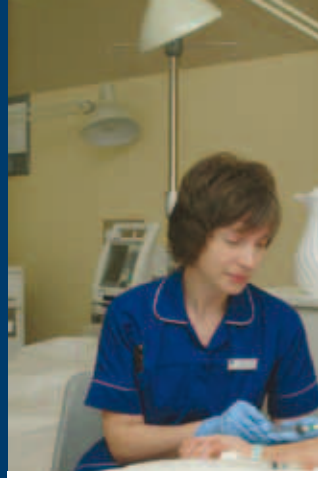

UK CLINICAL RESEARCH COLLABORATION
igniting our potential

R&D Today

SPRING 2006
Issue 7

Clinical Research

This edition of R&D Today focuses on clinical research and gives an overview of where we are and where we are heading. The last four years have seen a renewed interest in and emphasis on clinical research throughout the UK. The next four years will see even greater efforts to embed clinical research in the heart and mind of the NHS/HPSS. The R&D Office is only one of a number of partner organisations with an interest in and passion for clinical research. One newsletter cannot provide a complete account of what we do and can only give a partial view of the complete picture of clinical research in Northern Ireland. There are inevitably important areas of R&D activity that it has not been possible to cover. The newsletter does however capture the essence of clinical research in Northern Ireland. A new HPSS R&D Strategy will be issued soon for consultation and it will build on the initiatives described here.

Overview

The R&D Office supports a wide spectrum of research and development activity across the HPSS as a means of improving health and social well-being. This R&D activity involves a range of HPSS professionals, working in many different areas of science and in many organisations within and without the HPSS. Given the R&D Office remit, we are increasingly concerned with how advances in basic science can be translated into better health and social care and health and social care services. The R&D Office has therefore over the last number of years been focusing on clinical research leading to advances in the understanding of health and wellbeing and advances in diagnosis, treatment, rehabilitation and social services. This includes experimental medicine, health and social care services research, population sciences, the translation of basic research to human health and disease, and research in social care.

The classification of research activity is notoriously difficult and contentious and attempts to delineate or separate research topics are prone to ambiguity and challenge. The R&D Office uses the clinical research descriptor in an inclusive sense, one which can be further refined or restricted in the context of a specific funding opportunity or scheme to ensure support for research that is close to patients and clients and that is likely to directly impact on the delivery of health and

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social care. The position of the R&D Office in promoting clinical research is not a value judgement on other types of research, all of which are essential, but it is a reflection of the purpose of HPSS R&D funding.

UKCRC Initiative

This emphasis on clinical research is in line with national policy and with the creation of the United Kingdom Clinical Research Collaboration (UKCRC) in 2004. The UKCRC is a partnership of over 20 organisations encompassing the four Health Departments, the Medical Research Council (MRC), research charities, patients and industry - all with a shared vision of enhancing the ability of the NHS/HPSS to carry out clinical trials and clinical research. The UKCRC brings together the major stakeholders that influence the clinical research environment in the UK. It provides a unique opportunity to utilise the power of partnership to advance clinical research for the benefits of patients, improve national health, increase national wealth and enrich world knowledge. The industrial link is key to the UKCRC and the initiative is a central part of the Government's 10-year Science and Innovation Investment Framework. This Framework recognises that for the UK economy to succeed in generating growth, productivity and employment it must invest more strongly in its knowledge-base and translate this knowledge more effectively into business and public service innovation. The Government believes that health research plays a key role and is determined to make the UK the best place in the world for health research and innovation.

To secure all these goals, the UKCRC is working to develop a comprehensive infrastructure to facilitate clinical research; building up an expert research workforce to support clinical research; developing incentives for clinical research in the NHS; streamlining the regulatory and governance environment; and developing a co-ordinated approach to research funding.

Under-pinning the UKCRC is the UK Clinical Research Network (UKCRN) providing a world-class nation-wide health service infrastructure to support clinical research. This network will provide clinical researchers with access to large numbers of NHS/HPSS patients/clients, facilities and research staff. The network will support:

- population sciences to help identify the determinants of health and disease
- translational research to apply knowledge that is generated from laboratory-based investigations to patient studies
- experimental medicine studies to better understand mechanisms of normal health, disease and the actions of drugs
- clinical trials to evaluate preventative, diagnostic and therapeutic procedures before they are introduced into clinical practice
- health and social care services research to discover how interventions can be effectively organised and delivered

The UKCRN will consist of a managed set of Clinical Research Networks. The initial networks will cover cancer, mental health, medicines for children, diabetes, stroke, and Alzheimer's and neurodegenerative disease. Over time, it is intended that the UKCRN will enable research to be conducted across the full spectrum of disease and clinical need. A UKCRN Co-ordinating Centre has been established along with six topic specific co-ordinating centres each supporting the work of their respective networks. Scotland, Wales and Northern Ireland have the opportunity to join with these by developing their own clinical research structures.

The National Cancer Research Institute (NCRI) preceded the establishment of UKCRN and its National Cancer Research Network (NCRN) provides a model for other disease areas. The Northern Ireland Cancer Clinical Trials Unit (NICCTU) is already affiliated with the NCRN and is a full participant in its activities. Northern Ireland may not wish to put in place research networks in all of the currently specified areas, but plans are well developed to create a number of topic specific networks which, together will provide a foundation for a comprehensive Northern Ireland Clinical Research Network (NICRN). The NICRN will provide managed research networks that will enhance the capacity of the HPSS R&D community to engage with the larger UK research networks and will also contribute to the generation of high quality local clinical research. The networks will also be able to link with researchers in the Republic of Ireland. These managed networks will build on existing research capability and infrastructure to:

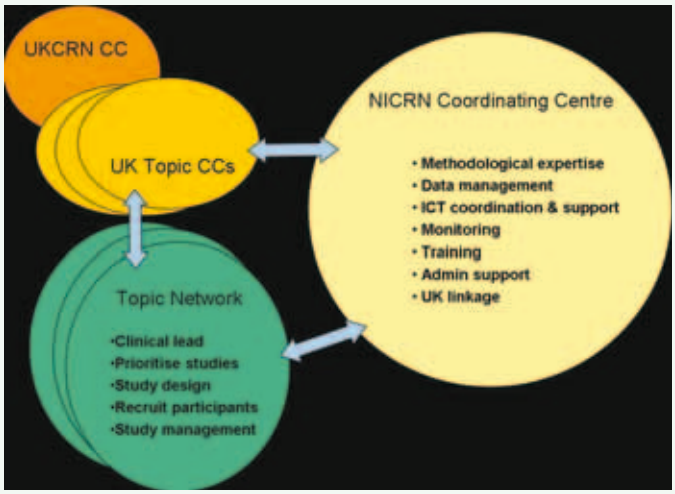
- improve patient care
- improve research co-ordination
- decrease research start-up times
- improve research quality
- increase research participation
- strengthen collaboration with industry

The Clinical Research Support Centre (CRSC) will act as the NICRN Co-ordinating Centre providing:

- methodological expertise
- data management
- ICT co-ordination and support
- monitoring
- training
- admin support
- UK linkage

An NICRN Manager will be appointed along with a number of Network Co-ordinators to provide dedicated support for the NICRN. The Network Co-ordinator will act as the critical link to the topic specific networks, which in turn will each have a clinical lead and an executive committee to develop a research strategy and to oversee resource allocation and network performance. The configuration and operation of each topic-specific network will be tailored according to the prevailing clinical environment and opportunities for partnership development. Key drivers will include the current and future organisation and delivery of clinical services, existing professional networks, the location of research active/interested HPSS sites, academic partnerships, and the scope for strategic research development. The networks will provide the opportunity to extend clinical research across Northern Ireland and we aim to have trial co-ordinators and research nurses in each of the five new Trusts. The topic-specific networks will hold primary responsibility for prioritising the clinical research studies they undertake, designing those studies, recruiting participants and managing individual studies. All networks will be required to adopt Good Clinical Practice (GCP) research standards and common audit processes, and will share expertise and experience across the whole NICRN. Dr Karen Bailie, Director of the CRSC is already working as a member of the UKCRN Operational Group to implement the UKCRN concept and put in place the national joint working arrangements and the planning, structural, cultural and communications mechanisms that will bring the UKCRN concept to life.

The R&D Office is committed to supporting the NICRN and is considering the level of resources that can be made available. In addition to funding specific posts in the CRSC, funding will also be made available for sessional time for lead clinicians in the topic specific networks. As the new networks emerge, other areas of infrastructure support eg protected time for research staff, research pharmacy, or radiology provision will be considered in order to remove potential barriers or bottlenecks that might impede the conduct of clinical research across the networks.



The functions of the NICRN co-ordinating centre and local networks in the context of the UK-wide clinical research networks

As a UKCRC partner, the R&D Office has been encouraging researchers across Northern Ireland to look at the potential for establishing networks in the topic areas and to engage with the UKCRN. Already some of our researchers are active members of the national Clinical Study Groups (CSGs) set up by the new topic specific networks, eg the Medicines for Children Research Network. These CSGs will determine the research priorities within the networks and it is important that Northern Ireland has influence at this level. Further details on the NICRN are available from the R&D Office website under the 'What's New?' section.

The NICRN must build on existing strengths and capacity. The Recognised Research Groups (RRGs) are central to the success of HPSS R&D and they already align with the six priority disease areas for the UKCRN. It is important that the RRGs and the networks are closely allied and that an increasing amount of RRG activity is channelled through the networks. It is equally important that where appropriate, primary care is heavily involved in the NICRN. In England a Primary Care Research Network is being created and we are discussing with the primary care community whether such a network should be created in Northern Ireland. We are aware that the Medical Research Council (MRC) General Practice Research Framework has a large number of practices enrolled in Northern Ireland and this may provide an opportunity for further development.

Just as the UKCRN is only one of a number of national initiatives the NICRN is only one part of the overall clinical research vision for Northern Ireland. The rest of this Newsletter sets out the bigger picture for clinical research and describes what is already in place, what is about to be put in place and what is being developed.

What is already in place?

Northern Ireland has taken great strides in advancing HPSS R&D over the last seven years and achieved a lot for clinical research in the last four years. This section looks at various initiatives that already exist to support clinical research in and around the HPSS.

Policy Infrastructure

As well as funding specific research projects, the R&D Office invests in a range of infrastructure that supports and facilitates the conduct of high quality HPSS R&D. That infrastructure investment is not limited to physical entities such as the CRSC but also extends to more abstract infrastructure such as the legislative and policy environment within which HPSS R&D takes place. The R&D Office, in conjunction with the DHSSPS, has devoted significant resources to ensure the necessary policy and legislative instruments are in place but this is an ongoing process with new requirements emerging from the EU as well as the National legislation. Recent examples include the Human Tissue Act and the EU Directive on Clinical Trials and forthcoming EU Directive on Medicines for Children.

While recognising the benefits of clinical research - in promoting and protecting health and well-being and in the development and maintenance of effective health & social care services – the risks associated with research must also be recognised. Research involving human beings be they patients, clients, or healthy volunteers inevitably introduces risk. The management or governance of these risks has created a substantial research governance agenda requiring the input and co-operation of many different people working in a range of organisations with different responsibilities and interests. Proper governance of research is essential to ensure that society can have confidence in, and benefit from, quality research in health & social care. Society has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

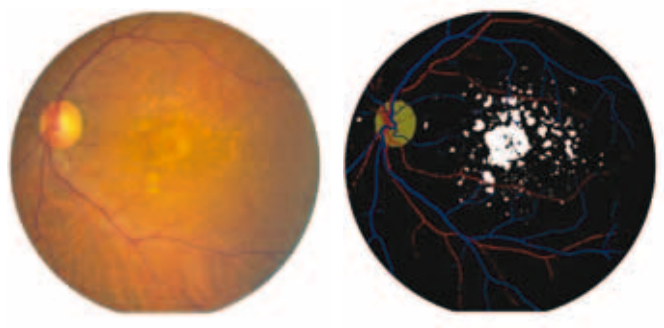
The challenge for research governance is to balance the administrative safeguards which aim to protect the rights and dignity of research participants, principal investigators, researchers and others with the desire to facilitate and enable high quality research. Legislation, regulation, policies and procedures are often portrayed as a bureaucracy - an unnecessary overhead obstructing researchers and impeding research. In reality bureaucracy is an inherent part of good governance - an essential mechanism to improve safety and assure quality - but it must not be allowed to unnecessarily hamper or delay clinical research.

In order to ensure that research governance is a managed and coherent process, a regional Research Governance Working Group (RGWG) was established in 2001 and continues to oversee this important agenda. The RGWG has worked with the R&D Office and the DHSSPS to issue the Research Governance Framework for Health & Social Care, to put in place new effective research ethics arrangements and take forward a regional approach to research management. The RGWG has, since the outset, worked to minimise and streamline the regulation and approvals process to ensure the bureaucracy of research governance is an enabling feature of the research environment that works with, and not against, the production of high quality research.

The Research Governance Framework for Health & Social Care is designed to maintain and continuously improve the quality of research within the HPSS and addresses the three essentials of governance:

- arrangements to **define** and communicate clear quality standards
- **delivery** mechanisms to ensure these standards are met
- arrangements to **monitor** quality and assess adherence to standards.

As with clinical and social care governance, research governance aims to bring general performance up to that of those at the leading edge. The Framework provides a context for the encouragement of creative and innovative research and for the effective transfer of



A state-of-the-art computerised colour image analysis system for objective quantitative analysis of colour fundus photographs, developed by The Advanced Macular Diagnostics (DRI AMD) laboratory at the Doheny Retina Institute, is being evaluated in the Macular Clinic at RGHT by Professor Usha Chakravarthy, following her sabbatical at the Doheny Institute which was funded by the R&D Office.
Image kindly provided by Dr SriniVas Sadda and Dr AC Walsh, Doheny Retina Institute

knowledge, technology and best practice to improve care. The Framework also aims to prevent poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learned and shared when poor practice is identified.

The standards in the Framework apply to all research undertaken in the HPSS or by, or on behalf of, the DHSSPS, or HSS bodies including non-Departmental Public Bodies, that might have an impact on the quality of health & social care services. This includes clinical and non-clinical research, research undertaken by HPSS staff using HPSS resources, and research undertaken by industry, the charities, the research councils and universities within the health & social care systems.

The conduct of high quality research requires research to be performed to accepted high standards with all key stakeholders fully aware of their individual and corporate responsibilities. The Framework provides a single repository for the various statutory requirements. The Framework is currently in draft form but will be reissued in 2006. In the interim the draft Framework can be accessed via the R&D Office website **www.rdo.centralservicesagency.n-i.nhs.uk** or via the DHSSPS website **www.dhsspsni.gov.uk**

Research Ethics Arrangements

Ethical review underpins the development of high quality, well-managed clinical research. It helps ensure that the rights of research participants are recognised and respected and that risks to the safety of both participants and researchers are properly managed. Although ethical review may be seen as an impediment, and at times an unwelcome challenge to the researcher, it is nonetheless a key part of research governance and a vital safeguard and enabling mechanism for the researcher, the research participant, the care organisation, the employing organisation and the funders of HPSS R&D.

Ethics is recognised as one of five key domains within the Research Governance Framework Document, and the Medicines for Human Use (Clinical Trials) Regulations 2004 has made it a criminal offence to conduct a clinical trial of an investigational medicinal product without a favourable opinion from a recognised research ethics committee. The 2004 Regulations provided a significant challenge for HPSS R&D but also acted as an impetus to improve the ethical review of HPSS research in Northern Ireland. To meet that challenge HPSS ethical review arrangements in Northern Ireland were substantially revised and a new HPSS Research Ethics Service created. There are now three HPSS Research Ethics Committees (HPSS RECs), supported by an Office for Research Ethics Committees for Northern Ireland (ORECNI). The new ethical review arrangements provide for the consideration of health & social care research proposals, for commercial and non-commercial research, and for the full range of clinical trial activity including 'first in man studies' and trials that involve healthy volunteers and HPSS service users.

These arrangements place Northern Ireland some way in advance of other regions of the UK, but there is still scope for improvement. ORECNI is in the midst of a user satisfaction survey designed to identify those areas of strength and weakness in the current arrangements. The results of this survey will help further improve the HPSS Research Ethics Service. The user satisfaction survey is complemented by a national consultation exercise on new proposals to deliver a more efficient and responsive research ethics service.

In 2004, the Department of Health (England), commissioned an Ad Hoc Advisory Group to review the work of the NHS Research Ethics Committee system in England. The Report of this group, in 2005, made nine recommendations focusing on the need to improve efficiency and avoid delays, the need to streamline the research ethics approval system and the requirements of research governance. The National Patient Safety Authority (NPSA) was charged with producing and consulting on an implementation plan to take forward these recommendations, through its Central Office for Research Ethics Committees (COREC). A high level Change Advisory Group, consisting of a wide range of research ethics stakeholders, was convened to produce this plan. This Group included representatives from Northern Ireland, Scotland and Wales, and consultations on this plan are underway in all four regions. The responses to the consultation exercise will inform subsequent consideration of whether Northern Ireland should adopt some or all of these proposals, and will inform wider discussions to establish consistent arrangements for ethical review throughout the UK.

Certain aspects of the NPSA implementation plan are however, not relevant, or only partially relevant, to the current HPSS Research Ethics Service as change along the lines suggested has already taken place in Northern Ireland. For example the HPSS RECs all have the same appointing authority, are already compliant with national standards and operating procedures established by COREC, and are already supported by a common administrative centre - ORECNI, managed by Dr Siobhan McGrath.

ORECNI
Contact: **info@orec.n-i.nhs.uk**
Website: **www.orecni.org.uk**

Research Management Systems (RMS)

The Research Governance Framework document mainly focuses on outcomes. However the RGWG was also concerned with putting in place efficient, integrated and streamlined processes to deliver those outcomes. A regional Pathfinder Project was convened in 2003 to develop, pilot and support the implementation of RMS. Phase 1 of the Pathfinder Project was completed in September 2004 with the launch of the RMS in the RGHT. The RMS consists of a common set of documented policies and procedures which can be adapted to the specific circumstances of an individual HSS Trust. It can be operated as a manual system supported by an Excel spreadsheet or can utilise a more sophisticated bespoke database developed by the Pathfinder Project in conjunction with the supplier, EPS Software. The RMS is sufficiently flexible to meet the needs of all Trusts and this flexibility is evidenced by its successful adoption and adaptation by the Northern Ireland Hospice.

Phase 2 of the Pathfinder Project refinement and roll out across the HPSS is continuing. Currently the AAHT, BCHT, GPHT, RGHT each have Research Offices with designated staff operating the regional RMS and incorporating the Research Manager electronic database. Other trusts such as CAHT, UHT, SEBT, DLT, MIT while not having full-time staff in place are still actively pursuing the implementation of the regional RMS. Phase 3 of the Pathfinder Project, the development of electronic approvals/applications and reporting mechanisms, is described in a later section of this Newsletter.

By working to streamline and integrate the processes supporting the delivery of research governance, Northern Ireland is someway ahead of other regions of the UK. While much work is still to be done, Northern Ireland already has many of the prerequisites recommended for effective research governance. There is a regional standardised approach to research management, with agreed Standard Operating Procedures, standardised information requirements, a standardised IT system taking projects through from initial approval to completion, alignment with ORECNI, and within trusts a Research Office providing PIs with a one-stop-shop to facilitate researchers navigate the research approvals process.

A Research Management Users Group continues the work under the Pathfinder Project and is tackling a range of issues to further streamline and improve areas such as indemnity, honorary contracts, peer review and consent. The R&D Office recognises the importance of research governance and the contribution an efficient and effective RMS can make to clinical research. The R&D Office is part-funding the staff in trust Research Offices, and where relevant meeting the development and purchase costs for the Research Manager software.

The advent of RPA will provide the opportunity to further consolidate a common and consistent approach to research management across the five new HSS Trusts so that researchers will experience a consistent research approvals and management process right across Northern Ireland.

UK Clinical Research Collaboration (UKCRC)

The UKCRC is driving forward a wide range of initiatives in order to secure the Government's vision of building a UK-wide clinical research and clinical trials infrastructure that will support the conduct and delivery of high quality clinical research through collaboration with the NHS, academia and industry. These initiatives are organised under five workstreams:

1. **Building up the infrastructure supporting clinical research**
2. **Developing incentives for research in the NHS/HPSS**
3. **Building up the research workforce**
4. **Streamlining the regulatory and governance process**
5. **Co-ordination of research funding**

The HPSS is fully engaged in many of these and the R&D Office is committed to ensuring that Northern Ireland will derive the maximum benefit from the work of the UKCRC. Within each workstream a number of working groups have been established. Some of the people from Northern Ireland involved in these working groups are listed on the next page.

UKCRC ENGAGEMENT	
Group	**Member**
UKCRC Board	Professor Bob Stout (Director of R&D for the HPSS, R&D Office)
UKCRC Sub-Group for UKCRN	Professor Bob Stout (Director of R&D for the HPSS, R&D Office)
Workstream 2	
UKCRU Research Passport Working Group	Mrs Frances Burns (Research Co-ordinator RGHT)
Workstream 3	
UKCRC Sub-Committee for Nurses in Clinical Research	Dr Nicola Armstrong (Programme Manager - Nursing, R&D Office)
UKCRC Expert Reference Group	Dr Nicola Armstrong & Professor Hugh McKenna (Dean) Faculty of Life, Health & Sciences, University of Ulster
Workstream 4	
Regulation & Governance Steering Group	Dr Michael Neely (Operational Director, R&D Office)

UK CLINICAL RESEARCH NETWORKS	
Group	**Member**
Operational Steering Group of the UKCRN	Dr Karen Bailie (Director, Clinical Research Support Centre, Royal Victoria Hospital)
UKCRN Training and Education Group	Dr Karen Bailie (Director, Clinical Research Support Centre, Royal Victoria Hospital)
Medicines for Children Research Network	
Operational Group of UKCRN Medicines for Children Research Network (MCRN)	Professor Henry Halliday (Consultant Neonatologist, Royal Jubilee Maternity Hospital)
Clinical Studies Group for Neonatology	Professor Henry Halliday (Consultant Neonatologist, Royal Jubilee Maternity Hospital)
Clinical Studies Group for Pharmacy UKCRN, MCRN	Professor James McElnay (Dean of the Faculty of Medicine, Health & Life Sciences, Queen's University Belfast)
Pharmacy subgroup on Pharmacokinetics, UKCRN, MCRN	Professor James McElnay (Dean of the Faculty of Medicine, Health & Life Sciences, Queen's University Belfast)
Northern Ireland Clinical Studies Group for Paediatric Respiratory Medicine and Cystic Fibrosis, UKCRN, MCRN	Professor Michael Shields (Professor of Child Health, Queen's University Belfast, Consultant Paediatrician, Royal Belfast Hospital for Sick Children)

National Cancer Research Network	
Operational Steering Group, UK National Cancer Networks	Dr Richard Wilson (Senior Lecturer in Oncology, Queen's University Belfast, Consultant Oncologist, Belfast City Hospital)
Board Sub-group for clinical and Translational Research, NCRN	Dr Richard Wilson (Senior Lecturer in Oncology, Queen's University Belfast, Consultant Oncologist, Belfast City Hospital)
Dementias & Neurodegenerative Disease Research Network	
Selection Committee for UK Dementias and Neurodegenerative Diseases Network (DeNDRoN)	Dr Margaret Cupples (Senior Lecturer in General Practice, Queen's University Belfast)
Primary Care Research Network	
Selection Committee for Primary Care Network for England	Dr Margaret Cupples (Senior Lecturer in General Practice, Queen's University Belfast)

Many of the UKCRC initiatives are described in this issue of R&D Today. More detail is available from the quarterly electronic newsletter **UKCRC Update** circulated widely by the R&D Office, and you can also find out more about the UKCRC via its website.

UKCRC
Contact: **info@ukcrc.org**
Website: **www.ukcrc.org**

Clinical Research Support Centre (CRSC)

The CRSC recently published its second annual report, detailing progress to date and plans for the next phase of development

The CRSC was set up with core funding from the R&D Office to provide a resource for investigators conducting high quality clinical trials and other well-designed clinical research studies relevant to the HPSS. Since its inception in 2002, the CRSC has broadened its range of advisory and support services. Under the leadership of Dr Karen Bailie, the CRSC now has a staff complement of 20 whole time equivalents, incorporating skills in medical statistics, health economics, epidemiology, clinical data management, regulatory requirements and the management of intellectual property related to research. As well as providing advice and consultancy the CRSC provides a training programme and delivers a range of specialised clinical research services.

The consultancy activity tends to draw mainly on the Centre's statistics and health economics expertise. With over 100 consultations on specific research proposals, advice has been provided across a variety of clinical specialities, from a range of service providers, and embraces the full range of study design including: surveys; case-control and cohort studies; and controlled clinical trials.

The training component of the CRSC remit offers a wide range of training activities. The CRSC team has developed and delivered a series of 'Research & Design' training workshops and a rolling programme of 'Good Clinical Practice (GCP) Awareness' sessions. The workshops are designed to assist new and established researchers, and cover a wide variety of research related topics. Evaluations from participants to date have been favourable, and all feedback is used to amend and improve the programme for future participants. More information on these workshops can be found on the CRSC website. Individual staff also give specially tailored training sessions or seminars to a variety of groups and institutions across Northern Ireland.

The growing range of complex clinical research services provided by CRSC include:

Clinical Trial Unit (CTU) Functions:

The design, conduct and analysis of clinical trials is a complex task requiring input from a range of disciplines to ensure that high quality, successful and timely research meets scientific objectives and regulatory and governance requirements. Input is available at a range of levels up to collaborator/co-applicant; and is supported by specialist IT and data management services (see below):

Preparation

- developing both outline and full trial protocols (in accordance with the principles of GCP), including advice on: trial design, project planning and costing

Trial set-up

- application for relevant trial approvals eg MHRA, ethics
- feasibility testing, identification and contact of centres, co-ordinating visits to centres
- ensuring quality assurance systems are in place

Trial management and co-ordination

- trial oversight – Trial Steering Committee, Safety & Data Monitoring Committee
- organisation of collaborators meetings
- central trials management and coordination – randomisation of patients; central data management (see below)
- monitoring to ensure the ethical and safe conduct of the trial (see IT section)

Data Management:

Activity in this area supports both intervention and non-intervention studies. The service includes case report form design, the production of study documents, data collection and data entry, database design, data validation, discrepancy management and production of study status reports. The data management service is underpinned by a dedicated IT staff with expertise in:

- the design, development and support of specialised database systems used to capture and allow the analysis of clinical trials and other research data
- the procurement and installation of an electronic clinical trial data management system – Macro 3.0 (InferMed) has significantly enhanced the data management and database design services. The system meets all regulatory specifications and has electronic data capture capability. The latter is particularly important in coordinating and managing trial activity within clinical research networks and other multicentre settings
- currently, data entry is undertaken within CRSC; however plans to facilitate data entry at clinical trial sites using web based or client server technologies are being developed.

Innovation and Intellectual Property (IP) Management:

The Innovation Advisor can provide assistance with the identification, protection and management of IP arising from the conduct of HPSS R&D. This area includes the use of IP clauses in R&D contracts, due diligence procedures relating to new ideas, IP protection strategies, and access to prototype or proof of concept development funding (see later).

CRSC
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Website: **www.crsc.n-i.nhs.uk**

Northern Ireland Cancer Clinical Trials Unit (NICCTU)

NICCTU has been funded by the R&D Office since 2000, following the establishment of the Cancer RRG and is headed by Dr Richard Wilson. The Unit co-ordinates and promotes cancer clinical trials, and runs a full range of phase I to phase IV trials, along with genetic epidemiology and other studies. These are a mix of commercial and non-commercial investigator-initiated studies, the latter originating from the cancer research charities such as Cancer Research UK (CR-UK), the National Cancer Research Network (NCRN) and research councils. Other studies originate in the US and are organised by the National Cancer Institute (NCI). NICCTU is based in BCHT and is closely associated with the new Northern Ireland Cancer Centre and with the Queen's University Belfast Centre for Cancer Research and Cell Biology (CCRCB) as well as linking with the Cancer RRG. NICCTU is also part of the NCRN and participates in trials from the NCRN portfolio. NICCTU currently recruits approximately 400 patients annually to clinical trials representing 6% of incident cancers. Forty-six clinical trials protocols are currently open for accrual and thirty-nine are progressing towards opening for accrual. These studies concentrate on haematological malignancies together with four major solid tumour sites: cancers of the breast; ovary; gastrointestinal tract, and lung. Paediatric haematological and solid tumour trials are based in the Royal Belfast Hospital for Sick Children (RBHSC), where the Unit has one full-time out-posted clinical research nurse. The developmental therapeutics programme has four phase I and II studies and one CT-PET based study open for accrual.

Historically the funding for NICCTU was provided by the R&D Office but this situation is progressively changing with increasing amounts of funding coming from CR-UK, local cancer charities and commercial sponsors.

NICCTU studies are run by a team of senior medical, clinical and haematological oncologists supported by a manager, clinical research nurses, data managers, data clerk and administrative staff. The current facilities for clinical research in BCHT include a dedicated area (10 chair/bed area) within the Bridgewater Suite and a 40-bed day hospital for cancer patients. The Unit has dedicated pharmacy support and chemotherapy reconstitution facilities alongside the HPSS facilities. The new Cancer Centre has also afforded additional laboratory and office space for the NICCTU.

Patients are accrued into trials from all over Northern Ireland but activities are currently focussed on NICCTU, incorporating BCHT and RGHT. This creates access problems for patients attending the four other Cancer Centres in AAHT, UHT, CAHT and UCHT. However NICCTU has recently won over £1million additional funding from Cancer Research UK to build on the staffing and research activity already supported by the core R&D Office grant. This will allow the cancer clinical trials networks to extend beyond the NICCTU and place a specialist cancer trials nurse in the other four cancer centres. This funding will also provide the opportunity for a formal link with the CR-UK Clinical Trials Unit (CRCTU) in Birmingham so that NICCTU in conjunction with the CRSC will be able to draw on the expertise and experience of an accredited and established CRCTU. This mentoring relationship will help the development of the CRSC's trial management, trial co-ordination, statistical support, monitoring and training services within the specialist area of cancer research. In the medium term the NICCTU in conjunction with the CRSC will aim for recognition as a CRCTU.

NICCTU

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Cancer Research NI
Senior Research Nurse/Clinical Research Nurse Co-Ordinator
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National Translational Cancer Research Network (NTRAC)

The NTRAC programme was initiated to improve the quality of cancer care by creating a national network of cancer research centres, embedded in the NHS, that integrate scientific and clinical expertise, and share knowledge and resources for the benefit of cancer patients. Full NTRAC Network Centre status and funding has now been awarded to fourteen centres of scientific and clinical excellence in the UK, including one in Belfast, which integrate the expertise of the bench researcher with the front-line clinician. The Northern Ireland NTRAC Centre opened in 2003 and linked the ongoing work of the former QUB Centre for Cancer Research and the NICCTU. It is focussing on building capacity in early phase clinical trials, developing biomarkers for prediction of response and toxicity, and applying functional imaging technologies in the monitoring of responses to normal therapeutic agents. The NTRAC grant is exploiting existing facilities, capabilities and expertise by funding additional staff who can capitalise on established success and existing expertise.

Dr Dean Fennell is the NTRAC lead and joined the new CCRCB as a Cancer Research UK Clinical Scientist. He co-ordinates the Belfast Centre's delivery of specialist expertise in microarrays and predictive biomarkers leading to the development of new tissue and tumour specific arrays; tumour tissue banks; specialist expertise in computational biology including the development of molecular pharmacological dendrograms identifying biological relationships between gene expression and families of drugs; specialist expertise in developmental therapeutics and clinical pharmacology providing preclinical and clinical drug evaluation through pharmacokinetic and pharmacodynamic assessment; and bioluminescent imaging technology and PET imaging technology. The NTRAC Centre demonstrates the value that can be added through partnership, marrying leading edge experimental/translation research with clinical needs to produce valuable clinical research.

NTRAC
Contact: **d.fennell@qub.ac.uk**

Website:**http://www.ntrac.org.uk/networkcentres/Belfast/Belfast.aspx**

Nucleic Acid Extraction Centre (NAEC)

NAEC is based alongside the clinical genetics laboratory in the BCHT. It was established in 2001 to provide a centre of expertise for the extraction and storage of DNA and RNA. As well as banking nucleic acid, the banking facilities store blood and tissue samples at -80^{o}C. Manual and robotic extraction facilities are available incorporating extensive quality control procedures. Extraction results are held in an electronic database and can be accessed by the researchers via the HPSS Internet. User group meetings are held regularly to ensure that the Centre continues to respond to the needs of the research community. The service is open to all users and the cost of extraction is highly competitive as it is subsidised by the R&D Office and can be as low as £3 per sample.

NAEC
Contact: **colin.graham@bll.n-i.nhs.uk**

Website: **www.bll.n-i.nhs.uk/medgen2/medgengeninfo.htm**

Positron Emission Tomography (PET) Institute

The Northern Ireland PET Institute, led by Professor Peter Jarritt, was established in 2001 through a partnership involving the Regional Medical Physics Agency, RGHT, BCHT, QUB and the R&D Office. Charitable donations enabled the purchase and installation of a state of the art hybrid full ring PET and Computed Tomography (CT) system adjacent to the Nuclear Medicine Department at RGHT. This GE Discovery LS PET/CT was the second of such scanners in the UK and one of the first six in Europe. PET is a medical radionuclide imaging technique that can demonstrate *in vivo* function, including basic metabolism, in the human body - molecular imaging. These hybrid scanners combine anatomical high resolution X-Ray CT images with the lower resolution functional images of PET, providing potential improvements in disease management and unique research opportunities especially in cancer, cardiology and neurology.

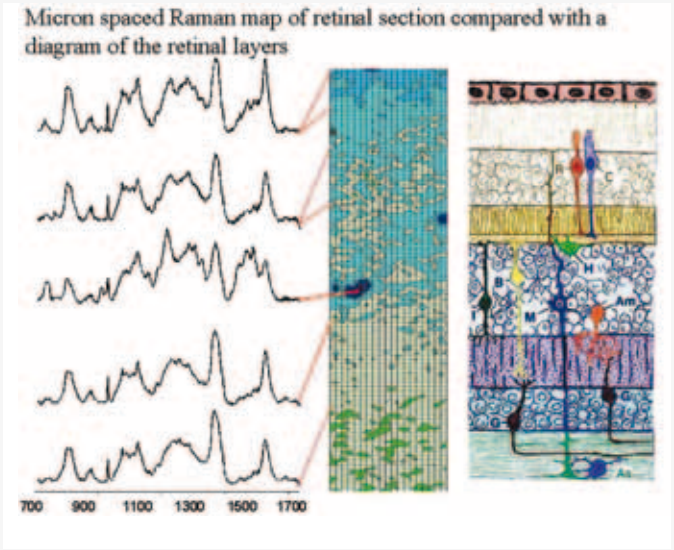
The Executive Funding Programme from OFMDFM supported a three-year programme to develop a PET Scanning Service and to evaluate the clinical effectiveness of PET imaging. This has now been extended until April 2008. Funding from the R&D Office and QUB was provided to pump prime research infrastructure and activity prior to seeking full funding. The research portfolio includes an R&D Office funded project looking at the use of PET/CT data for radiotherapy planning as well as national and international multi-centre trials evaluating the role of PET/CT imaging in the management of lymphoma, testicular, lung and head and neck cancer. The Institute is involved in a Health Technology Assessment programme evaluating PET imaging in clinical applications and is currently developing projects to evaluate and monitor new chemotherapy and radiotherapy treatments for cancer.

The next phase of development of the PET Institute will see the installation of a Cyclotron and Radiopharmaceutical production unit in the Phase II Imaging Centre at the RGHT due for completion in March 2007. This will increase the opportunities for research as well as expanding the clinical service capabilities.

PET Institute
Contact: **peter.jarritt@mpa.n-i.nhs.uk**
Website: **www.medicalphysics.n-i.nhs.uk**

Clinical RAMAN Microscopy Centre

The Clinical RAMAN Microscopy Centre, was established in October 2003, combining RAMAN spectroscopy expertise within the QUB School of Chemistry, with the emerging interest of clinical researchers in the biomedical applications of RAMAN technology. It aims to establish a leading edge, internationally recognised Centre of Excellence for Clinical RAMAN microscopy in Belfast. Following the success of a Biotechnology and Biological Sciences Research Council (BBSRC) bid from a consortium of clinicians, clinically-related scientists and spectroscopic chemists, for the purchase of a RAMAN microscope, the R&D Office agreed to provide five-year funding to help staff the Centre, which is now led by Professor Stuart Elborn.



The RAMAN Microscopy technique originated within the physical sciences, but has begun to find application in the specific identification of molecular species in biological materials. When molecules in a tissue or fluid sample are exposed to monochromatic light, the scattering patterns produced have a characteristic spectrum or 'fingerprint' of vibrational

frequencies, which can be related to the molecular composition of the sample. Accurate positional mapping of distinct molecular species is possible if the scattering is viewed with a confocal microscope. The potential applications of the technology include tracking of drug delivery and drug interactions, and identification of molecular changes specific to cancerous and other diseased cells. RAMAN microscopy offers the opportunity for the development of highly sensitive and novel non-invasive diagnostic and therapeutic tools.

A series of potential biomedical applications of RAMAN Microscopy, funded by the R&D Office and others, is under investigation within the Centre. Teams have already demonstrated the ability of the technology to discriminate between benign and cancerous cells in lung and prostate cancer, to reveal molecular interactions during neural degeneration in the retina, and to monitor molecular behaviour during drug processing. The Centre has already begun to capitalise on this leading edge facility by building national and international collaborations, and it represents a valuable resource for clinical researchers in Northern Ireland.

Clinical Raman Microscopy Centre
Contact: **stuart.elborn@bch.n-i.nhs.uk**
Website: **www.ch.qub.ac.uk/spectroscopy.html**

Disease Registries

Population Disease Registers represent an important infrastructure resource for clinical research as well as for the delivery of health and social services care. Examples in Northern Ireland include the Northern Ireland Cancer Registry and the Northern Ireland Cerebral Palsy Registry. These Population based registers provide an essential resource for public health surveillance, the planning of health care provision, the monitoring of disease burden in a population or monitoring the effect of an intervention e.g. screening.

The Northern Ireland Cancer Registry holds validated cancer incidence data 1993-2004, identifying all cases in the Northern Ireland population. This provides accurate information on cancer rates, trends, survival and patterns within Northern Ireland and provides a basis for international comparison. The Register facilitates the investigation of alleged disease clusters and the monitoring of care processes and patient outcomes. The NI Cancer Registry and the Irish Cancer Registry use the same data collection and classification systems so that all-Ireland analyses and reports can be undertaken.

The Cancer Registry has an active research portfolio maximising the unique datasets it holds. An all-Ireland research study explored the largely unknown aetiology of Barrett's oesophagus and oesophageal adenocarcinoma through their association with a wide range of exposures including environmental and lifestyle factors. The study findings included specific advice which can be utilised by health care professionals, such as GPs, for at risk patients such as the avoidance of weight gain, cigarette smoking, and the adoption of a diet low in fat and high in fruit. This information is particularly important for those patients diagnosed with Barrett's oesophagus. The study also indicated that the use of anti-inflammatory drugs may be especially appropriate in these conditions.

Northern Ireland Cancer Registry
Contact: **NICR@qub.ac.uk**
Website: **http://www.qub.ac.uk/nicr/racc.htm**

Cerebral Palsy Registry
Contact: **j.parkes@qub.ac.uk**
Website:
www.liv.ac.uk/PublicHealth/ukcp/registers.html

Institute of Child Care Research (ICCR)

Much of the Social Care research funded by the R&D Office is conducted at the ICCR, based at Queen's University Belfast. Established in 1995, the ICCR receives core funding from the R&D Office and aims to play a key role in influencing the development of child care policy and practice in Northern Ireland. Under the leadership of its newly appointed Director, Dr Rosemary Kilpatrick, this is achieved through identifying and conducting original research into child care needs and services, offering training and consultation on undertaking and applying child care research, and providing postgraduate research supervision.

At present there are three core programmes of research: the *"Belfast Youth Development Study"* - a

longitudinal survey of adolescent development focusing on the onset and desistance of adolescent drug use; the *"Growth, Learning and Development Study"* - which examines the interaction between child and parental factors on physical growth, cognitive and motor development, amongst growth-faltering and control children; and the *"Pathways to Permanency Study"* - a longitudinal study examining the care careers of a population of Looked After Children in Northern Ireland. Further information on these studies, and on other research currently underway is available on the Institute's website.

The Institute promotes knowledge transfer to help maximise the potential for dissemination and implementation of its research findings throughout the HPSS. Alongside more traditional means of knowledge transfer such as publication in peer reviewed journals, the ICCR is engaged in a number of innovative activities. An example of this is the Child Care Research Forum, which is chaired and facilitated by the Institute. The forum is an intersectoral, interagency and multidisciplinary initiative, which aims to develop a cross cutting child care research culture in Northern Ireland.

The forum has recently developed a Children's Research Database, which provides online access to the latest research relating to children in Northern Ireland. The Database is sponsored by the Children and Young People's Unit in the Office of the First Minister and Deputy First Minister (OFMDFM), and can be accessed using the following link:
http://www.ark.ac.uk/orb/childabout.html

The Forum is funded by the R&D Office and has wide ranging membership, including representation from: the OFMDFM; the Northern Ireland Commissioner for Children and Young People; the NSPCC; Voice of Young People in Care; Queen's University Belfast and the University of Ulster. Further information on the Forum may be obtained by contacting its Chairperson, Kathy Higgins on 02890 975401.

The Institute also has a Scientific Advisory Committee and Professional Liaison Committee. The latter meets twice per year to act in an advisory capacity, and includes representation from: the DHSSPS; the HSS Boards; the voluntary sector and the Northern Ireland Social Care Council. The ICCR plans to establish a complementary advisory group of young people to support and guide its work.

ICCR
Contact: **r.kilpatrick@qub.ac.uk**
Website: **http://www.qub.ac.uk/ss/cccr/**

Recognised Research Groups (RRGs)

The RRGs are fundamental to the HPSS R&D Strategy and to the success of clinical research in Northern Ireland. The Groups were formed to facilitate focused good quality research and to create a critical mass within a vibrant co-operative research environment. By combining the collective expertise and skill mix of the group members, the aim of each RRG was to establish collaborations locally, nationally and internationally, publish their findings in high impact journals and develop a strong reputation in their field, which would enhance their ability to attract external research funding.

Currently there are seven RRGs, each headed by its own Chair, in the following areas:

• Cancer	Professor Charles Campbell
• Child Health & Welfare	Professor Henry Halliday
• Endocrinology & Diabetes	Professor Brew Atkinson
• Epidemiology	Professor Gerard Linden
• Infectious Diseases	Professor James Johnston
• Neurosciences	Dr Janet Johnston
• Trauma & Rehabilitation	Dr Madeleine Rooney

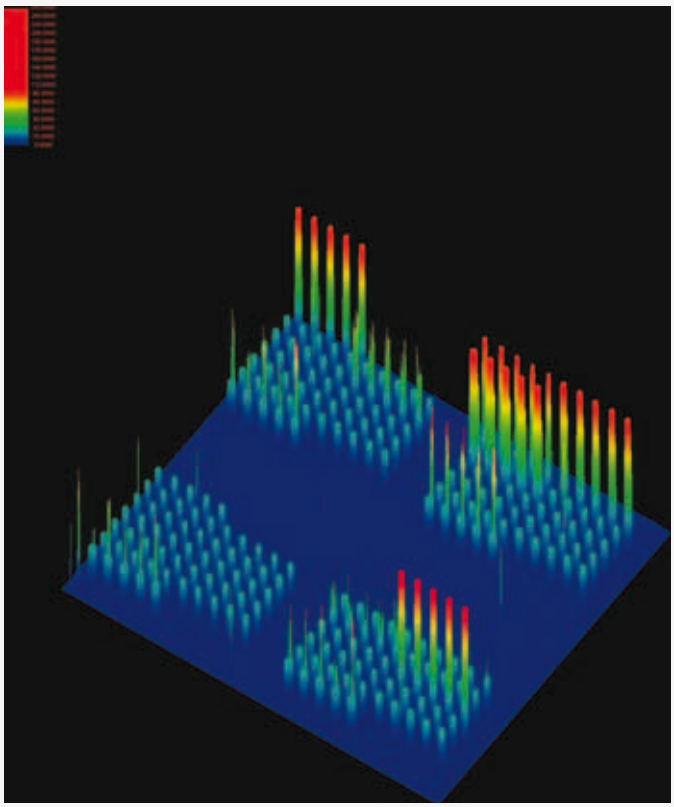
The Groups welcome members from all health & social care professions and related academic disciplines, from both HPSS and higher education institutions, thus providing a fertile environment for the development of multidisciplinary research projects. Each group is provided with an annual cohesion fund to support group activity and function. A key added value function of the Groups is the provision of significant training opportunities at all levels. This is facilitated by well-established programmes of training including seminars, workshops, conferences, grant writing committees, mentoring and facilitating attendance at short courses.

Each RRG was set up with an initial group of projects funded by the R&D Office, and a five-year review of

Skeletal Joe, an interactive 3D model included in a new spinal measurement proposal and as an educational resource for students of spinal anatomy, under development by Justin Magee at the Art & Design Research Institute, University of Ulster, within the Trauma and Rehabilitation RRG. Image kindly provided by Justin Magee

the RRG concept was carried out in 2005. The Review Panel found that the clustering of resources within RRGs (as opposed to funding on a project-by-project basis) added real value. They concluded that this clustering had helped the groups to attract external grant funding, as indicated by attraction of some £60million of additional grant funding. In addition, research by the Groups has real commercial possibilities with some 29 patents being filed. The RRG concept was judged to be beneficial in the recruitment and retention of research staff. Overall the evidence presented indicated that the Groups were a valuable resource for the exchange of information and had made an important contribution to HPSS research. The Panel recommended that a further five years of R&D Office support should be offered. Each RRG was asked to develop a forward strategy, and these, along with proposals submitted in response to a fresh call, are currently undergoing evaluation.

RRG research is leading to real benefits for patients and clients. For example, research by the Child Health & Welfare RRG has developed a simple non-invasive test for meningococcal meningitis and an Infectious Diseases RRG project has led to the introduction of real-time PCR assays for microbial detection into clinical practice. Research using the SPECT brain imaging system, funded by the Neurosciences RRG, has resulted in the establishment of a brain SPECT service at BCHT which is being used in the diagnosis of dementia. As well as this local relevance, much of the research conducted by the RRGs is of national and international relevance. This provides an ideal platform for Northern Ireland to become involved under the emerging UKCRC initiatives. A number of the new UK Clinical Research Networks map very clearly onto the areas of expertise of the RRGs.



A PCR-based respiratory microarray for parallel detection of pathogens is under development by Dr Peter Coyle and his team in the Regional Virus Laboratory, RGHT as part of the work programme of the Infectious Diseases RRG. Image kindly provided by Dr Conall McCaughey

Cancer RRG - Contact:
http://www.centralservicesagency.com/display/rdo_cancer

Child Health & Welfare RRG - Contact:
http://www.chawrrg.qub.ac.uk/

Endocrinology & Diabetes RRG - Contact:
http://www.rrgendocrinologyanddiabetes.com/

Epidemiology RRG - Contact:
http://www.centralservicesagency.com/display/rdo_epidemiology

Infectious Diseases RRG - Contact:
http://www.centralservicesagency.com/display/rdo_infectious_diseases

Neurosciences RRG - Contact:
http://www.qub.ac.uk/neurorrg/meetings.htm

Trauma & Rehabilitation RRG - Contact:
http://www.centralservicesagency.com/display/trauma

All Island Co-operative Oncology Research Group (A-ICORG)

The Co-operative Group was formed under the aegis of the Ireland/Northern Ireland/National Cancer Institute Cancer Consortium established in 1999 following the signing of the Belfast Agreement. The Consortium supports initiatives to improve cancer care, research and training on an all-island basis. The co-operative group is funded by the HRB in Dublin and R&D Office in Belfast. The principal role of the co-operative group is to initiate and co-ordinate clinical trials in cancer in both parts of the island.

The Co-operative Group currently comprises eleven clinical centres throughout Ireland, NICCTU and two central offices, one in Dublin and one, the CRSC, in Belfast. The CRSC provides the statistics and data management function for the group, while the Dublin office provides a co-ordinating and administrative role.

The CRSC is tasked with responsibility for all quantitative aspects of co-operative group activities. These include:

- contribution to the design, conduct and analysis of clinical studies
- all data management and processing functions for the group
- providing scientific support for protocol development and group audit
- development of a group ICT strategy
- development and participation in group training programmes

The CRSC Director and Senior Statistician have executive responsibilities, contributing to the oversight, high level decision making processes and strategic direction of the group.

Key components of the co-operative group are the disease-specific subgroups, which are open to all interested members. There are now seven of these subgroups, covering the areas of lung, gastro-oesophageal, breast, colorectal and gynaecological cancers, lymphoma and translational research. Subgroups in myeloma, leukaemia, melanoma, pancreatic and prostate cancer are envisaged. Each subgroup has a remit to prioritise trials for potential inclusion in the group portfolio (a group executive decision) and to contribute to research ideas for development in conjunction with the CRSC team in Belfast.

There are currently 34 active trials in the A-ICORG portfolio, of which four are "own account" protocols, having been developed within the group. These trials are also included in the CRSC portfolio.

Ireland-Northern Ireland National Cancer Institute Cancer Consortium

Website: **http://www.allirelandnci.org/index.asp**

The Cochrane Library

The Cochrane Collaboration is an international non-profit and independent organisation, dedicated to making up-to-date, accurate information about the effects of healthcare interventions readily available worldwide. The Cochrane Library is one of the vehicles used to achieve this, and represents a unique source of information, hosting a database of current systematic reviews - Cochrane Reviews - of the effect of interventions in healthcare. Systematic review underpins evidence-based health & social care, and it is considered good practice to perform such a review before embarking on any major clinical research project, to help refine research questions, inform study design and avoid duplication.

In 2002, Ireland became the first country to provide free national access to the Cochrane Library, an initiative co-funded by the R&D Office and the HRB. In addition to this, the HRB and R&D Office continue to fund a series of annual training programmes in systematic reviews and to administer an annual Cochrane Fellowship programme to build capacity on the island of Ireland in conducting systematic reviews for inclusion in the Cochrane Library. In October 2006, Ireland has the honour of hosting the XIV World Cochrane Colloquium in Dublin.

Cochrane Library
Website:
http://www.cochrane.org/reviews/clibintro.htm

Cochrane Fellowships and Colloquium
Website:
http://www.centralservicesagency.com/display/cochrane1

What is coming next?

There is a lot in place already to help clinical research develop in Northern Ireland but there is also much more on its way. This section highlights key initiatives that are well advanced. In some instances delivery is a matter of time and effort, in others delivery is dependent on funding, time and effort. Although the HPSS R&D Fund has been cut by £1million per year the R&D Office is working to secure additional external funding to ensure we can move forward and extend clinical research facilities and research programmes. While a number of initiatives are awaiting the outcome of funding bids a number have already been successful, demonstrating the ability of Northern Ireland to succeed in the competition for new resources and new research infrastructure.

UKCRC Experimental Medicine Initiative

As part of the UKCRC's initiative to provide an under-pinning infrastructure for clinical research, the major funding bodies are working closely to build national capacity in experimental medicine. In 2005 the UKCRC issued a Framework for Experimental Medicine call worth £82million over a five-year period. The R&D Office is an active partner in this initiative working alongside the Wellcome Trust, Wolfson Foundation, MRC, British Heart Foundation and the Health Departments.

Clinical Research Facility

A £6million Northern Ireland bid for a Clinical Research Facility (CRF) was submitted under this call. It has passed through initial evaluation and the final outcome should be announced in July 2006. This bid was submitted by Professor Ian Young on behalf of the RGHT, BCHT, QUB, UU and the R&D Office. If successful the bid will provide funding for the construction, equipping and running of a CRF based in the RGHT plus a 3T MRI scanner in the Northern Ireland Cancer Centre on the BCHT site. The CRF and the MRI scanner will be core resources for the Northern Ireland clinical research community providing significant additions to the clinical research infrastructure.

The CRF will provide a high quality clinical environment in which patients can undergo research programmes safely and effectively according to robust, ethically approved trial protocols. Under the leadership of a Director and Deputy Director, trained research nurses and other support staff, including those in the nearby CRSC, will work with PIs from HSS Trusts and Universities to develop, evaluate and implement research protocols. Researchers using the facility will be supported by administrative and laboratory services, and have access to the full range of clinical and non-clinical services provided by both Trusts. The CRF will be situated within Phase 2b of the RGHT hospital redevelopment on the seventh floor, immediately above the Intensive Care Unit and contiguous with the Education Centre. The building will link directly with all patient care areas and with new state-of-the-art imaging and cardiology centres currently being completed in Phase 2a of the RGHT redevelopment project.

The CRF will comprise a suite of six rooms equipped for clinical investigation and collection and processing of biological samples. This will provide designated space for: studies and trials requiring psychophysical assessment of visual function and *in vivo* imaging of ocular structures; cardiorespiratory function testing; assessment of vascular function and insulin resistance; three multipurpose clinical rooms equipped for patient consultation; a tissue and biological sample processing laboratory, to allow rapid processing of biological samples and temporary storage prior to analysis; a kitchen, suitable for the preparation of meals for dietary studies and a waiting and reception area.

The 3T MRI scanner will be situated within 1km of the CRF in the Northern Ireland Cancer Centre on the BCHT

site, which opened in March. This will be available for research not only in cancer but in neuroscience and other areas.

The CRF and 3T MRI scanner will facilitate internationally excellent experimental medicine and translational research, drawing on existing strengths within the NI research community and helping to attract new expertise to the region. In addition, the CRF will encourage new researchers and clinicians to participate in the NICRN. The availability of a pool of trained and experienced CRF nursing and technical staff will avoid delays in staff recruitment for individual projects by helping to create a cadre of experienced clinical research staff. As well as bringing improved training opportunities for clinical researchers the CRF will allow more patients to benefit from participation in local and national research trials and to participate in other clinical research initiatives flowing from the UKCRC.

Experimental Cancer Medicine Centre

In a second experimental medicine initiative Cancer Research UK and the four Health Departments have committed a further £35million to a separate but complementary call in experimental cancer medicine. This will help ensure that the UK remains at the forefront of international efforts to develop new treatments for cancer and that these treatments are targeted at those patients most likely to benefit. This initiative builds on the existing NTRAC network incorporating existing centres and encouraging new centres. The Northern Ireland Experimental Cancer Medicine Centre (ECMC) bid was submitted in December 2005 under the leadership of Professor Patrick Johnston. This bid will enhance the existing NTRAC facility and speed up the development of new discoveries for the benefits of cancer patients. The ECMC will provide the means to translate research in experimental cancer medicine within the CCRCB at QUB, linking laboratory and clinical research programmes.

The ECMC will focus on the development of clinical pharmacology, improved diagnostic predictive markers for both response and toxicity, and the development of normal therapeutic targets using functional imaging technologies to determine response. Cancer patients will benefit from improvements in their cancer care and from improvements in the quality of cancer research programmes in Northern Ireland. Under this proposal the new Centre plans to double accrual to early phase clinical trials, mechanistic Phase I and early Phase II clinical trials, over the next three years.

As with the initial NTRAC funding the grant will fund sessional time for pathologists, radiologists and radiographers and the employment of research pharmacists, research nurses and research fellows. However, whereas the initial funding for the NTRAC Centre was provided solely by the R&D Office, the new call brings in substantial partnership funding from Cancer Research UK.

CRSC - HPSS Innovations

In January 2006 the CRSC secured additional funding of £1.65 million to create *HPSS Innovations* and enhance its existing Innovations/IP service. The additional funding was obtained through a bid to the third round of the Public Sector Research Exploitation Fund (PSREF) and comprised £750,000 from the PSREF, £600,000 from Invest Northern Ireland and £300,000 extra support from the R&D Office. This funding will enable CRSC to establish *HPSS Innovations* as an innovation management service providing:

- efficient identification, assessment, and management of intellectual property (IP) assets through protection and technology development processes
- training of staff in the management and control of HPSS IP assets and commercialisation activity
- acceleration of potential products to market via commercial and non-commercial routes and the eventual generation of revenue streams

The new funding will also provide limited proof of concept funding for the HPSS as a means of directly supporting the innovation process.

HPSS Innovations will run proactive promotion and awareness campaigns within the HPSS and look to generate new IP with potential to accept proof of concept funding and exploit commercial and non-commercial opportunities for the application of new ideas.

There will be capacity to complete more detailed investigation, audit and qualification of market

opportunity for all potential innovations. This support should lead to an increased number of funding opportunities through licensing revenue, new company development, and benefits back into the cycle of healthcare innovation.

HPSS Innovations will use a secure web-based Intellectual Asset Management system to facilitate, manage and track innovations and IP and any relevant commercial opportunities which flow from these.

The new *HPSS Innovations* team will build on the collaborations already initiated by Dr David Brownlee and they will work closely with InvestNI, BioBusiness NI, other NHS Innovation hubs, the National Institute for Improvement and Innovation, venture capital funders, amongst others to secure appropriate technology transfer arrangements for innovations arising from the HPSS. Innovation flowing from clinical research will help secure improved service provision and the opportunity to generate better health and more wealth. CRSC is currently recruiting new staff to help Dr David Brownlee realise the *HPSS Innovations* vision.

CRSC
Contact: **david.brownlee@crsc.n-i.nhs.uk**
Website: **www.crsc.n-i.nhs.uk**

CRSC - Regional Monitoring Service

The CRSC is currently establishing a central HPSS on-site monitoring service for clinical research bringing benefits of economy of scale, objectivity and a standardised quality driven process. This service will facilitate HSS Trusts discharge their governance and management responsibilities to oversee the progress of clinical research, ensuring that it is conducted and recorded in accordance with the approved research protocol, and, where applicable, Standard Operating Procedures, GCP and regulatory requirements. As well as protecting the rights, safety and wellbeing of research participants, on-site monitoring helps verify the accuracy and completeness of reported data. Individual HSS Trusts will still be responsible for identifying the level of monitoring required for a given project but the service will allow HSS Trusts to call on trained staff to carry out on-site monitoring of specific research projects. This may include an initiation visit, annual/interim visits and a close-out visit.

CRSC
Contact: **paul.biagioni@crsc.n-i.nhs.uk**
Website: **www.crsc.n-i.nhs.uk**

Northern Ireland Longitudinal Study (NILS)

Over the last three years, the R&D Office has been working with the DHSSPS and the Northern Ireland Statistics and Research Agency (NISRA) to generate a database of information which can help inform the development of public health policy. NILS will provide a unique anonymised dataset comprising linked demographic and health & social care information from the linkage of Census returns, information on births, deaths, migration, and HPSS data. Enabling legislation was enacted in February 2005 to allow the project to proceed and three demonstration projects have been completed as exemplars of the type of research that can be supported by this infrastructural investment. Future research will look at the effectiveness of health & social care services predictors; institutional care for older people; early life influences on adult health outcomes; health inequalities; and intergenerational differences in fertility and mortality.

Other Longitudinal Studies are already in place, notably in England and Wales where the dataset stretches back 30 years, and in Scotland. However, the longitudinal study in Northern Ireland is distinguished by the large sample size (33 per cent of the population) and the links that have been made through the Unique Patient Client Identifier into the HPSS datasets.

The first phase of the project is being brought to conclusion with the dataset going live in December 2006. In the interim the NILS will be launched at an information day later in 2006.

In the next phase of this infrastructure investment the R&D Office will be working with its partner organisations to establish a NILS Research Support Function. This will act as a front end to the dataset, helping researchers with the design of projects and the analysis of the dataset. Matched funding has already been secured from the Economic & Social Research Council (ESRC) to put the Support Function in place and to fund a series of initial research projects that can exploit the NILS and deliver some of the potential benefits from this important dataset. Professor Ian Diamond, the Chief Executive of the ESRC, will be the guest speaker at the forthcoming Information Day, underlining his Research Council's commitment to the project, and NILS potential contribution to clinical research.

Electronic Data Store (EDS)

A previous section of this Newsletter described the initial and ongoing development of the RMS through Phases 1 and 2 of the Pathfinder Project. Phase 3 of the Pathfinder Project aims to capitalise on the regional RMS by providing a mechanism to allow researchers to capture information once, for a variety of purposes, and avoid the task of repetitive entry of information on multiple forms. The RMS is also utilized by the R&D Office to manage its research awards/grants. In this context the RMS has been augmented with peer review and evaluation panel modules, and has been integrated into the Office's financial and information systems.

Phase 3 is now well advanced, with a software tool - the EDS, in the later stages of development. The EDS provides a researcher-driven platform for capturing information relating to proposed research projects. It is designed to hold a minimum defined data set that can be populated on an iterative basis as best matches the specific circumstances of the individual research. The software uses an Excel front end, with a proprietary Form Scribe software core. Information entered by the researcher on one form is automatically transferable to corresponding fields on: HSS Trust approval forms; the R&D Office electronic application form; and to 3rd party web based application forms. Data is automatically uploaded from EDS to web pages on the COREC, CTA/EurdraCT and RCUK sites. The EDS also allows transfer to the NHS Research Forms System. The technology has the potential to be adapted to populate any web based application form. Once testing of this software is complete, the scope of the EDS will be extended to cover the new Je-S application form used by the Research Councils. Consideration will also be given to extending the scope of the EDS to include other health/social care funders from within Northern Ireland.

What is in Development?

A number of important initiatives are at an earlier stage of development but many of these will be in place within the next twelve months underlining the pace of change in clinical research here in Northern Ireland and throughout the UK.

National Advice Centre

A recent initiative flowing from the UKCRC is the establishment of a single source of definitive advice for NHS/HPSS researchers. The intention is to have a national web-based portal available from Summer 2006. Researchers will be able to access:

- Definitive guidance documents
- A library of frequently asked questions (FAQs)
- A telephone helpdesk/query line for specific questions

Questions will be fielded by the help desk and, where appropriate, queries will be answered by referral to the relevant regulatory body/policy body. As specific queries arise and are addressed these will be added to the library of FAQs. Although this initiative will result in a single portal it will be addressing the needs of all of the UK and will accommodate differing nuances of research activity in the UK.

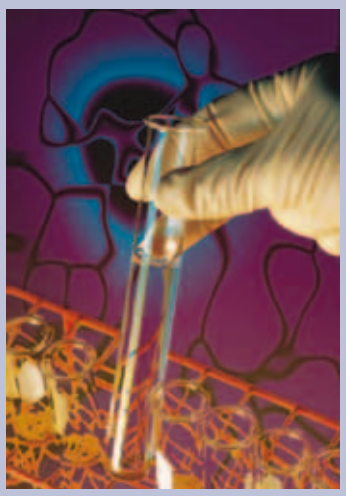
Research passport

The UKCRC is currently developing the concept of a Research Passport following the completion of a pilot project in the North West of England. The Research Passport is designed to avoid problems associated with issuing Honorary Research Contracts to researchers with no contractual relationship with the NHS/HPSS. The Research Passport helps both the researcher and the HPSS and will clarify the responsibilities and liabilities of all parties, helping improve patient safety and avoid unnecessary duplication of effort in Research Offices and Human Resources Directorates. The Passport will provide assurances from the relevant substantive employer to the potential honorary employer about the applicant and confirm that an agreed list of pre-employment checks have been carried out. The benefits of the Research Passport concept are enhanced where a researcher undertakes research in two or more HSS bodies. Northern Ireland is represented on the Research Passport Working Group which is working to roll out the National Research Passport concept across the UK. Given the imminent reorganisation of HSS Trusts under the RPA it is unlikely that the concept can be implemented in Northern Ireland before 2007.

UKCRC Standard Agreements

Prolonged negotiations over contracts or agreements between the various parties involved in clinical research can cause unnecessary delays in the approvals process and extend the start-up times for research studies. The UKCRC is working on a set of standard agreements to cover commercial and non-commercial research in the areas of pharmaceuticals and medical devices. The first of these agreements, a model Clinical Trial Agreement (mCTA) for contract pharmaceutical research in the NHS/HPSS, is due to be launched in Spring 2006. This mCTA revises the existing mCTA developed under the auspices of the Pharmaceutical Industry Competitiveness Task Force (PICTF). The existing PICTF agreement is already in use in the NHS and the HPSS but it has become subject to ad hoc amendments. The mCTA has therefore been revised to take account of: the provisions of the EU Clinical Trials Directive; the Freedom of Information Act; new undertakings with respect to registration and publication of data; and experiences in the use of the original agreement. The objective in revising and relaunching the mCTA is to devise an agreement which can be used without modification by pharmaceutical companies and accepted without reservation by the NHS/HPSS. This will help reduce delays in clinical trial initiation and reduce nugatory legal fees, increasing the efficiency of the contracting process and the competitiveness of the UK as a research environment. Northern Ireland has been involved in the revision of the mCTA, and the new mCTA will offer a Northern Ireland version taking account of Northern Ireland law. Work is also ongoing to develop similar agreements to cover medical devices and non-commercial clinical research. Guidance on the use of the new mCTA will be issued as part of the programme to announce and promote the use of the new agreement.

UK Panel for Research Misconduct & Fraud



The Research Governance Framework highlights the need to prevent misconduct and fraud in research as a means of enhancing its ethical and scientific quality and to safeguard both research participants and those affected by the application of research findings. A national three-year project has just commenced with the aim of establishing a UK Panel for Health & Biomedical Research Integrity to promote high standards of integrity in the leadership, governance and management of biomedical research across the university and NHS/HPSS sectors.

The Panel will provide a Register of Advisers comprising individuals with particular expertise in managing research misconduct. Members of the Register will act as a source of good practice advice and advisers may join local inquiry panels at the request of an employing institution.

This major UK-wide three-year initiative, part funded by the R&D Office, will run until February 2009 and produce a code of good practice which will draw on existing frameworks and policy statements. The code will set out clear principles and guidance on the promotion of research integrity and the effective management of research misconduct. The expectation is that this code of good practice will become widely recognised as the authoritative source of practical guidance for the governance and management of health and biomedical research integrity.

A project website will be established in 2006 and will be developed over the lifetime of the project providing a first point of contact for the Panel's services and offering regular updates/briefings, electronic resources, and providing specialist guidance on the various aspects of research integrity. A central database will also be developed to enable an index of activity to be maintained; this will provide different categories of information such as the number of research misconduct cases per year, the number of complaints received, the mechanisms which are deployed by universities and NHS/HPSS trusts.

The Panel will work closely with employers, professional networks and other stakeholders to embed good practice within mainstream processes. During its second and third year of operation the Panel will work in partnership with other organisations to establish a programme of staff development and training.

A link to the project website will be added to the R&D Office website once the project web address is made available.

CRSC - Clinical Trials Unit Accreditation

The CRSC, working with NICCTU, is seeking accreditation as a UKCRN CTU. The CTU is a vital component of the UKCRN, providing a centre of excellence and expertise that can develop and coordinate national multi-centre clinical trials. In order to gain accreditation a CTU must provide evidence of essential competencies including:

- A track record and experience of coordinating multi-centre trials
- The presence of a core team of expert staff to develop, conduct and analyse studies
- The presence of robust quality assurance systems and systems to ensure adherence to regulatory and research governance standards, including the NHS Research Governance Framework and the EU Directive for Clinical Trials
- Knowledge of specific disease areas
- Evidence of longer-term viability of capacity for trials coordination and the development/maintenance of a trials portfolio

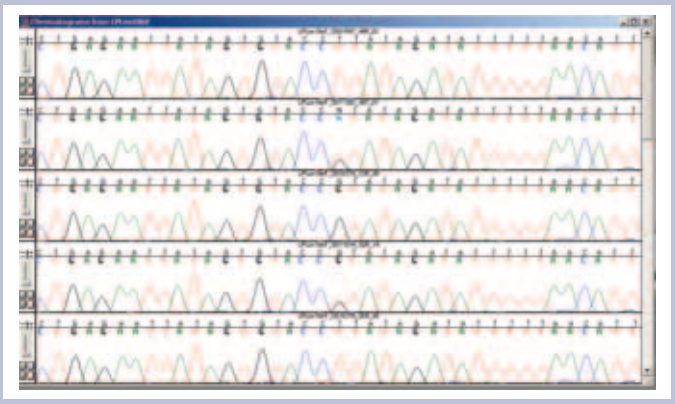
CTUs within the UKCRN will share expertise, systems and knowledge, avoiding duplication of effort and facilitating development of standard IT systems, common approaches to SOP development and approaches to assessing data quality. Links with the UKCRN CSGs will ensure that the Groups have access to relevant and expert support and advice in developing and assessing new research protocols.

Academic-Business-Clinical Research and Innovation Facility (ABC-RIF)

In the North West, AAHT in conjunction with UU and Derry City Council is taking forward an ABC-RIF initiative. The development of the ABC-RIF originates from discussions within the North West Science and Technology Partnership, which comprises local industry representatives, clinical practitioners and academics who are keen to support local science and technology based infrastructure projects in the North West. The innovation facility aims to improve health and create wealth, promoting the North West region as an attractive location for clinical research, innovation and development; bringing high-value added employment to the region. The ABC-RIF facility is intended to provide a setting where clinicians, academics and private sector businesses can conduct research with significant commercial potential. The initiative is at an early stage of development and a business case is being finalised. The R&D Office has indicated its support in principle and will provide recurrent funding for some core ABC-RIF staff. The ABC-RIF will bring an important focus to the roll out of the NICRN in the North West. As well as facilitating participation in the various disease specific networks, the ABC-RIF aims to provide a high quality purpose built environment for the conduct of patient-orientated clinical and basic research, as well as providing leasable space for spin out companies and inward investment companies seeking access to clinical research.

GeneLibrary Ireland

The proposed GeneLibrary Ireland has the potential to become part of the long-term infrastructure for clinical research in Ireland. The library will hold anonymised DNA and blood samples collected from a random sample of 10,000 volunteers throughout the island of Ireland, the results of detailed medical examinations and answers to a questionnaire on aspects of their lifestyle and environment. Samples would be collected over a two-year period providing the largest, most detailed survey of Irish health ever undertaken, and giving significant baseline information. The library would provide a cost effective common resource for a control group, which researchers can use to study the role that different genes play in sickness and health, facilitating research that could lead to discoveries about the cause of disease, new diagnostic tests, new



DNA sequence information can be generated from samples stored in the GeneLibrary collection, and matched to phenotypic data collected from participants. Image kindly provided by Dr Colin Graham

drugs and new cures. The proposal to develop GeneLibrary Ireland was consulted on following the work of an Expert Group chaired by Professor Bernadette Herity. A workshop was held in Dublin in November to discuss GeneLibrary Ireland and another was held in March 2006 in Belfast. Further details are available from the R&D Office website. If there is significant support from the research community North and South, the R&D Office in conjunction with the HRB in Dublin, will take the concept forward and secure funding.

Regional Peer Review System (RPRS)

Peer review is an important governance mechanism and one which helps secure research quality and relevance. It should provide an appropriate process of independent expert review to demonstrate that a research proposal is worthwhile, of high scientific quality and represents good value for money.

An HSS body may in some circumstances take responsibility for the provision of peer review, eg in the case of 'own account' research. In order to help HSS bodies ensure adequate peer review, a RPRS is planned.

The proposed RPRS will be designed around a register of volunteer reviewers from specific areas of expertise, who will provide independent advice on research quality. Each HSS body will have access to the regional system via a RPRS co-ordinator. The Research Office or research lead of an HSS body, will forward a research proposal requesting peer review. Details of research proposals will then be sent via a RPRS co-ordinator to reviewers, who will perform the review and return assessment sheets, again via the co-ordinator, to the Research Office or research lead. The RPRS co-ordinator would take responsibility for the day to day running of the peer review system and a steering group would be responsible for overseeing all aspects of the system.

A sub-group of the Research Management User Group is currently working on the development of a RPRS in Northern Ireland. Such regional peer review systems are already in place elsewhere in the UK, e.g. the North West Peer Review System, which can be used by all NHS Trusts and Primary Care Trusts in the North West of England.

User involvement

There is a growing aspiration for researchers to include "user", "consumer" or "public" involvement in their research. The Research Governance Framework for Health & Social Care states *"research participants or their representatives should be involved, wherever possible, in the design, conduct, analysis and reporting of research."* Organisations such as INVOLVE (a national advisory group, funded by DH, which aims to promote and support active public involvement in research) affirm that public participation in research will improve the way that research is prioritised, commissioned, undertaken, communicated and used.

The term "public" is employed to cover a range of people/groups, including consumers, and people who use health and social services. INVOLVE suggests a variety of ways in which the public may become involved in research eg by assisting in the design of research projects or by becoming members of project advisory groups. Details of publications, training and conferences which focus on public involvement in research are available on the INVOLVE website **http://www.invo.org.uk/.**

The UKCRN has stated that patient/public involvement is fundamental to improving clinical research in the UK. The UKCRN is developing a national strategy for patient/public involvement along with a patient/public involvement group (with representation from a range of partners including INVOLE). It has appointed a patient/public Liaison Lead to ensure a co-ordinated and generic approach across the networks.

The R&D Office advocates patient/public involvement in the research it supports. The Office will monitor developments from INVOLVE and the UKCRN to guide in the adoption of this important initiative. Steps have already been taken to include patient/public involvement in the R&D Office Strategic Advisory Group, and on the Northern Ireland Forum for Health and Social Care Research.

A 'clinical trials aware' patient population that is educated with respect to the benefits of clinical trials balanced against the associated risks, is an asset that would help make Northern Ireland a more attractive centre for pharmaceutical companies and investigators wishing to conduct multi-centre trials. The R&D Office, with the help of the research community, aims to raise public awareness of the value in terms of health and economic benefit that clinical research and clinical trials would bring to the community as a whole.

Future Opportunities

Northern Ireland has many clinical research strengths and we are well placed to take advantage of the opportunities emerging from the UKCRC and to improve the wealth and health of Northern Ireland. Nevertheless, there are many untapped opportunities to do a lot more and the R&D Office is committed to exploring the potential for new and more innovative partnerships in Northern Ireland and further afield. Close working relationships already exist with the HPSS, Queen's University Belfast (QUB), University of Ulster (UU), the Department of Enterprise, Trade and Industry, Invest Northern Ireland, Biobusiness Northern Ireland, the Health Research Board (HRB), the Medical Research Council, the Economic and Social Research Council, Cancer Research UK and other research charities and with the National Cancer Institute (USA). That exploration will however be conducted against a context of radical change. Both local Universities have undergone internal reorganisation with the establishment of research institutes and realignment of research strengths and groupings. In UU the Centre for Molecular Biosciences presents the potential to link with cutting edge technologies. In QUB the new Centre for Cancer and Cell Biology aligned with the new Cancer Centre in Belfast City Hospital Trust presents another range of possibilities and opportunities to collaborate with high quality researchers and high quality science. The advent of full economic costing for University research presents the opportunity to maintain and improve world class research facilities but also presents a challenge to secure higher levels of support from research funders.

The proposals to merge the MRC and Department of Health (England) budgets announced in March 2006 introduce potential uncertainty as to how health related research will be funded in future.

In the HPSS, the Review of Public Administration (RPA) heralds a significant period of change and accompanying uncertainty for the HPSS. We hope this will not impair the ability of our researchers to undertake research. Whether the review will change the arrangements for the R&D Office remains to be decided. However, there are opportunities that will arise from the review. In particular, the reduction in the number of trusts from 18 to 5 will give the opportunity for a better co-ordinated Northern Ireland-wide infrastructure for clinical research. We would envisage R&D Offices in each of the five trusts, providing key regulatory and governance arrangements and providing help and support for clinical research. The RPA provides an opportunity to review, rationalise

and, if necessary improve research management and governance, to further streamline the approvals and regulation processes that underpin HPSS R&D and clinical research in particular. Northern Ireland is well placed, perhaps better placed than other regions of the UK, to build on its existing research management systems to secure consistent governance and management procedures, helping get research started quickly and managed effectively and efficiently through to successful completion, and helping reduce the demands on researchers, care organisations, funders and sponsoring organisations.

The R&D Office welcomes these opportunities and challenges, and will continue to promote, co-ordinate and support excellence in research and development, working in partnership with other stakeholders and making every effort to deliver the benefits of improvements in health and wealth that successful clinical research can bring for Northern Ireland.

Abbreviations

AAHT	Altnagelvin Area Hospital Trust
ABC-RIF	Academic-Business-Clinical research and Innovation Facility
A-ICORG	All Island Co-operative Oncology Research Group
BCHT	Belfast City Hospital Trust
BBSRC	Biotechnology and Biological Sciences Research Council
CCRCB	Centre for Cancer Research and Cell Biology (Queen's University Belfast)
COREC	Central Office for Research Ethics Committees
CRCTU	CR-UK Clinical Trials Unit
CRF	Clinical Research Facility
CRSC	Clinical Research Support Centre
CR-UK	Cancer Research UK
CSG	Clinical Studies Group
CT-PET	Computerised Tomography - Positron Emission Tomography
CTU	Clinical Trials Unit
DHSSPS	Department of Health, Social Services and Public Safety
DLT	Down & Lisburn Trust
ECMC	Experimental Cancer Medicine Centre
EDS	Electronic Data Store
EORTC	European Organisation for Research and Treatment of Cancer
GCP	Good Clinical Practice
GPHT	Green Park Healthcare Trust
HITF	Healthcare Industries Task Force
HPSS	Health & Personal Social Services
HRB	Health Research Board
HSCSR	Health & Social Care Services Research
HTC	Healthcare Technology Co-operatives
ICT	Information and Computing Technology
IP	Intellectual Property
Je-S	Joint electronic Submission system
MHRA	Medicines and Healthcare products Regulatory Agency
MIT	Mater Infirmorum Hospital Trust
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
NCI	National Cancer Institute
NCRN	National Cancer Research Network
NHS	National Health Service
NICCTU	Northern Ireland Cancer Clinical Trials Unit
NICRN	Northern Ireland Clinical Research Network
NILS	Northern Ireland Longitudinal Study
NISRA	Northern Ireland Statistics and Research Agency
NPSA	National Patient Safety Agency
OFMDFM	Office of the First Minister and Deputy First Minister
ORECNI	Office of Research Ethics Committees NI
PCR assay	Polymerase Chain Reaction assay
PSECT	Single-photon emission computed tomography
PSREF	Public Sector Research Exploitation Fund
QUB	Queen's University Belfast
RBHSC	Royal Belfast Hospital for Sick Children
RCT	Randomised Control Trial

REC	Research Ethics Committee
RGHT	Royal Group of Hospitals Trust
RGWG	Research Governance Working Group
RMS	Research Management Systems
RPA	Review of Public Administration
RPRS	Regional Peer Review System
RRG	Recognised Research Group
SEBT	South & East Belfast Trust
SME	Small Medium Enterprises
SOP	Standard Operating Procedure
UHT	United Hospitals Trust
UKCRC	UK Clinical Research Collaboration
UU	University of Ulster