THE CITY COLLEGE OF NEW YORK  
DEPARTMENT OF BIOMEDICAL ENGINEERING  
Senior Design Course and Project Overview  
BME 450-BME 460  
Fall’06-Spring’07

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This document is intended for potential Senior Design Project Sponsors and Senior Design Students. This document introduces the scope and objective of BME Senior Design, outlines the course structure, defines the criteria for a design project, the responsibilities of a project sponsor and the student team, and provides a sample project (as would be submitted by a project sponsor).

Description:

A two-course sequence in which a year-long group project will be undertaken to design and construct a biomedical engineering device or system. Course topics include project planning and management as well as the regulatory, ethical, and legal aspects of medical device systems.

Objectives:

Work with industry and hospital partners to train CCNY BME Students in engineering design, and innovation.

A combined academic, public health institution, and industry taught course educating students on how to approach, organize, and execute a biomedical engineering devise design project. This course includes explicit training on project definition, and on the design, development and technology transfer of potential biomedical products in the context of the student's project.

Students will develop leadership, team-work, and written/oral presentation skills.

Overview:

The BME senior design course (BME 405/406) is the capstone 2-semester course of the City College of New York Department of Biomedical Engineering Bachelors’ degree program. Students taking this course are completing their course-work in the program
which includes advanced classes in mathematics, systems analyses, biology, instrumentation, signal processing, (bio) transport, and (bio) mechanics. In BME Senior Design, students are expected to integrate relevant component of this training with design principles to produce a biomedical product.

Semester I (BME 405) Literature/prior art searches, stages of design process, project definition, product development, written/oral presentation skills

Semester II (BME 406) Clinical regulatory issues, clinical trial design, process/quality control, intellectual property, technology transfer, entrepreneurship, commercialization, financing, marketing, scientific and professional ethics.

Projects must meet specific requirements established by the BME department and the Accreditation Board for Engineering and Technology. The Senior Design course directors assemble a list of potential projects. Projects are selected from the list by a team (4-5) of students. Each team selects a team leader. Each team is closely supervised a graduate-assistant TA (with technical expertise relevant to the specific project), the course technician, and the two course directors.

Projects are solicited from interested members (‘project sponsors’) of the biomedical engineering/biotechnology community.

General project specifications are defined by project sponsors. Project sponsors may be affiliated with academic, hospital, or industrial institutions. The sponsors primary role it to provide the general project specifications. Advantages to sponsors for involvement include:

1) Development of a product that fulfills a specific sponsor need, including development of a proto-type or evaluation of different design approaches.
2) Opportunity for collaboration with the City College Department of Biomedical Engineering and the New York Center for Biomedical Engineering faculty.
3) Interaction with biomedical engineering seniors. These seniors are actively researching post-graduate opportunities in academia/medicine/industry.

Senior Design Project Scope:

The project must be biomedical in nature. The project should develop technology to address a basic medical problem or to provide a tool used in biomedical research.

The project must be tractable by a team (3-5) of senior biomedical engineering students, working an average of 10 hours per week each, for a total of 8 months. The project (including prototype and final device construction) must be realistic using resources available to the students either through City College or the sponsor.

The project must have a clear and substantial design component. The design must be open ended with multiple potential engineering solutions. Prior to construction of a
prototype, there must be methodology to theoretically evaluate/consider the benefits/pitfalls of each potential solution.

The project cannot be basic research based. The project cannot be largely limited to data collection using existing technology.

The project can include an improvement to an existing device but cannot be a copy of an existing device or simply replicate the function of an existing device without improving device specifications (e.g. function/efficacy, signal to noise, safety, cost…) in a fundamental manner.

The project can include construction from basic components (e.g. resistors, tubing…) or involve combination of existing stand alone devices. In the latter case, the selection/interfacing of existing devices must involve significant design and detailed engineering analysis. The project cannot be limited to a ‘shopping expedition’.

Project largely limited to computer programming/software design may be accepted under specific circumstances.

The project does not need to end in a commercially viable product. The product does not need to adaptable to mass production; the product may be designed to meet the needs of a specific individual / task.

The student project cannot involve invasive human testing. The device development, testing, and construction cannot put student/subject health at risk.

**Student responsibilities:**

Students will work in team of 3-5. Each team will select one team leader. The team leader is responsible for delegating responsibilities. The team will receive a single score for all activities. The student team leader may bring concerns about team performance to the course TA/director.

The entire teams of students is primarily responsible for ensuring: 1) the project stays on a defined time-line; 2) meeting all bench-marks; 3) preparing all reports/presentations; 4) arranging regular meeting with the project TA (weekly) and course directors (monthly; at times that are convenient to the TA/directors); 4) producing a product that meets or exceeds device specifications.

The students are responsible for ensuring they fully understand the project scope and specifications. If the specifications provided by the sponsor are not sufficiently clear/specific, it is the students’ primary responsibility to clarify these issues with the sponsor/TA/course director.

It is the student’s responsibility to determine if the project meets the BME Senior Design project scope (see above) including if the project is feasible given the defined time-
table/bench-marks, and using available resources. Failure to meet project objectives due to unavailable resources (including space, proprietary technology, equipment/supply back-order, time…) is not an acceptable excuse. Resource management is a central component of the design project.

Student will present their progress throughout the course in interim oral/written presentation. Students will be regularly evaluated on project progress, commitment, and professionalism. Inadequate progress/performance will result in course dismissal.

**Project sponsor responsibilities:**

It is the project sponsors responsibility to develop and provide students with the general project objectives and product specifications. The project sponsor should provide students with a brief justification for the project (what biomedical needs does the device address).

The project sponsor is *not* primarily responsible to ensure all dead-lines/specification are met, but the project sponsor should have a strong interest in project success and student education.

The project sponsor should be regularly available (response time <5 days) to answer short and direct questions by students/course directors requesting clarification on project specifications.

The project sponsor should read and understand the project scope above. The sponsor must note that to his/her knowledge the project does not completely reproduce prior art (i.e. there must a significant novel component to the device).

In addition to proving device specification, the project sponsor may suggest methods for evaluating device performance. The project sponsor may suggest ‘primary’ versus ‘secondary’ device specifications (only the former being critical) or may suggest ‘minimal’ versus ‘ideal’ performance standards.

The project sponsor is not required to provide financial or product support for the project. However, the project sponsor may choose to provide such assistance. The level of assistance may be defined in project specifications. In specific cases, certain projects may require that the sponsor provide specific technology/resources for the project to be feasible.

The sponsor (or his/her representative) should attend the Dec’06 prototype students’ presentation and the final Spring ’07 design presentation. At these times the sponsor should provide feed-back to the students and performance evaluation to the course director. The sponsor is not responsible for grading the students (The student’s grade is determined solely by the course directors, though the sponsor’s evaluation will be considered in grading). The sponsor should not address any (logistical) questions by
students regarding grading/dismissal, but should address specific technical question relating to criteria for evaluating device performance.

The sponsor may request regular updates/presentations from the students. The sponsor may request copies of all paper-work/presentation material relating to the project. The sponsor may request to be given the prototypes/final device after the final presentation; only in such cases, the Department may ask sponsor to provide material costs. The Department of Biomedical Engineering will work actively with the sponsor to address any legal/intellectual property concerns. Template agreements are available.

All sponsors/sponsor institutions will receive from the Department of Biomedical Engineering a formal acknowledgment of their support. This acknowledgment will note The City College of New York’s status as a Minority Serving and Hispanic-Serving Institution.

Any involvement in project supervision beyond that specified above is encouraged. In addition, sponsors may suggest specific lectures they would be interested to give as part of the engineering design program.

The following is an imaginary example of senior design project developed in collaboration with a sponsor. This example is proposed only to serve as a rough guide on the type of material a sponsor may initially provide.

Example Project Title: Basic system of Electrocardiography for iPod

Sponsor Information

Primary contact: John Smith
Sponsor Institution: John Smith Medical, 10900 Main Dive, New York, NY
Contact information: E-mail (preferred) smith@smithmedical.com
Tel: 212-555-6791

Design request, justification and specifications (by the sponsor)

This is a statement describing the project proposed by the sponsor to design a biomedical device or system. The statement includes a brief justification on why this device must be designed (e.g. customer or clinical needs for the product). Moreover, it contains general operational/functional specifications about how the device functions or what the finished device is required to do (these may be qualitative). These specifications will determine the problem to be solved and the device to be built. Specifications may be quantitative (e.g. no more than 10 cm long) or qualitative (e.g. as small as possible). The sponsor is not required to provide any information about how the device is to be built (the technical details of how the specifications are to be met). Finally, the statement explains any specific/unusual attributes about the desired device.

Specification may be divided in required (minimal, inflexible) and desired (not critical but improving the device performance in a practical way). If the design project involves modifying an existing device, the existing device is reference.
**Example:**

**Design request.** Apple computer has expressed their interest for providing a portable digital audio player (iPod) capable of acquiring ECG data. The present project consists in designing a system for acquisition of ECG signals to be embedded into an iPod device (US Patent XXXXXXX).

**Justification.** In a recent health care analysis an increase in cardiac problems associated with intense exercise in young people was demonstrating; this shows a clear need for ECG monitoring during severe physical activity. A small, portable and inexpensive ECG device will offer the option of monitoring heart activity in these cases, allowing for early detection of cardiac problems related to high physical stress. While most (young) users will not be look favorably on the use medical equipment in their everyday life, they expressed a favorable opinion for a device offering integrated ECG monitoring and music entertainment. This kind of computer-based ECG monitoring systems is expected to drive growth within the youth and middle age market for resting and/or stress ECG products by offering cost-effective solutions as well as scalability. As a growing number of people add standard ECG monitoring to their quotidian life, fewer patients will be referred to hospitals for ECG monitoring.

**Required Specifications (mandatory).** The system of ECG acquisition needs to be able to monitor changes to your heart under various physical conditions, such as in bed or after exercise. The quality of the ECG waveforms is expected to be comparable with that of ECG's signals acquired with medical grade devices. Development of appropriate software allowing displaying the electrical signal from the ECG under either Windows or Macintosh is required. The system must be designed to fulfill the FDA and electrical safety regulations.

**Desired Specifications (optional).** The simplest design in terms of cost, size, weight, noise rejection, robustness and energy consumption is beloved. Moreover, ECG's waveforms and patient data might be recorded, stored and printed out using a personal computer. Lead number and size should be minimized; the use of the earphone as ECG leads can be explored.