Institution:
University of Ulster

Unit of Assessment:
3B Allied Health Professions, Dentistry, Nursing and Pharmacy – Biomedical Sciences

a. Context ***(Note**: web site hyperlinks are in blue and underlined throughout this document)*

The Biomedical Sciences Research Institute's (BMSRI) research outputs have impacted on society globally through the better prevention and diagnosis of disease, and the development of new drugs for the improved therapeutic treatment of degenerative diseases; and also impacted on health and well-being by informing national and international health policy. The Institute has supported economic development and job creation through the transfer of knowledge and generation of IP which informs healthier diets; it supports the creation of novel products for the food industry, generates new biomarkers of disease, new therapies and drug delivery processes; this in turn gives rise to new spin-out/in companies which are purchased, or licensed by the diagnostics and pharmaceutical industries regionally and internationally. Our Groups have provided these impacts: the Diabetes Group has developed new drugs for treatment of diabetes and for obesity and Alzheimer's disease, and has generated an impressive patent portfolio, a spin-out company and licence deals. NICHE has impacted on health and dietary recommendations world-wide, informed the intake for key micronutrients, identified new pharmaceuticals, and transferred technology to the food industry. The Nanosystems Biology Group has contributed to safety aspects of nanoparticles and xenoestrogens, and innovative Bio-imaging instrumentation design has led to the development of new 'state-of-the-art' nano-imaging modalities, now manufactured. The Stratified Medicine Group has developed better diagnostics for prioritising rheumatoid arthritis and cancer patients for specific treatment and these diagnostics are being exploited by a global diagnostics company. The Transcriptional Regulation & Epigenetics Group has developed tools for inactivating genes; Pharmaceutical Science & Practice Researchers have developed drug delivery systems protected by patents and exploited via a new spin-out company; The Vision Group has developed personalised medicine diagnostics and treatments for vision defects.

b. Approach to impact

Our policy has been to engage strategically with key research end-users, with formal partnerships with Health Trusts, policy makers and industry. Our infrastructure includes the 6,200m^2 **Centre for Molecular Biosciences** (CMB, opened in 2003) at Coleraine, reinforced in 2008 by the new 4,000m^2 **SAAD Centre for Pharmacy & Diabetes** (with £1.84M from the SAAD Group, £3.2M from the SRIF3 programme and £1.3M university funding). Also in 2008, the £2M 1,000m^2 **Clinical Translational Research and Innovation Centre (C-TRIC)** was opened at Altnagelvin Hospital, Derry~Londonderry. Continued commitment to clinical impact has resulted in the opening of three additional major clinical research centres as partnerships: the **Northern Ireland Functional Brain Mapping Facility (£5.5M)**, 50% funded by Invest NI (Regional Development Agency) as a multidisciplinary cross-faculty initiative led by the Faculty of Computing & Engineering's Intelligent Systems Research Centre, and the BMSRI; **the £4M Wellcome Trust-Wolfson Foundation Northern Ireland Clinical Research Facility (NICRF)**, a partnership between University of Ulster, Queen's University of Belfast, the Health & Social Care R&D Office and Belfast Hospital Trust; and more recently the **£11.5M Northern Ireland Centre for Stratified Medicine**.

Engagement with end users: our staff have served on the Boards of, and sometimes had extended periods of secondment to, companies and regulatory bodies. We have **influenced global policy** by contribution to international influential regulatory bodies; Prof Strain (NICHE Research Group Leader), the 24th President of the Nutrition Society, is Vice-Chair of the Dietetics, Nutrition & Allergies Panel of the European Food Safety Authority (EFSA), the key EU risk assessment authority for food and feed safety, and has chaired the Working Group on Health Claims. Such participation has enabled us to influence International policy. We have also encouraged **full-time secondments** to regulatory bodies; for example, Dr S Ní Bhriain seconded (2012-2014) to the Food Safety Authority of Ireland (FSAI; 2012-2014), and Drs B Whelan (2010-2012) and L Keaver (2013-2016) to *safe*Food, an all-Ireland body to disseminate food and nutrition research findings to consumers. Prof Livingstone is a member of the *safe*Food Scientific Committee (2005-2011); Prof Gibney is Chair of FSAI; Prof McNulty is a member of the FSAI Nutrition and Novel Foods Sub-Committee, and this approach is repeated across the BMSRI.

Core Facility Units (CFUs): We have spent £2.7M updating our specialist equipment, managed by dedicated teams led by Academic and Technical Co-ordinators. We can run, if required, projects to Good Clinical Laboratory Practice (GCLP) quality standards, and can arrange for third-party accreditation/certification on demand. We have ensured a wide audience for these services through our CFU brochure, and we have increased support for start-up companies, SMEs and major industry, including some of the world's leading pharmaceutical and diagnostic companies, on a partnership, consultancy or contract research basis, via Innovation Ulster Ltd (see below).

Translating our research & engaging with key end-users:
(i) C-TRIC: a partnership company between BMSRI, the Western Health & Social Care Trust (WHSCT) and Derry City Council is strategically sited at Altnagelvin Hospital, the second largest acute teaching hospital in Northern Ireland, facilitating access to large patient cohorts. C-TRIC's focus is the promotion and translation of clinical research, reduction of time to market and of costs of research and development of innovative health technologies, medical devices, and therapeutics. This collaborative Centre streamlines developments from laboratory to patient and products to marketplace, through a focused 'bench to point of care' approach that has created commercial opportunities for partnerships between academic researchers, clinical practitioners and industry. C-TRIC's Bio-Entrepreneur Programme supported 15 start-up Bio-Entrepreneurs, 12 of whom are trading, and seven client Bio-Entrepreneurs who have progressed to become Invest NI (Northern Ireland Development Agency) client companies. C-TRIC has also attracted six Inward Investment Projects and 36 visits from potential investors. This addresses the key objectives of UK Government, Invest NI, DETI and Research Councils, of ensuring that research outputs have maximum impact on end-users. In recognition of such innovation, C-TRIC was the recipient of the **Irish Times Innovation Award** for Excellence in 2010. C-TRICs international Advisory Board includes the Director of Innovation at Partners Health Care in Massachusetts, Trung Do; and ex entrepreneur in residence at Massachusetts Institute of Technology, Dr Susan Whoriskey.
(ii) Wellcome Trust-Wolfson Foundation Northern Ireland Clinical Research Facility (NICRF): The BMSRI, in partnership with Queen's University Belfast, established the NICRF at the Belfast City Hospital Campus, with a leading role taken by our Nutrition and Vision groups. This facility provides clinical trial infrastructure and facilities in the area of nutrition, optometry, respiratory medicine, and oncology. The BMSRI appointed the Deputy Director (Prof Ward) for this facility, and works closely with the Northern Ireland Clinical Research Network (NICRN).
(iii) Office of Innovation (OoI): At HEI level, the OoI at the University of Ulster provides a focus for enterprise innovation, networking, industry training and development projects, consultancy and funded programmes to promote impact, facilitating business and industry access to a wide range of University services. Business Liaison and Technology Commercialisation Managers have worked in partnership with clients to identify contacts within the University for innovative solutions to meet business needs, and the BMSRI research groups have engaged extensively with the OoI to foster many industrial partner engagements. The OoI uses the Higher Education Innovation Fund (HEIF) for an annual Proof of Principle (PoP) Award Scheme (up to a value of £10,000 per project). Since 2008, over £100K has been invested in BMSRI related PoP projects, which have gone on to secure in excess of £2.1M in Invest NI Proof of Concept (PoC) development funding.
(iv) Innovation Ulster Ltd (IUL): IUL is University of Ulster's successful knowledge venturing company, managing IP, consultancy and spin-out company formation for the BMSRI. The BMSRI has played a full role in the economic and social development of Northern Ireland through IUL. The BMSRI Director (Prof Bjourson) is a Director of IUL. Several spin-out companies have been established by BMSRI staff and developed by IUL venture capital investment, including Gendel Ltd, EFMB, Diabetica Ltd, and Jenarron Ltd (Pitchfest 2011 overall winner). IUL has marketed our BMSRI CFU and research group capability to regional and international companies to promote contract research, consultancy and collaborative ventures. Since 2008, BMSRI researchers have secured **PoC awards (see above),** undertaken **22 Fusion projects (£419K)** (Fusion is the all-Island of Ireland equivalent to KTP)**,** and won **£492,264 in consultancy**. We have also maintained and **protected IP** arising from our research; we have filed **48 new Technology Disclosures** through IUL, maintained **25 active patents (three of which have recently been granted)**, and **filed 28 new patents,** all managed by IUL.

c. Strategy and plans

The BMSRI has a number of strategies to develop, support and promote the embedded impact from our research and those in the hospitals and community. This impact is achieved partly through e**xploitation of Central HEI Impact Support Initiatives via** OoI PoP funding scheme described above, which has provided seed corn funding for projects with commercial potential, and enabled evaluation of new ideas disclosed by staff via IUL. Further, we have **used BMSRI (UoA specific) Impact Support Initiatives:** these relate to strategies that are UoA specific and aim to develop and support impact. In particular, ***Targeted Clinical Impact Promotion*** began in 2008 in partnership with the Western Health & Social Care Trust (WHSCT/C-TRIC), with an annual **Clinical Impact Grant Award Scheme**. The BMSRI Director and the Director of Research at the WHSCT match-funded projects with potential for clinical utility or commercial exploitation, specifically involving collaborations between hospital clinicians and BMSRI researchers. A fund of £100K/year was made available on a competitive basis; individual projects were funded up to a value of £10,000. The projects generated data to pump-prime collaborative projects between hospital clinicians and BMSRI academic researchers, with subsequent substantive external applications (greater than £100K/year) submitted for follow-on funding. Such projects have supported multidisciplinary interactions and support for early career researchers.

BMSRI Campaign: In 2008 the BMSRI Director and Head of School of Biomedical Sciences reviewed the alignment of our research activities with the economic and business needs of three key industrial sectors: pharmaceutical, diagnostics and food and nutrition industrial sectors, nationally and internationally. This led to formal research partnerships with major companies and the establishment of industrially funded posts (Professorships, Research Fellowships and PhD studentships; notably the **Norbrook Laboratories Chair in Pharmaceutical Science (£1M)** and the **Randox Fellowship in Personalised Medicine (£320K)** and to new collaborative projects. We have also appointed representatives from key industry sectors as Visiting Professors or members of our external advisory panels, to inform our impact policies and practices.

Northern Ireland Centre for Stratified Medicine: This **£11.5M Centre,** with funding for 22 new posts and input from 10 Consultant Clinicians (based at the WHSCT), is developing personalised medicine diagnostic panels (in hypertension, diabetes, mental health, oncology, inflammatory disease and vision) with clinical and commercial utility; within five years, we aim to leverage 200 jobs in diagnostics and pharmaceuticals to the region. Over the next 12-24 months, the Centre will integrate with our new Functional Brain Mapping Centre and the University of Ulster Bamford Centre for Mental Health to develop a **new multidisciplinary Clinical Data Analytics and Health Economics Centre** as a partnership between BMSRI and the Faculty of Computing & Engineering's Intelligent Systems Institute, the Health Trusts, global Industry and regulatory stakeholders. This will be delivered by **a new £20-25M Institute for Health & Wellbeing** in Partnership with hospitals in Derry~Londonderry and Letterkenny in the Irish Republic. We will also seek to establish **a new TSB Catapult Centre for Diagnostics in Stratified Medicine initiative,** in partnership with Queen's University Belfast, Randox, ALMAC, other Centres in the UK and across Ireland. We seek to link pharma, diagnostics and healthcare systems, in the UK and Ireland, and enable businesses on these Islands to exploit stratified medicine.

d. Relationship to case studies: NICHE's outputs have had substantial impact globally, contributing to five case studies.

NICHE: The Northern Ireland Centre for Food and Health, one of the largest and most productive nutrition research groups in Europe, was established in 1996 as a Centre of Excellence with EU structural funds to provide greater strategic understanding of diet-related health issues for industry. At a local level NICHE personnel (Strain, McSorley) were involved in the formation of a Food Liaison Group with Agri-Food and Biosciences Institute (AFBI), Department of Agriculture & Rural Development (DARD) and Queen's University Belfast. NICHE provides expertise to industry and regulatory bodies partly via its aligned Human Intervention Studies CFU. NICHE's priority objectives have been aimed at identifying food components or dietary regimes likely to lead to benefits for human health - particularly those related to prevention of obesity, heart disease, stroke, osteoporosis and cancers. A key aspect of the work is the development and validation of biomarkers (early indicators) to facilitate dietary intervention studies in healthy subjects at risk of

disease. NICHE has been highly successful in generating impact, as evidenced by its contribution to five case studies. Membership of **national and international Government bodies is a key feature;** Prof Strain is Vice-Chair of the Nutrition Panel of the European Food Safety Authority (EFSA) and Chair of the Working Group on Health Claims. As President of the Nutrition Society, Prof Strain has established official nutrition research international links with China, the USA, Taiwan, South Korea, Australia and Africa. He has been instrumental in forming official agreements with Nutrition Societies in Germany, Belgium and France to organise joint scientific meetings and for the establishment, with the American Society of Nutrition, the African Society of Nutrition, a consortium of African Universities and Cambridge University Press, of an on-line learning resource hub for capacity building initiatives on the African continent. He was also Vice-Chair of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption, Rome, 2010. NICHE played a leadership role in the creation of the NICRF (see above) and the NICRF Deputy Director was appointed from this Group (Prof Ward).

Diabetes: To maximise commercial impact, in 2004 (supported by IUL), the Diabetes Group formed Diabetica Ltd to commercialise its research. Intellectual Property (IP) on GIP agonists was licensed by IUL/Diabetica Ltd to Amylin Pharmaceuticals Ltd (now BMS) in March 2006, with a licence fee of £284,375 and milestone payments of up to £23M plus royalties (£251,629 received). Further research agreements have been executed for the Group's human insulin secreting cells and for diabetes biomarkers, licensed to Boehringer Ingelheim, Sanofi Aventis and Domain Therapeutics (income £62,567). Evaluation licences have been granted for eight other pharmaceutical companies (AstraZeneca, Celther Polska, Eli Lilly, Nordic Bioscience, Novartis, Novo Nordisk, Takeda, and Tranzyme Pharma,) and a strategic Research Collaboration has been entered into with Sanofi Aventis for development of novel peptide therapeutics for diabetes. The Group's novel drug candidates have also shown pre-clinical utility in the treatment of Alzheimer's disease, a diversification that has resulted in new IP and Licence agreement with Sanofi Aventis as well as the clinical development of the drug liragutide as a treatment for Alzheimer's disease. Prof Flatt is on the Advisory Board to Novo Nordisk, past Member of Diabetes UK Advisory Council, Member of Diabetes UK Research Committee and Chairman European Foundation for Study of Diabetes/Glaxo Smith Kline Research Committee, and Prof Gault is a Member Diabetes UK Annual Professional Conference Programme Committee. Prof O'Harte was an EU assessor for the Innovative Medicines Initiative. In 2011 and 2012 he chaired a research grant panel of international experts in Helsinki for the Academy of Finland to consider peer-reviewed health research funding.

Nano Systems Biology: The BMSRI has strategically developed core facilities for bio-imaging, coordinated by the Nano Systems Biology Group. Bio-Imaging is one of six CFUs that are operated on financially sustainable bases, and undertakes research for SMEs and major pharma on a contract research, consultancy or collaborative basis. With £5M state-of-the-art instrumentation, it provides a unique opportunity for access to imaging modalities rarely found within a single laboratory. Dr McKerr has a very productive long-standing collaboration with FEI, the major European manufacturer of electron microscopes. The CFU has Reference Laboratory status (led by Prof Downes and Dr McKerr), on two fronts (EM and super resolution optical microscopy), has extensive collaborative links with global industries and has ongoing collaborations with instrument manufacturers and software developers. These instrumentation developments have been profitably exploited by Prof Howard for the study of nano-particle toxicology, and the facility is a leading European nanotoxicology center, with numerous nanotoxicology papers published from this work. This has led to Prof Howard's leading role in CEC and WHO task forces and committees reporting on hazard assessment for nanoparticles.

Exemplar Prizes, Awards, Honours: British Nutrition Foundation Prize 2012, (Strain); Member Royal Irish Academy (Strain, Flatt, McNulty, Livingstone); Niall O'Meara Award Lecture of Irish Endocrine Society 2009 (Flatt); Ernst Friedrich Pfeiffer Memorial Award Lecture of EASD (AIDPIT) (Flatt); Norbrook Chair in Pharmaceutical Science (Callan); EASD Rising Star Award, Vienna, 2009 (Gault); Global Center of Excellence Award (Visiting Fellowship); Academic Enterprise Awards Europe (ACES), Award Winner in Life Sciences category 2008 (Flatt, McClenaghan, O'Harte).