Institution: University College London

Unit of Assessment: 15 - General Engineering

a. Context

The focus of UCL's submission to UoA 15 is Biomedical Engineering, as conducted within the framework of UCL's Institute of Biomedical Engineering (IBME). The vast majority of the Unit's research is undertaken with the aim of enhancing human health and wellbeing by providing faster or more accurate diagnosis, more effective or less expensive treatment and therapies, or improvements in quality of life. Its extra-academic benefits are realised in several ways, including: bringing new healthcare devices to market; informing and shaping clinical practice; influencing public/patient attitudes and behaviour (for example by promoting their acceptance of new technologies or of healthier lifestyles); and defining new international standards. This includes working directly with doctors and other healthcare workers to benefit their patients and patients' families. Launched in June 2012, the IBME serves as a bridge between the six biomedical, engineering, life and physical science faculties at UCL, and the twenty-five NHS Trusts and Hospitals that comprise the UCL Partners Academic Health Science Centre. It has been established to support and promote innovation and translational research in medical technologies, particularly in terms of the non-pharmaceutical products used to diagnose, monitor, and treat human diseases and medical conditions. The submission to this unit of assessment comprises staff drawn primarily from three UCL departments/institutes:

The **Department of Medical Physics & Bioengineering** (MPB), whose very broad range of beneficiaries include newborn infants in intensive care for whom new optical methods of measuring cerebral oxygenation have been developed, severely paralysed patients for whom implanted devices are providing ways to regain control of bladder and bowel function, and breast cancer patients for whom new injectable magnetic contrast agents have been patented and marketed to broaden the availability of the procedure known as sentinel lymph node biopsy, a major component of breast cancer treatment.

The **UCL Institute of Orthopaedics and Musculoskeletal Science** (IOMS), whose research is directed towards patients who benefit from novel prostheses and engineered tissues, including those with spinal and nerve injuries, osteoporosis, and diseases of childhood.

The **UCL Department of Mechanical Engineering**, whose work on novel forming of biostructures, biomedical ultrasonics and cardiovascular engineering benefits myriad patient groups. These include patients requiring heart-valve replacement, those who benefit from novel patented and commercially available methods of encapsulating drugs and contrast agents for imaging, those suffering from ptosis, and those undergoing ablative therapies of tumours using high intensity focussed ultrasound.

b. Approach to impact

The importance of impact beyond academia is central to UCL's Research Strategy and embodied in its four Grand Challenges formulated in 2008, two of which – Global Health and Human Wellbeing – are fundamental to this Unit. The delivery of impact within this Unit has been guided by the overall strategy for impact adopted by UCL Partners, a collaboration established in 2009 between twenty-five leading medical research centres and hospitals whose purpose is to translate cutting-edge research and innovation into measurable health gain for patients and populations in London and beyond. Specifically, this Unit has followed the clinically-led approach to research through partnership between healthcare providers, patient groups, academics, government and industry.

Our Unit's primary approach to impact is to **create awareness of unmet clinical needs** among our academics and provide the forums for interaction between engineers and clinicians and other potential end users. Clinical partners are the conduit through which much of this Unit's impact is achieved: they are the surgeons that utilise our new implants and engineered tissues; they are the consultants or nurses employing our new diagnostic and monitoring tools.

Cross-disciplinary interaction is heavily promoted through regular widely-advertised events, organised by UCL, the IBME, and individual departments. UCL holds workshops, research speed-

dating events, and town meetings, all designed to encourage and facilitate inter-disciplinary partnerships. The IBME also organises regular one-day "Meet the Engineers" events, at least three times per year, focussed on fostering new links between academics and clinicians. For example, a meeting entitled "Technology for Therapeutic Healthcare and Assisted Living" was held in April 2013 to enable doctors and scientists with the UCL Faculty of Brain Sciences to highlight their engineering needs and our Unit's engineers to present potential neuro-applications of their technologies and expertise. In June 2013, the IBME held a week-long "MedTech Week", designed to inform staff and students about medical technology and the biomedical engineering landscape across UCL. Such events commonly trigger new collaborations with strong potential for high impact, by putting basic researchers in contact with end users. For example, a UCL "speed dating" event in 2010, designed to enable scientists to pitch ideas to multiple potential collaborators, prompted a new joint venture between a biomechanical engineer (Ben Hanson) and a neurophysiologist (David Holder), in different UCL departments, ultimately resulting in a patented electrode for head imaging using electro-encephalography (EEG) and electrical impedance tomography (EIT).

Establishing **collaborative relationships between academics and clinicians** not only promotes new ideas, but ensures that the full impact of the research can be delivered by facilitating academics' access to patients (including clinical trials), patient data, tissue samples, and hospital facilities such as operating theatres, radiology suites, and radiotherapy units. The institution supports this by enabling scientists and clinicians to occupy physically adjacent or shared facilities, or enables research staff and students to be embedded within a clinical unit (e.g. some MPB physicists developing new therapeutic techniques are based within the UCLH radiotherapy department). This integrated approach to maximising opportunity for impact is exemplified by IOMS, where research is strategically aligned with the interests of the Royal National Orthopaedic Hospital (RNOH) Trust on whose site it is based. Likewise, MPB benefits from being a joint department with the UCLH NHS Trust Department of Medical Physics, which comprises clinical physicists and engineers engaged in support activities for hospitals within the Trust. This link helps facilitate the historically strong connection between MPB and the UCLH clinical departments and institutes of Radiology, Radiotherapy, Surgery, Nuclear Medicine, Neurology, and Women's Health. Research within MPB is heavily clinically driven, with over 75% of grant income involving clinical co-investigators. Meanwhile, biomedical engineering research in the Department of Mechanical Engineering involves active clinical collaboration, e.g. novel forming of biostructures (Whittington Hospital, Royal Free Hospital, Moorfields Hospital, Great Ormond Street Hospital), biomedical ultrasonics (UCLH), and cardiovascular engineering (Royal Free Hospital, London Heart Hospital).

Awareness of impact support mechanisms across UCL is promoted by the Vice-Dean for Enterprise for the UCL Faculty of Engineering as well as by Knowledge Transfer & Enterprise Champions designated for individual departments. The **commercialisation and exploitation** of research outputs constitutes another important approach taken by the Unit to maximise the impacts of its work in non-academic fields. This has been facilitated by UCL Business (UCLB), UCL's technology transfer office, which exists to help industry and business make the most of UCL innovations. This Unit has submitted 40 invention disclosures via UCLB since 2008, and 72 IP protections have been secured during this same period. For example, following development of new tissue engineering processes by Robert Brown, UCLB negotiated a licensing agreement to enable UK SME, TAP Biosystems, to market kits for rapid laboratory fabrication of living tissues. These tissues are used for testing pharmaceuticals (significantly reducing the demand for animals), evaluating new drug and cell delivery mechanisms, and for surgical implantation. The commercial product, known as RAFT, was launched in June 2012.

This unit of assessment has many notable examples of successful UCL-driven translation, with successful spin-out companies (including Endomagnetics, Evexar Medical, Stanmore Implants, and AtoCap – the latter as the result of winning the 2010 Venture Prize) bringing products to market, and licensing deals with healthcare technology providers. In 2011, Stanmore Implants received USA FDA approval for its JTS non-invasive extendible implant for children with bone cancer, developed at IOMS. The market for this device is expected to be in excess of $30M (extendable prostheses case study). In general, we often seek to involve an industrial partner at the earliest possible stage, including feasibility testing and prototype design. Since 2008 the Unit

has established relationships with no less than 42 private industry investors, and industry and government contributed 37% of the Unit's research income. UCL supports its academics in this respect through the provision of institutional support such as "Impact Awards", which provide 50% funding for PhD studentships to match that from a collaborating company (about 30 have been awarded to staff within this Unit so far). The Unit has also been proactive in seeking external support from research council and elsewhere for this important strand of its approach. Companies directly funding studentships (either 100% or via a CASE studentship award) since 2008 include BASF, GE (two), IBA, Invibio, Optronix, Rapiscan Systems, SCA Products, Simavita Pty, TAP Biosystems, and Unilever.

Many of the submitted staff are regularly involved in **consultancy and the provision of expert advice** to external agencies. Examples include Nick Donaldson, ten percent of whose salary was paid by Smith & Nephew UK for several months in 2010 for consultancy involving research and design, and Gary Royle, who has served since 2012 as an Advisor to the Department of Health (roughly one day per month) for their UK Proton Therapy Programme.

To ensure that impacts delivered are as responsive as possible to the needs of beneficiaries, some research groups **work directly with patient groups** and/or their advocates during the development of their new technologies. Prior to December 2013, hundreds of elderly patients distributed over many centres (including care homes for the elderly) have been involved in an evaluation of new incontinence technology by the group of Alan Cottenden (incontinence management case study). In another example, dozens of women referred to a breast clinic were recruited in for the assessment of a new breast imaging method by Jem Hebden and Adam Gibson in the period up to October 2011. In these and other cases, the opinions of participating volunteers, patients and their carers are formally assessed via questionnaires.

Many of the Unit's researchers are involved in **public engagement**, including national science festivals and contributions to science programmes on radio and TV, newspapers, and magazines. The promotion of our research throughout the global media is facilitated by the UCL's Media Relations team. A major benefit is a more informed media discourse on new technologies, leading to more rapid acceptance and clinical uptake. The creation of the world's first completely synthetic trachea at UCL generated more than 1200 media reports around the world following transplantation in June 2011, prompting considerable public debate (synthetic organs case study). Since 2010 this Unit's public engagement activities have been coordinated by a Beacon Mentor in Public Engagement (Clare Elwell) with the help of the UCL Public Engagement Unit (one of six funded by the Beacons for Public Engagement programme set up by HEFCE, RCUK and the Wellcome Trust). Unit staff have contributed to many high-profile activities, including the prestigious 2010 *Royal Institution Christmas Lectures* (Mark Miodownik), an exhibit at the 2008 *British Association of Science Festival* (Clare Elwell); BBC TV's *Horizon* (Clare Elwell 2009), *Bang Goes the Theory* (Clare Elwell 2010), *Dara O Briain's Science Club* series 1 and 2 (Mark Miodownik 2012, 2013) and *Materials: How It Works* 3-part series (Mark Miodownik 2013), and BBC Radio's *Any Questions?* (Mark Miodownik 2013).

c. Strategy and plans

Impact is being facilitated increasingly through UCL's recently established Institute of Biomedical Engineering (IBME), the primary mission of which is to support and nurture impacts on medical technology, quality of life for patients and people with disabilities, and healthcare policy. It represents a cohesive inter-connected community of biomedical scientists and engineers, medical physicists, and clinicians, and was created to instil in that community a culture of enterprise and innovation in order that the translation of research outcomes into clinical adoption and patient benefit becomes a reality. IBME's strategy for facilitating impact is heavily focused on offering timely practical advice and support to staff engaged in early-stage research with significant translational potential. This is based on a recognition that maximising the success of translation requires a holistic approach and support at all stages of the innovation cycle. The following initiatives will be implemented by the IBME to maintain and enhance the impacts of our research:

a) Clinical need identification via workshops with UCLH consultants about challenges related to biomedical engineering and medical technology. These events, which began in 2013 and are attended by many of the Unit's research staff, will be held at least three times per year.
b) Promoting a culture of enterprise and innovation by encouraging and facilitating interaction

among staff, and by disseminating good practice examples via regular subject-specific seminars, a monthly newsletter, and a continually updated website with news from across the medical technology community.

c) Helping researchers to identify and nurture laboratory-based activity with a very strong potential for patient benefit. In June 2013 the IBME launched its MedTech Accelerator initiative, in partnership with the NIHR UCLH Biomedical Research Centre. This is an "introduction and connection" service: the IBME (via its Associate Director for Enterprise & Translation) provides timely and detailed guidance on what to do and who to see (e.g. to navigate complex regulatory or IP protection issues) as a project evolves from an initial concept towards an end product. Within the MedTech Accelerator, the IBME runs an Industry Liaison Programme which facilitates engagement between medical technology companies and UCL academics and clinicians, and provides a single point of contact through whom a company may explore opportunities for collaboration.
d) Early market validation by reviewing freedom to operate, health economics and regulatory issues at an early stage of the research. Funding for such activity is available via UCL's EPSRC Impact Acceleration Account (until September 2015), distributed by UCL's Translational Research Office, established in 2009 to support translation in medicine and life sciences.
e) Providing end-user and adoption advice via experts in socio-economic metrics, NICE technology appraisal and NHS procurement. Henceforth, this support will be provided to projects at both early and late stages of innovation.

The IBME will also provide a framework for support of postgraduates through the "MedTech Enterprise Academy," and courses on "MechTech Entrepreneurship," starting in October 2013. This will have a strong emphasis on the Medical Devices sector, which has unique challenges for successful enterprises due to its regulatory procedures, ethical considerations and production line management. Our long-term aim is to make training in Enterprise in Medical Technologies available to all UCL students, staff and alumni, engineers and clinicians. Flexible, relevant modules and study packages will be created in areas such as entrepreneurial finance, intellectual property, ethics and regulation, medical informatics and clinical trials. Research impact is already being emphasized within PhD training programmes at UCL, and is formally recognised during annual staff appraisal and as part of the promotion process. Finally, UCL has recently set up a new Department of Science, Technology, Engineering and Public Policy in order to facilitate and enhance the impact of research on public decision making and policy processes.

d. Relationship to case studies

• The delivery of impact through the pursuit of clinically-led research in partnership with clinicians is exemplified by all this Unit's case studies. For example, well-established, institutionally facilitated links between academics at IOMS and orthopaedic surgeons have led to the development of the non-invasive **extendable prostheses** (UCL15-BLU), and research into **metal-on-metal hip replacements** (UCL15-HAR). Likewise, the substantial impact on **incontinence management** (UCL15-COT) and **cardiovascular implants** (UCL15-BUR) has both resulted from a long-standing partnership between academics, clinicians and other healthcare providers.

• Research into **extendable prostheses** and **magnetic contrast agents** (UCL15-PAN) has led directly to establishment of successful spin-outs. The development of the **cardiovascular implants** and **synthetic organs** (UCL15-SEI) are both now either commercial products or are undergoing commercialisation.

• The Unit's case studies include several examples where major impact has been achieved via consultancy with industry and/or the provision of expert advice to regulatory agencies and other professional bodies. Consultation with manufacturers and health agencies regarding **metal-on-metal hip replacements** led to changes in health policy and medical device regulation. Similarly, research on **incontinence management** involved consultation with leading product suppliers, advising the NHS on handling tenders for products, and establishing new international standards.

• Working directly with patient groups has been a highly productive route to impact for improved **incontinence management**. Patient feedback has also been a vital element in the development of **extendable prostheses**.

• Carefully managed engagement with international media following transplantation of the first synthetic trachea led to an examination of public attitudes towards **synthetic organs**.