**Institution: Cardiff University**

**Unit of Assessment: UoA1**

**a. Context**

**Structure:** Cardiff University (CU) UoA1 comprises researchers from the Institutes of Cancer and Genetics (ICG) and Infection and Immunity (I&I) within the School of Medicine (SoM). Several researchers are members of both Institutes, facilitating extensive collaboration across the Unit. Our research includes clinical and pre-clinical molecular, cellular, animal and human studies, and has resulted in a broad range of impact - from improvements in the provision of healthcare to commercial partnerships with industry for patient and economic benefit.

**Beneficiaries:** The main non-academic beneficiaries of UoA1 research are: **patients, their families and the public**; **policy makers and practitioners working** in environment, health protection, safety and education (including the NHS, Welsh Government, Government agencies/departments such as HSE, DEFRA, DoH, MoD, and International health organisations (WHO, IFIC, UICC)); **healthcare charities** working on infectious, immune-mediated and neoplastic diseases; and **industry**, particularly pharmaceutical and diagnostic companies, and SMEs working in immunology and cancer to develop tests, therapies and devices.

**The main types of impact resulting from UoA1 research** are: **1)** improvements in international and UK clinical practice and health service provision; **2)** commercialisation of novel diagnostics, therapeutics, devices and tools in partnership with industry for patient and economic benefit; **3)** increased awareness among our non-academic beneficiaries of our research successes and ensuing benefits, that translates to increased financial and popular support; **4)** commercial funding - during the REF period our impact has generated 22 granted patents, 14 licencing agreements and over £1.75M in direct income to the University.

**Examples of impacts relating directly to UoA1 research activity include**:

- Identification of new genes predisposing to serious inherited disorders and cancer, and development of diagnostic/predictive tests for these disorders that are now implemented globally.
- Establishment of new standards of care for acquired and inherited diseases and cancer that have been incorporated into national and international guidelines.
- Development of techniques, tools and standards that have been commercialised through partnerships with industry and/or adopted by not-for-profit organisations.

**b. Approach to impact**

*UoA1 achieves research impact* by working with potential beneficiaries to identify key priorities and issues in its areas of expertise and designing research to address these priorities. Unit staff and students actively engage NHS clinicians, clinical scientists and managers locally and nationally and involve patients, patient organisations, charities, funders and policy makers at each stage of the research process, including the planning and conduct of research, thus facilitating the timely implementation of research findings in practice. We have 5 **Innovation Champions**, who are highly motivated and experienced and promote an innovation culture by engaging proactively with staff to identify potential impact. They are supported by University **Research, Innovation and Enterprise Service (RIES)** (http://www.cardiff.ac.uk/racdv/) to guide researchers through IP protection and commercialisation and identifying and negotiating with commercial partners.

**Evidence for and examples of these relationships** include:

1. **Joint working with the NHS**: **1)** co-located R&D offices led by a joint R&D director has removed artificial barriers to joint working; **2)** a joint Innovation Network with dedicated collision space has driven new projects; **3)** integrated research teams involving NHS and academic staff delivered patient benefit measured by audit; **4)** direct involvement and leadership by UoA1 clinical academics with honorary NHS contracts guides development of local and national NHS services and policy; UoA1 staff are clinical area leads in cancer, dermatology, diabetes, arthritis, infection and gastroenterology; **5)** co-authored publications and successful joint infrastructure/research grants, for example, in August 2013, £2.15M was awarded from the Wales Health Technology Fund to purchase the first robotic surgery system in Wales (http://wales.gov.uk/newsroom/healthandsocialcare/2013/130808htf/?lang=en screenshot saved on 4/11/2013 and available from HEI).

**2. Direct transfer of research findings to improved patient care:** Numerous achievements locally and nationally, including innovations in gene testing, sentinel node biopsy in breast cancer

and combined radiotherapy and hormone therapy in prostate cancer, are further detailed in our case studies. **Device and technology development** is a particular success, involving collaboration with industrial partners and other commercial organisations, from local SMEs to multinationals, supported through mechanisms that include direct funding and two Knowledge Transfer Partnership (KTP) awards. A KTP with Agilent is developing technology to detect genome wide DNA damage. A SoM spinout, Biostatus Ltd, (http://www.biostatus.com screenshot taken 3/11/13 and available from HEI), pioneering far-red fluorescent dyes for biomedical applications including toxicology testing and drug development, won the 2012 Teamwork in Innovation Award of the Royal Society of Chemistry. Innovative life-saving devices from UoA1 research include the Hall Lock system, a patented (2011) invention addressing unmet clinical need by reducing risk of drug administration error. This won 5 innovation awards, including Partnership with NHS/Academia Award and NHS collaboration with Industry Award, and is now in production (Flexicare Medical) and marketed worldwide (http://www.halllock.com/ screenshot taken 4/11/13 and available from HEI).

**3. Working with other partners:** UoA1 staff are actively encouraged to join committees, boards and other bodies that influence research and healthcare. Involvement includes:

**i) Input into government healthcare policy** at local, national (Wales/UK) and international level, through UoA1 staff appointments to Advisory Groups, Panels and Boards (45 appointments), enabling UoA1 research to contribute to and be incorporated in broader research strategy, funding priorities and national clinical guidelines; for example, UoA1 research from Cardiff cited as evidence by national/international bodies in diagnosis/treatment guidelines for acquired haemophilia A (World Federation of Hemophilia), psoriasis vulgaris (NICE), leukemias (British Committee for Standards in Haematology) and other cancers as described in our case studies.

**ii) Links with pharma** that include many Unit staff on advisory boards and/or consultancy groups across a variety of large and small companies (e.g., GE Healthcare, GSK, NAPP, Roche, Novartis, Baxter Healthcare, Pfizer, Fresenius, Sanofi Aventis, Nordic Pharma), and the conduct and publication of clinical trials jointly with partners from the pharmaceutical and diagnostics sectors (for example, with Myriad Genetics, Immunocore Ltd, Spirogen Ltd, Ipsen Ltd, Leuchemix Inc, Novartis, GSK, Adaptimmune Ltd, Apoxis SA, Astra Zeneca, Pfizer, Oncolytics);

**iii) Other Industrial partnerships** have been developed through spin-out companies, licensing and user agreements with commercial impacts including novel diagnostics, product development and marketing, knowledge transfer, training and licensing of knowledge and tools;

**iv) Engaging involvement of patients, their families and lay organisations** in research across the Unit. Lay groups and patient advocates are involved in *clinical trials* at all stages; helping study design, as major contributors to patient recruitment and representing patients on trial steering committees. They aid recruitment to *tissue banks*, a vital research infrastructure (e.g. contributed to the rapid growth of the Wales Cancer Bank). Unit researchers host open days and update meetings and encourage involvement of patients and their advocates in research in partnership with NISCHR.

***v*) Contributing to charities that support research for patient benefit***:* Unit members sit on Boards, Funding Committees and Advisory Groups of National and local charities, for example, Arthritis UK, Tenovus and Cancer Research Wales and speak at fund-raising events and contribute to patient-targeted newsletters (MS Society, Arthritis UK, Alzheimer's Society).

**The Unit specifically supports and enables staff to achieve impact** through the application of CU's Innovation and Engagement strategy (established in 2006; evolved through RIES), delivering advice, training and financial support for realising impact, and hosting networking events to facilitate interaction with partners and beneficiaries. The strategy encourages Unit researchers to develop new impacts in collaboration with internal and external groups and organisations; for example, the MRC-funded Severnside Alliance for Translational Research (SARTRE) led by Unit researchers has successfully driven translational collaboration between CU and Bristol. Other key partners include Health Boards, Welsh Government's science arm BETS, MediWales the focus for device development, National Institute of Social Care and Health Research (NISCHR) the portal for NHS R&D funds, and NIHR i4i and other funding. An annual CU-wide Innovation and Engagement Awards competition provides a showcase for staff and student impact successes.

**The Unit makes use of Institutional resources through several mechanisms***:* Translation is supported by Technology Transfer expertise available in RIES, with dedicated staff now embedded

in the Unit. CU's Commercial Advisory Panel assesses potential of Unit research, assisted by the Unit's own Innovation Champions. In 2011, the School established the **Translation, Innovation, Methodologies and Engagement Institute (TIME)**, bringing together all trials units, core facilities and engagement support, to act as the catalyst in the School for delivering translation through training, supporting innovation and encouraging entrepreneurial activities of our researchers. These School structures interface directly with RIES to identify and develop innovation. The Unit's effectiveness in translation and innovation has been recognised through several prizes including a track record of success in the Queen's Anniversary Prizes (2008; 1998).

CU has partnered with Fusion IP, a commercial exploitation and investment group, to facilitate the identification and exploitation of IP arising from research. UoA1 staff generated 24 granted patents between 2008-2013. One patent filed in 2010 by University of Alabama with a Unit member as named inventor for work done in Cardiff, is applying for FDA approval for treatment of contrast dye-induced nephropathy. Patent income from UoA1 during the period is £1.25M, with 11 licences granted. The Cardiff MediCentre, a joint economic development project between CU, Cardiff Council, Welsh Government and local Health Boards, was established in 1992 on the University Hospital site. It has nurtured several UoA1-led biotechnology and medical technology start-up companies, including **MedaPhor, AssayMetrics, Diurnal, i2c Pharmaceutical Services, INDOOR Biotechnologies, Cansford Laboratories, Expert Forensics**. Major successes in the period include: **BioDynamics Research** (acquired by Quotient BioResearch in 2008), **Q-Chip** (awarded $6M in 2011 to establish a manufacturing facility), and **Synexus** Clinical Research (the largest clinical trials management/patient recruitment organisation in Europe http://www.cardiffmedicentre.co.uk/start-ups/success-stories screenshot saved on 4/11/13 and available from HEI).

**c. Strategy and plans**

**Strategy: The primary objective** is to expand our research portfolio, enhance translation and impact in health, wealth and knowledge gain. This will be achieved by developing stronger ties with beneficiaries, creating an environment that helps us to better understand their needs and facilitate research translation, and an environment in which other CU researchers, national and international partners, user groups and wider beneficiaries recognise UoA1 as a trusted partner for translating research into impact. The immediate goals are:

**1.** To increase the proportion of translational research that will improve human health.

**2.** To attract more user investment in research, development and training, including from charities, commercial companies, research councils and other sources to fund translational research, including PhD studentships with innovation at their core.

**3.** To extend training in impact and engagement to all UoA1 staff and students, embed the topics in medical and science curricula, establish training opportunities at all career stages and develop Innovation Champions to link staff and students with successful innovators in CU and beyond.

**4.** To strengthen the focus on impact in our research applications and outputs and to emphasise impact in dialogue with all stakeholders identified above.

**5.** To be proactive in identifying the best partners in outside Institutions and companies and to increase investment in the development of these collaborations and strategic partnerships.

**Plans for supporting and enabling impact: Dissemination to and training of researchers**

**1.** We have designated **Impact Champions** who are resourced and tasked to support and advise Unit staff and students in all aspects of impact and offer specific training – for example, a series of Workshops titled "**Translation for the Terrified***".*

**2.** All researchers are encouraged to identify ways to increase impact and develop robust methods of monitoring and recording impact. These measures are embedded in annual appraisal and supported by a comprehensive portfolio of training within the unit.

**3.** The new undergraduate medical curriculum (**C21**; launched 2013) exposes undergraduates to the principles and practice of translation and impact via specific modules led by proven innovators. We will develop these modules for PhD students, postdocs and fellows and embed them in professional development. One novel approach is the use of video case studies with linked learning outcomes that highlight examples from the Unit's successful innovators.

**Communication and dissemination to stakeholders**

**1.** We will exploit a range of approaches to make our research known to policy makers, industry, 3rd sector bodies and the public; these will include websites, embedded videos, open days, school

and college visits, linking with local and national media.
**2.** We will use our status as both CRUK and Leukaemia and Lymphoma Research Centres to attract patient volunteers willing to participate in Trials, Biobanks and other UoA1 research and extend this approach, well established in Cancer, to other aspects of the work of the Unit.
**3.** We will use the resources of the highly successful Wales Gene Park to publicise our successes and engage the community locally and across Wales.
**4.** We will publicise our successes in linking with China (Peking-Cardiff Cancer Centre established in 2012 with £5M funding; Capital Medical–Cardiff Translational Centre in late stages of development) and build on these achievements.
**5.** We will utilise the SE Wales Academic Health Science Partnership (established 2012), an alliance involving and funded by all HEIs and NHS organisations in the region, to create new synergies in translation and innovation between partners, funders, industry and Government and deliver on key priorities in health, economy and science. UoA1 staff are on the Partnership Board.

**Resources to support and enable impact**
We will make funds available on a selective basis to support efforts to develop/monitor the impact of our research. We will exploit external funding opportunities to increase research impact, e.g. KTPs (two already in Unit), Knowledge Economy Skills Scholarships, BBSRC Activating Impact Awards, Wellcome Institutional Strategic Support Funds (already used for this purpose in Unit).

**d. Relationship to case studies.** We have selected case studies from our broad research portfolio to illustrate the success of our approach to identifying unmet need, supporting innovative research and its translation to impact. Each has benefited from the impact strategy of the Unit, and led directly to significant improvement in healthcare. Our case studies demonstrate that our approach to impact enables our researchers to produce tangible health and wealth outcomes.
**1. Research that has translated into new technologies, diagnostics and therapies.** The Unit boasts numerous examples of direct translation of research into improving therapies adopted internationally and improving patient outcomes. **Case Study 4** describes translation of basic research on inherited bowel cancer into a diagnostic test for causative mutations. Commercial potential was identified and IP secured with assistance from CU and Wales Gene Park. The invention was licensed to Myriad Genetics Inc. providing a platform for genetic testing in the large US market. The test, launched 2008, has already generated >$5M income and >£320K royalties. This success contributed to the award of a Queen's Anniversary Prize to Unit researchers and CU in February 2008. **Case Study 7** describes the creation, with support from CU and MediCentre, of a spinout company based on UoA1 research and IP secured on innovative fluorescent molecular probes for healthcare, drug discovery and life sciences applications. The growing company has won major awards and earned >$3.2M in sales. **Case Study 5** describes the translation of local clinical research into practice. The Unit-led ALMANAC trial of sentinel node biopsy in breast cancer helped to fundamentally change management of breast cancer, demonstrating that the century-old practice of axillary lymph node clearance was unnecessary in many cases. This change in practice markedly reduced morbidity, spawned Unit-led national and international training programmes and established new clinical guidelines in the UK, Europe and USA.
**2. Policy development for patient benefit** Our basic and clinical research translates directly into new clinical policies and treatment guidelines with major impact in areas of need. **Case Study 2** describes translation of clinical research on haemophilia into new international and UK guidelines on disease management that markedly improved patient outcomes, reducing bleed-related mortality from 22% in the 1980s to less than 3% in 2009. **Case Study 3** describes translation of clinical research on prostate cancer into new standards of care, now embedded in European and US guidelines, which dictate that all patients are offered combined modality therapy; a conservative estimate is that 50,000 lives are saved/yr. worldwide. **Case Study 1** describes research on the impact of skin diseases on patient health and well-being that led to the development of the Cardiff Dermatology Life Quality Index, now used in national psoriasis guidelines in 12 countries, translated into 85 languages, used in >600 clinical research studies and generated over >£880K in royalties to CU. **Case Study 6** describes translation of basic research on a novel microbial antibiotic resistance pathway (NDM1) into evidence that this resistance gene has become widely distributed in bacteria across continents and led directly to worldwide changes in policy and new public health recommendations regarding water provision and sanitation.