R&D

SUCCESS IN ATTRACTING FUNDING TO NORTHERN IRELAND

SUCCESSFUL KNOWLEDGE TRANSFER

SUPPORTING RESEARCH & DEVELOPMENT

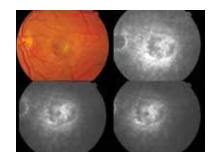
IMPORTANT
CHANGES FOR HSC
RESEARCHERS

NOTICEABLE ACHIEVEMENTS

A MAJOR CLINICAL TRIAL

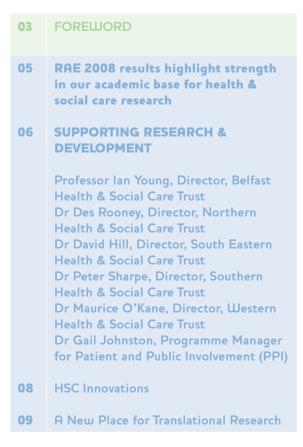
Issue 11 SPRING 2009

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An important clinical trial of a new health technology has commenced in the UK, led by investigators from Northern Ireland.

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Belfast, BT2 8BS

#### **NOTICEABLE ACHIEVEMENTS** 2008 NCI Cancer Prevention Courses 2008 Cochrane Fellowships 2008 Joint Awards - GParts 2009 Doctoral Fellowship – Clinical 2009 Doctoral Fellowship – Health & Social Care Education & Training - HSC Studentship Top-Up Scheme Education & Training - Bursary Scheme Belfast Team Develop Novel Approach to the Diagnosis of Lung Cancer SUCCESS IN ATTRACTING FUNDING TO NORTHERN IRELAND 14 Research for Patient Benefit Programme Identifying the research priorities for the therapy professions In Ireland Northern Ireland Researchers Secure Funding to Develop Novel Medical Implant Devices

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## FORFUJORD

Professor Bernie Hannigan Director of R&D and Chief Scientific Advisor

Welcome to issue 11 of our newsletter - R&D Today. As the third holder of the post of Northern Ireland's Director of R&D for Health and Social Care, I would pay tribute to my predecessors: Professor Bob Stout and the founding Director, Professor Dame Ingrid Allen. My role is to build upon the 10 years of their achievements in line with best practice worldwide.

When I speak to researchers and others, a key message is our need to consider the origin of our HSC R&D Fund. That money, if it were not used for R&D, would provide for other aspects of service delivery. So the work we support must lead to enhanced quality and efficacy of services and care for the population of Northern Ireland today and tomorrow, regardless of how distant that 'tomorrow' may be. We will move to supporting a portfolio of research that focuses on needs: the needs of patients and clients, the needs of policy-makers and the needs of health and social care staff.

We must not underestimate the complexities involved in moving research findings closer to users who could benefit from them, nor the time that it takes. But neither should me undervalue the impressive benefits that lead from research. All of these points are set out clearly in a new report entitled 'Medical Research: What's it worth?' that is available from The Wellcome Trust www.wellcome.ac.uk/economicbenefits. Findings about investment in health-related research include a 30% annual return directly into the economy and a 9% annual return in health gains (based on disease prevention and new therapies); but an average time-lag of 17 years between research and health benefits. If we could shorten the time-lag, returns would be even more significant. A report on the effective translation of a HSC R&D-funded project is included on page 21 of this Newsletter. Our recent call for proposals through our Knowledge Transfer scheme will enable more researchers to translate their findings to practice, to policy or to products.



In my previous role as Pro Vice Chancellor for Research & Innovation at the University of Ulster I spent a lot of time considering the best ways to support the translation of research findings into practice. One approach that may seem simple but really can work is to involve end-users in all stages of a research project. In health and social care research our end-users are patients, clients, practitioners and policy-makers. Are we involving them? To support this good practice the newest member of our office, Dr Gail Johnston, has lead responsibility for Patient and Public Involvement (PPI). A brief profile of Gail is on page 07.

We must change to ensure that this needs-led ethos prevails. We will rebalance the number of investigator - proposed projects that dominates our current portfolio with an increased number of projects that respond to health and social care needs.

The impact of the Northern Ireland Clinical Research Network (NICRN) will be felt increasingly across the province as more clinical trials get underway supported by commercial or noncommercial funds. A large multi-site clinical trial in ophthalmology (IVAN) that has been attracted to the province is detailed on pages 19-20. It is a very good example how our national and international leadership in a specific research area – in this case Vision Science – leads to commercial investment in our health services. Other developments will also flow from the recent appointment of an R&D Director in each HSC Trust with dedicated research support staff and a range of infrastructure elements that are, or will be, put in place. On pages 6-7 you will find details of local and national support for all researchers and specifically for those within HSC Trusts. The streamlining of

research application processes through the IRAS is explained on the back cover and page 23.

Our budget for R&D is limited but of course we are just one of many funders. Co-operation is now very evident, for example between the UK research councils and NHS/HSC funders such as us. Some projects that are supported by funds from outside of the province are profiled in pages 15-18. This will enable our portfolio of supported projects to shift from much early-stage research (i.e. the domain of research councils and other funders) towards work that is more clearly focussed on outcomes for patients and clients. HSC R&D is also happy to work in partnership with other funders to support projects that would be outside of the scope of a single funder alone.

Finally, I would draw your attention to the stream of email communications from our office that raises awareness of forthcoming opportunities. The next one might indicate the very best opportunity for you. If you do not receive our emails and would like to, please let us know.

At the outset of an appointment it is very easy to write about all the things we are going to do. I've enjoyed that, but now I look forward to future newsletters when I will review progress.

#### Professor Bernie Hannigan Director of R&D and Chief Scientific Advisor



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# **PE 2008 Results**

## RAE 2008 RESULTS HIGHLIGHT STRENGTH IN OUR ACADEMIC BASE FOR HEALTH & SOCIAL CARE RESEARCH

In December 2008 the outcome of the 2008 Research Assessment Exercise (RAE2008) were announced. The RAE evaluated the quality of research carried out between 2001 and 2007 in UK universities. Quality was judged primarily through peer review, backed up by validated data, by UK and international experts organised into 67 subject-specific Units of Assessment (UoAs). The principal factors reviewed were research outputs, most usually published journal articles and books; external grants attracted to support research; success in the graduation of research students and the esteem in which staff were held. For some UoAs, evidence

of the impact of research, e.g. on policy, patients or industry was also considered. The results were expressed as grades that can be summarised as: 4\* - world-leading; 3\* - internationally excellent; 2\* - recognised internationally; 1\* - recognised nationally and unclassified.

Both of our local universities made substantial RAE submissions. The published results do not relate to individual researchers but to the research groupings submitted. The table below indicates the number of researchers (as whole-time equivalents) submitted to the principal UoAs that are relevant to health

Unit of Assessment	UK total QUB no.		% 2* or	Ulster no. staff	% 2* or
Onit of historial	no. staff	staff	better	Oister iio. stair	better
Cardiovascular Medicine	359	0	-	0	-
Cancer Studies	678	37.00	95%	0	-
Infection & Immunology	650	0		0	-
Other Hospital-based Clinical Subjects	1,624	13.00	90%	0	-
Other Laboratory-based Clinical Subjects	252	8.00	85%	0	-
Epidemiology & Public Health	545	23.50	90%	0	-
Health Services Research	506	0	-	0	-
Primary Care & Community-based Clinical Studies	151	0	-	0	-
Psychiatry, Neuroscience & Clinical Psychology	779	0	-	0	-
Dentistry	399	13.00	95%	0	-
Nursing & Midwifery	642	10.68	70%	25.90	100%
Allied Health Professions & Studies	1,456	14.00	85%	Biomed Science 60.75	95%
				Rehab Science 14.00	55%
Pharmacy	440	23.00	95%	0	-
Pre-clinical & Human Biological Sciences	580	0	-	0	-
Social Work & Social Policy & Administration	1,243	21.61	90%	15.60	95%
Sociology	927	23.00	85%	0	-
Psychology	1,659	19.50	80%	27.00	70%
Total	12,890	206.29		143.25	

and social care research and the % that achieved a rating of 2\*, 3\* or 4\*.

The major conclusion to draw from the results is that a very high proportion of research is internationally recognised, or better. This is extremely commendable and shows that our universities are an excellent source of research that can benefit patients and clients. The results inform the distribution of research funding from the Department of Employment and Learning (DEL) so the existence of this resource can be assured for the future. But look also at the number of UoAs to which neither university made a submission. These include disciplines that are highly relevant to the province's burden of illness, e.g. cardiovascular medicine or health services research. No university has the resources to support excellent research across the full range of disciplines so such gaps are inevitable, indeed essential, so that the research that is done can be the best possible. However health and social care services must cover all specialisms and all must use research evidence to the same extent. Fortunately, the vast majority of research findings are now available online regardless of where the work was done. It is essential that all practitioners understand how to access research findings and how to evaluate the reliability of sources and evidence. HSC R&D recognises the need to translate good research into practice, whether the research is conducted locally or elsewhere. This will be evident in activities and initiatives now in development that focus both on researchers and practitioners.

#### SUPPORTING RESEARCH & DEVELOPMENT

#### **HSC TRUST DIRECTORS OF R&D**

#### **BELFAST HSC TRUST**

#### PROFESSOR IAN YOUNG, DIRECTOR, BELFAST HEALTH & SOCIAL CARE TRUST



Professor Ian Young is Associate Medical Director, Research & Development and Consultant Chemical Pathologist for the Trust. He is also Director of the Northern Ireland Clinical Research

Network. In his role as a Clinical Academic he is Professor of Medicine and Director of the Centre for Public Health at Queen's University Belfast. Professor Young's main clinical and research interests are in lipids and nutrition, particularly the biological effects of nutritional antioxidants. He is an author of over 220 published research papers and has obtained over £12M of research grant income in the last ten years. He is on the editorial boards of a number of leading international journals, and is an Associate Editor of Clinical Chemistry, which is ranked as the number one journal in laboratory medicine. In addition, he is Vice-Chair of the Scientific Division of the International Federation for Clinical Chemistry and Laboratory Medicine.

#### **NORTHERN HSC TRUST**

#### DR DES ROONEY, DIRECTOR, NORTHERN HEALTH & SOCIAL CARE TRUST



Dr Des Rooney is Head of Research & Development for the Trust and Consultant Physician in diabetes and endocrinology at Antrim Hospital. Previous positions include Consultant Physician at the

Victoria Infirmary in Glasgow from 1997-2001 and Clinical Director of the medical directorate at Antrim Hospital from 2004-2007. He was a diabetes and endocrinology Research Fellow in Belfast from 1988-1990, leading to an MD from Queen's University Belfast in 1991. Subsequently he was an Associate Fellow at the University of Minnesota, USA from 1992-1994, leading to further diabetes and metabolism research publications

#### **SOUTH-EASTERN HSC TRUST**

#### DR DAVID HILL, DIRECTOR, SOUTH EASTERN HEALTH & SOCIAL CARE TRUST



Dr David Hill is
Associate Medical
Director, Research &
Development for the
Trust and a Consultant
in Anaesthesia & Pain
Medicine. Dr Hill is
currently Dean of
the Faculty of Pain
Medicine, College of

Anaesthetists of Ireland. He is also interested in obstetric analgesia and anaesthesia and is an officer bearer of the Obstetric Anaesthetists Association UK (OAA). Dr Hill's research interests are mainly in obstetric anaesthesia and he was awarded MD in 1994 for work on various aspects of epidural pain relief. Dr Hill also works alongside palliative medicine in the Marie-Curie Hospice, Belfast.

#### SUPPORTING RESEARCH & DEVELOPMENT

#### **SOUTHERN HSC TRUST**

#### DR PETER SHARPE, DIRECTOR, SOUTHERN HEALTH & SOCIAL CARE TRUST



Dr Peter Sharpe is Associate Medical Director, Research & Development for the Trust. Dr Sharpe has been a Consultant Chemical Pathologist and Specialty Lead for Clinical Biochemistry at Craigavon Area Hospital

since 1998. Previous to that he trained in General Medicine and Chemical Pathology and was Research Fellow in Belfast from 1995 to 1996 which led to an MD from Queen's University Belfast in 1997. Dr Sharpe's main clinical interests are Lipidology, Diabetes and Nutrition. He also has a keen interest in Point of Care Testing and has been the Chairperson of the Trust's Point of Care Testing Committee since 2003. His main research interests are in Lipids, Cardiac Biomarkers and Nutrition.

#### **WESTERN HSC TRUST**

#### DR MAURICE O'KANE, DIRECTOR, WESTERN HEALTH & SOCIAL CARE TRUST



Dr Maurice O'Kane is Director of Research & Development for the Trust and Consultant Chemical Pathologist at Altnagelvin Hospital. Dr O'Kane graduated in Medicine from the University of Edinburgh and undertook

postgraduate training in Scotland, Northern Ireland and France. Between 2000 and 2007 he was Clinical Director of Pathology Services at Altnagelvin. Maurice's research interests are in the clinical biochemistry of diabetes.

#### NEW PROGRAMME MANGER FOR PPI DR GAIL JOHNSTON, PROGRAMME MANAGER FOR PATIENT AND PUBLIC INVOLVEMENT JOINS HSC R&D



Dr Gail Johnston has recently been appointed as Programme Manager for Patient and Public Involvement in the HSC R&D. This is a newly established post to support researchers in involving patients and the public at all stages of the research process as well as raising awareness about the benefits

of participating in clinical research with service users and members of the general public.

Gail undertook a degree in Social Science at Edinburgh University before going on to train as a nurse and district nurse. She subsequently worked as a research sister and fellow in Ninewells Medical School, Dundee, on a variety of health service research projects and completed her PhD there in 1997. She moved to Belfast in 1998 and for 9 years worked as a Macmillan Lecturer, initially in the Dept of General Practice at Queen's University and latterly in the Macmillan Education Unit, Belfast, supporting the professional development needs of Macmillan postholders throughout Northern Ireland.

#### HSC INNOVATIONS SUPPORTS KNOWLEDGE TRANSFER

HSC Innovations is a centre of expertise in intellectual property management for all HSC bodies. The service works closely with the Research Offices of the five HSC trusts and HSC R&D to promote effective intellectual property management in support of the Research Governance Framework and HSC Innovation Policy.

The service can help you exploit the commercial potential of research results and innovations from practice by assisting with:

**Collaborative** arrangements with third parties - for example the intellectual property aspects of research or material transfer agreements with universities and companies, to ensure that the HSC contribution is acknowledged.

**Technology** and market due diligence to assess the technological novelty and commercial potential of inventions emerging from research or clinical practice.

**Protection** of ideas and inventions, from copyright through trade marks to patents. The service has funding to secure the assistance of patent attorneys and to file for local and international patent protection.

The service offers a number of resources to help you:

- Bespoke advice by telephone, e-mail or in person.
- A newsletter including case studies and opportunities.
- A series of information sheets on intellectual property management.
- A website providing news and information.

Contact us to find out more:

tel: 028 9060 5794

e-mail: innovations@crsc.n-i.nhs.uk web: www.crsc.n-i.nhs.uk/innovations (intranet http://crscweb/innovations)



ranslational Resear

#### SUPPORTING RESEARCH & DEVELOPMENT

#### A NEW PLACE FOR TRANSLATIONAL RESEARCH

The Clinical Translational Research and Innovation Centre (C-TRIC) is a unique centre promoting and facilitating translational and clinical research. The primary objective of the Centre is to reduce both the time and cost of bringing innovative health technologies, medical devices and therapeutics from the laboratory bench to the point of care.

The project was developed by the University of Ulster and the Western Health and Social Care Trust (WHSCT), in partnership with Derry City Council. It combines world class research expertise from the University of Ulster, whose Biomedical Sciences Research Institute was rated as amongst the best in the UK by the 2008 Research Assessment Exercise, along with the Trust's research and clinical capability. This is supported by a major recent investment in a new state of the art laboratory/pharmacy complex and a new clinical block.

Based on the Altnagelvin Hospital campus, C-TRIC's unique infrastructure and key support staff facilitate clinical research and innovation, enabling the streamlining of the development process. This focused activity creates commercial opportunities and helps the development of partnerships among academic researchers, clinical practitioners and businesses. The project has attracted over £2M in funding.

C-TRIC's unique infrastructure and situation on a major acute hospital campus optimises the potential for high quality clinical research, including clinical trials. The centre supports a vibrant and growing biotechnology cluster and represents an ideal access point for US-based biotech industry to navigate the European regulatory compliance process, and to explore access to wider European healthcare markets.

#### SERVICES OVERVIEW

C-TRIC provides specialist workspace and services for academic and clinical researchers and the biotechnology industry. It caters for the pharmaceutical, bio-pharmaceutical, medical device and healthcare technology sectors. C-TRIC is licensed to handle, process, and store, clinical materials and data.

#### Speciality Services include:

- In-house clinical trial capability including clinical study design, clinical knowledge, clinical trial statistics, and access to wider clinical research networks
- Assistance with governance and ethical approvals
- Access to skilled research nursing staff to record, collect and collate clinical data, provide phlebotomy services, collect and label clinical materials
- Access to skilled technical staff to process, analyse and store clinical materials
- Market validation through facilitated access to clinical expertise and advice on healthcare economics
- Access to clinical innovation programmes
- Specialist advice on R&D support, intellectual property, regulatory affairs
- Access to world class scientific and academic knowledge
- Sector-specific advice on technology and knowledge transfer





Paul Turkington

Karen Humphries

#### **NOTICEABLE ACHIEVEMENTS**

Applicant	Course Title		A STORY	
			General P	
Katherine Dorrity		Behaviour Analysis	Training S	
Bronagh Duggan	MSc in Applied	Behaviour Analysis	Name	
Lisa Hutchinson	MSc in Applied	Behaviour Analysis		
Susan Keery	MSc in Applied I	Behaviour Analysis	Dr Tara Jain	
Cormac MacManus	MSc in Applied I	MSc in Applied Behaviour Analysis		
Zara McCambridge	MSc in Applied (	Behaviour Analysis		
Gillian Murphy	MSc in Applied E	Behaviour Analysis	S. C.	
Geraldine McGaughey	MSc in Applied E	Behaviour Analysis	100 A	
Emma Nicolls	MSc in Applied E	Behaviour Analysis	<b>经验证的</b>	
Siobhan Owens	MSc in Applied E	Behaviour Analysis		
Christine E Patrick		Behaviour Analysis		
Caoimhe McVeigh		Behaviour Analysis		
Roberta Niblock	MSc in Biomedic			
Roisin Cassidy	MSc in Clinical Pharmacy			
Barbara Allen	MSc in Health Pr Population Healt			
Suzanne Doyle	MSc in Health Sc			
Nicola McMahon	Msc in Health Sc	ience		
Patrick McGill	MSc in Health Sc	ience		
Iris Wylie	MSc in Health Sc	tiences		
Lorraine Hayes	MSc in Physical F Population Healt	Activity and		
Michael Matthews	MSc in Nursing			
Norah Holmes	MSc in Nursing			
Barbara McDonagh	MSc in Nursing	E1	1	
Mairead Coulter	MSc in Nursing	vancati.	on and	
Martina Conlon	MSc in Nursing	Educati Train	2) 12/1	
Simon Higgs	MSc in Nursing			
James Mullan	MSc in Nursing	- Bursary Su	cheme 2008	
Rosemarie Hanna	MSc in Nursing	7		
	9		A CONTRACTOR OF THE PARTY OF TH	

MmedSci in Education for Health

MmedSci in Education for Health

Care Professionals

Care Professionals

Practice Academic Research Scheme (GPARTS)

1cAleavy 2008 Joint Awards - GPARTS

2008 Cochrane Fellowships

Cancer Courses

		100001431-114	
Award Holders	Title		
Dr Helga Sneddon	Cognitive-behavioura aged 10-18 who sexu	ral therapy (CBT) interventions for young people ually offend	
Mrs Cathy Payne	Workplace based her intervention for prev	ralth promotion interventions versus no venting and reducing adult obesity	
Dr Chris Bleakley	Cold water immersion (cryotherapy) for preventing and treating muscle soreness after exercise		
Professor Kader Parahoo			
Dr Emma Borthwick	CARG 174 High Volume haemofiltration as a treatment for		
Mrs Brenda Nugent	Enteral feeding meth with head and neck (	nods for the nutritional management in patients cancers being treated with radical radiotherapy	
Dr Janice Christie	Workplace based health promotion interventions versus no intervention for preventing and reducing adult obesity		

Name	Course		
Dr Lakshmi Venkatraman	Molecular Prevention Course		
Professor Valerie McKelvey-Martin	Molecular Prevention Course	2008 NCI	
Dr Caroline McGoohan	Molecular Prevention Course		
Dr Leanne Stevenson	Molecular Prevention Course	Prevention	
Dr Caitriona Holohan	Molecular Prevention Course		
Dr Joanne Reid	Principles and Practice of Cancer Prevention and Control Course		
Ms Farhana Haseen	Principles and Practice of Cancer Prevention and Control Course		
Ms Marie Bradley	Principles and Practice of Cancer F	Prevention and Control Course	

## Education and Training - HSC Studentship Top-Mp Scheme

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Applicant	Course Title				
Claire Millar	A study exploring health care professionals' perceived needs of advanced cancer patients with cachexia				
Esther Reid	A prospective study exploring risk factors associated with fetal macrosomia and women's experiences delivering a large for gestational age infant.				
Jennifer McGowan	Follow-up at three years of age of term infants who received neonatal intensive care				
Jonathan O'Neill	Rehabilitation of movement disorders employing virtual reality simulation in adult survivors of brain injury				
Deborah Anderson	Controlled drug polymer conjugates for sustained anti-infective biomaterials				
Heather Barry	The management of pain in patients with dementia				
Rebecca Houston	Development of innovative approaches for modulating ion channel function in disease				
Pamela McClean	Surveillance of antimicrobial consumption in nursing homes for older people in Northern Ireland				
Martin James Garland	Micro-needle enhanced iontophoretic drug delivery				
Simon Tipping	Novel Strategies to Improve the Aqueous Solubility of Poorly- Water-Soluble Active Pharmaceutical Ingredients				
Gillian Brown	The role of Runx2 in resistance to apoptosis in breast and prostate cancer				
Louise Ming	The role of hypoxia in the malignant progression of androgen dependent prostate cancer				
Keith Thomas	The involvement of NOTCH in T cell Acute Lymphoblastic Leukaemia (T-ALL)				
Nason Ma'ani-Hessari	DNA Topologies in the Regulatory Genome				
Jonathan Kennan	Crystallin Distributions in the eye lens				
Mairead Goodall	A Follow-up Longitudinal Cohort Study on Maternal Nutrition in Pregnancy and its impact on Child Development				
Janine Blaney	Survey of the experiences of cancer-related fatigue, quality of life and the barriers and facilitators of exercise among a mixed sample of cancer survivors				
Denise Earley	Pulmonary rehabilitation in COPD				
lan Montgomery	Assessment of the potential of GIP receptor antagonism for diabetes therapy				
Sara McCullough	Higher Order Ocular Aberrations in Down Syndrome (DS)				

#### CLINICAL

	Personnel/Contact:	Project ID	Title:
1	Dr Donal O'Kane	EAT/3972/08	2009 Doctoral Fellowships: The role of epithelial to
_	Dr Elisabeth Ball	~ ~ ~	Thresenery Hai transition in cutaneous sclerodorms
	or Eisabeti Dail	EAT/3974/08	2009 Doctoral Fellowships: Defining hand arthritis in systemic lupus erythematosus using Magnetic Resonanc Imaging and Ultrasound
}	Ms Caroline Bleakley	EAT/3975/08	2009 Doctoral Fellowships Targeting mismoral
	Dr Declan Bradley	EAT/3976/08	dysfunction in young hypertensive patients  2009 Doctoral Fellowships: A Genome-Wide Association of Genetic Risk Factors for Abdominal Octain Oct.
	Mr Conor McGarry	EAT/3977/08	2009 Doctoral Fellowships: Studies of the biological implications of different IMRT (Intensity Modular I
	Dr David Comer	EAT/3978/08	Radiation Therapy) planning and delivery techniques 2009 Doctoral Fellowships: Cigarette Smoke Extract and Predisposition to Infection: The role of Toll-like receptors TLR-3 and TLR-4
	Dr Thomas Bourke	EAT/3984/08	2009 Doctoral Fellowships: Clinical validation of a rapid qualitative near-patient molecular test to detect Neisseric meningitidis

#### HEALTH AND SOCIAL CARE

	Personnel/ Contact:	Project ID	Title:	
1	Mrs Anne-Marie Doherty		health & well-being in Northern Ireland: How health	
2	Ms Suzanne Mooney	EH1/3962/08	2009 Doctoral Fellowships: Promoting a Sense of Coherence and Wellbeing in Tennagor, and Va	
3	Dr Shivaram Bhat	LI 11/3303/08	Adults with Cancer Receiving Hospital Care  2009 Doctoral Fellowships: Surveillance for Barrett's oesophagus - A population based cohort study and mathematical modeling	

#### NOTICEABLE ACHIEVEMENTS

#### BELFAST TEAM DEVELOP NOVEL APPROACH TO THE

#### DR NICHOLAS MAGEE

A multidisciplinary team of clinicians and scientists from the Belfast Health and Social Care Trust, has developed a novel and exciting approach to the diagnosis of lung cancer using Raman microscopy. Dr Nicholas Magee, Specialist Registrar in Respiratory Medicine, is undertaking this work for his PhD project, supported by a HSC R&D Doctoral Fellowship Award. The team has shown that Raman microscopy can accurately diagnose lung cancer from tissue sections and predict early recurrence in patients undergoing surgery. Analysis of induced sputum can distinguish control subjects at risk of developing lung cancer from both healthy control subjects and lung cancer patients. Raman spectra can be obtained from lung tissue using a Raman mini fibre optic probe suitable for use with a bronchoscope and this technique can distinguish malignant tissue from normal tissue with 100% accuracy. Throughout these studies, Raman spectroscopy has also elucidated some of the chemical differences involved in carcinogenesis and smoking related lung disease, and shows considerable potential for use in the clinical diagnosis and prognosis of lung cancer, from tissue sections, induced sputum and in vivo through a bronchoscope.

Lung cancer is still the most common cancerrelated death globally. One of the most important factors influencing the chances of survival from lung cancer is the extent of disease. Early diagnosis and treatment of lung cancer is therefore a key aim in the management of this condition, including autofluorescence bronchoscopy and low-dose computed tomography and although both of these tools have demonstrated the ability to detect early lung cancers, there is no evidence yet that either improves lung cancer mortality and thus their clinical utility is uncertain.

Raman spectroscopy is a well-established analytical technique where the structure and binding of molecules may be studied by examination of their light scattering properties. Raman spectroscopy is well suited for cancer diagnosis for several reasons. Firstly it is non-invasive and may preclude the need for invasive biopsies. Secondly it is sensitive to subtle molecular changes within tissues. It requires minimal tissue preparation and is without the need for markers, fixatives or special stains. It also can be directed through fibre optical systems and therefore be used in endoscopy. Raman microspectroscopy has the spatial resolution to investigate single cells and has been used for a number of biomedical applications including solid organ cancers. In their first study, the team used a Raman microscope to analyse normal and malignant lung tissue sections obtained from 27 surgically resected lung cancer specimens. Using Random Forests Classification, a novel statistical method, malignant tissue could be distinguished form normal lung tissue with a sensitivity of 90% and a specificity of 75%. Some of the biochemical differences related to carcinogenesis were elucidated during this study, including an increase in porphyrin-containing substances in the normal samples and an increase



in DNA in the tumours. Comparing the Raman spectra of 34 patients' tumours with their clinical outcome at one year after their operation, the team also found that Raman spectroscopy could predict early postoperative recurrence with an accuracy of 74%.

#### DIAGNOSIS OF LUNG CANCER

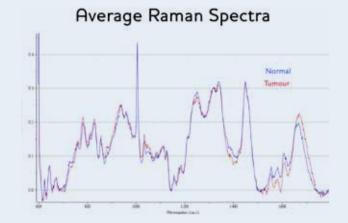
In the second study induced sputum from 19 healthy control subjects without any risk factors for lung cancer, 19 control subjects with at least one risk factor for lung cancer and 21 lung cancer patients were analysed using the Raman microscope. Both the cellular and supernatant components of the sputum were analysed. In the analysis of the sputum supernatant, the sensitivity and specificity of Raman spectroscopy to distinguish lung cancer patients from at risk controls by analysing their sputum supernatant was 81% (17/21) and 67% (14/21). The sensitivity of Raman spectroscopy to distinguish at risk control subjects from healthy control subjects was 86% (18/21) and 73% (11/15). Porphyrincontaining substances were higher in the controls at risk of lung cancer than either the healthy controls or the lung cancer patients.

Lung cancer is usually diagnosed by obtaining biopsy samples from tumours via bronchoscopy which involves inserting a fibre optic endoscope into the lungs via the mouth and trachea. In vivo Raman spectroscopy analysis of lung cancer thus requires a thin fibre optic probe to remotely analyse the tumour via the working channel of the bronchoscope. For the third study, the team obtained a mini fibre optic probe with an external diameter of 2.1 mm and length of 3 m suitable for the working channel of a bronchoscope. Both normal and malignant lung tissue exhibited strong fluorescence and thus shifted subtracted Raman spectroscopy. This method, which greatly reduces the influence of fluorescence and fixed-

pattern noise in the spectra, was incorporated into the system. Normal and malignant lung tissue from 7 patients was obtained from lung cancer surgical resections. These were analysed using the Raman mini probe and a custom-built Raman spectrometer. Principal component analysis of the spectra distinguished malignant tissue from normal tissue with 100% accuracy.

Additionally, induced sputum from normal controls, at risk controls and lung cancer patients was analysed using Surface-enhanced Desorption-lonization Time-of-flight mass spectrometry (SELDI-TOF MS), a method that traps specific proteins and elucidates their protein make-up using mass spectrometry. Using principal component analysis, SELDI-TOF MS was able to distinguish lung cancer patients from control patients at risk of lung cancer with a sensitivity of 96% and a specificity of 65%. It was also able to distinguish control patients at risk of lung cancer from young healthy subjects with a sensitivity of 70% and a specificity of 100%.

This novel approach shows considerable potential for use in the clinical diagnosis and prognosis of lung cancer, from tissue sections, induced sputum and in vivo through a bronchoscope.



Average Raman spectra from normal (blue) and malignant (red) lung tissue'

#### RESEARCH FOR PATIENT BENEFIT PROGRAMME

## THE NEED FOR URGENT CARE: the perspectives and pathways of people with a long term condition

#### 14 Applicants

Research Institute, School of Health and Social Studies, University of Warwick.

Prof. Vivien Coates: University of Ulster/ Western Health & Social Care Trust.

Mrs Jane Canny: The Royal London Hospital Mr Ash Pandya: Trustee, Long Term Conditions Alliance

Prof. Kate Seers & Dr Natasha Posner: RCN

Grant: approx £212,000 Duration of study: September 2008 – October 2010

#### Background

People with long term conditions often have a significant disease burden. They may also have acute exacerbations of their condition resulting in a perceived need for urgent care, and often an unplanned hospital admission. The Department of Health (2006) wishes to develop

a more integrated approach to requirements for urgent care. If this is to be fully effective, then understanding patients' perspectives when an unplanned hospital admission occurs is crucial. The reasons why people can no longer cope with their condition, and what triggers a hospital admission need to be explored, so this knowledge can be added to the development of a primary care based package to meet urgent care needs in a patient focused way.

#### Aims

- To increase understanding of the experiences of people with diabetes who have unplanned admission to hospital
- To investigate the factors that precipitate admission to hospital and influence the routes/care pathways taken
- To identify sources of support for people with diabetes which would help to avoid unplanned admissions where appropriate
- To determine any barriers to accessing this support amongst different sectors of the diabetic population
- To develop an intervention or interventions that can be trialled to address this situation in a subsequent study.

#### The two sites involved:

Barts and the London NHS Trust sited in Tower Hamlets & Altnagelvin Hospital in Western Health & Social Care Trust

Note from HSC R&D: The Research for Patient Benefit (RfPB) Programme is a nationally co-ordinated funding stream for regionally commissioned research. There are ten regional funding committees to commission local health service research. http://www.nihr-ccf.org.uk/site/programmes/rfpb/default.cfm

Researchers based in Northern Ireland may apply as co-applicants or may lead proposals to undertake work that is of relevance to the region to which the application is being made.



## IDENTIFYING THE RESEARCH PRIORITIES FOR THE THERAPY PROFESSIONS IN IRELAND

Funding for health care research is often limited. Therefore, it is important that such scarce research resources are focused on priority areas. The Irish Department of Health and Children provided funding to the Health Research Board (HRB) to seek answers to the following question: 'What are the research priorities for the therapy professions in Ireland'. A multiprofessioonal team from the University of Ulster led by Professor Hugh McKenna was awarded the contract.

#### The Study

The Delphi Technique is being used to answer the research question. For over twenty years, Hugh and colleagues have been gaining national and international recognition for their work on this methodology. The Delphi was a product of the Rand Corporation's programme of research on the likely impact and aftermath of nuclear war in the 1950s. The name originates from Greek mythology where the Oracle at Delphi was said to be able to forecast future events. The technique is intended for use as a judgment

or forecast enhancing tool involving a panel of experts to whom intensive questionnaires and feedback is given to obtain consensus on a particular topic. It has been used increasingly in health care contexts across the globe to identify priority areas in need of research and development.

#### The Participants

All therapy professionals from the identified groups (Occupational Therapy, Physiotherapy, Dietetics, Speech and Language, Podiatry and Orthoptics) with three years experience in a clinical or academic setting, are eligible to participate. The researchers are also obtaining he views of managers, policymakers and service users. The research will be completed in May 2009.

**Note from HSC R&D:** We have reached agreement with the HRB that this study can be extended to Northern Ireland. We have made the funding available and work is due to start in June 2009.



Professor Hugh McKenna

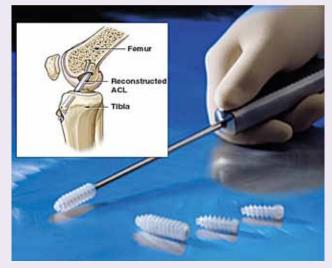
#### NORTHERN IRELAND RESEARCHERS SECURE FUNDING TO DEVELOP

A team of bioengineers from Queen's University has recently been awarded a grant from the Department Of Health's Health Technology Devices Scheme to develop medical implants that will have improved bioresorption properties after their useful life is over. The team is headed by Dr Fraser Buchanan, from the School of Mechanical and Aerospace Engineering and the commercial partners include medical device manufacturer Smith & Nephew and irradiation specialists Isotron plc.

This is the first project led by researchers from Northern Ireland to receive funding under this scheme. The Health Technology Devices Scheme offers funding for projects involving a collaboration between academic and commercial partners, where a product has been developed with a potential route into the healthcare market. HSC R&D invested in this scheme to open it up to applicants from Northern Ireland.

Current bioresorbable medical devices available on the market remain as space-fillers long after their useful strength has deteriorated. This prevents the highly desirable ingrowth of natural tissue that allows for complete healing. It can also lead to an 'acid-burst' where a sudden release of acidic material can damage surrounding cells and cause unpredictable inflammation late in the healing process.

Dr Buchanan's co-investigators are Professor John Orr (School of Mechanical and Aerospace Engineering) and Dr Glenn Dickson (School of Medicine and Dentistry) and Ms Marie-Louise Cairns has recently been appointed as research fellow on the project. The team proposes to develop a device that will lose mass from the surface initially and retain strength for as long as required within its core. This will allow gradual replacement of the available space with natural tissue whilst still providing some structural support. By designing polymeric implants with a graded molecular weight through electron beam treatment this behaviour will be achieved and offer a significant advantage over current bioabsorbable devices. Such a possibility would prove extremely attractive to medical device companies and offer them the potential to gain the market edge over opposition in a very competitive marketplace.



Applications where the developed technology would potentially enhance product performance would include hard and soft tissue orthopaedic devices for fracture fixation, interference screws, suture anchors, meniscus repair and ACL reconstruction. More speculative applications would include porous, bioresorbable scaffolds for tissue engineering. If bioactive agents (e.g. nanoor micro-scale calcium phosphate particles) were incorporated within the bioresorbable polymer matrix then these would be released from the surface first and later from the core, as they were required to enhance tissue remodelling.

#### **NOVEL MEDICAL IMPLANT DEVICES**

The overall objective of the proposed work plan is therefore to utilize electron beam technology to develop a unique process that can modify the through-thickness molecular weight profile of polymeric bioresorbable medical implants and thereby optimise their bioresorption behaviour. The final project deliverable will be completion of validation trials for the technology.

Key technical challenges will be: to identify optimum electron beam process conditions that modify the surface-to-core bioresorption rate of a medical device in a controlled manner; to address issues related to varying geometries of medical devices; to provide a validated and concurrent method of device sterilisation; to prove the potential clinical effectiveness of the technology in a biological model.

Queen's University, Belfast (QUB) will provide facilities for polymer processing and characterisation using equipment available in the Medical Polymers Research Institute (MPRI). QUB also hold the patent rights for this technology. Smith & Nephew (York, UK) will provide materials and devices suitable for modification using ebeam technology and facilities for product validation. They will also provide a viable route to commercial exploitation of the technology. Isotron Plc (South Marston, UK) will provide facilities and expertise for ebeam modification of the medical devices.



## THE RIGHT PROJECT: RESEARCH INTO GLOBAL HEALTHCARE TOOLS

Professor Sally McClean, Professor of Mathematics, University of Ulster

The RIGHT project is an EPSRC funded collaborative research venture between five UK universities (Brunel, Cambridge, Cardiff, Southampton and Ulster) that aims to assess the feasibility of applying best-practice modelling and simulation methods to decision-making in healthcare. In so doing, RIGHT is applying research to a widely recognised gap in healthcare management.

RIGHT is currently engaged in developing a framework and method selection tool that enables researchers to categorise their problems, evaluate the resources available to them and select an appropriate modelling strategy. This tool is being tested by NHS experts and an associated workbook is available for purchase.

The Ulster RIGHT researchers, led by Professor Sally McClean, have been funded by HSC R&D to develop methods for modelling and costing stroke services. This work is being taken forward by Maria Barton, a qualified nurse with PhD in Social Psychology and a PhD student, Lalit Garg.

In collaboration with Dr Ken Fullerton and the Stroke Team at the Belfast City Hospital, hospital and community stroke data are being collected to facilitate modelling, analysis and development of efficient solutions for patient management.

Finding better ways of managing stroke disease, that cost less and are focussed on patient-centred care, is imperative. Research has indicated that some patterns of delivery of stroke care, such as stroke units, early supported discharge schemes or thrombolysis can have a significant impact on mortality and dependency. Modelling can assess where and how stroke patients should be treated by weighing up different options, and identifying bottlenecks in the system.



The RIGHT team, at a meeting in Wales

#### A MAJOR CLINICAL TRIAL

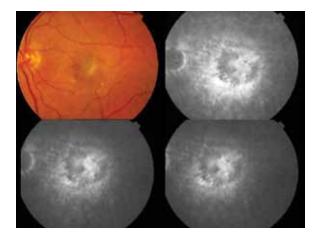
#### THE IVAN CLINICAL TRIAL

#### **Professor Usha Chakravarthy**

An important clinical trial of a new health technology has commenced in the UK, led by investigators from Northern Ireland. A randomised controlled trial of alternative treatments to Inhibit Vascular Endothelial Growth Factor (VEGF) in Age-related choroidal Neovascularisation (IVAN) has been funded by the the HTA. Led by Professor Usha Chakravarthy of QUB, a multidisciplinary consortium of researchers will recruit some 600 participants which will compare two drugs (Lucentis and Avastin) as well as test a reduced frequency treatment regimen with both drugs in the management of neovascular age-related macular degeneration, a condition which causes severe sight loss in older people.

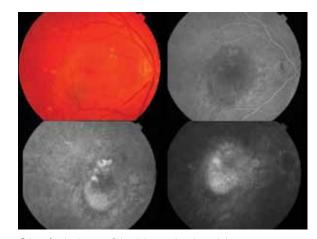
Neovascular macular degeneration is due to a pathological process of neovascularisation where abnormal blood vessels develop within the sub pigment epithelial and sub retinal spaces (choroidal neovascularisation; CNV) or within the retina (Retinal Angiomatous Proliferation (RAP)). Both CNV and RAP lesions leak fluid and because they are fragile can bleed easily. The collection of fluid and or blood between the tissue layers and within the neural retina causes blindness. Until recently, available treatments only slowed down the rate of sight loss with most patients becoming moderately or severely visually impaired in the affected eye despite optimal management.

Very recently a new treatment with a drug known as Lucentis (Ranibizumab) was found to prevent sight loss in over 90% of recipients when given as injections into the eye with CNV for periods of up to two years. Lucentis is extremely expensive (approximately £750 per injection) and wet macular degeneration is common (about 25,000 newly affected people each year in the UK). There is little evidence on which to base criteria for stopping treatment and so there is considerable uncertainty about precisely how much treatment might cost in the longer term.



Top left, colour fundus photograph of the left eye showing a neovascular lesion in the macula. Accompanying sequential angiographic frames captured over a period of 10 minutes reveal leakage of fluorescein dye forming a hyperfluorescent pattern in the macular retina. The spatial and temporal pattern of hyperfluorescence are consistent with a phenotypic variant of neovascular AMD known as fibrovascular pigment epithelial detachment

#### A MAJOR CLINICAL TRIAL



Colour fundus image of the right eye showing subtle pigmentary changes in the macula. The fluorescen angiogram reveals a homogenous hyperfluorescence which has assumed a circular disposition and is typical of a serous pigment epithelial detachment.

With respect to possible side effects of treatment, concerns remain that the recommended dose of Lucentis (0.5mg) may increase the risk of vascular ischaemic events, as a 4-fold higher rate of stroke was observed when compared to the lower dose (0.3mg). Another drug, called Avastin (Bevacizumab), which is licensed for colorectal cancer therapy is similar to Lucentis in its properties. This drug has also been used to treat neovascular AMD patients and also is thought to confer similar benefits but the data come from multiple small uncontrolled studies.

Avastin is cheap as the dose for ocular injection is small (i.e. the amount of drug needed for one colorectal cancer treatment can be made into very many doses for injection into the eye). With respect to possible side effects of treatment, there is little robust information on the systemic safety of Avastin.

The large number of small uncontrolled studies, and an internet survey which compiled information on several thousand treated patients, have not reported any serious adverse effects. The IVAN trial is a prospective randomised controlled clinical trial which will (a) compare the clinical efficacy of the two drugs; (b) compare a reduced treatment regimen versus two years of continuous treatment; (c) describe the cost

effectiveness of different drugs and treatment regimens; (d) describe both eye-related and systemic side effects with different drugs and treatment regimens.

IVAN is being undertaken in 20 ophthalmology units UK wide with each centre recruiting between 30 and 40 participants. Patients are monitored monthly with functional testing and morphological imaging of the retina and will receive monthly injections of trial drug into the vitreous of the study eye for 24 consecutive months if in the continuous treatment arm.

Patients randomised to discontinuous treatment arms are treated based on rigorous re-treatment eligibility criteria. The IVAN pharmacy is located in the University of Liverpool and supplies the study drugs. Trial coordination and statistical support is provided by Dr Barney Reeves of the Clinical Trials Unit in the University of Bristol.

Quality of life outcomes and health economic evaluations are being collected and will be analysed by collaborators in the University of Oxford and Southampton. The Belfast Trust is the main sponsor for the trial with QUB and the University of Bristol acting as co sponsors. HSC R&D acts as a partnership funder, for the Northern Ireland participants, picking up the service support costs.

## GLAD Study

#### SUCCESSFUL KNOWLEDGE TRANSFER

#### **DESIGNING AND IMPLEMENTING A KNOWLEDGE TRANSFER STRATEGY:**

LESSONS FROM THE GROWTH, LEARNING AND DEVELOPMENT (GLAD) STUDY

The GLAD study was a project which was carried out at the Institute of Child Care Research, QUB, funded by by HSC R&D through the Child Health and Welfare Recognised Research Group. It was led by Dr Moira Stewart (Consultant Paediatrician) and Dorota Iwaniec (Professor of Social Work), and the multidisciplinary research team included input from psychology, health visiting, speech and language therapy and nutrition. The study aimed to identify risk and protective mechanisms for poor weight gain by comparing weight faltering one year old infants to normally-growing peers. Almost 300 families took part in the study, each receiving five home visits. Data was collected on a broad range of factors, including infant feeding, oral motor behaviours, cognitive development, parenting stress, depression and social support. As a result, the study yielded a wealth of information on parenting and child development which we felt was of interest to a wide audience, over and

#### above the findings relating to weight faltering.

We felt that it was imperative to feed back information to the parents who had given up many hours of their time to take part in the study. We felt that the most effective way of doing this was by designing a 'Parent Newsletter'. We worked closely with multimedia designers at Queen's University to develop a 'family friendly' leaflet, and tailored the language accordingly. The cost of designing and reproducing these leaflets was covered by the Child Health and Welfare RRG Cohesion Fund. The leaflets were posted out to all the families who took part. Through the course of our follow-up study, we have received very positive feedback from families and we feel this has helped maintain engagement with the research team. A further effort to reach parents and child care providers was made by publishing a two-part summary of the GLAD study in the NIPPA Magazine (Winter 2007). To engage another audience, we gave a talk at the Big Into Baby Exhibition (Kings Hall, Winter 2007), which is open to the public, and gave an associated Radio Interview on U105.



(L-R) Ms Seaneen Sloan, Dr Laura Dunne and Ms Aideen Gildea

#### SUCCESSFUL KNOWLEDGE TRANSFER

Health visitors played a major role in recruitment of families for the study, therefore we wanted to ensure our results reached them also. We had originally planned on holding a conference for this purpose, but felt that few health visitors would be able to allocate the time and expense required to do this. Instead, we decided to plan our dissemination to health visitors around their monthly meetings. By prior arrangement with managers, we were able to arrive at the end of meetings, provide a sandwich lunch, and deliver a 30 minute presentation of GLAD study results, followed by questions and discussion. In doing this, we were able to talk to health visitors throughout the Eastern Board. Additionally, feedback from this forum helped inform research questions for the follow-up study. Findings from the GLAD study helped tailor two training sessions delivered by the team to primary healthcare professionals through the Beeches Management Centre. An article on the GLAD study was also published in Primary Care Today, a monthly publication which is distributed to healthcare professionals across the UK.

In order to reach an academic audience, several research papers have been published in peer-reviewed journals, with several more under review or in preparation. A summary document with all the key findings and recommendations was published in Child Care in Practice.

Colleagues were informed of findings through annual school based seminars.

Results from the GLAD study have been presented through posters and presentations at local, national and international conferences, including;

- 8th Northern Ireland Community Nursing Network Conference, Belfast
- Community Pratitioners and Health Visitors Association Annual Professional Conference, Harrowgate
- Allied Health Professionals Conference, Antrim.
- Area Child Protection Committee Conference, Antrim
- Association for the Study of Obesity Conference, Liverpool
- 2nd Congress of the European Academy of Paediatrics, Nice
- XIIth European Conference on Developmental Psychology, Tenerife.
- European Academy of Childhood Disability, The Netherlands
- Child Health & Welfare Recognised Research Group Annual Scientific Meeting, Belfast

While this strategy was broad and labour intensive, it was very worthwhile. We felt we had done justice to their findings by targeting appropriate audiences and delivering key messages in a range of formats. It was also felt that those who had given so much time and energy in contributing to our work had been acknowledged in some way. We will use this experience to shape future dissemination strategies.

#### IMPORTANT CHANGES FOR HSC RESEARCHERS

#### STREAMLINING THE RESEARCH APPLICATION PROCESS

From 1 April 2009 Site Specific Assessments will be carried out by HSC Trusts rather than through ORECNI. The application process will be facilitated by the latest version of the Integrated Research Application System (IRAS) which will generate a Site Specific Information (SSI) Form for submission to the relevant HSC Trust. Usage levels of IRAS are set to increase in April as the existing National Research Ethics Service (NRES) on-line application will not be available after 01 April 2009. The Table below lists the various review bodies that accept applications generated by IRAS.

IRAS provides a user friendly system for capturing data on an HSC research project and generating

relevant application forms avoiding the need for duplicate data entry on multiple systems. The latest version of IRAS can generate an application to the MHRA, in the appropriate format, for investigational medicinal products (IMPs). Researchers need only to go to EudraCT to obtain their EudraCT number.

The SSI and the R&D Form generated by IRAS are accepted by all HSC Trusts whose research offices provide dedicated support for researchers requiring permission to conduct research within the HSC. All five HSC Trusts are working under a new memorandum of understanding to speed up the permissions process. Under this new system a single 'lead' Trust takes responsibility

for sign-off on a specific set of generic issues for each new research study that involves more than one HSC Trust producing a Governance Report on behalf of all participating Trusts. Site-specific issues are considered in parallel and separate permission is given by each additional Trust.



Work is underway on other initiatives to further streamline HSC research governance. These include a HSC Research Passport to reduce the delays in obtaining honorary contracts. Full information on IRAS can be found at www. myresearchproject.org.uk. All HSC researchers are encouraged to logon, register and start using IRAS.

#### Table 1

Review Body	Type of Application
Administration of Radioactive Substances Advisory Committee (ARSAC)	Application for ARSC certificate by nuclear medicine professional administering radioactive exposures in research
Gene Therapy Advisory Committee (GTAC)	Application for ethical opinion on a trial of a gene therapy medicinal product as well as cells derived from stem cell lines
Medicines and Healthcare products Regulatory Agency (MHRA)	Notification of a clinical investigation of a medical device  Application for authorisation of a clinical trial on an investigational medicinal product
Ministry of Justice (MoJ)	Application to conduct health research involving prisoners (England and Wales only)
NHS/HSC Research Offices	Application for NHS management permission
NRES/NHS/HSC Research Ethics Committee	Application for ethical opinion on a research project, tissue bank or database
National Information Governance Board for Health and Social Care (NIGB)	Application under Section 351 of the NHS Act 2006 to process identifiable patient data without consent (England & Wales only)



#### IMPORTANT CHANGES FOR HSC RESEARCHERS

### ARE YOU USING IRAS?

The Integrated Research Application System (IRAS) has been available since January 2008. However, usage statistics suggest few Northern Ireland based researchers have tried the new system. One early adopter, Dr McAuley is enthusiastic "I recently used the new IRAS form to apply for sponsorship and ethical approval. Surprisingly the form does actually reduce the paperwork required for these approvals, producing the forms for both the governance and the ethics application. Data entered automatically populates the required fields for both forms and avoids the need for duplicate completion of forms".

Go to www.myresearchproject.org.uk



#### STOP PRESS

Under Phase 2 of the Review of Public Administration the former HSC R&D Office has transferred to the new Public Health Agency (PHA) for Northern Ireland. Our physical location remains unchanged as do our telephone and fax numbers but our email addresses change to the format: firstname.surname@hscni.net The PHA website address is www.publichealth.hscni.net although the original website can still be accessed during a transition period.

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