

2.75J (H), 2.750J, 6.025J, 6.252J, HST.552 (UG CI-M AUS) Medical Device Design – Spring 2022 Syllabus

Units: 3 - 0 – 9

Prerequisites: One of the following – 2.007, [2.008](#), 2.009, [22.071](#), 6.101, 6.111, 6.115 or permission of instructor

Updated: 7 January 2022

This course: Provides an intense project-based learning experience around the design of medical devices with foci ranging from mechanical to electro mechanical to electronics. Projects motivated by real-world clinical challenges provided by sponsors and clinicians who also help mentor teams. Covers the design process, project management, and fundamentals of mechanical and electrical circuit and sensor design. Students work in small teams to execute a substantial term project, with emphasis placed upon developing creative designs - via a deterministic design process - that are developed and optimized using analytical techniques. Instruction and practice in written and oral communication provided. Students taking graduate version complete additional assignments. Enrollment limited.

To take this class, all students are required to read this syllabus in its entirety: taking the class implies that they have read and understood all the requirements.

Teaching Staff

MechE Instructor	MechE Instructor	EE Instructor	MechE/IMES Instructor	Comm. Instructor
Dr. Nevan Hanumara Room: 3-470 Phone: 617-258-8541 hanumara@mit.edu	Prof. Gio Traverso Room: 3-340 Phone: 617-417-8061 cgt20@mit.edu	Anthony Pennes Room: 38-575/38-501 Phone: 845-219-6691 ampennes@mit.edu	Prof. Ellen Roche Room: E25-344 Phone: 617-258-6024 etr@mit.edu	Dave Custer Room: 24-611 Phone: 617-253-2872 custer@mit.edu
Comm. Instructor	Admin. Guru	Design Guru	MechE Instructor	TA
Mary Caulfield Room: E18-240B custer@mit.edu	Irina Gaziyeva Room: 3-461 Phone: 617-253-5592 igaziye@mit.edu	Coby Unger cobyu@mit.edu	Alex Slocum (on leave) slocum@mit.edu	Keegan Mendez kmendez@mit.edu

Website: <https://meddevdesign.mit.edu>

Materials: <https://web.mit.edu/canvas>

Wiki: <https://wikis.mit.edu/confluence/display/275/>

Lecture: Monday & Wednesday 13:00 – 14:30 EST

Room: 3-270

This class emulates a real-world product development effort, with students working in fast paced, professional R&D teams to develop a proof of concept prototype. Lectures cover fundamental mechanical and electrical engineering concepts, as well as industry specific topics and case studies. Attendance is expected at all on-line lectures and students should review materials pre-and post and ask questions. Good term projects have often resulted in published papers and sometimes real products, which is a huge boost to one's resume!

Course e-mail lists

Students agree that these e-mail lists will be strictly limited to course use only.

2.75-2022@mit.edu Contacts the entire course students and staff

2.75-staff@mit.edu Contacts the course teaching staff

Teams are asked to create their own internal e-mail lists, with or without their project sponsor, and post them to the Wiki.

Team Term Project

The goal of the project is to follow a deterministic design process to rapidly and efficiently develop a proof-of-concept prototype device that addresses a real need, demonstrated during the final on-line presentations and documented in a journal format written paper.

Students will work in small 4 – 5 person teams to execute a substantial, health-focused project, which spans the entire term. Potential projects are presented by clinicians and companies in the second week of term and students are asked to *individually* rank

their preferences, considering where they can contribute the most. Teams are then formed by the staff, based on student preference and skills. Given the wide array of student interests and expertise, there have been few past difficulties in satisfying everyone.

Please understand that given the project-clinician/proposer relationship, small teams and aggressive schedule, signing up for a project constitutes an implicit agreement NOT to drop the class.

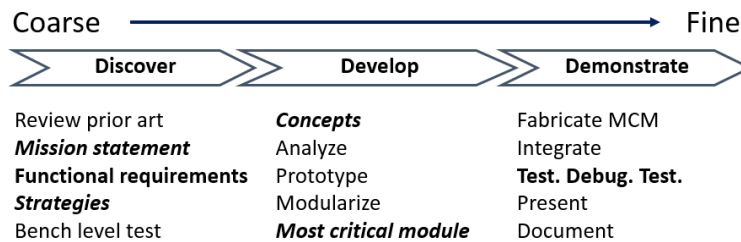
Project mentors have committed to being accessible, are ready to engage with you on a regular basis and will truly be part of your team! Let the staff know if you have any issues interfacing with your mentors.

To help maintain a fair pace, consistent with the units for the class, tasks for each person to complete before the next meeting will be set each week and recorded on the team wiki. At the next meeting, progress made by each team member will be recorded by the team mentor. This will help all members stay focused, ensure work balance between team members, and help achieve grading fairness.

Note: Because full participation in the project is integral to the class, listeners cannot be accommodated. Students CANNOT take 2.75 and another major lab/product development class in the same semester, nor a class that overlaps time wise.

Together, teams will follow a deterministic design process which fosters creativity inspired/guided by analysis but eschews shoot-from-the-hip design (this is NOT a hackathon class.) The project process is roughly broken up into thirds:

1. **Discover** – Problem presentation by client, team formation, detailed problem understanding, investigation of prior art, definition of functional requirements and exploration of possible solution *strategies*.
2. **Develop** – With a specific *strategy* selected, specific *concepts* are developed, analyzed and tested. The design is divided into modules and attention focused on the *most critical*.
3. **Demonstrate** – The entire system is fabricated, integrated and tested. Proper documentation is an important, oft shortchanged, step that begins the *design history file that documents the design’s development*, essential for any quality product (e.g., ISO 9000) and especially for medical products (FDA requirements).



Three-phase, 14 week deterministic design process

Throughout the deterministic process, all decisions must be backed up by appropriate analysis, experiments, and [PREP – Peer Review Evaluation Process](#), where each team member keeps a detailed design notebook (and peers review each other’s work. In the event that IP results, inventorship must be corroborated by individuals’ notebook entries.

Failure IS defined as a non-working prototype (if can be built this semester, else “paper design”) and no idea why it failed. Failure is NOT defined as a prototype that functions, but conclusively demonstrates that a concept will not meet clinical requirements. The former is lack-of-focus and the latter is research.

Teams are expected to meet every week with their project mentors, at a mutually convenient time.

Weekly Team Mentor Meetings

Each team will be assigned two course staff mentors who will meet with teams and the project mentor weekly to review progress, brainstorm/solve project design problems and locate resources. In order to maximize productivity and minimize frustration, it is critical (and good professional practice) for each team to meet before the mentor meeting, *peer review* their ideas and prepare an agenda that addresses three key questions:

1. What did you do last week?
2. What will you do this coming week?
3. What resources do you need?

In the context of questions 1 and 2, every week one or more overall project milestones will be due. We will require students on Canvas to evaluate how well they achieve their milestones as well as their teammates' milestones. This will help us keep each other accountable and to set realistic goals.

At the end of each mentor meeting teams and mentors, together, will identify and assign the action items for the next week. Holding each other responsible is key to a fair distribution of workload among team members and across the semester. Yes, mentors can get action items too!

Each team member is required to maintain individual notes and teams must also take weekly notes and post them the Wiki.

Bottom line, the better prepared a team, the more the mentors can help the team achieve a successful and satisfying conclusion!

Teamwork

Teamwork is central to functioning of this class and any modern engineering endeavor and it is expected that students will work together in a *safe, professional, and collegial manner* as defined in MIT's policies and procedures, especially 9.0 "Relations and Responsibilities Within the MIT Community," <http://web.mit.edu/policies/9/>.

During the first weeks of teamwork, please identify any perceived problems with your team's dynamics promptly, and bring them to the attention of your team members and/or course staff, who will help resolve issues. This is important in the professional world where there are no "safe spaces" and issues must be addressed politely and proactively. We can help make $1/\otimes = \odot$.

COVID-19 Policy

This is policy is subject to change based upon MIT guidelines and instructor discretion.

We will make every CDC/MIT approved effort to ensure that this course remains in person. In order to accommodate anyone who may be unfortunately quarantined (student or instructor) we are planning to stream the lectures in real time. If someone is quarantined and physically able, we do expect attendance. If anyone is quarantined, because we are all professionals, please communicate with the instructors and your team. The instructors agree to do the same. While we can't anticipate every scenario this Spring, we can promise to be flexible and work with individuals and teams to succeed together.

Peer Evaluations & Midterm Review

In addition to the weekly checks, just before midterm, an anonymous peer review will be conducted using the [CATME tool](#), developed at Purdue. The results will be reviewed by the course staff who will intervene as needed to help improve team performance. Grades, as an indicator of performance thus far, will be provided to each student along with constructive feedback. Consider this a performance review – it does not define your final grade but can help with focus and direction if needed.

At the end of the course, team members will again review each other and the combined ratings can be used to adjust individual grades by up to a full letter. To be clear, the focus is on professional performance, not popularity.

Quizzes

There will be frequent, 5 – 10 minute quizzes in Canvas, opened at the beginning of some lectures, based on the pre-reading or the previous lecture's content. These are designed to reinforce the lectures, as well as provide important feedback to the instructors. They should not cause undue stress and the two lowest quizzes will be dropped.

Labs

During the course there will three lab assignments:

1. Design, build, and test a kinematic coupling (KC) which demonstrates the principles of exact constraint design, important for any mechanical device. (Hobby Shop, safety training required, with help sessions scheduled)
2. Design, build, and test a simple, non-invasive electronic heart monitor – the ECG, which uses electrodes and circuitry, to detect and report heart rate. (EECS Lab, safety training required, with help sessions scheduled)
3. Syringe pump lab with an individual at-home preparation assignment, followed by an in-class build session. (in-class)

The objective of both labs is to help familiarize students with knowledge, tools, equipment, and hands-on skills needed for R&D in the field of medical devices.

Although materials for the two lab assignments will be provided, though students are welcome to use their own supplies and be creative! Because good design demands a process (measure twice, cut once) the labs will be completed in two parts: First a written proposal with engineering drawings must be submitted, and then following build and test, a brief lab report and on-line demonstration, posted to Canvas. Both can also be posted on your personal websites, and in the past, they have had a very positive

impact on student's ability to get the good job they were hoping for. Accordingly, labs will count as substantial portion of the course grade.

Prototyping & Budget

Each team will have a budget of about \$2,000 (exclusive of MIT overhead) to develop, prototype, and test their solution. Legitimate expenses include components, machine shop services (must get an estimate for cost of job), local travel (mileage, taxi...), etc. You cannot charge food under any circumstances.

Your mentor will guide you in efficient use of your budget. Remember, your time has value, thus there is a tradeoff between your fabricating (which will be difficult as parts need to be secured on-line but extreme care must be exercised because the budget can be rapidly depleted with on-line services) and sourcing outside components. Remember the three D's: Deliverables – Deadlines – Dollars!

Irina Gaziyeva will administer team accounts and oversee purchasing procedures and guidelines. Students will be asked to use standard class ordering procedures and are *required to provide all order confirmations and packing slips to Irina Gaziyeva*. Please appoint a single person to manage the budget and coordinate with Irina. Teams are required to track their expenses on their Wiki. If Irina is missing a receipt from a team, the team will be missing a final grade at the end of the semester! So whenever an order is placed, c.c. Irina with the team name. Whenever a receipt is obtained, cc Irina or write team name on it, scan it, and email it to her.

If you buy something local you need to use the MIT tax exempt number, as you cannot be reimbursed for sales expenses. Any purchasing questions, ask Irina! This is an MIT requirement for audit purposes. *No packing slip, no grade!*

The course staff has many contacts with helpful vendors that are able to accommodate the needs of prototype projects (the cheapest vendor is not always the best ...) and we are happy to have new suggestions. When in doubt, ask!

Facilities

Since each project is different, staff will work individually with teams to ensure that they obtain the necessary resources. Benches, for immediate use, and lockers for storage are available in 38-501.

Teams are welcome to use any other safe lab / fabrication facilities that they have access to and permission to use. Please consult MIT COVID guidelines around accessing fabrication spaces.

Some available resources might include (students need to check to see if access available this Fall).

[Mobius](#) - Can help you locate and access some of the campus' 45 major maker spaces.

[MIT Hobby Shop](#) – Semester membership provided to students in 2.75. Safety training required – contact Coby.

[EECS Lab](#) (38-501) – bench space, instruments, tools, and proto boards available. Safety training required – contact Anthony.

open hours~ M-F 9am-11:45pm and Sunday 1pm-11:45pm.

[Metropolis](#) (6C-006B) – General fabrication, laser cutter, etc.

[Edgerton Center Student Shop](#) (6C-006) – Open to all MIT students - Safety and machine operation training required.

[MakerWorks](#) - LMP (35-122) – Restricted to Mechanical Engineering students, safety training required.

Teams are responsible for keeping all workspaces clear and returning equipment to the proper storage to avoid access revocation.

NOTE: BeaverWorks should not be used for course 2.75 projects.

Fabrication spaces – to find more spaces, consult [Our Network » MIT Project Manus](#).

Meeting Spaces - Teams looking for spur of the moment meeting locations are recommended to use the QuickRoom tool:

<https://classrooms.mit.edu/classrooms/#/quickroom>

Note: Projects requiring cell / tissue / BL2 work should coordinate with the instructors to access approved spaces.

If there are any questions / doubts regarding fabrication or safety - ask the course staff immediately.

Documentation

Documentation is especially important to the medical device industry for the purposes of establishing a *design history file*, which is required for regulatory approval, establishing inventorship and building an IP portfolio.

Notebooks

Each student is expected to maintain a paper or digital design notebook with sketches, calculations, pictures, etc. that document their individual contributions, late night ideas and general project notes. These may be reviewed during mentor meetings and factor into grading. Instructors also keep notebooks, which they update during meetings and presentations and use them to help manage the teams and document their own contributions. *Notebooks document the design's development*, essential for any quality product (e.g., ISO 9000) and especially for medical products (FDA requirements).

Canvas

Canvas will be used for syllabus, lab materials, zoom links and recordings (where applicable), quizzes, surveys and class announcements.

Wiki

The course Wiki serves as a long-term project archive, independent of Google, Dropbox, etc. where each team must create and maintain their page. Weekly teams must document their progress of their project with notes from internal, project proposer and mentor meetings posted to the Wiki. Key design decisions, important milestones, decision matrices, images, papers, etc. should be posted to the Wiki. This Wiki is viewable by everyone in the class and instructors will use it to track team progress. You are encouraged to look at past projects for inspiration and organization!

All project deliverables are “turned in” by posting to the Wiki, including in-class and final presentations and written deliverables.

Intellectual Property

IP is sometimes generated in this course, and thus it is essential that all team members (clinicians and instructors included) keep bound, signed, dated and ideally witnessed design notebooks to record individual contributions. Not everyone will necessarily be an inventor, but the more engaged a team member is, the greater the likelihood that he or she will contribute specific features (claims) to the IP and, thus, be formally considered an inventor. Whether or not you are an inventor has no effect on your grade, because you can be a person who helps reduce an idea to practice and thus be a critical team member and journal paper author even though you might not in the legal sense be an inventor. IP and any royalties (this is an extremely rare occurrence) will be shared amongst the inventors and their institutions. IP created by students in an MIT course is considered property of the students, however, the inventors may decide it is best for it to be assigned to the MIT Technology Licensing Office for prosecution.

If a staff member is an inventor, then MIT policy states that the IP belongs to MIT and inventors share any future royalties in accordance with [MIT TLO policy](#). NOTE “getting a patent” is expensive and useless unless team members are dedicated to on their own time following up development of the idea. It is exceedingly rare that an idea worked on for a single semester is ever simply adopted by a company and turned into a product. It is far more valuable in general for a team to do a great project and then publish a peer reviewed article on how the idea was developed, and then maybe one day it is picked up and built on (and referenced). The [MIT Emergency Ventilator Project](#) began with a 2.75 project from 2010.

Communication

This is a communication-intensive course where all students are required to communicate as professionals, both in writing and during on-line presentations and design reviews. For undergrads this fulfills the CI-M requirement and can be used in place of 2.009. For graduate students the communication requirements are an important part of professional development.

The communication requirements are fulfilled in the context of each team’s project and include:

- Weekly peer review of each other’s work in design review meetings (with the instructors).
- In-class strategy presentation
- In-class concept presentation
- In-class *most critical module* review
- Final presentation video and in-person
- Final paper & one-page project description.

Further details and presentation guidance will be provided during the term.

Presentations

The in-class course presentations are intended to be conducted in the manner of design reviews. Quickly introduce or remind everyone about your project and then dive into an update of the most critical details and the current challenges that the teams if facing. Then be sure to leave ample time for discussion – this is your chance to harness the “hive” and receive fantastic feedback from the entire class, students and instructor alike.

Final presentations should present the project’s arc and an honest evaluation of the results. We invite industry visitors to these presentations and their questions and written feedback has been invaluable to projects and helped final papers become publications. These will be a combination of recorded and live and we will provide further guidance during the semester.

Final Paper

Each team will write a journal format, publication-quality, final paper. This must follow the guidelines of an established journal, i.e. the [ASME Journal of Medical Devices](#), [ASME Journal of Mechanical Design](#) or [IEEE Transactions on Biomedical Engineering](#). As you conduct background research for your project, you will encounter many good examples of “A” papers.

This adds structure, facilitates brevity and has enabled many past teams to successfully submit their work for publication!

Write early and write often: It is critical to write as-you-go to prevent last minute panic, i.e. but the end of September every team will be able to write their background section. Therefore, ideally by the end of the term only editing will remain. Teams will also write a 1-page executive summary or make a project brochure.

By the end of the course, we expect every student to become comfortable talking about their work and, effectively, be ready to give a podium presentation at a conference. The communication instructors are resources to help each team and individual to develop their communication skills; please reach out as needed.

Recommended Texts

1. FUNdaMENTALS of Design, A.H. Slocum, posted to the course website. This is a MUST download and read (as well as the design spreadsheets). Carefully reading and comprehending this design knowledge will lead the greatly enhanced design happiness in the class and in your professional design career.
2. Precision Machine Design, A.H. Slocum, for the serious deep thought machine designer. Copies are available from Irina at the author price.
3. “Fundamentals of Electronics” Lectures, posted on course Wiki.
4. “The Art of Electronics 3rd Edition”, Horowitz and Hill, Cambridge University Press.

Grading

This is an advanced design course for students who are ready to step up to act as professional engineers! Therefore, as in industry, we will not be giving detailed weekly grade feedback, nor a detailed midterm expected grade. We will conduct a mid-term review and often assign project action items to individuals. Together, these should provide a good sense of your progress and instructors are available to provide feedback as needed.

Work hard and efficiently and you will do great! Remember — the grade is not nearly as important as learning a design process and developing a prototype and documenting what YOU did with the team to bring it to life, so you can be proud and show your work to potential employers. Many past 2.75 students have told us that it was going over their design notebook or their website with an interviewer that led to their good job.

The course grade is based on: A = 90-100; B = 80-90; C = 70-80

Term Project – Team Grade Execution of the design process Meeting scheduled milestones Use of time and \$ Quality of design & execution (details & execution)	40%
Individual Performance Contributions to project (monitored via weekly check offs) Use of lab notebook PREP (peer review) effectiveness Participation in class presentation Q&A Communication intensive meetings	10%
Formal Communications Team Presentations Final Paper	20%
Peer weekly assessment of team members	10%
Individual EKG lab & KC Labs & team lab	20%
Total:	100%

Post semester, should there be any grade concerns, students must present their design notebook for review, be prepared to discuss any of the materials covered in the class and then accept that their grade may go up or down.

Student Disability Services:

MIT values an inclusive environment. If you need a disability accommodation to access this course, please communicate with us (the faculty/teaching staff) early in the semester. If you have your accommodation letter, please meet with the faculty so that we can understand your needs and implement your approved accommodations. If you have not yet been approved for accommodations, please contact Student Disability Services at uaap-sds@mit.edu to learn about their procedures. We encourage you to do so early in the term to allow sufficient time for implementation of services/accommodations that you may need.

Student Support Services: *If you are worried that you are about to (or do) fall behind...*

If you are dealing with a personal or medical issue that is impacting your ability to attend class or complete work, please discuss this with [Student Support Services](#) (S3). The deans in S3 will verify your situation, and then discuss with you how to address the missed work. Students will not be excused from coursework without verification from Student Support Services. You may consult with Student Support Services in 5-104 or at 617-253-4861.

Graduate Students: Please reach out to the [deans for personal support](#) in the Office of the Dean for Graduate Education.

Other Concerns

If you have significant travel or personal needs that you believe may impact your ability to work effectively in a fast-paced team, this may not be a good course choice, please discuss your concerns with a member of the course staff.

We are committed to making this a positive learning experience for all of us, so please come and talk to us.

DRAFT

Schedule

Please note that the schedule may be modified as circumstances demand during the course of the term.

SPRING 2022 - Medical Device Design - Schedule					
Wk #	Lecture/Lab	Date	Lecture / Lab	Speaker(s)	Tasks / Milestones for the week
1	Lecture	31-Jan-22	Welcome - Medical Device Design	Alex, Nevan	Read this syllabus fully Load Solid Works / Fusion
	Lecture	2-Feb-22	Project Presentations	Proposers	
	Lab				
2	Lecture	7-Feb-22	Project Presentations	Proposers	Project preferences due 2/8 by noon Teams announced Meet with project proposers Schedule weekly mentor meeting Start prior art search
	Lecture	9-Feb-22	Fundamentals - 1/2/3 Library Resources Communications & Teaming	Alex, Nevan Courtney (our librarian) Dave	
	Lab		KC - Assignment kickoff		
3	Lecture	14-Feb-22	Fundamentals - continued Hobby Shop Introduction	Alex, Nevan Coby	Team Wiki page populated Documentation of prior art Mission statement drafted Functional requirements identified Work on KC in Hobby Shop
	Lecture	16-Feb-22	Mission Statement Communications	Nevan, Dave	
	Lab				
4	Lecture	21-Feb-22	PRESIDENT'S DAY-HOLIDAY		Top 3 strategies identified FRDPARRK filled out KC due on Friday 2/25
	Lecture	22-Feb-22	Teams Strategy Presentations	Teams	
	Lecture	23-Feb-22	Teams Strategy Presentations	Teams	
	Lab				
5	Lecture	28-Feb-22	Electronics lecture, KC show and tell	Anthony	Top Strategy selected Concept generation begun for Strategy Work on EKG in EECS lab Identify key analysis
	Lecture	2-Mar-22	Electronics for med dev	Anthony	
	Lab				
6	Lecture	7-Mar-22	Mechatronics Team Lab Syringe Pump	Staff Anthony	Top 3 Concepts identified Bench level experiments designed

	Lecture	9-Mar-22	Syringe Pump Demo Case Studies / Communication	Staff	Paper Introduction done ECG lab due on 3/11
	Lab				Peer evaluation #1 completed by 3/11
7	Lecture	14-Mar-22	Team Concept Presentations	Teams	Draft paper Background section Top Concept selected FRDPARRC completed for Concept Sketch model
	Lecture	16-Mar-22	Team Concept Presentations	Teams	
	Lab				
8	Lecture	21-Mar-22	SPRING BREAK		ZZZ Catch up on sleep
	Lecture	23-Mar-22	SPRING BREAK		ZZZ
	Lab				
9	Lecture	28-Mar-22	Portal Instruments Case study	Bobby Dyer (CTO)	Schedule to completion Most critical module (MCM) designed Paper Background section done
	Lecture	30-Mar-22	Regulatory / reimbursement	Mary Christian Charles Mathews	
	Lab				
10	Lecture	4-Apr-22	MCM Presentations	Teams	Ordering Fabrication
	Lecture	6-Apr-22	Med Product Case Study	Alex	
	Lab				
11	Lecture	11-Apr-22	Design freeze for preclinical - skateboard model, when to draw the line	TBC	MCM complete and tested Design supporting modules Fabrication
	Lecture	13-Apr-22	Global Health - Gradian Health Systems	David Ettl (COO) Lina Sayed (CEO)	
	Lab				
12	Lecture	18-Apr-22	PATRIOT'S DAY-HOLIDAY		Last chance to order anything Continue fabricating Test, Revise, Test Draft Paper Methods section
	Lecture	20-Apr-22	In vivo/human and ethical considerations	TBC	
	Lab				

13	Lecture	25-Apr-22	Mass Manufacturing/Scale Up - how to go from 1 to billion level of devices - Gio can invite	Gio and MIT Committee on Animal Care	Modules integrated Testing Experiments completed Draft Paper Results section
	Lecture	27-Apr-22	IP - MIT TLO Newco Formation	Ben Rockney Josh Fox	
	Lab				
14	Lecture	2-May-22	The world of startups in MedTech - a female founder perspective	TBC	Fine tuning Full paper draft complete Presentation draft complete Mentors available to review
	Lecture	4-May-22	Stories about career and device development	Adam Jacobs Aidan Petrie Alexia Sibony	
	Lab				
15	Lecture	9-May-22	FINAL PRESENTATIONSS TUESDAY MAY 10, 6-9 PM	Teams	Written deliverables due Wiki updated with all materials Peer evaluation #2 completed by 5/13