2.75J (H), 6.525J (H), 2.750J, 6.025J, HST.552 (UG CI-M AUS) Medical Device Design - Fall 2019 Syllabus

Units: 3 - 0 – 9
Prerequsites: 2.008, 6.101, 6.111, 6.115, 22.071, or permission of instructor
Updated: 4 September 2019

From the catalogue 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 expected to read this syllabus in its entirety and ask questions as needed.

Teaching Staff

ME Instructor	**EE Instructor**	**Instructor/Coordinator**	**Comm. Instructor**	**ME Instructor**
Prof. Alexander Slocum Room: 3-445 Phone: 253-0012 slocum@mit.edu	Gim P. Hom Room: 38-644 Phone: 324-3373 gim@mit.edu	Dr. Nevan Hanumara Room: 3-470 Phone: 258-8541 hanumara@mit.edu	Dave Custer Room: 24-611 Phone: 253-2872 custer@mit.edu	Prof. Gio Taversero Room: 3-340 Phone: 417-8061 cgt20@mit.edu
Comm. Instructor	**MechE TA**	**EE TA**	**Admin. Guru**	**IMES Mentor**
Dr. Amy Carleton Room: E18-228Q Phone: 253-3039 amymarie@mit.edu	Aaron Ramirez Room: 35-029 aeram00@mit.edu	Julian Chacon-Castano julianch@mit.edu	Irina Gaziyeva Room: 3-461 Phone: 253-5592 igaziyev@mit.edu	Prof. Ellen Roche Room: E25-334 Phone: 258-6024 etr@mit.edu

Website: **http://web.mit.edu/2.75/**

Lecture: **Monday & Wednesday 1:00 - 2:30 PM in Room 3-270**
The room is reserved for an additional 30 minutes after class to facilitate meetings & discussions.

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 lectures and students should review materials pre-and post and ask questions. Just as in real life, where consistent blank looks will put you at the top of the list to be replaced/outsourced, we expect students to come prepared to peer review designs presented by others. Grades will reflect demonstrated consistent effort and the upside is that good 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.

2.75-2019@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. Prototypes are evaluated, demonstrated during the final presentations and documented in a journal format written paper.

Students will work in small 3 – 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.

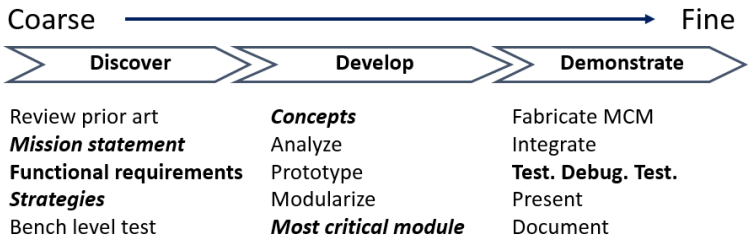
Projects are selected competitively and the proposers have committed to being accessible, are ready to engage with you on a regular basis and will truly be part of your team!

To help maintain a fair pace, consistent with the units for the class, each week tasks for each person to complete before the next meeting will be set and recorded on paper. 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 (e.g., 2.009) in the same semester, nor a class that overlaps time wise.

Together over 12 weeks, 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.*



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 notebooks. In the event that IP results, inventorship must be corroborated by individuals' notebook entries.

Failure is defined as a non-working prototype 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, at a minimum of every two weeks, with their project proposer, at a mutually convenient time. They bring the clinical/need expertise to the project and you the technical talent - you each have separate, but equally important skills!

Weekly Team Mentor Meetings

Each team will be assigned two course staff mentors who will meet with teams 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. They will be reviewed with mentors and progress should be posted to the team's secure Wiki page. 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.

Note: Project proposers do not need to attend weekly mentor meetings, however they are welcome. If you encounter any difficulties with your project proposer, speak to your team's mentor.

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/☹ = ☺.

Peer Evaluations & Midterm Review

At midterm an anonymous peer review will be conducted and the results reviewed by the course staff who will intervene as needed.

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

In order for your projects to succeed, it is critical to learn the principles presented in the readings and lectures. Short 5 - 15 min quizzes will be given randomly at the beginning of lectures to help keep folks focused and sharp! Questions will draw upon the assigned readings, which should be done in advance, and as well as highlights of the preceding lecture. Real-time, in-class design exercises or short P-sets may also count as quizzes.

Note: Quizzes are also essential to helping us gauge the effectiveness of our teaching. If everyone does badly the staff have failed.

Quiz grades will range from 0 (absent physically or mentally) –> 10 (got it!).

There are no excused absences, quizzes, however the two lowest grades will be dropped. This parallels a work environment where occasional absences can be excused, but makeups don't exist.

Labs

At the onset of the course there will be two lab assignments:

1. Design, build, and test a kinematic coupling (KC) which demonstrates the principles of exact constraint design, important for any mechanical device.
2. Design, build, and test two simple, non-invasive electronic heart monitors - the PPG, which uses optics, and the ECG, which uses electrodes and circuitry, to detect and report heart rate.

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

The Hobby Shop and lab space in EECS will be made available and both require safety training and a signed acknowledgment.

Standard 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 in-class demonstration. 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.

Optional Labs for Extra Learning

Each lab will earn you the equivalent of 1 extra dropped quiz:

Surface Mount Technology (SMT) Lab: Electronic devices today are manufactured using surface mount technology. In this lab you will assemble a surface mount two channel 2 watt audio amplifier powered by the USB port. Attach a pair of speakers, plug in your audio source with a 3.5 mm jack and enjoy the music.

Prototyping & Budget

Each team will have a budget of about $4K (exclusive of MIT overhead) net 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), 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 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 send all order confirmations (scan, e-mail, paper) and packing slips to Irina Gaziyeva – be sure to indicate your team*. If receipts are missing at the end of the semester, accordingly your grades will be missing.

Please appoint a single person to manage the budget and coordinate with Irina and track their team's expenses on their Wiki.

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!

Fabrication Resources

There are no dedicated fabrication / lab spaces set aside for this course and since each project is different, staff will work individually with teams to ensure that they obtain the necessary resources. Teams are welcome to use any other lab / fabrication facilities that they have access to and permission to use.

Some available resources include:

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.
EECS Lab (38-601, 38-530) – bench space, instruments, tools, and proto boards available. Safety training required.
Edgerton Center Student Shop (44-023) – Open to all MIT students, safety and machine operation training required via a special course as required by the shop.
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 *cannot* be used for course 2.75 projects. Lincoln Labs will claim ownership over any potential IP for any work done at BeaverWorks. If you complicate the IP situation for your team, you will not receive a grade for the class until YOU fix it!

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 are a key part of the design history file that t*hat documents the design's development and rational behind key decisions*, essential for any quality product (e.g., ISO 9000) and especially for medical products (FDA requirements).

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 class 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 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. Inventorship has no effect on grades; you can be a person who helps reduce an idea to practice and, thus, be a critical team member and journal paper author even if you are not legally 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 in itself useless in the absence of a commercially viable path forward and team members who are dedicated to continuing the development of the idea. It is exceedingly rare that an idea worked on for a single semester directly adopted by a company and turned into a product; it is generally far more valuable for a team to do a great project, publish a peer reviewed article on how the idea developed and then be built upon and referenced.

Communication

This is a communication-intensive course where all students are required to communicate as professionals, both in writing and on their feet during presentations and design reviews. For undergrads this fulfills the CI-M requirement and can be used in place of 2.009, 2.013,2.014, 2.017, 2.019, or 2.760. For graduate students this is important 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
- Final paper & one pager

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

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 add 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.

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 have quizzes, 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	20%
Formal Communications Team Presentations Final Paper	15%
Preparation: In-Class Short Quizzes	15%
Individual EKG lab & KC Labs	10%
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, complete work, or take quizzes, 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. Also, S3 has walk-in hours Monday-Friday 9:00 - 10:00am.

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.

Schedule

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

Wk #	Start Date (Mon)	Monday	Wednesday	Weekly Tasks & Project Milestones
1	9/2	**No Class**	• Welcome, Course Introduction & Design Process (Nevan) • Communications intro (Dave) • Intro to KC lab (Luke)	• Install Solid Works and practice as needed (Visit IS&T) • Fill team member pre-survey - link on Wiki (due Friday) • Begin reading course material - Real engineers prepare for known forthcoming meetings, events, design reviews, etc…! • Sign up for Hobby Shop training - link on Wiki Review and sign Hobby Shop form in advance
2	9/9	• **Clinician Presentations** • Communication (Dave)	• **Clinician Presentations** • **KC Proposal Due**	• Team formation open Thursday 13 - 8 AM – 12 PM - link on Wiki • **Teams Announced** (e-mail on Friday) • Hobby Shop safety training scheduled
3	9/16	• FUNdaMENTALS Topic 2 (Alex) • Lit and Patent Search (Courtney Crummett, MIT Libraries, crummett@mit.edu) • Teams schedule meeting with project proposer	• FUNdaMENTALS Topics 3, 4 (Alex) • Milwaukee Tool Micro Case Study (Beth Cholst) • Teams schedule weekly mentor meeting time	• Teams formed and weekly meetings scheduled • Begin to research prior art including products, literature and patents • Document literature and prior art search findings (include references) • Identify extract functional requirements • Begin to research strategy options • Team Wikis functional
4	9/23	• EECS Overview (Gim) • ***EE PreLab Announced*** *(Gim)* • ***ECG Lab Announced*** *(Julian)*	• Bits & Bytes (Gim) • Questions on EE or ECG Lab • Mission Statements (Nevan) • ***KC Writeup Due & Expo***	• Create mission statement • Top 3 strategies selected, and described with FRDPARRC table(s) • KC Fabrication Sessions • Review and sign EECS lab safety form
5	9/30	• **Teams' Strategy Presentations** (begin with your mission statement)	• **Teams' Strategy Presentations** • **Prelab Writeup Due** *(upload)* • **ECG Proposal Due** *(upload)*	• Conduct bench level experiments to help select strategy
6	10/7	• FUNdaMENTALS Topics 6, 8 (Alex)	• More Bits & Bytes (Gim) • Communications (Dave) • Complete Peer Evaluation	• Best Strategy Selected with its FRDPARRC table complete • Design and make sketch models / experiments • EKG Fabrication begun • Draft of *introduction* section of 2.75 final paper/journal article • Peer Evaluation #1 completed by end of week
7	10/14	• **Columbus Day – Holiday**	• FUNdaMENTALS Topics 10, 11 (Alex)	• Develop concepts, run bench level experiments • Report experimental results • Top 3 Concepts selected, and described with their FRDPARRC tables completed • Create detailed schedule to completion • Draft of *background* section of 2.75 final paper/journal article • Optional Lab: SMTs (Gim & Julian)

8	10/21	• **Teams' Concept Presentations**	• **Teams' Concept Presentations** (Post slides to Wiki) • ***ECG Writeup Due***	• "Best concept" should be selected, and good sketch model done and tested so as to enable "real parts" to be made • Create solid model of "Best Concept"
9	10/28	• Transforming the pill: from daily to weekly/monthly dosing (Gio) • Midterm feedback	• FUNdaMENTALS Topics 5, 7 (Alex)	• Most Critical Module (MCM) engineering complete • Begin engineering of other modules • Final paper outline
10	11/4	• FUNdaMENTALS Review & Details (Alex)	• Heat, Noise, PCB, Manufacturing (Gim)	• MCM complete and demonstrable (ready for the Design Reviews) • Prepare to send remaining parts out for fabrication!
11	11/11	• **Veterans Day – Holiday**	• **Rapid MCM Reviews** 3 slides – 5 min Last chance for class feedback	• Engineering for other modules complete • Send parts out for fabrication! (later and they will not arrive on time) • Final manufacturing begun • Draft of *design/methods* section of 2.75 final paper/journal article; the *methods* draft can be in the form of a testing proposal
12	11/18	• Intellectual Property – Ben Rockney, MIT TLO • Portal Case Study	• Adventures in MedTech – Aidan Petrie, Ximedica	• Final manufacturing complete • Integration of modules started
13	11/25	• Reimbursement 101, Charles Mathews, ClearView Healthcare Partners • Course surveys	• **Happy Thanksgiving**	• Prototype complete & ready for testing • Final paper draft
14	12/2	• Models for evaluation of your biomedical invention: from cadavers to pigs (Gio)	• Team working session • Fabricate to finish!	• Testing complete and documented, tweaked & ready to present • PowerPoint slide deck
15	12/9	Staff in classroom during class hours for presentation dry runs **Final Presentations Wednesday December 11a*** **Presentations loaded on class laptop in 3-461 (Irina) by midday.** Room 3-270 6:00 – 6:45 Dinner (for student presenters only) 6:45 – 7:00 Doors open 7:00 – 10:30 Presentations		Final Deliverables – Uploaded to Wiki, by Monday December 17 • Final presentation in PDF and PowerPoint • Paper following a known Journal format in PDF and Word • One page concise description in PDF and Word • Any video media that you may have created • Complete Peer Evaluation #2 • Final Wiki updated with deliverables for archival purposes
	12/17	**Done!**		Whew!

*If the final presentations conflicts with your regularly scheduled evening class you MUST attend that class. In this case, missing (or arriving late to the) the final presentations is acceptable. Be sure to advise the instructors and work with your team to ensure that you pull your weight on preparing the final presentation and deliverables.