

BME 580.480/680 Precision Care Medicine



Course Instructors:

- Raimond L Winslow (rwinslow@jhu.edu)
- Sridevi V Sarma (ssarma2@jhu.edu)
- Joe Greenstein (jgreenst@jhu.edu)
- Adam Sapirstein (asapirs1@jhmi.edu)
- Veteran TAs
 - Hanbiehn Kim (hankim@jhu.edu)
 - Hieu Nguyen (hnguye78@jhmi.edu)

Project-Based learning course, part of the new “BME 2.0 Curriculum”

We will turn you into “forged steel” by ***working with real healthcare data to solve real healthcare problems***

2019 – 2020 Projects

Advanced Risk Stratification and Prediction of Venous Thromboembolism in Critically Ill Patients

Biomedical PIs: Sapirstein (asapirs1@jhmi.edu) & Faraday (nfarada1@jhmi.edu)

Engineering PIs:

Risk factors for neurologic injury and mortality in critically ill children supported on ECMO

Biomedical PIs: Bembea (mbembea1@jhmi.edu)

Engineering PIs:

Predicting Acute Kidney Injury after elevated risk non cardiac surgery

Biomedical PIs: Goeddel, Metkus, Dodd-O, Fine, Moeller, Faraday

Engineering PIs:

Predicting respiratory decompensation in Pediatric ICU

Biomedical PIs: Fackler, Bembea, Bergmann

Engineering PIs:

Delirium Prediction and Subtype Identification Using a Large Multi-Center ICU Database

Biomedical PIs: Stevens & Suarez

Engineering PIs:

A Computational Model to Predict Neurological Recovery Following Moderate and Severe TBI

Biomedical PIs: Stevens & Suarez

Engineering PIs:

Examining the Natural History of ADHD in a Clinical Setting

Biomedical PIs: Kalb & Holingue

Engineering PIs:

Syllabus

Thursday August 29 (Introductory Lecture & Meet the Faculty; Winslow)
Wednesday Sept 4 (Probability Theory; Sarma)
Monday Sept 9 (1)
Wednesday Sept 11 (Maximum Likelihood Estimation; Sarma)
Thursday September 12 (Meet and Greet with ACCM Faculty and Dr Koch)
Monday Sept 16 (2)
Wednesday Sept 18 (Data Pre-Processing & Exploration: Winslow)
Monday Sept 23 (3)
Wednesday Sept 25 (Special Impact Session)
Monday Sept 30 (4)
Wednesday Oct 2 (Class time for developing work plan, preliminary results, plan presentation)
Monday Oct 7 (5)
Wednesday Oct 9 (Generalized Linear Models; Sarma)
Monday Oct 14 (6)
Wednesday Oct 16 (Binary Classification; Winslow)
Monday Oct 21 (7)
Wednesday Oct 23 (Team Presentations on Project and Work Plan)
Monday Oct 28 (Detecting Transition Events; Winslow)
Wednesday Oct 30 (Hidden Markov Models; Sarma)
Monday November 4 (Class time used for project work)
Wednesday November 6 (Class time used for project work)
Monday Nov 11 (Class time used for project work)
Wednesday November 13 (Class time used for project work)
Monday November 18 (Class time used for project work)
Wednesday November 20 (Class time used for project work)
Thanksgiving Break November 25 – December 1 2019
Monday December 2 (Class time used for project work)
Wednesday December 4 (Class time used for project work)
Friday December 6 last day of classes

Grading

- Grading policy
 - 10% weekly PI meeting assessments
 - 15% quizzes
 - 25% mid-term project plan
 - 25% mid-term progress presentation
 - 25% final term progress presentation



SECTION I: OVERVIEW OF RESEARCH COMPLIANCE COURSES

Human Subjects Research at JHU

The Institutional Official who has authority over the JHM Human Subjects Protection Program is the **Vice Dean for Clinical Investigation**. The current Vice Dean for Clinical Investigation is **Dr. Daniel E. Ford**.

The Johns Hopkins Medicine Institutional Review Boards (JHM IRBs) are responsible for protecting the rights and welfare of the human subjects of research conducted by faculty and staff at the Institutions. The JHM IRBs review all human subjects research projects conducted by Hopkins faculty and staff. To fulfill the agreement underlying the assurances, and to satisfy institutional policy, all faculty and staff at the Institutions must submit for JHM IRB review any human subject research project, regardless of funding source (or lack thereof) and/or location at which the research will be conducted.

The IRB Website

Overview of the IRB Website

- ▶ IRB is completely electronic for all transactions
- ▶ **Website:** <http://irb.jhmi.edu/eIRB/>
 - To log onto the eIRB website, use your JHED ID and password)

IRB Compliance Training

- ▶ **Website:** https://www.hopkinsmedicine.org/institutional_review_board/training_requirements/
- ▶ PIs and study team members are required to complete IRB compliance training prior to submission of a human subjects research eIRB application
- ▶ For eIRB applications that are determined to be not human subjects research (NHSR), IRB compliance training is not required
- ▶ If the required courses have not been completed by the PI and all study team members prior to submission of the application, the application will be returned to the PI

IRB Compliance Training Courses Overview



1. Basic Human Subjects Research (BHSR)
2. Conflict of Interest and Commitment (COI)
3. Health Privacy Issue for Researchers (HPIR)

Who needs it: PIs and study team members listed on a Convened/Expedited/Exempt eIRB application

Exceptions: PIs and study team members listed on a Non- Human Subjects Research (NHSR) eIRB application are not required to complete BHSR compliance training

Basic Human Subjects Research (BHSR)



Basic Human Subjects Research (BHSR):

- ▶ This online course provides a broad overview of the ethical background for regulations in human subjects research, as well as an overview of the IRB review requirements to be met before a human subjects research project may begin. This course is administered through the Collaborative Institutional Training Initiative (CITI)
- ▶ The IRB will accept CITI training certification completed at another institution. The IRB training specialist will review your previous training to determine that it meets all of our IRB requirements. If the compliance training certificate is more than three years old at the time of IRB submission, PI's and study team members will be required to take the JHM BHSR course.

Conflict of Interests and Commitment (COI)



Conflict of Interest and Commitment (COI)

- ▶ This online course is designed to introduce researchers to the topic of financial conflicts of interest in research, including what financial conflict of interest means, sources and risks of financial conflicts of interest in research, federal regulations and institutional policies designed to address the risks, and researchers' obligations under the regulations and policies
- ▶ The federal government's regulation on conflict of interest (COI) in research, which is intended to promote research objectivity, was revised in August 2012. This course is designed to fulfill the training requirements included in the regulation and in Johns Hopkins policy.

Health Privacy Issues for Researchers (HPIR)



Health Privacy Issues For Researchers (HPIR):

- ▶ This online course covers specific HIPAA requirements for research involving health information. This new course replaced “HIPAA for Research.”

Registration

How Do You Register?

You must register for the required courses on the Hopkins myLearning website at:

<http://training.jhu.edu/ComplianceTraining/>

Steps for Registration

On the first screen you will be asked a few questions to determine your required courses, and then will be instructed to log in to MyLearning to register for these courses

- ▶ On the drop down list select “Johns Hopkins Hospital”

If you are going to be the PI, click “yes” to the first 2 questions

If you are going to be a study team member, click “yes” to first question

After answering the 5 questions that appear (next slide), the 3 compliance training courses will appear in the lower left of your screen. You can select the courses and enroll in each of them

Registration

Questions

The following questions will be asked:

- ▶ Engaged in human subject research***this answer is “Yes” for students***
- ▶ Plan to be PI***this answer is “No” for students***
- ▶ Previous notifications from Clinical Research Support Services***this answer is “No” for students***
- ▶ Previous notifications from Clinical Management Services***this answer is “No” for students***
- ▶ Research under purview of Stem Cell Research Oversight Committee***this answer is “No” for students***

 **JOHNS HOPKINS MEDICINE** **SOM/SON/JHH/JHCP/HCGH/SH/SMH Human Subjects Research Compliance Training**

This questionnaire will help you determine the courses you must complete for Human Subject Research Compliance Training. You must answer all of the following questions for an accurate assessment of your course requirements.

Answer all of the following questions:

Are you or do you plan to be engaged in human subjects research? Yes No

Are you or do you plan to be a principal investigator? Yes No

Have you been notified by Clinical Research Support Services that you must take clinical research billing orientation? Yes No

Have you been notified by Clinical Research Support Services or Clinical Research Management System that you must take clinical research management system training? Yes No

Are you conducting or do you plan to conduct research that is under the purview of the Institutional Stem Cell Research Oversight Committee? Yes No

Compliance Training Courses

Basic Human Subjects Research (CITI)
HIPAA for Research
Conflict of Interest and Commitment
Responsibilities and Duties of Scientists (REWARDS)

When you are satisfied with your answers, click the Done button.

Registration

Selection of Courses

From this screen, you can click on each course and enroll through MyLearning.

The screenshot shows a web page titled "Human Subjects Research Compliance Training" from Johns Hopkins Medicine. At the top, there is a logo for Johns Hopkins Medicine and the text "SUM/SUN/JHH/JHCP/HUGH/SH/SMH". Below this, a section titled "Answer all of the following questions:" contains five questions related to research compliance. To the right of these questions, a red box highlights a list of steps for enrolling in courses. A larger red box highlights the "Compliance Training Courses" section, which lists "Basic Human Subjects Research (CITI)", "HIPAA for Research", and "Conflict of Interest and Commitment". At the bottom of this section is a button labeled "Enroll in Selected Course".

This questionnaire will help you determine the courses you must complete for Human Subjects Research Compliance Training. You must answer all of the following questions for an accurate assessment.

Answer all of the following questions:

Are you or do you plan to be engaged in human subjects research?

Are you or do you plan to be a principal investigator?

Have you been notified by Clinical Research Support Services that you must take clinical research billing orientation?

Have you been notified by Clinical Research Support Services or the Office of Management System that you must take clinical research management?

Are you conducting or do you plan to conduct research that is subject to Institutional Stem Cell Research Oversight Committee?

Compliance Training Courses

Basic Human Subjects Research (CITI)

HIPAA for Research

Conflict of Interest and Commitment

You are required to take the Compliance Training courses listed on the left side of the screen. To enroll in these courses, please do the following:

1. Select one of the courses on your list.
2. Click the "Enroll in Selected Course" button.
3. A pop-up window will open. Within this window, log into "myLearning" by entering your JHED ID and password. If you are not affiliated with Hopkins, please contact your Principal Investigator's department administrator to assist you with obtaining a JHED ID.
4. Enroll in the course (and add it to your Learning Plan) by clicking the "Add to My Plan" button. (Please note: REWARDS registration is outside of "myLearning." Follow instructions on the registration form.)
5. Toggle back to this window.
6. Repeat steps 1-5 with the remaining courses on your list.

Once you have completed this process, you may begin taking the courses that you added to your Learning Plan. (Note: Once you have completed REWARDS, it will be listed in your history along with all other completed courses.)

Designed by Learning Solutions @ The Johns Hopkins University

MyLearning

Selection of Courses

MyLearning will track your course completion. The BHSR course is administered through CITI.

- Click on “My Learning History” on the left side navigation to obtain a copy of your course completion report. You may be asked to give a research coordinator a copy of your course completion report to be uploaded on an eIRB application the first time you are a study team member.
- ***Only you can access course completion reports in MyLearning. Administrative coordinators and research coordinators cannot access these reports or dates of completion.***

The JHU Data Trust

The Data Trust Council, established in 2013, has taken on the important task of creating systems and policies to ensure Johns Hopkins Medicine data are both useful and safe.

Ten analytics teams, with 140 people total, coordinate the flow of data between categories, including ambulatory quality, hospital operations and research. Working together, the teams “assure we are a data-driven organization with well-coordinated analytic efforts,” says Valerie Smothers, Data Trust coordinator for Johns Hopkins Medicine.

Members of the JHU Data Trust have “blessed” the use of data in this course under the guidelines to be put forth by your project mentors

Travel to East Baltimore

- Mondays will be at Bensen Library (Zayed 6206), Zayed Towers, East Baltimore
- Shuttle, and Winslow, Sarma, Greenstein cars

Teams

- Teams of ~ 5
- Team leader – grad student in data science or computational medicine area
- Mix skills and levels
 - Undergrads vs grads
 - Biology vs engineering majors

To Do's

- Do the online course training and send completion documentation to Drs. Winslow & Sarma
- Review the projects. Email Drs. Sarma, Winslow & Greenstein your rank ordered preference for projects in descending order. We will assign projects.
- Arrange your first meeting with Project PIs. Meet week of Sept 8th and every week after.
- cc Dr. Greenstein on all meeting arrangements because he will attend each

To Do's (cont)

- First big goal – project proposal/work plan due Wed Oct 17
- Review these online course materials as they will help you with cardiovascular physiology:
 - <http://oacapps.med.jhmi.edu/CVlectures/index.html>



Click on the links below to view the Video

[Cardiovascular Framework \(Shoukas\)](#)

[CV Systems Integration Part 1 \(Shoukas\)](#)

[CV Systems Integration Part 2 \(Shoukas\)](#)

[The Autonomic Nervous System in Cardiovascular Regulation \(Schramm\)](#)

[CNS Regulation of the Cardiovascular System \(Schramm\)](#)

[The Physiological Response to Hemorrhage \(Shoukas\)](#)

[The ECG \(Kass\)](#)

[Study Answers \(Shoukas\)](#)

Special Event

- “Meet and Greet” in East Baltimore Dept Anesthesiology and Critical Care Medicine, hosted by Dr. Colleen Koch, Dept. Director
- Arrive at XPM to complete HIPAA paper work and get into scrubs
- Tour operating rooms, SICU, NCCU
- Meet faculty
- Sept 12 4:00PM Benson Library Zayed 6206