before continuing through the handbook, please learn the cardinal rules of being a Student Research Associate (SRA). These are printed in a much larger font than anything else in the book and are in bold and in a separate box. You may have noticed they also have their own table of contents entry. These rules are restated in a variety of forms throughout the manual. You can therefore assume these are very important:

1. IF IN DOUBT ABOUT ANYTHING, ASK!

2. BE RESPECTFUL AND COOPERATIVE WITH ALL STAFF, ALL THE TIME

3. GET TO KNOW THE STAFF

Nobody will be upset with you if you ask a question. We're all here to learn. If you try to fake something and screw it up, rest assured that someone, an important someone, will be VERY upset.

Throughout this Manual we suggest that you make every effort to be polite and respectful to all ED staff and patients at all times. As obvious as this should seem, it is critical to your success in your role as an observer and a data collector. If that doesn't motivate you, significant complaints about you will adversely affect your grade.

Beyond general courtesy, it will be extremely helpful to you if you can develop some rapport with individual staff members. In particular the nurses, clerks, and techs can be extremely helpful in helping you locate information you need and identify patients for clinical studies. In many instances these staff members have a detailed understanding of the clinical environment as well as substantial medical expertise and may be willing and/or interested in teaching you.

Even if it is not evident to you, staff members may be managing critical patients and juggling multiple conflicting responsibilities. Patients and their families are often going through a very stressful time. For these reasons, at times the respect and courtesy you extend may not always be returned. Do not take this personally and do not return any real or perceived discourtesy – it will without doubt cause you more problems in the long run. As difficult as it may be, your job is to *apologize* (even if you don't know why) and *politely walk away*. If you have concerns about anything that happens, you should contact course faculty.

WHEN FACED WITH ESCALATING ANGER, DE-ESCALATE: *APOLOGIZE* AND *POLITELY WALK AWAY*

Course Overview

This course has a wide variety of goals. It is hoped that these goals will come together in a coherent way that provides a good educational experience as well as valuable service to the patients and clinicians you will be working with in Grady Memorial Hospital's Emergency Care Center (ECC) and Emory University Hospital Midtown's Emergency Department.

Educationally, this course will be composed of some didactic lectures as well as small group activities that will occur during the scheduled class times. These lectures are intended to provide the training you need work in the Emergency Departments and to provide some context to the work you will be doing. Other lectures and small group activities will be focused on learning and applying techniques to hone your observational skills in a clinical environment and to begin using your observations to identify and solve problems in this environment.

The bulk of your time in this course will be spent in the Emergency Departments. In this environment you will assist the research and quality improvement efforts of the clinicians from Emory's Department of Emergency Medicine by collecting research data and by identifying and enrolling patients in ongoing research studies. This provides you access to a dynamic clinical environment which you will immerse yourself and observe.

The Student Research Associate Position

The Emergency Medicine Department at Emory University is an acknowledged leader in clinical research. The current Clinical Observational Design Experience course and prior Clinical Research Practicum program are modeled after a very successful program at the University of Pennsylvania, created in 1994 by Dr. Judd Hollander and his colleagues[1]. Similar programs have been reproduced in a variety of forms at several other academic Emergency Medicine departments[2-4]. As a student in this course you will be taking on the role as a Student Research Associate. The in this capacity you will support the research and quality improvement initiatives of the Emory University School of Medicine Department of Emergency Medicine.

The current course was first taught in Spring 2010 and differs from the previous Clinical Research Practicum course which preceded it in that the didactic program focuses on using the clinical immersion experience as a starting point for design processes for the clinical environment rather than as a introduction to clinical research methodology.

The clinical immersion and experience will be split between two sites: the Grady Memorial Hospital Emergency Care Center (GMH-ECC) and the Emory University Hospital Midtown Emergency Department (EUHM-ED). GMH is the largest Level I trauma center in the Atlanta metropolitan area and provides emergency services to over 100,000 patients per year. GMH is now a certified stroke center. EUHM is a certified chest pain center and offers many specialty services as expected from a tertiary care center associated with a major medical school. The Associates program offers a unique opportunity to participate in clinical research, observe Emergency Department (ED) operations, and learn from the physicians, nurses, and staff other in the ED. The Student Research Associate position is an important responsibility requiring maturity, initiative, diligence and excellent interpersonal skills.

In addition to accruing experience in conducting medical research, acquiring familiarity with healthcare and emergency department systems and operations, and developing some facility for observational design techniques, associates can earn the respect and recognition of the

distinguished Medical School faculty. (Hint: a good opportunity to meet faculty and get letters of recommendation for medical school[1], employment or graduate school.[5])

The data collected by the Student Research Associates are analyzed and interpreted by the research faculty and their associates in support of a number of ongoing studies and continuous quality improvement projects (CQI). Whether the studies yield a new application to the Emergency Department, or long-term procedural changes in Emergency Medicine, the benefits accrue to medical knowledge and ultimately superior patient care.

Strict attention to detail is paramount in assuring valid outcomes for each study. To that end you must completely familiarize yourself with all of the ongoing studies. Descriptions of the current studies as well as their associated procedures will be available on T-Square.

Professional behavior is essential. At EUHM, and to a lesser extent GMH, the Student Research Associates' presence, role and duties, are still relatively new. At times the ED staff (faculty, residents, nurses, clerks, and techs) may be unaware of your role. Your attitude toward the professional and paraprofessional staff of the Emergency Department will determine your success in winning their good will, trust and cooperation. Your success leads to the success of the program as whole.

Words of Wisdom: *Do not be snotty to any of the staff and then expect them to drop everything to help you. It won't happen. Get to know the staff and help out where you can. They'll return the favor. This is critical to developing a good understanding of the complex environment you are working in and observing.*

[1] Research has shown that participants in programs like this are accepted to medical schools at higher rates than students with comparable grades and test scores who have not participated in such programs

Observational Design

Observational design, in the context of this course, is a design process which starts with observation of people and environment to identify and define problems and later use the same observations to develop solutions for them. There are a variety more rigorously defined methods that follow this premise. These include "User Centered Design" and "Human Centered Design". Many of these processes have been specifically developed or adapted to particular industries or types of problems. In this course we will take an approach most similar to Human Centered Design[2][6, 7]. When you look at how techniques like this are used the range is astounding – customer flow and quality improvement in fast food restaurants, software design and engineering, device development, development of aid programs in developing countries, and furniture design.

In general, most problem solving techniques, and therefore product development, start with a statement of problem. Even more problematic is when developers start their design with a solution without fully considering what problem their design aims to solve. These approaches face the common pitfalls that if the starting point is wrong, the end result will be less than optimal. Likewise, this approach will miss potentially relevant context that may also result in a suboptimal solution. Asking users about problems they are having is not always useful in that they may not be aware that there is a problem or have misidentified what it is. In very technical fields users frequently have difficulty communicating effectively with designers and engineers. This often occurs due to a lack of shared knowledge of the domain.

Observation provides a focused point around which to structure questions as well as areas for the designer to focus outside research. Anthropologists have developed qualitative research techniques for observing and understanding groups of people. These techniques, broadly described

[2] For those who are interested there is an excellent article and follow-up commentary by Don Norman (see the references) that explores the potential pitfalls of the HCD approach and codifies my concern about specifically following this approach. It is notable that he advocates for "activity centered design" which represents focusing on the task rather than the people performing the task. You might notice my leaning towards the principles Norman espouses. The observational approach is remains central to these methodologies.

as ethnography, are easily adapted towards understanding and improving complex technical systems and processes as well as the technology used within these systems.

A complete treatment of the subject of ethnography and ethnographic methods is well beyond the scope of a single semester undergraduate course. As such you will learn by doing. Due to the limited time in this course, we will focus primarily on observing and identification of problems. The techniques we use can be extended further through the design process into development, prototype testing, and product improvement.

It is hoped that students who have not yet begun the BME senior design course sequence or other capstone project sequence may develop ideas that can be pursued further. If you are interested in continuing a project that you begin exploring as part of your senior design course, contact Dr. Ackerman and he will serve as your advisor or will find an appropriate person to help you continue your project.

Emergency Department Basics

There are a variety of methods for organizing Emergency Departments. Since you will be spending time in two very different Emergency Departments, it is important to understand how Emergency Departments generally function as well as some of the specifics of the sites you will be working in. Both Emergency Departments have recently undergone substantial organizational changes. These changes will be continuing throughout the semester. We will try to tell you in class when additional changes are made or are expected, but often these changes occur with relatively little warning.

The nursing staff members in our Emergency Departments are excellent, but they are overworked and understaffed. Usually nurses cover approximately 4-5 patients each. **Be kind and respectful to the nursing staff!** Awareness of who may be responsible for any given area at any particular time will be useful during your shifts.

Most Emergency Departments have an area or areas for triage, areas for care of non-emergent patients, care of "acute" patients, as well as care of "critical" patients.

The GMH ECC has 7 distinct areas of operation served by two triage areas (walk-in and ambulance triage). GMH is referred to interchangeable as GMH or Grady. The ECC is often referred to as the "ER", "ED", or "the Zones":

The Marcus Trauma Center (MTC) – an area focusing on the care of traumatically injured patients. It opened in November 2011.

The Blue Zone (mostly patients without traumatic injury) with two critical care rooms (with 4 beds each) and the "CPR" room for more active resuscitations

The Red Zone (includes the old trauma resuscitation bays) – this is currently supposed to be focused on lower acuity patients and also hosts our psychiatric care area.

PACe (fast-track, non-emergent patients) staffed primarily by midlevel providers

Detention (care of prisoners) with 8 beds and areas for supervising law enforcement officers – there is also a prison area behind a locked door where prisoners are held before and after their medical evaluation and treatment (in the Blue Zone)

"Red Obs" (psychiatric observation) with 4 beds (in the Red Zone)

Clinical Decision Unit (8 beds for short hospital stays). This unit is expanding to 20 beds.

The EUHM ED has a single triage area off the waiting room, and patients coming in by ambulance are often triaged in the department (at bedside). EUHM should be referred to as EUHM or "Midtown". You will hear it referred to as "Crawford Long[8]"[3]. The department is composed of the following areas:

Acute Care where most of the patients are seen – currently divided into staffing "pods" or clusters of rooms which are managed by a small team of staff. The split of rooms into pods has varied and is therefore not included here.

Express Care which is for the non-emergent fast-track patients

Clinical Decision Unit (8 beds)

Triage

Triage is both a location and the process that occurs there. The term "triage" comes from the French verb "trier" meaning "to sort" and was first described during the Napoleonic Wars. Historically triage has three categories – patients who will die, those who will live, and those in whom prompt care will change their outcome. Currently EUHM and GMH use the Emergency Severity Index (ESI) system[9] which is a five tiered system. Patients that can clearly be triaged as level 1 (that is the sickest or potentially sickest patients) often bypass triage and are taken directly to the treatment areas. At Grady this process is (depending on severity and resources needed) a

[3] EUHM had previously been Emory Crawford Long Hospital and was renamed Emory University Hospital Midtown in February of 2009. The hospital was deeded to Emory in 1940 and until approximately 2007 was known just as Crawford Long Hospital. The hospital itself opened as the Fischer-Davis Sanatorium in 1908 and was relocated to the present site in 1911. The hospital was renamed in honor of Dr. Long in 1931. Dr. Crawford W. Long is generally credited with being the first surgeon to use general anesthesia for operations (diethyl ether). He was born in Danielsville, Georgia in 1815. There is a small museum about Dr. Long in the atrium of the 1911 portion of the hospital.

"STAT Pack" or "Express Registration". Posters showing the ESI algorithm are posted near the triage areas and similar posters can be found at triage at EUHM.

It is at triage the medical the medical evaluation process begins. The process of triage is an initial evaluation during which time get vital signs taken and a basic evaluation is done so that the patient can be sorted to an appropriate level of acuity. Based on this sorting, the patient the patient to be placed either in the waiting room or one of the zones. Patients are rapidly interviewed and assessed by a nurse. If triage is busy, patients wait in the waiting room to be seen by the triage nurse. In the GMH ECC there are two triage locations - one is located next to the Ambulance entrance and the other is located off of the waiting room. The triage area off of the waiting room is the initial point of contact for all walk-in patients. At EUHM walk-in triage is located behind the registration desk and ambulance triage is often conducted at the bedside as the patient is assigned to an ED bed.

STAT Pack

At GMH Stat Pack is a designation for patients that are severely injured or ill that meet predefined criteria (gunshot wound to the chest, cardiac arrest, etc). Because these patients have a high probability of critical injuries they usually receive this designation based on reports from the paramedics who are bringing the patient to the hospital. Special packets with registration numbers, identification stickers, and critical care charts are used for these patients in order to speed the process of getting labs and other tests. Once the patient is stabilized, the patient can be formally registered and the temporary medical record number can be linked to any pre-existing records. Trauma patients who are designated as "STAT Packs" are met by the Trauma Surgery team on arrival in the ED.

EUHM does not typically get trauma patients, but patients of equivalent severity are triaged as "Level 1" or "a red". A physician is typically called to the bedside and a team of nurses rather than a single nurse begin the initiation of care of these patients.

Express Registration

Patients with potentially unstable condition who do not meet criteria for STAT Pack processing may arrive with "Express" status. These patient's are met in their room by registration personnel who expedite the registration process so labs and tests can be ordered more rapidly than if they went through the routine registration process. "Express" patients frequently undergo a rapid evaluation in the trauma suite or a critical care room immediately following arrival. For trauma victims designated as "express" the Trauma Surgery service does not participate in the patient's evaluation on arrival in the ED but are instead consulted later if the patient's injuries warrant a consultation from the trauma service.

Registration

Registration collects information necessary to assign the patient and medical record number or to attach their current visit to an existing medical record number. At GMH this area is adjacent to Triage in front of the Ambulance entrance and on the side of the waiting room. At EUHM this area is at the window in the waiting room. Due to requirements of Federal law, detailed registration including gathering insurance and payment information is implemented as a process that is asynchronous with medical evaluation.

CDU

The CDU is an area of the EDs at both sites used to manage and observe patients who likely do not require hospital admission but who do need to receive additional treatment or testing to ensure that discharge home is appropriate. Patient's in this unit generally stay there for less than 23 hours and follow a planned protocol based on their diagnosis. Examples of protocols used include Chest Pain, Asthma/COPD, cellulitis, and Chest Pain. There are Android and iOS apps available for free which describe these protocols.

The Emergency Department Staff

There are many staff members who work within the Emergency Department. Understanding their background, training, and responsibility will help you understand what you are observing. It will also help you identify staff to shadow or to interview as you develop project ideas.

Attending physicians

Frequently referred to as "Attendings", these are physicians who have completed residency training and supervise medical students and residents in the emergency department. The Attending Physicians can be identified by the green area on their Emory and Grady ID badges. Attending Physicians staff both red and blue zones as well as the MTC. Red Zone is covered by one attending. The Red zone Attending covers all of Red zone and PACE. Blue zone has two Attending Physicians from 9 am – 1 am, and one attending thereafter. On weekends the second attending schedule has varied and remains in flux. The Blue zone was recently splint into A and B teams. The A-team is usually staffed by an attending, a 3rd year Emergency Medicine resident and a resident rotating from one of the other clinical programs. The B-team is generally staffed by an attending, a 1st and a 2nd year Emergency Medicine Resident and often additional rotators or 1st year residents. The Blue zone Attending covers the blue zone, the "asthma" room, the detention room, and the observation unit. During a typical shift the attendings are supervising care of a large number of patients (possibly approaching 50 patients at some times) including patients under the care of paramedics in the field. Given the breadth of their responsibilities these physicians may be difficult to approach. Many generated the research and quality improvement projects which you are gathering data for and would like you to have a positive experience. When they offer to show you something or answer questions you should take advantage of the opportunity provided.

Residents Physicians

Residents, supervised by the Attending Physician, see and evaluate all patients in the GMH ECC. There are 3 levels of Emergency Medicine residents working in the ER (Interns – 1st year,

2nd year, and 3rd year). In addition, residents from other services may be completing rotations in the ED or may be in the ED completing consultations or caring for patients who are still in the ED but who have already been admitted to the hospital.

The 3rd year Emergency Medicine resident in each zone is in charge of the other residents and directs flow. They will share responsibility for managing critically ill and injured patients with the 2nd year resident. The 3rd year resident may also be directly responsible for supervising a medical student.

The 2nd year Emergency Medicine resident in each zone will be focusing their attention on the management of the critically ill or injured patients. They will also be seeing less critically ill patients as well. The 2nd year resident may frequently is responsible for supervising and teaching Physician Assistant Students who rotate through the ED.

Emergency Medicine residents may be present in the zones in a variety of other roles. They may be providing consultations as part their education experience as part of another service. Residents will be assigned to perform ultrasound exams as part of their education in performing these exams. There will be a resident assigned to "orthopedic procedures" who is working with orthopedics and is available to assist completing procedures in the zones

Many other residents will be present in the zones. Some will be working in the zones for the Emergency Medicine portion of their residency's requirements. Others will be managing admitted patients who have not yet been moved to another area of the hospital. Others will be providing consultations from specialty services regarding the management of Emergency patients.

Residents generally have a yellow stripe on their Grady and Emory ID badges.

Other ED Staff

There are a large number of additional ED staff members that you will see. Some of them can be important resources for you and you are encouraged to find out about their roles. These include, but are not limited to, the following:

- ED Techs are circulating ED staff members who maintain par quantities of ED supplies. They may be able to provide needed supplies such as specimen

containers, vacutainers, test tubes, labels and bags, etc. They are familiar with Central Supply and procurement of ED materials

- EKG Techs: perform electrocardiograms
- Equipment Techs: stock and maintain disposable and re-usable equipment
- Radiology Techs: acquire x-rays and CT scans. They perform these studies in the radiology suites as well as portable studies in the ED
- Phlebotomists: draw blood for labwork
- Translators: for patients who cannot speak English adequately the hospital has some foreign language translators to good communication
- Social workers: coordination of medical care and outpatient care can be challenging. Many of our patient's have limited resources as well. These professionals assist in coordinating the financial, social, and other issues that are not directly in the purview of the medical staff
- Respiratory therapists: Assist in management of patients with difficult breathing. They assist management of ventilators and non-invasive positive pressure ventilation devices and collect and run specimens for arterial blood gas measurement
- Pharmacists: review medication orders and reconstitute medical solutions. Pharmacists and pharmacy students are frequently present at our resuscitations to advise and assist administration of potential dangerous medications

Words of Wisdom:

Get to be very good friends with the nurses, pharmacists, medics, clerks, and techs. (Has this point been made sufficiently clear?)

Medical Students

Medical students also frequent the ER. Most of the medical students you see will be third or fourth year medical students from the Emory School of Medicine or the Morehouse School of Medicine, but students from a wide variety of medical schools come to Grady as part of their training. These students may be completing an Emergency Medicine rotation or may be working with other services within the hospital. Since medical students typically have the least emergent responsibilities of the many providers in the ED, they can be excellent resources to explain what is happening. You need to be respectful that they, like you, are there to learn and have a wide range of responsibilities. You should also bear in mind that, as students, they may not be the best source of some types of information.

The Student Research Associates' Desk

The Student Research Associate should not sit at the computers behind the desks at either site. These computers are for clinical staff only. You will be shown on the tour where the desk is in the ECC. There is a workroom at EUHM that you may use as well. At both sites there are other people who may need to use these desks and computers and they should have priority using this space and equipment.

Location of 'Critical' Items

Toilets

For staff these are located in the rear of the ED across from the Blue zone and next to the GMH Jail area. You should mark these on your maps of the departments so you can find them in the event of an emergency.

Research Offices

EMORY FACULTY OFFICE BUILDING: The main research offices are located on the first floor of the Emory Faculty Office (FOB) building, across the street from the ECC. Lauren's office is on the first floor of the Steiner Building which is across the street from the ECC.

Blank study forms

Study forms can be found in the file cabinet in the resident breakroom/research office.

Important: Please notify your TAs or Lauren if you see that the supply of forms is running. They will instruct you to either make copies or will insure that the forms are replaced.

ED Research Basics and Definitions

Definition

Research studies: Ongoing investigations and discrete data gathering operations of (long or short) finite duration, involving patients and their conditions.

Forms

A research sheet, or set of forms, has been created for each study. These forms define the boundaries of the population being studied.

Examine these forms carefully. It is your responsibility to understand which forms need to be completed for which study. It is the responsibility of Student Research Associate to prepare the forms, include them in the patient's chart, follow them through the ED examination and treatment, confirm their completion, and ensure that they are documented completely.

Be certain to screen each and every form to ensure that all items on the form have been completed.

All completed forms are placed in completed forms bins located in the Steiner Research Offices.

Make certain the forms do not remain with the chart. They must be separated after completion and must be placed in the completed forms bin.

Criteria

Criteria are the indications used to distinguish who should and should not be included in the study.

Inclusion criteria (Patient meets criteria to be put in study)

Exclusion (Patient is left out of the study if they have any of these)

Learn what signs and symptoms are important for each study.

Signs and symptoms

Signs are objective: You observe a laceration; the patient's blood pressure is measured. You see it for yourself or it is measured.

Symptoms are subjective

The patient states "I have chest pain". You have to rely on what the patient is telling you

Important: The Research Practicum Associates' effectiveness centers on their ability to recognize patients arriving for treatment who meet the various criteria

Consent

Many studies require a patient's consent to participate. Consent is not the form that the patient may sign, but a process. It is important that the consent is obtained in an honest open manner. Patients have the right to full disclosure of the risks, benefits, and expectations of the study that they participate in. They also have the right to refuse to participate if they wish and should at no time feel pressured to participate.

For most studies, the Research Practicum Associate can obtain consent. For studies involving treatment modifications, the physician must obtain consent. Simply remind the resident or attending to get consent.

ED Study Log

Upon starting your shift it is important to sign in on the Study Log Sheet (See Attachment). This is especially important for students receiving course credit. If you are not signed in, you did not do the shift. This will affect your final grade. Do not remove the log from the rolling study cart, or take out any of the daily sheets with the exception of the current day's data. You are expected to fill in information for each patient you screen for studies. This allows us to track if patients are participating in studies and that they have had the opportunity to participate. It also allows us to track your performance.

Tracking Boards

Grady and EUHM now both utilize electronic medical records that are tied in to electronic tracking boards. Unfortunately each site uses a different electronic medical record system with different tracking boards. We will review what information you can get from the tracking boards

Computers and Electronic Medical Records

As a Research Associate you should not be using computers in the Emergency Department. When you need to obtain information from electronic medical records, you will need to locate appropriate staff to access this information for you. Do not use anyone's accounts without them.

Military (UTC/Zulu) Time

Times in the ED should always be documented in what is called Military time. This is sometimes also referred to as UTC or Zulu time (designated by Z for short). It is useful because if you were to say it was **9 O' Clock** when you did something, no one could tell if it was 9AM or PM without more information. Using military time is simple:

All times should be written as 4 digit numbers. For afternoon and evening hours add 12 to the time. After midnight and before 1AM replace 12 with 00. Everything else stays the same. It is easiest to explain by examples.

REGULAR TIME	CONVERSION	MILITARY/ZULU TIME
1AM	NONE	0100
6:30AM	NONE	0630
11AM	NONE	1100
12:59PM	NONE	1259
1PM	+12	1300
4:30PM	+12	1630
10:45PM	+12	2245

See? Simple![4] Trust us. You'll get used to it.

[4] For those of you who care and want to get a little more technical – since Zulu/UTC is based on Greenwich Mean Time rather than the time in your current time zone 1PM in Atlanta is more properly written as 1300 UTC -5 or 1300 Z -5 indicating that you would subtract five hours to correct to the true "universal time". The latter "Z" notation is outmoded and should not be used. If you've read this far you are probably wondering why we use UTC (Universal Time, Coordinated) as the acronym instead of CUT (Coordinated Universal Time) or something that actually makes sense and would be much cooler. Chalk it up to the French. They would prefer we use Temps Universel Coordonné (TUC) and the international compromise was made to UTC to further confuse and upset everyone. UTC is based on time from an atomic clock and is off by as much as 0.9 seconds from solar time. For that reason UTC includes leap seconds to keep it coordinated to UT1 (Universal Time 1) which is based on observations from the Royal Observatory in Greenwich. UT0 is based on celestial observations from where you are currently on earth which varies from UT1 depending on your latitude. Do you feel smarter now?

Essentials

Operational Procedures for Studies

Ask physicians if they have candidates for the approved studies, and if they mind you speaking with them.

Compare their presenting signs and symptoms to the criteria for each study.

If the signs and/or symptoms fit the criteria, the patient is a candidate for the appropriate study. In studies with the requirement of informed consent, the MD or study coordinator should obtain the consent, unless otherwise specified.

Select the correct form from supplies at the SRAs' cart, or other indicated supply locations.

Locate the patient, if the patient's admission was direct to a treatment area.

Prepare necessary materials in advance. Time is of the essence. Associates should anticipate the requirements of these studies, noting any due-times.

Note: occasionally, during examination, physicians may rule patients ineligible for inclusion in certain studies, although patients appear to associates to fit the criteria. This is documented by associates in the study log. Remember only the primary care provider, usually the physician or nurse practitioner, can determine that patients are not eligible for inclusion in the study.

Record the time, patient's initials, study name, Y/N qualifying criteria, attending MD name, resident MD/NP name on the daily log sheet. These entries are appropriate for all studies, always.

Timed study notations are appropriate for specific studies.

Infection Control (OSHA 1910.1030)

Universal precautions is a common medical term. It means that, when handling or contacting body fluids, anyone and everyone is assumed to be infectious. Medical professionals have been trained in and certified as aware of the hazards, and competent in dealing with blood, urine, sputum, vomit, feces, cerebrospinal fluid, etc. All Student Research Associates have the personal responsibility to become knowledgeable of any/all body fluids, sharps (needles, test-tubes, etc.) and potentially pathogenic materials.

! * ! * !

Infection Control 1910:1030 Bloodborne pathogens

It is not only the law, and a requirement of working here. It might very possibly save your life.

! * ! * !

All Student Research Associates must cooperate in controlling the spread of infection. Procedures for the control of infection from:

patient to patient
patient to personnel
personnel to patient
from anyone/anything to you

To assist in the prevention of contamination, **good hand washing technique is essential:**

When you report & before you leave
Before and after breaks and meals
After using restroom
Before and after patient contact or
Any materials used by patients.

Use soap, hot water, and be thorough (nails, too), with vigorous friction, for 30 seconds twice. Rinse completely, dry completely. Alternatively, hand cleansing containers are located throughout the ECC. Thoroughly cleansing hands with this material is sufficient unless your hands are visibly soiled. Wash after every contact with a biohazardous material (i.e., blood or another bodily fluid).

Disposable gloves are available throughout the ED and must worn when handling blood or other specimens, used only once, and disposed of in RED-BAGS only (masks and goggles are also available). **In general, if you have to put on gloves, you are most likely overstepping your role.**

Patient Confidentiality

Under no circumstance should you ever discuss a patients' condition with anyone except the attending physician or staff and then only in treatment areas. Friends and family not participating in the program should not accompany you into the ED. Do not give patient information out even to the family members of the patient. If asked, get the nurse or physician caring for the patient to answer all care related questions.

Lateness and absences

Lateness to a shift should be avoided (as if these were your patients who depend on your presence) and must be reported to class faculty or TAs. If you know in advance you are going to be late, you should contact one of the TAs. Students will be required to make up the time lost. Please see details below for results of unexcused tardiness or absences.

If you know in advance you are going to be absent you must get a replacement for the shift. Again, students will be required to make up the time lost. Course faculty, TAs, and research staff will be spot checking at both sites. Should they be unable to locate you over a reasonable period of time during a shift, this will be reported as an absence.

Note: If you fail to sign in on the study log it will count as an absence. If you didn't record it you didn't do it.

- If another student is found to have signed in on your behalf and you were not actually there, both of you will automatically fail the class.
- If you miss a shift or class (unexcused) or are found to be substantially late, you will lose a letter grade.
- Should you miss two shifts (excused or unexcused), course faculty will automatically review your status in the program with the option of removing you from the course.

Dress Code

Student Research Associates should dress in a practical and professional manner. Shorts, blue jeans, tee-shirts, and open toe shoes are not allowed at any time in the Departments. Shirts should be collared. Student Research Associates should wear the blue lab coats ordered online (www.target.com) and hospital ID whenever they are in the ED.

Interpersonal Skills & Creating Good Will

As ED Student Research Associates, your first responsibility is to complete the requirements of the research studies. As part of the observational component of the course you will be expected to observe patient care and process elements in the ED. Prolonged observation if procedures and patients of interest should only be undertaken insofar as it does not interfere with your research responsibilities and does not interfere with patient care. From multiple years of experience with students taking this course, this is not a difficult balance to achieve. You are not allowed to examine/handle patients, give medications, or perform any medical procedures while in the ECC.

When observing patient care, it is paramount that you do so without interfering with patient care. With that in mind, **no more than one student at a time** is to be observing in the resuscitation rooms unless specifically permitted by the staff. If you are asked to move by any member of the ED staff, do so IMMEDIATELY and without any further discussion. In the MTC you should remain outside the darker tiled region on the floor at all times during a resuscitation.

If you have questions or concerns about patient care you have observed, you should ask the nurse or physician privately, in a way that does not undermine the patient's confidence in the care they have been provided nor interferes with care of patients. Usually that means after the excitement is over and after physicians and staff have had a chance to place orders and document the event on the computer. Significant class time is allotted to discussing things you see. The more you record and are able to report, the more effectively your classmates will be able to understand what you saw and faculty will be able to teach you. Take notes.

Grady Orientation

This session will most likely occur on a weekend. This will consist of a tour of the Grady ECC with a review of procedures. These will be done in small groups and will take approximately 45 minutes.

Badges

While in either of our clinical sites you are required to be wearing an ID badge at all times. Your badge must be worn above your waist and must be visible. Please make sure you are wearing the correct badge for the site that you are at.

Getting a badge requires a health screening, a criminal background check, and some additional paperwork. You will complete the request for criminal background check on-line. Items you are likely to need include:

- Immunization Records – proof of 2 MMR dates (the students will be required to have a current flu vaccination)
- Driver's License
- Social Security Card
- Documentation of completion of Grady on-line training
- Documentation of PPD (or alternatively have one placed by Grady)

Grady Volunteer Services

This course had previously worked with the Grady Office of Volunteer Services for credentialing and assistance with parking. As of Fall 2012, the Volunteer Services office no longer provides any support for this course. When at Grady for this course you must wear your course-issued ID and not a volunteer badge. You are not permitted to use volunteer parking nor other perks of being a volunteer while working as part of the course.

The Volunteer Services office coordinates a variety of volunteer opportunities within the Grady system that you might find interesting and valuable. You are encouraged to pursue volunteering within the Grady system outside of your duties within this course.

Parking

Parking vouchers at Grady will be provided. We encourage you to ride with the colleague who will be working the same shift as you, for two reasons. First, you will only have one car to find a spot for. Second, it is always good to have someone to walk with you around Grady or EUHM. Late at night, I encourage you to have security walk you to your car.

Keys/Access

At EUHM your ID badge contains an RFID chip that should allow you to open most of the doors to get into and around the Department.

You will not receive keys or RFID cards for Grady. At Grady, there are two doors in the research area, located between the Red and Blue Zones, each with their own code. The outer door's code is 1980. This will provide access to the lockers. The inner door has a cipher lock, whose code is 5620. This will provide access to the file cabinet with research files as well as the Research Associates' computer. These doors should be closed behind you when you leave.

Special Materials:

You are required to obtain a blue lab coat to be worn in the ECC. This can be obtained online at: www.target.com (search medical lab coat, light blue). You are responsible for keeping

and laundering this lab coat for the semester. http://www.target.com/Medical-Lab-Coat-Light-Blue/dp/B000BIXTDQ

You will be required to keep an observational journal for recording your clinical observations. Previous experience has shown that your selection of journal does impact the quality of observations. It is highly recommended that you use one of the following options for your journal: a ring binder containing engineering-ruled paper, a bound or spiral notebook containing graph paper, or a notebook similar to a "BlueSky ProNotes™" with lined paper facing pages of graphing paper. These options provide flexibility for including drawings and diagrams as well as lines for organizing simple charts during your shifts. Observations should be recorded in ink and should be dated, and ideally timed.

Course Curriculum

The course is comprised of several didactic lectures as well as group conferences and discussion sessions. In the initial phase of the course we provide a basic overview of clinical research and complete the needed certifications and educational components that are required before you can participate in observation and research studies in the ED. Additional brief lectures will be given as briefings for ongoing research projects. All students will participate in an intensive training program on observational technique. All students will be assigned to "shifts" in the ED when they participate in clinical observation and data collection. The remaining scheduled class time will be dedicated towards organizing the groups' observations into coherent form ultimately leading to clear problem statements and preliminary proposed solutions.

Because context is critically important to understanding of the observations you are making in the clinical environment, there will be a generous amount of time dedicated to discussion of clinical medicine. There will likely be guest lectures from clinical faculty as well as in-class visits from faculty, residents, and staff to allow you opportunities to interact with these personnel outside of the clinical environment.

As this course is still evolving, you should anticipate that we may need to deviate significantly from any particular planned content. As a participant in this course you have the

opportunity to shape both your course as well as the future of this course and suggestions, comments, and critiques are encouraged.

Grading/Assignments

Supplemental Reading Exam (a.k.a in class graded exercise)	5%
Clinical Observation Notebook (3 checks)	15%
Observational Design Processes	
Environment	10%
Process	15%
Devices	15%
Safety	15%
Clinical Case Write-Up	15%
Narrative Write-Up	5%
Course Evaluation	5%

It is assumed that all course participants will attend scheduled classes and will be present for their scheduled shifts and these items are therefore not included in the grading. Processes for missing events and associated penalties are discussed elsewhere.

As junior and senior university students, it is assumed that you have significant proficiency in written English. Although this is not a writing course, written assignments that need significant editing, revision, or re-formatting will be penalized for these deficiencies. Georgia Tech offers multiple resources to assist you in this regard, most notably the Communication Center (http://www.communicationcenter.gatech.edu/), which offers peer and professional assistance.

Clinical Observation Notebook

The Clinical Observation Notebook is your way of recording your observations and saving them for use in class activities. As such it is difficult to say what constitutes varying degrees of "goodness" in completion of the notebook. Depending on what is happening that day and your

focus for the day, your entries may vary substantially. You will be in a very busy environment for four hours. As such a small handful of data points for that time period will not be considered sufficient. Data may take a variety of forms and a single detailed drawing may provide equal insight to the events around you as a second-to-second description activities. Other types of information might best be organized in a chart. You are expected to bring your notebooks with you to class and class TAs will review your notebooks during class sessions.

Observational Design Process Papers

Through the course you will work in a small group to pool observations and identify patterns of problems. You will be expected to provide a total of five write-ups that summarize the data that you observed, your interpretation of what this data means and the resulting statement of problem. I would like you to briefly propose several possible solutions and comment on what you would expect to see change if the solution were implemented and you returned to observe. More details of these write-ups will be provided in class. For those of you who have not yet started the Senior Design course, it is hoped that some of these write-ups may become the basis for senior design projects in future semesters.

Approximately two weeks before your final assignment is due, you will be expected to turn in and present your "problem statement". The issue of what makes a good problem statement will be addressed in an in class lecture.

Presentations will be expected to follow a modified "pecha kucha" format. The pecha kucha format is 20 slides with 20 seconds per slide. For this course you will only be allowed 10 slides. You will prepare PowerPoint or similar slides with the presentation set so the slides change automatically after 20 seconds. This format forces limits on the length of each group's presentation. For most it requires some rehearsal and preparation. Although problem statements and presentations are not independently graded, particularly good presentations might benefit your assignment grade while particularly poor ones will harm it.

Problem statements likewise are not independently graded. Turning in a problem statement affords you an opportunity to get some feedback on your direction. A poorly

constructed problem statement, as it appears in your turned-in assignment, is the surest way to get a bad grade on the assignment.

A synopsis of the topics is as follows:

Environment/Furniture

A wide variety of factors affect us psychologically and physiologically. In clinical environments we frequently overlook the broad range of factors that can be modified for patient comfort as well as to improve clinician performance. Would a more comfortable chair result in decreased physician fatigue or does it result in decreased efficiency due to increased time spent sitting? Does organization of supplies effect patients?

Systems and processes

Complex systems often evolve. Sometimes systems evolve to where previously essential components now are superfluous. Sometimes a process is adopted by default. Processes have potential to cause errors and delays that may not always be apparent to those who use them.

Safety

Safety in clinical systems is paramount. In a busy clinical environment there are many potential dangers. These include medication errors, delays in diagnosis or treatment, injury from supplies and equipment. As the final write-up you are encouraged to dredge through your now extensive experience to identify a problem that impacts the safety of patients and/or staff. Potential topics include process and environmental changes as done in the previous write-ups, devices, training and education, or any combination of these.

Devices

As a biomedical engineering student you spend most of your academic effort learning about the engineering principles that go into designing devices. Now, as you are being exposed to a working clinical environment, do the existing devices work as intended?

Are there devices that frequently fail in this environment? Is there a need for which there is not an existing device?

Clinical Case Write-Up

Each student is required to complete a clinical-case write-up. While in the emergency department, you are required to find a patient complaint or condition of interest to you. You might look and listen for patients that the residents and attendings are engaging in longer discussions as to their care and management as this will afford you with additional information about the patient and the care of their condition. It is not important if the patient's condition is unusual.

The three required elements of this assignment are:

1. a medical history on this patient
2. an observational narrative of their stay in the ED. You are expected to tell the story of what happened to, near, and relevant to the patient.
3. a discussion how the issue you identified in one of your observational design processes affected this patient and speculate on how your proposed design might have improved their experience.

Your medical history should include the following:

Age and circumstances of ER visit (weekend, evening, etc)

Chief complaint and history of present illness: this is a history of why the patient decided to come to the emergency department, the duration and type of symptoms they are having, the changes they have noticed, and any other pertinent information they have noticed.

Past medical history: any chronic medical conditions with which the patient has been diagnosed (hypertension, HIV, heart disease, etc.)

Medications: Any medications that the patient is currently taking. This may include over the counter medications (vitamins, etc)

Physical examination and diagnostics: Miscellaneous testing (laboratory or imaging) or pertinent findings that have led to the patient's diagnosis. You may need to speak to the patient's physician or review their medical record in order to obtain details of this. You are not to perform any physical exam yourself, but you may observe an exam performed by staff if the patient has consented.

Final diagnosis

Do not include specific identifying information such as the patient's birth date, address, name, or date of service.

Narratives

You will create a total of two narratives based on your observations. This is part of your clinical write-up (above) and a separate narrative assignment. Details will be posted on t-square.

A narrative is a story. Your narratives need to tell a story. They should have a beginning, middle, and end. They should have at least one character. Your narratives should not describe a simple sequence of events; it should paint a picture of the events and the context so that your reader can better understand what happened.

Telling stories is a critical communication skill. Improving your story-telling skills forces you to become a better observer.

Attendance

Attendance at all class meetings is essential. If you are late by more than 10 minutes you are considered absent. Because I cannot realistically verify that every student is present for every shift, instructors and TAs will be doing spot checks. Each unexcused/uncovered absence from class or your clinical shift will decrease your grade one grade. If schedule changes are desired, it is the responsibility of the individual(s) signed up for a particular shift to find coverage (switch) for that shift. However, a minimum of 2 clinical shifts per week are required by each person unless prior approval is obtained (batching or stacking shifts must be approved by the course coordinators and must not leave a hole in the schedule).

Professionalism and Behavior

There is no excuse for inappropriate or unprofessional behavior.

ANY

UNPROFESSIONAL OR INAPPROPRIATE BEHAVOIR REPORTED TO COURSE FACULTY MAY IMPACT YOUR GRADE OR MAY CAUSE YOU TO FAIL AND/OR BE REMOVED FROM THE COURSE

Based on past experience most issues have been minor misunderstandings or lapses in judgment and a single infraction may be overlooked. Repeated reports from separate occasions from multiple sources are unlikely to be excused. Those infractions that are not judged to be isolated minor occurrences will result in the loss of a letter grade for each incident. Any significant issue related to patient or staff safety, patient privacy, or illegal behavior will result in a failing grade and immediate removal from course activities, even if it was an isolated incident. You will be given the opportunity to explain the incident prior to any finalized judgment.

Honor Code

In this course plagiarism is the most likely source of Student Honor Code violations. Students are cautioned to be mindful that the submission of material that is wholly or substantially identical to that created or published by another person or person, without adequate credit notations indicating authorship constitutes plagiarism. When you refer to work of other people in your reports make sure you use proper reference citations.

It is possible to plagiarize yourself by "reusing" your own work. Published work and work handed in for other courses can be referenced and reused for this course but proper attribution must be provided.

In fairness to the honest majority, **ALL** incidents of suspected academic misconduct will be reported to the Office of the Dean of Students.

CITI Training

All students MUST complete Human Research Ethics training through the CITI Training site in order to participate (http://www.citiprogram.org). You must add Emory as a site on your CITI account and you must complete the Emory version of the course. YOU MUST PRINT OUT YOUR COMPLETION CERTIFICATE to a PDF file at the end of your training and turn it in via T-Square.

Textbooks and readings

The prior CRP course used *Designing Clinical Research* by Cummings et al. Third Edition as its text. This text is an excellent reference an introduction to clinical research which you may wish to read for better context on the research studies, but the text will not be required.

The content of this course follows a path that is very similar to that found in the first 2 chapters of *Biodesign: The Process of Innovating Medical Technologies* by Zenios et al.

Additional readings will be distributed in class or electronically via e-mail and/or T-square. A variety of other references are listed on T-square for those who are interested.

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