University of Toronto
Major Modification Proposal

This template should be used to bring forward all proposals for major modificiations to existing graduate and undergraduate programs for governance approval under the University of Toronto's Quality Assurance Process. It is designed to ensure that all evaluation criteria established by the Quality Council are addressed in bringing forward a proposal for a new program.

Section 1

Version Date:	**March 13, 2011**
Institutional Contact:	Jane E. Harrison, Director, Academic Programs and Policy, Office of the Vice Provost, Academic Programs *jane.harrison@utoronto.ca*
Faculty / Academic Division:	**Applied Science & Engineering (FASE)**
Department / Unit (if applicable) where the program will be housed:	**Institute of Biomaterials & Biomedical Engineering**
Program being modified:	**PhD in Biomedical Engineering**
Effective date:	**September 2011**

Section 2

1. Executive Summary

Please provide a brief summary of the change(s) being proposed outlining the implications of and rationale forand and the change.

This is a proposal to create a concentration in clinical engineering within the existing IBBME PhD. Students in the concentration will complete the normal requirements of the PhD with the following changes: graduate students without a clinical engineering background will normally be required to complete an additional specified half course; students in the concentration require joint engineering-health scientist supervision; all students in the concentration must conduct research within a clinical healthcare environment. In addition, this proposal seeks to add an option in the PhD program to allow the transfer of MHSc clinical engineering graduate students into the PhD program and this concentration. We expect an initial enrolment in the concentration of 3 to 5 students.

Clinical engineering has become a unique sub-specialty of biomedical engineering given its specific emphasis on enhancing patient safety, quality of care and quality of life. As evidence of its maturing identity, certification in clinical engineering was introduced in Canada in 2010 by the American College of Clinical Engineers. Increasingly, there is an emerging need for research clinical engineers within hospital research institutes, universities and medical device industry to lead research and innovation. The demand for clinical engineering scientists will heighten in the years to come with the nascent biodesign teaching curricula across North America, the sprouting of interdisciplinary research institutes such as the newly formed Ontario Brain Institute, and the international growth of clinical engineering research at major research-intensive hospitals (e.g., UHN, Massachusetts General). Over a third of IBBME's current clinical engineering students and recent alumni (last 2 graduating classes) have expressed an interest in pursuing a PhD with a clinical engineering concentration. Already 6% of IBBME's MHSc Clinical Engineering class

are moving on to the PhD. Likewise, over half of current faculty supervising clinical engineering graduate students have indicated interest in engaging such students in doctoral level research. The proposed change reflects IBBME's on-going commitment to graduate students, that is, to respond to the growing graduate student interest in clinical engineering research and to pro-actively prepare for the expanding demand for clinical engineering scientists. Fortuitiously, the proposed change is well-aligned to IBBME's 2009-2014 academic plan, a key priority of which is "to expand the graduate curriculum in order to provide a greater innovative/biodesign/entrepreneurship training experience, with an emphasis on the PhD level".

2. Rationale

- *Outline the rationale for the proposed change(s) and the fit with the unit's and division's academic plans*

Since 1984, the Institute of Biomaterials & Biomedical Engineering (IBBME) has offered a Master of Health Science (MHSc) in Clinical Engineering, which remains the only research-intensive clinical engineering program in North America. In each of the last 4 years, enrolment in the MHSc program has more than tripled the annual average in its first 20 years of existence. The program now receives in excess of 50 applicants for approximately 15-20 positions. The quality of the candidates remains unequivocally high, as witnessed by the escalating number of external scholarship holders (27% of currently enrolled students) and student-authored journal publications (about 33% of the class are publishing). The number of faculty who are directly financially supporting clinical engineering graduate students has also stepped up accordingly (100% of the current roster of 20 clinical engineering supervisors).

In recent years, the global community has witnessed a rapid expansion of the medical device sector (currently pegged as a $90 billion market, not including stem cell technologies and other engineered biological therapeutics and diagnostics). In the US, the health care industry consumes 10% of the gross domestic product. Health care is projected as one of the world's largest and fastest-growing industries, reaching 19.6% of the the US GDP by 2016. Engineering principles are applied in hospitals, nursing homes, diagnostic laboratories, pharmacies, medical device manufacturing, rehabilitations services and many other areas to yield expenditure in the US alone of $2.1 Trillion (2006 figures). In light of these forecasts, it is not surprising that the profession of clinical engineering has also gained significant attention nationwide; the certification of clinical engineers is being introduced in Canada in November of 2010 as part of the American College of Clinical Engineering's international certification process. An IBBME faculty member, Dr. Tony Easty, is chairing the certification committee for Canada. As healthcare becomes increasingly technology-dependent, the need for clinical engineering scientists and clinically-savvy engineers is only expected to grow for the foreseeable future.

IBBME's PhD program does not currently provide a transfer option for clinical engineering graduate students from the MHSc. There is an increasing number of excellent students who wish to specifically focus on applied science and engineering research, fundamentally to enhance patient safety and the delivery, integration and management of contemporary, technology-mediated healthcare. Given the rich intensity of clinically applied research among the University of Toronto's teaching hospitals (eight of whom have approximately 45 senior research scientists appointed into IBBME), there exists tremendous opportunity for IBBME to lead the formation of clinical engineering scientists. Currently, there are no PhD programs with a clinical engineering concentration in North America.

Fit with IBBME's academic plan

The present proposal aligns with a key priority in IBBME's 2009-2014 academic plan which is "to expand the graduate curriculum in order to provide a greater innovative/biodesign/entrepreneurship training experience, with an emphasis on the PhD level, within the framework of IBBME's GTA network and with international collaborators." This initiative is recognized in the language of the Faculty of Applied Science and Engineering's research academic plan where the current PhD program for IBBME is located. FASE's

research plan recognizes "The challenges facing our healthcare system place financial strain on government resources and are pushing the frontiers of biomolecular science and patient-specific therapies and diagnostics. Integration of engineering practices with medical sciences, as well as the existing collaboration between Engineering, the Faculty of Medicine, and the University affiliated hospitals, helps us identify and study more efficient diagnostic strategies and better disease-monitoring leading to an enhanced quality of life." The establishment of this clinical engineering concentration in IBBME's PhD program is also in line with the core values of the Faculty of Medicine's current and on-going strategic planning which emphasizes "Integration, collaboration and partnerships" as well as an emphasis on knowledge translation and social responsibility. As described below this proposal speaks to all of these themes, given that the program involves the participation of the Institute in partnership with Toronto hospitals, and is focussed on translational research with an emphasis on active patient involvement, thereby integrating technology with society. Dentistry's current academic plan is focused on using its interdisciplinary strength to capitalize on strategic alliances in order to establish new partnerships and build an environment of growth that will lead to the translation of knowledge in the clinic. Towards these goals they have recently established a Clinical Studies Centre and have retained several of the Institute's faculty members in teaching their graduate courses. Hence, the proposed concentration in Clinical Engineering is well aligned with their agenda. Both the Faculties of Medicine and Dentistry have been provided the proposal for their review and no issues have been raised to the initiative.

3. Description of the proposed major change (s)

- *Describe what changes are being proposed. In particular, please address the following as applicable:*
  - *Requirements that differ substantially from those existing at the timeof the previous cyclical program review*
  - *Significant changes to learning outcomes*
  - *Significant* changes *to the faculty engaged in delivering the program and/or to essential physical resources as may occur, for example, where thre have been changes to the existing mode of delivery (e.g. different campus, on-line delivery, inter-institutional collaboration)*
- *As an Appendix, please provide full, revised calendar copy. In the interest of clarityit is recommended that the attached template be used to show original requirements, propsed changes and final clean copy with all proposed changes accepted.*

IBBME proposes to modify IBBME's existing PhD program with an opportunity for students to take on a clinical engineering concentration. The degree nomenclature will remain a "PhD in Biomedical Engineering". Clinical engineering students who have expressed interest in pursuing a PhD have vetted this nomenclature and IBBME has confirmed with the Amercian College of Clinical Engineers that our doctoral graduates would be eligible for certification. Doctoral students opting for the clinical engineering concentration will be expected to take a plurality of clinical engineering courses from IBBME's existing graduate course offerings, and will have specific supervisory and research environment requirements as outlined below. The concentration will adhere to the level of research excellence, critical thought, originality and research output of IBBME's PhD program. The specific proposed changes are to:

- Formalize a transfer option for graduate students enrolled in the MHSc program, whereby a student may transfer to the PhD program under conditions stipulated below and in accordance with the SGS regulations for transfers. This option currently exists only for students enrolled in the MASc program in IBBME.

- Introduce an additional clinical engineering course requirement as detailed below, above and beyond the existing PhD requirement, for students without a degree in clinical engineering.

- Add a multi-disciplinary supervision requirement for students pursuing the clinical engineering PhD concentration; their PhD research would normally be jointly supervised by faculty from engineering and the health sciences. The IBBME-appointed (primary) supervisor will assist the student in arranging joint supervision and will be the primary person responsible for guiding the student through the SGS

regulations and timelines.

- Add the requirement that the research must be carried out, at least in part, in a clinical environment, broadly understood to be any setting where a person is receiving care, for example, including, but not limited to a hospital-based laboratory, an assisted living centre, nursing home or outpatient clinic, where human subjects will be engaged.

Admission requirements

Highly qualified students in the Clinical Engineering MHSc or Biomedical Engineering MASc programs may be considered for transfer into the PhD. Applicants must meet the following requirements:

- Clinical Engineering MHSc students must complete 3.0 full-course equivalents within the MHSc curriculum

- All students must have passed a transfer exam consisting of an oral defense of a written PhD proposal before a committee of 3 SGS-appointed faculty members (in the case of the students transferring to the PhD program and who are being considered for the clinical concentration at least 1of the 3 SGS-appointed members will be a clinically-appointed faculty member) within 12 months of initial registration

All students applying to IBBME's PhD program may apply to the concentration in Clinical Engineering option if they satisfy the following requirements:

- Meet the minimum admission requirements of the PhD.

- Be eligible for clinical engineering certification. This entails having an undergraduate degree in engineering.

- For students applying with a master's degree, the degree must be in clinical engineering or other clinically-related engineering field. For students transferring from a master's program, the program from which the student is transferring must be in clinical engineering or other clinically-related engineering field.

Direct admission from a bachelor's may be considered in exceptional cases.

Program requirements (Please also refer to the revised Calendar Entry in the Appendix)

Supervisory requirement - Students taking the concentration in Clinical Engineering would normally be co-supervised by both engineering and health science faculty. The primary supervisor must be IBBME-appointed, however the co-supervisor could be from a clinical unit other than IBBME, however must be appointed to SGS. IBBME's PhD program currently allows for co-supervision from non-IBBME SGS appointed faculty.

Research environment requirement – Students must conduct their research in a clinical environment.

Existing IBBME PhD requirements - These include 1.0 full-course equivalent (FCE), successful completion of a thesis, participation in two seminar courses, passing a qualifying examination within 12 months of registration, annual supervisory committee meetings and oral defense of the thesis (departmental and senate oral).

Clinical Engineering course requirement - Normally, if the student does not have a formal degree in Clinical

Engineering, one additional course in clinical engineering is required.

- 0.5 FCE from one of the IBBME clinical engineering courses (BME 1405, BME 1439, BME 1436 or BME4444)*

* A student who possesses protracted professional clinical engineering experience (5 or more years) will be exempt from this requirement.

All course requirements must be fulfilled with graduate level courses.

Program length

The proposed change will not impact the established program length for IBBME's PhD program, namely, 4 years (full-time) from a Master's degree or 5 years (full-time) for direct entry or transfer students. It is anticipated that the additional 0.5 FCE required of those without a clinical engineering master's degree would not prolong the residency in the program.

Mode of delivery

Only standard delivery as a full-time program will be implemented. The rationale is that the inherent nature of research in which these students will engage necessarily dictates continuity of work over a few years. In particular, human participants will be engaged in the vast majority of cases. Such research is bound by timelines of research ethics approval. Further, recruited research participants can only be retained for limited periods of time. Finally, the rapid cycle of clinical engineering advances in many areas would tend to favour the publication of research that is more current and timely.

Assessment of teaching and learning

Assessment of student achievement will be consistent with the current procedures within the IBBME PhD program. Namely, after completion of the qualifying exam, students will continue to meet with their supervisory committee at least once every 12 months until recommendation for the Departmental Oral Examination is made. At each meeting, the committee provides a written assessment of the student's progress along with recommended considerations or changes, as appropriate.

4. Impact of the change

- *Outline the expected impact on continuing students, if any, and how they will be accommodated*
- *Describe impact on other programs, divisions describing consultation with affected units.*

Impact on teaching

Over 30 faculty including scientists and clinician scientists in the affiliated hospitals presently contribute to the didactic components of the clinical engineering curriculum (courses and observerships). These include BME1405 & BME 1439 (Clinical engineering instrumentation I and II), BME 1436 (Clinical Engineering surgery) and BME4444 (Clinical engineering internship). The additional students in these courses as a result of the clinical engineering concentration will be incremental at first, as most of the initial candidates to be either current Clinical Engineering graduate students or alumni. Impact on teaching will be re-assessed as the concentration develops. Additionally, IBBME's most recent Academic Plan identifies a potential new hire in the area of Biodesign who will contribute to teaching in the clinical engineering concentration.

Impact on continuing students

The proposed change will have no impact on continuing students within IBBME's PhD program.

Impact on other programs

There are no other programs of this nature anywhere on campus or in Canada. Currently the only PhD program on campus with an Engineering emphasis, which comes close to what is being proposed is IBBME's own PhD program. The introduction of the clinical concentration will be a further magnet for some of the country's and the world's best biomedical engineering students. The number of students applying to the current program already exceeds the number of funded positions among professors in IBBME so it is not anticipated that there will be any recruitment impact. A similar scenario occurred in 2006 when IBBME's MHSc program expanded from 6-8 graduate student spots to 30 spots. In the previous transformation in 2006, the draw did not deplete the MASc pool since the MASc-PhD program has continued to expand throughtout the Ontario Graduate Incentive years of 2006-2010.

5. Resources:

- *Describe any resource implication on the change(s) including but not limited to faculty complement, space, libraries, enrolment/admissions,*

Space

As in the existing MHSc program, lab and office space for graduate students in the clinical engineering PhD concentration will be made available through the affiliated hospital facilities of the supervising faculty.

Administration

The clinical engineering concentration will be administered through the existing graduate program office within IBBME. IBBME's Associate Director will continue to oversee all PhD admissions. Day-to-day program administration will be facilitated by the clinical engineering graduate coordinator and program assistant. These human resources will be able to support the program's initiation. Staffing levels will be revisited as necessary as the program evolves.

Faculty

A plurality (53%) of faculty who are either supervising or have recently supervised a clinical engineering graduate student responded positively about supervising and funding PhD students with a clinical engineering concentration. The quality of our current roster of clinical engineering supervisors, their competency to supervise students in related areas of research, and their ability to promote innovation and foster an appropriate intellectual climate are demonstrated in the attached summary of key faculty. This list includes several named and CRC chairs (Drs. Chau, Easty, Mihailidis, Popovic, Shojania just to name a few - www.ibbme.utoronto.ca). The current faculty roster includes 7 Full Professors, 5 Associate Professors and 9 Assistant Professors. It is anticipated that in the initial years, additional PhD students will be supervised by the key faculty featured in the attachment (typically 1 student/faculty member).

Tuition

- Tuition (existing PhD tuition + related ancillary fees as appropriate). Rationale: Tuition fees remain fixed for PhD programs across the University

Funding

IBBME currently has a roster of 20 SGS-appointed core and cross-appointed faculty who are supervising

and funding clinical engineering graduate students. Over half have expressed interest in funding clinical engineering PhD students. These faculty members are already conducting research at the interface between engineering and health care, are well-funded (over $10 million in active grants) with established research programs, and would be well-positioned to mentor doctoral students pursuing a clinical engineering thesis.

The proposed clinical engineering concentration would be philosophically aligned to an NSERC CREATE program in rehabilitation engineering (CARE, 2009-2015) that is housed at IBBME. Students pursuing the clnical engineering concentration would be eligible for support through CARE, at $19,500 per annum, for the first two years of study. The CARE program has the capacity to support up to 14 PhD students at this level in any given year. Given the caliber (average admission GPA of 3.62/4.0 in final 2 years of study for current first year class) and scholarship track record of students (27% hold external scholarships) entering the clinical engineering MHSc program, it is anticipated that a healthy contingent of clinical engineering PhD students will also be competitive for national scholarships through NSERC or CIHR.

The Dean of Applied Science and Engineering has allocated the required 2011-12 portion of FASE's new 40 PhD positions to this program.

Enrolment

Initially, IBBME expects between three to five students to choose the clinical engineering concentration, with increasing numbers in future years. A steady state enrolment of about 20 students will be attained within the first seven years of the introduction of the clinical engineering concentration. This estimate is based on the potential capacity within our MHSc program (53% of active clinical engineering supervisors have indicated their interest in funding and mentoring PhD students with a clinical engineering concentration) and interest among recent students (35% among those recently surveyed responded affirmatively about pursuing a PhD with a clinical engineering concentration).

Source of applicant pool

The proposed clinical engineering concentration would attract three types of students. The first would be students holding an MHSc in Clinical Engineering or students currently enrolled in the MHSc in Clinical Engineering program at the University of Toronto. The latter would have the option of reclassifying into the PhD program as outlined above. The second group of students would be those coming from a doctoral stream master's program, such as IBBME's MASc in biomedical engineering (i.e., students without an MHSc in Clinical Engineering). The third would be candidates with a Bachelor's in Engineering and an exceptional academic record in their last 2 years of study, who have also accumulated 5 years or more of clinical engineering experience either in the medical device industry or hospital setting.

6. Governance Process:

Levels of Approval Required
Dean's Office Sign Off
Faculty/Divisional Council
Submission to Provost's Office
AP&P – reported annually
Ontario Quality Council - reported annually

Appendix A:

Original Calendar Copy	Proposed Changes (Additions highlighted)	New Calandar Copy
Doctor of Philosophy **Minimum Admission Requirements** • Graduate in dentistry, engineering, medicine, or one of the physical or biological sciences with an appropriate master's degree. • Direct admission may be considered in exceptional cases. **Program Requirements** • Normally at least 1.0 full-course equivalent (FCE) and successful completion of a thesis, representing an original investigation in biomedical engineering. • Within 12 months of registration, students must pass a qualifying examination covering the broad field of biomedical engineering appropriate to their background. • Students will continue to meet with their supervisory committee at least once every 12 months until recommendation for the Departmental Oral Examination is made. On the recommendation of the supervisory committee and special approval from their department Graduate Chair or Coordinator, candidates have the opportunity to waive the Departmental Oral Examination and	**Doctor of Philosophy** **Minimum Admission Requirements** Applicants are admitted into the program via one of three routes: • **With a master's degree:** applicants must have an appropriate master's degree dentistry, engineering, medicine, or one of the physical or biological sciences. • **Transfer:** Highly qualified students in the Clinical Engineering MHSc or Biomedical Engineering MASc programs may be considered for transfer into the PhD. Applicants must meet the following requirements: o Clinical Engineering MHSc students must complete 3.0 FCE within the MHSc curriculum o all applicants must have passed a transfer exam consisting of an oral defense of a written PhD proposal before a committee of 3 SGS-appointed faculty members within 12 months of initial registration • **Direct-Entry:** Admission for those with a bachelor's degree may be considered in exceptional cases.	**Doctor of Philosophy** **Minimum Admission Requirements** Applicants are admitted into the program via one of three routes: • **With a master's degree:** applicants must have an appropriate master's degree dentistry, engineering, medicine, or one of the physical or biological sciences. • **Transfer:** Highly qualified students in the Clinical Engineering MHSc or Biomedical Engineering MASc programs may be considered for transfer into the PhD. Applicants must meet the following requirements: o Clinical Engineering MHSc students must complete 3.0 FCE within the MHSc curriculum o all applicants must have passed a transfer exam consisting of an oral defense of a written PhD proposal before a committee of 3 SGS-appointed faculty members within 12 months of initial registration • **Direct-Entry:** Admission for those with a bachelor's degree may be considered in exceptional cases.

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proceed directly to the University of Toronto Final Oral Examination. • Engineering and physical science students are required to take a life sciences course, such as JPB 1022H (or an equivalent); while life science students are required to take a physical sciences course, such as JPB 1055H (or an equivalent). • Students pursue a thesis topic relevant to Biomedical Engineering and are expected to take BME 1450H Bioengineering Science. • Students participate in two seminar courses: one of BME 1010H or BME 1011H Graduate Seminar series, and JDE 1000H Ethics in Research. **Normal Program Length** • 4 years (full-time PhD); 5 years (direct-entry PhD)	Concentration – Clinical Engineering • In addition to the minimum admission requirements above for the PhD, applicants must meet the following requirements in order to be considered for admission: • **With a master's degree:** the degree must be in clinical engineering or other clinically-related engineering field. • **Transfer:** the program from which the student is transferring must be in clinical engineering or other clinically-related engineering field and at least one of the 3 SGS-appointed faculty member committee will be a clinically appointed faculty member. • **All applicants (including direct-entry):** applicants must be eligible for clinical engineering certification. This entails having an undergraduate degree in engineering. **Program Requirements** Students admitted with a master's degree or via transfer from a master's program: • All course requirements must be fulfilled with graduate level courses. • Normally at least 2.0 FCE (2.5 for students in the Clinical Engineering concentration) which	Concentration – Clinical Engineering • In addition to the minimum admission requirements above for the PhD, applicants must meet the following requirements in order to be considered for admission: • **With a master's degree:** the degree must be in clinical engineering or other clinically-related engineering field. • **Transfer:** the program from which the student is transferring must be in clinical engineering or other clinically-related engineering field and at least one of the 3 SGS-appointed faculty member committee will be a clinically appointed faculty member.. • **All applicants (including direct-entry):** applicants must be eligible for clinical engineering certification. This entails having an undergraduate degree in engineering. **Program Requirements** Students admitted with a master's degree or via transfer from a master's program: • All course requirements must be fulfilled with graduate level courses. • Normally at least 2.0 FCE (2.5 for students in the Clinical Engineering concentration) which

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	Students admitted via direct-entry: • All course requirements must be fulfilled with graduate level courses. • Normally at least 3.0 FCE (3.5 for students in the Clinical Engineering concentration) which includes the following: o Students must complete 1.0 FCE in year 1 with a minimum average of A-. o BME 1450H Bioengineering Science o A 0.5 FCE breadth course. For engineering and physical science students this must be a life sciences course, such as JPB 1022H (or an equivalent); for life science students this must be a physical sciences course, such as JPB 1055H (or an equivalent). o 1.0 FCE from participation in two seminar courses: JDE 1000H Ethics in Research, and one of BME 1010H or BME 1011H Graduate Seminar series. • Within 18 months of registration, students must pass a qualifying examination covering the broad field of biomedical engineering appropriate to their background. • Successful completion of a thesis, representing an original investigation in biomedical engineering.	Students admitted via direct-entry: • All course requirements must be fulfilled with graduate level courses. • Normally at least 3.0 FCE (3.5 for students in the Clinical Engineering concentration) which includes the following: o Students must complete 1.0 FCE in year 1 with a minimum average of A-. o BME 1450H Bioengineering Science o A 0.5 FCE breadth course. For engineering and physical science students this must be a life sciences course, such as JPB 1022H (or an equivalent); for life science students this must be a physical sciences course, such as JPB 1055H (or an equivalent). o 1.0 FCE from participation in two seminar courses: JDE 1000H Ethics in Research, and one of BME 1010H or BME 1011H Graduate Seminar series. • Within 18 months of registration, students must pass a qualifying examination covering the broad field of biomedical engineering appropriate to their background. • Successful completion of a thesis, representing an original investigation in biomedical engineering.

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Developed: January 31, 2011