INFRASTRUCTURE

Northern Ireland Clinical Research Network (NICRN)

The NICRN is funded by HSC R&D and supports high quality clinical trials across all HSC Trusts

The aim of the NICRN is:

- To promote research within Northern Ireland
- To develop close partnerships and productive working relationships with key individuals and groups across the Network and the wider research community
- To ensure that targets, including accrual of patients into trials, are achieved and maintained

Activities:

- Maintain a portfolio of network studies
- Assist with processes involved in setting up a study, in particular ethical, regulatory and local research governance approval for clinical trials
- Facilitate Training & Education
- Ensure that research opportunities are maximised within available resources

The following is a list of areas of interest for the NICRN..

- Dementia
- Diabetes
- Cardiovascular
- Childrens
- Critical Care
- Primary Care
- Respiratory
- Stroke
- Vision

A formal process is required to ensure that the finite resources of the NICRN are used in a coherent and strategic manner for the benefit of the HSC. Therefore before a study is included in the NICRN portfolio it will have to be assessed against the following criteria

- Is the study fully funded?
- Has a sponsor been identified?
- Has the study had robust Peer Review?
- Is the clinical research of clear value to the Health Service?
- Does the study align with NICRN clinical and strategic priorities?
- Is it feasible for the study to be conducted at one or more NICRN centres?

All enquiries can be made via the NICRN Co-ordinating Centre:

NICRN Senior Manager:	Dr Paul Biagioni
NICRN Co-Ordinators	Ciara McKenna & Angelina O'Neill
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MRC Methodology Hub

The MRC Network of Hubs for Trials Methodology Research (HTMR) has been established to support the development of novel methodologies to improve the design, conduct, reporting, and analysis of clinical trials. Clinical trials are studies conducted in patients to evaluate the potential benefits (and risks) that new treatments could offer. They provide the 'gold standard' evidence base for informing and improving future patient care.

In 2008, the Medical Research Council (MRC) conducted a call for proposals to establish a Network of Hubs for Trials Methodology Research. Eight regional centres (Hubs) were successful in their bids and were awarded funding (£16 million across the Hubs) for core staff and students. The Hubs work together through the Network to strengthen the methodological platform underpinning UK trials research.

Network Management Structure

The Network of Hubs for Trials Methodology Research is overseen by a Network Executive consisting of the eight Hub Directors, the Network Coordinator, and the MRC Methodology Theme Leader. The Network Executive meets three times each year to discuss Network activities and priorities. The All-Ireland Hub for Trials Methodology Research led by Professor Mike Clarke is currently under development and recruiting staff.

Research Governance

The Health & Social Care R&D Permissions process is an important dimension of research governance. It is essential that any research undertaken on HSC premises or involving HSC service users or their tissue or data, staff, resources or premises has been scrutinized to ensure that all legal, ethical, feasibility and safety implications have been considered and obligations fulfilled. A sponsor must be identified whose responsibility it is to oversee these issues, and often that will be the lead HSC Trust. Research governance permission must be in place before any research project can commence, and protects all those involved in the research (participants, researchers, care organisations and employers) by ensuring that all the necessary regulatory and governance requirements are in place.
The documents below set out the process of application in detail and should be used by all researchers wishing to carry out research within the HSC.

Research Governance Guidance Note1

Research Governance Guidance Note2

Governance Arrangements for Research Ethics Committees (GAFREC)

This document is the policy of the UK Health Departments describing what is expected from the research ethics committees that review research proposals relating to areas of the UK Health Departments' responsibility. It also explains when review by these committees is required.

The policy covers the principles, requirements and standards for research committees, including their remit, composition, functions, management and accountability. It also describes the Research Ethics service in which the research committees operate and the review they provide.

This harmonised edition comes into effect on 1 September 2011. It revises and replaces editions of the policy previously issued separately in England and Scotland in 2001. It also applies to Wales and Northern Ireland.

Clinical Research Support Centre

The CRSC provides practical advice and assistance from experienced researchers to support others who wish to undertake high quality research within health or social care settings CRSC helps with:

- Getting started – defining study aims and objectives; study design
- Identifying resources – costing and grant applications
- Keeping on track – organisation, data collection and management, study oversight
- Finishing off – report writing, data archiving

CRSC is funded by HSC R&D

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Northern Ireland Cancer Trials Centre (NICTC) and Network (NICTN)

Northern Ireland Clinical Trials Centre (NICTC) and Network (NICTN is jointly funded by HSC R&D and Cancer Research UK (CR-UK) to support the formation of the Northern Ireland Cancer Trials Network (NICTN). This joint financial support is augmented by additional core funding to support network activities by HSC R&D Division. This will enable the NICTN to achieve its goals of promoting high quality cancer care in Northern Ireland by inclusion of patients on a geographically more equitable basis into cancer clinical trials, translational research and other well-organised cancer research studies.

The established strengths of NICTN, based on the Northern Ireland Cancer Trials Centre (NICTC; also funded by HSC R&D Division) activity over the years lie in the

following areas of clinical and translational research: haematological malignancy, GI, GU, gynaecological, breast and lung cancer, radiation and paediatric oncology.

There are other areas that NICTN wishes to strengthen and develop over the next five years, and which are also of high priority. These include:

- supportive and palliative care
- surgical trials
- imaging trials
- prevention and early diagnosis trials
- survivorship studies

NICTC will organise and co-ordinate their own and others' trials for both NICTC and NICTN staff in Belfast Health and Social Care Trust and also for NICTN staff in the other four HSC Trusts in Northern Ireland. The NICTN staff based outside BHSCT will deliver only a proportion of the overall trials portfolio (eg they will not perform early phase trials, paediatric trials or certain complex interventional trials). Their trials will also depend on the cancer services based in the units and the particular patient groups treated there.

Experimental Cancer Medicine Centre (ECMC)

Launched in October 2006, the Experimental Cancer Medicine Centre (ECMC) Network is jointly supported by Cancer Research UK and the Departments of Health for England, Scotland, Wales and Northern Ireland (via HSC R&D), providing a total of £35 million over five years to fund a network of 19 Experimental Cancer Medicine Centres across the UK.

Aim of the initiative

The goal of the ECMC Network initiative is to drive the development of new therapies to bring benefits to patients faster. Experimental medicine, also known as translational research can be defined as "the investigation undertaken in human beings to identify mechanisms of disease and to test the validity and importance of new discoveries or treatments." Put simply, it's all about taking discoveries made in the lab and turning them into effective new treatments and diagnostic tools for cancer, such as biomarkers.]

Each Experimental Cancer Medicine Centre (ECMC) brings together experts in cancer biology (lab scientists) with clinical researchers (cancer doctors) to speed up the flow of ideas from the lab bench to the patient's bedside. In this way, scientists can work with the clinic, to identify the needs of doctors and their patients, and come up with new ways to tackle cancer. Doctors therefore have access to the very latest new drugs to test in clinical trials, finding out if potential treatments are safe and effective.

Belfast ECMC

The aim of the Belfast ECMC is to further facilitate effective translational research in experimental cancer medicine within the Centre for Cancer Research and Cell Biology (CCRCB) at Queen's University Belfast. The Centre for Cancer Research and Cell Biology in Belfast supports GLP-standard core facilities providing expertise in clinical pharmacology, biological resources, genomics, bio-imaging and tissue pathology.

Research Areas

Early clinical trials, molecular predictive markers of response to chemotherapy, translational biology and molecular pharmacology, cellular signaling pathways, molecular pathology and radiation biology

All types of Cancer but particularly Breast Cancer, Colorectal Cancer, Haematological Malignancy, Lung Cancer (including Mesothelioma), Upper Gastrointestinal Cancer, Genito-urinary Cancer.

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Centre of Excellence for Public Health

The UK Clinical Research Collaboration (UKCRC) partnership of funders has provided a £20 million investment to establish the Centres of Excellence for Public Health throughout the UK. In addition to HSC R&D, the partners include the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, , Medical Research Council, National Institute for Health Research, Wales Office of Research and Development - Welsh Assembly Government, and the Wellcome Trust.

The Centres bring together leading experts from a range of disciplines working in partnership with practitioners, policy makers and wider stakeholders to tackle public health issues which are likely to have a significant impact on the health of the nation.

The work of the CoE in Belfast builds upon two existing major collaborative areas of strength in Queen's University Belfast, namely nutrition and physical activity and their association with chronic disease and the social and economic determinants of chronic disease. This provides excellent opportunities for multi-disciplinary research and training by exploiting data-sets, and in so doing, significantly extending expertise in, and application of, several novel methodologies.

Each workstream is divided into a number of research programmes, some of which build on existing successful research and some of which are branching into new collaborative ventures.

Following the inception of the UKCRC Centre of Excellence Award in August 2008, CoE investigators have been successful in obtaining further funding from the ESRC, DEL, MRC and the EU of approximately £4 million to support these new ventures.

CoE Contact details

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Northern Ireland Biobank

A collaboration between Queen's University Belfast, the Belfast Health and Social Care Trust (BHSCT) and the University of Ulster will create a unique Biobank of clinical samples to support biomedical research within academia and industry across Northern Ireland.

Phase 1 of the NI Biobank, led by CCRCB researchers Dr Jacqueline James and Professor Peter Hamilton, will establish a collection of high quality tumour tissues and bloods from consented patients being treated for cancer in the Belfast Trust. This bank of tumour samples will complement both the Experimental Cancer Medicine Centre (ECMC) and the CR-UK Centre initiatives within CCRCB and will promote translational cancer research across the School of Medicine, Dentistry and Biomedical Sciences. Collectively over £1.9M has been secured to develop the infrastructure necessary for tumour banking to be successful. The tumour samples held in the NI Biobank will be surplus to clinical need and will be redirected to the CCRCB by BHSCT pathologists. Tissue and bloods will be accrued from individuals with GI, Breast, Lung, Head and Neck, Gynaecological and Genitourinary malignancies; the bank will also support the storage of samples retained during trials undertaken in the NI Cancer Clinical Trials Centre and Network.
The NI Biobank will be supported by a secure information management system which will be accessible to data managers in the Northern Ireland Cancer Registry

in order to link the tumour samples anonymously with robust clinical and pathological information. The NI Biobank will follow all local, national and international guidelines for the collection, storage and release of samples and data; it will also promote sharing of information with other Biobanks through its membership of the UK Confederation of Cancer Biobanks. A collection of readily accessible, high quality, well annotated tumour samples will be essential in the discovery of new biomarkers for cancer prognosis, prediction and indicators of clinical response and will support the approaches in stratified medicine being promoted across the School of Medicine, Dentistry and Biomedical Sciences.

Funding for phase one of the NI Biobank is a syndicate of three partners. Cancer Research–UK has provided funds as part of the Belfast CR-UK Cancer Centre initiative to enhance the research infrastructure within the BHSCT Tissue Pathology department facilitating sample accrual and molecular typing (£430,263). HSC R&D has awarded a five year grant for £1,495,414 which will support day to day running costs and Biobank staff (including an administrator, two research nurses and two medical laboratory assistants in the first instance). The Friends of the Cancer Centre (FOCC) have awarded two grants, one for £58,163 to create an information management system and the other £12,913 for the purchase of a MacroPath Imaging System. The local digital pathology company i-Path Diagnostics have been awarded the tender by QUB to create and support the IT system for the Biobank.