Institution: University of Leeds

Unit of Assessment: UoA2: Public Health, Health Services and Primary Care

a. Overview

Public Health, Health Services and Primary Care research at the University of Leeds takes place within 4 of the 7 Institutes of the School of Medicine (SoM), one of 4 Schools within the Faculty of Medicine & Health. The School research strategy aligns with a broader University-wide Biomedical Health Research strategy, involving extensive collaboration between University researchers submitted in UoAs 1 to 5 and 12 as well as major partners including the NHS. The School research strategy focuses on areas of international excellence (**Applied Health Research, Cancer, Cardiovascular, Genes & Development, Medical Education, Musculoskeletal**) that encompass the full translational pathway, with the collective aim of improving patient and population health, and wealth creation (http://medhealth.leeds.ac.uk/medicine/strategy). Our Applied Health Research strengths unite around 4 major inter-disciplinary themes: **Cancer and Genetic Epidemiology** (within the Leeds Institute of Cancer and Pathology); **Child Health and Lifecourse Epidemiology** (within the Leeds Institute of Genetics, Health and Therapeutics); **Clinical Trials Research** (within the Leeds Institute of Clinical Trials Research); and **Health Services Research** (within the Leeds Institute of Health Sciences). Applied Health Research is guided by our strategy to develop and apply the best available methods to address major national and international health and healthcare challenges. Strategic appointments throughout the current REF period, combined with close collaboration between biostatisticians, epidemiologists, health informaticians, health economists, clinicians and healthcare providers, have ensured effective delivery of high-quality interdisciplinary research in: biostatistical methods development, refinement and application; randomised controlled trials; health service and health technology assessments; meta-analyses; and systematic reviews. Combining these strengths with an extensive network of national and international collaborators, including healthcare agencies locally and in developing countries, supported by funding bodies including Research Councils, UK and EU governments and overseas agencies, has resulted in a portfolio of high-impact research across the themes, with research expenditure during the current REF period of £38.9 million.

b. Research strategy

Our overarching long-term strategy is to undertake research that has substantial impact on major national and international health problems by anticipating emerging challenges in healthcare, including: an aging population with life-long accumulated exposures contributing to chronic disease and co-morbidities; evolution towards a more person-centred or stratified healthcare system; an increasingly complex healthcare environment and increasing use of technology for managing personal health; and a continuing move towards community-based interventions both in the UK and internationally, aimed at addressing health inequalities. We therefore focus on problem-based research, responding to the priorities of key end-users of our research findings, including the NHS, NICE, DFID (Department for International Development) and WHO. To ensure the clinical relevance of our research we have developed an **Applied Health Co-operative** (directors **Brown** and **Hewison**) with healthcare providers in local NHS primary care trusts and the Leeds Teaching Hospitals NHS Trust (LTHT), which employs academic researchers to develop and deliver research in collaboration with, and led by, clinicians. Central to our research is the integration of population-based, observational, longitudinal and clinical intervention studies, with methodological developments in data linkage, biostatistics, lifecourse epidemiology, clinical trials, health informatics and health economics. Through this approach we have characterised genetic, environmental, psychological and healthcare factors that influence the development, progression, treatment and outcomes of disease, both nationally and internationally.

Theme 1: Cancer and Genetic Epidemiology

This theme focuses on the development and application of statistical, data linkage and epidemiological methods to investigate the aetiology and prognosis of disease, and involves extensive collaborations with clinicians and epidemiologists in cancer (returned in UoA1) and within LTHT. Since 2008 this theme has been awarded grant income of £8 million and published >200 papers. ***Gastrointestinal cancer research*** ranges from studies of the genetic and environmental

determinants of risk to investigating effective cancer care delivery through analyses of routine NHS databases. We conduct studies to investigate the combined effects of genes and environment (predominantly dietary), and investigate biomarkers of response to treatment in advanced colorectal cancer (**Barrett, Morris**). Research into delivery of effective cancer care has enabled quantification of effects on outcomes that are not amenable to randomisation, e.g. caseload, treatment by general or specialist surgeons, temporal delay in receiving therapy, and type of treatment centre (**Morris**). Our research forms an empirical basis for the development and monitoring of cancer management policies, linking the results of clinical trials to policy formulation at the population level. Through development of methodologies for the analysis and linkage of routinely-held NHS and other cancer patient data, our research has enabled evaluation of service standards to improve outcomes. ***Melanoma research*** is underpinned by our expertise in statistical methodology for the analysis of large-scale genomic data, including pathway analyses (**Barrett, Iles**). We coordinate international collaborative efforts to evaluate the genetic and environmental factors underlying melanoma aetiology and prognosis (e.g. GenoMEL [the Melanoma Genetics Consortium, www.genomel.org] and BioGenoMEL [www.biogenomel.eu]), and have carried out the analysis of the largest international genome-wide association study of melanoma risk (**Barrett, Iles**). We have conducted an extensive case-control study to evaluate the joint effects of genes and UV exposure on risk of melanoma and have identified factors determining relapse following diagnosis, including tumour characteristics, germline variation and exposures (especially drug exposures) (**Barrett, Iles**).

Research highlights include*:*

- Carried out the first national linkage of cancer registry data with hospital episode statistics data to elucidate the factors associated with variation in mortality, and showed significant variation across NHS trusts identifying areas of good practice, and of concern, to guide improvements in cancer outcomes (**Morris #4**).
- Identified novel genes associated with melanoma susceptibility (**Barrett #3, Iles #1**).
- Carried out meta-analyses of world-wide studies of patterns of sun exposure, nevus phenotype and associations with melanoma risk (**Barrett #1**).

Future strategy: we will maintain focus on continuation of follow-up as our colorectal disease and melanoma cohorts mature. For colorectal cancer, the linkage of hospital episode statistics (HES) data, cancer registry information and further integration with national population screening data will provide further insights into the factors underlying variation in mortality both between NHS trusts within the UK, and critically also across Europe, to understand the poorer survival seen in the UK. The continuing focus of the melanoma cohort study will be the design of adjuvant therapy for melanoma, which will be informed by the discovery of biomarkers (both genetic and serum-based) and exploration of drug exposures potentially modifying outcome, identified by linking national prescribing information with outcomes among melanoma patients. In collaboration with clinicians and epidemiologists in musculoskeletal research in UoA1, application of our expertise in biomarker discovery to evaluate risk of rheumatoid arthritis and predict response to therapy will continue through our involvement in new national initiatives to develop stratified treatments for rheumatoid arthritis (**Barrett**).

Theme 2: Child Health and Lifecourse Epidemiology

This theme explores the epidemiology and aetiology of acute and chronic disease in children and adults, with a particular emphasis on cancer, diabetes and cardiovascular disease (in collaboration with clinicians and epidemiologists in UoA1) and the impact of early and late effects of treatment and wider health inequalities on health outcomes. Since 2008 this theme has been awarded grant income of £7.8 million and published >600 papers. The development and application of technical, statistical and methodological expertise underpins the collection, validation, linkage and analysis of routine NHS datasets, observational and longitudinal studies, and biomedical science applications. Particular research interests include the linkage of routine health records (**Feltbower, McKinney, Parslow**), solving problems associated with collinearity and missing or incomplete data, and the application of latent variable methods, functional data analysis and partial least squares to evaluate the early life antecedents of disease (**Gilthorpe, Greenwood**). The regional Specialist Registers of (a) Cancer and Diabetes in Children and Young People, and (b) Congenital Anomalies are essential to our child health research (**Feltbower, McKinney, Parslow**). Research on the

epidemiology of cancer among teenagers and young adults and the impact of delivery of care on clinical outcomes (in collaboration with clinicians in UoA1) contributed to a transformation of relevant national clinical services and influenced major European collaborations (European Network for Cancer research in Children and Adolescents, ENCCA). Through our leading role in the Paediatric Intensive Care Audit Network (PICANet: **McKinney**, **Parslow** [Principal Investigator]) we have made a major contribution to improving paediatric intensive care outcomes and regional and national policy on paediatric intensive care. PICANet has established a unique dataset for audit, clinical trials and research, and led to extensive national and international research collaborations including Trial Management Group membership of CHiP (Control of Hyperglycaemia in Paediatric intensive care), the largest clinical trial ever conducted in paediatric intensive care. We also contribute to the Born in Bradford (BiB) birth cohort study through membership of the BiB executive and Scientific Group (**Parslow, McKinney**). In lifecourse epidemiology we have addressed the problems associated with collinearity in evaluating response variables and multiple highly-correlated predictor variables through the application of partial least squares regression (**Gilthorpe**). We have applied multiple imputation to mitigate the problems of missing data, and applied multilevel modelling to data from cross-sectional cardiovascular disease registries (e.g. the Myocardial Ischaemia National Audit Project [MINAP]), prospective cohort studies (e.g. Evaluation of the Methods and Management of Acute Coronary Events [EMMACE-3]) and case-control studies to evaluate patient (genetic and environmental) and healthcare factors that influence the development, progression, treatment and outcomes of cardiovascular diseases (**Gale, Gilthorpe, Greenwood, Hall A**). Research is underpinned by extensive collaborations with clinicians and epidemiologists across the Applied Health Research themes and the wider School of Medicine, and an extensive network of national and international partners.

Research highlights include:

- Revealed UK prevalence of life-limiting conditions in children was double previous estimates and increasing (**Parslow #2**).
- Demonstrated that acute complications and drug misuse are important causes of death in young people (<30 years) with type 1 diabetes (**Feltbower #1**).
- Applied partial least squares regression to estimate the life course effects of growth in body size on later-life health outcomes (**Gilthorpe #3**).
- Identified factors affecting mortality in the elderly after acute coronary syndrome using contemporary multilevel modelling techniques to fully utilise the complex data structure of MINAP (**Gale #4**).

Future strategy: We will continue to develop, refine and apply innovative methodologies in linkage of routine health data, missing data, latent variable and partial least squares analysis to further characterise the epidemiology and aetiology of acute and chronic disease and health outcomes. A new Leeds-Bradford Chair in Epidemiology will consolidate our research links with BiB to strengthen and expand our research into the aetiology of childhood chronic diseases and lifecourse epidemiology. Key areas of strategic focus will be on (i) investigating the spatial epidemiology of chronic childhood disease using spatio-temporal modelling and investigating the infectious aetiology of childhood cancer and diabetes; (ii) expansion of PICANet into Europe (FP7-funded) and using PICANet to recalibrate mortality risk adjustment models used to assess between-institution performance; (iii) evaluating the influence of early life environmental exposures on child health, including cancer, diabetes, cystic fibrosis and mental health disorders in collaboration with BiB; (iv) developing our expertise in congenital anomalies as a key collaborator in a national network of congenital anomaly registers (Public Health England-funded); (v) expanding our research into disease aetiology, quality of care and prognosis of patients with cardiovascular disease through access to investigator-led registries including EMMACE-1 to 4, national longitudinal studies, and pooled national cross-sectional clinical data linked with administrative and primary care data.

Theme 3: Clinical Trials Research

This theme designs and executes multi-centre clinical trials that influence both national and international clinical practice. The Clinical Trials Research Unit (CTRU) is a National Cancer Research Institute (NCRI)-accredited and UKCRC-registered trials unit, with a national and international reputation for the design and delivery of innovative, complex, and rigorous multi-

centre clinical trials. CTRU provides multi-disciplinary academic leadership with input to all aspects of trials activity, including statistical design, protocol and database development, randomisation, development of outcome measures, data management, logistical issues, statistical analysis, interpretation of results and publication. The CTRU has rapidly expanded with a collective trials portfolio (across UoA1 and UoA2) totalling £46 million of external income, currently managing >17,500 patients in 50 trials. Since 2008 the Clinical Trials Research theme has been awarded grant income of £15.9 million and published >300 papers. We have portfolios spanning cancer (**Marshall, Brown, Sharples**), cardiovascular (**Brown, Sharples, Farrin**), and complex interventions in Applied Health Research including mental health, stroke and the elderly (**Walwyn, Farrin**) all underpinned by methodological developments. Our track record in conducting innovative, complex clinical trials and associated methodological research (efficient trial design and analysis, development and use of novel outcome measures and patient reported outcomes, and electronic data capture) in collaboration with colleagues returned in UoA1, inform the academic development of this specialised field of clinical trials research at national and international levels.

Research highlights include:

- Demonstrated that the routine use of zoledronic acid in unselected patients with early-stage breast cancer is not indicated (AZURE international trial; **Marshall #3**)
- Demonstrated that the use of MRI imaging for staging might be unnecessary in patients with primary breast cancer (Health Technology Assessment [HTA] COMICE trial; **Brown #1**)
- Demonstrated that the diagnostic strategy of endobronchial and endoscopic ultrasound (followed by surgery if negative) can be used in staging of potentially resectable lung cancer (international HTA ASTER trial; **Sharples #3**)
- Demonstrated that nurse-delivered gastrointestinal endoscopy is effective but doctors are more likely to be cost-effective (HTA MINUET Trial; **Farrin #1, #2)**
- Demonstrated that CBT and graded exercise therapy added to specialist medical care improve outcomes for chronic fatigue (PACE trial, **Walwyn output #1**)

Future strategy: We will continue to develop innovative trial designs, focusing particularly on biomarker driven designs, efficient early-phase trials, seamless phase 2-3 trials and adaptive later-phase designs. The recent appointments of a Professor of Evaluation of Complex Interventions (**Farrin**), a Principal Statistician in Complex Interventions Research (**Walwyn**) and a new Chair in Statistics in Clinical Trials Research (**Sharples**) will enhance our expertise in the design and evaluation of complex interventions in healthcare, musculoskeletal, cardiovascular and biostatistical methods research. We have started to develop an early-phase clinical trial portfolio, which includes development of clinical trials of investigational medicinal products within cancer, and medical device and surgical innovation alongside engineering (including infrastructure and trial grants from the Myeloma UK Clinical Trials Network, and the ESRC Innovation and Knowledge Centre), and encompasses a number of feasibility studies to provide the evidence required to develop larger-scale, complex intervention evaluations. Through collaboration with epidemiologists, health informaticians, statisticians and NHS colleagues we will explore the use of NHS data and other large datasets to facilitate and improve the design, conduct and interpretation of clinical trials.

Theme 4: Health Services Research

This theme evaluates health service delivery across primary and secondary care, both nationally and internationally, through collaborative research involving biostatisticians, health informaticians, health economists, clinicians and healthcare providers. Since 2008 this theme has been awarded grant income of £27 million and published >1000 papers. The theme has been strengthened during the current REF period through a number of strategic appointments, including an Academic Leadership Chair in Health Informatics (**Wyatt),** a Chair in Primary Care Research (**Foy**) and a Chair in Palliative Medicine (**Bennett**), the latter in an innovative arrangement funded by the local hospice St Gemma's. An essential element of our research is the use of routinely-collected NHS data and information communications technology to link primary and secondary care practitioners in delivering care. We employ a combination of primary and secondary quantitative research with concurrent qualitative methods (**Hewison**) to evaluate various aspects of health service provision. In stroke research, we have established the importance of rehabilitation that tackles psychological and social barriers as well as the physical consequences of stroke, and established the importance and impact of mental health problems on quality of life and stroke outcomes through a series of

high-impact studies, including two of the world's largest stroke rehabilitation trials (**Forster, Young**). In gastroenterology (**Ford)**, we have national and international links with research groups involving a large UK cohort, clinical trials and observational studies of gastro-intestinal disease across the primary/secondary care interface. Our research into health care delivery in low-income countries (**Newell, Walley; impact case study on TB**), includes evaluation of mechanisms to deliver health care to poor urban residents as part of COMDIS-HSD (a 6-year DFID-funded research programme consortium; **Newell**). Our research utilising large datasets provides insight into health inequalities and equity in health and health care in the UK and internationally (**Tubeuf, Hulme**). Measurement and valuation of health, health care and wellbeing is an established research area (**Kind, Meads**) and we utilise cost effectiveness analysis to inform health care resource allocation decisions (**Hulme, Tubeuf, Hall P**). Our research into the use of e-health data has shown its potential to drive improvements in healthcare and in e-health research and medical bioinformatics. We have a formal strategic partnership for research with the Health and Social Care Information Centre (HSCIC), and a contractual partnership with The Phoenix Partnership (TPP) in relation to its ResearchOne database, and good working links with the NIHR-CC.

Research highlights include:

- Demonstrated that collaborative care that includes *interactive* communication between primary and secondary care clinicians improves the management and outcomes of a number of clinical conditions (**Foy #2).**
- Demonstrated, using RCTs to unpack the components of rehabilitation, that structured 6 month assessment yields no benefit over usual care (**Forster #2**) and that post-acute community care planning delivered from community hospitals has the same cost-effectiveness as that delivered from general hospitals (**Young #1**).
- Demonstrated that women find surgical termination of pregnancy for foetal abnormality both less painful and subsequently less distressing than medical termination (**Hewison #1**).
- Demonstrated that computerised decision-support increases effective use of guidelines in cardiac rehabilitation (**Wyatt #1**).
- Demonstrated early improvements in quality of life after transcatheter aortic valve implantation and identified increased operator experience as a valid predictor (**Meads #4**).

Future strategy: Recent (**Wyatt**) and planned future appointments in health informatics will allow us to enhance our capacity to undertake large-scale, cost-effective research, and to develop novel approaches to understanding influences on (and heterogeneity in) the outcomes of health interventions. We will use NHS data to enhance understanding of real-world epidemiology, by facilitating recruitment into trials and our ability to generalise from trials (increase their external validity). The development and application of contemporary methods for data linkage, use of routine data, handling of missing data, analysis of large and complex observational data and analysis of longitudinal data, and extensive collaborations with colleagues in Themes 1-3, will increase our capacity to undertake research in primary and secondary care and wider populations. In response to the health service challenge posed by multi-morbidity in the elderly, we are broadening our research into (i) assessing the nature of frailty in the elderly and its impact on service use, (ii) enhancing the scope of our research on mental morbidity (delirium, dementia, depression) in physical healthcare settings, and (iii) developing a programme of research in residential care homes. Applying our expertise in complex interventions, we are planning trials of new interventions in relation to functional bowel symptoms in primary care and end-of-life care in the UK. Ongoing developments in research into public health in low income countries, supported by the appointment of a Chair in International Health (**Ensor**), include a portfolio of cluster RCTs in low-income countries, including studies of care for multi-drug resistant-TB (for which treatment takes 2 years). Programmes that link Applied Health Research expertise to that in more biomedical disciplines are planned, involving novel interventional technologies, biomarkers and other diagnostic tests, which require evaluative research that involves expertise in economics, applied health research designs, personalised medicine and health services research to enable evaluation of their value and costs when applied in healthcare environments like the NHS.

c. People

Staffing strategy and staff development: During the current REF assessment period, research within the SoM has undergone a major strategic academic review to consolidate research around

areas of existing and emerging strength and to ensure long-term academic success and financial sustainability. As part of this process, a number of important senior academic appointments have been made to support our Applied Health Research strategy, including an Academic Leadership Chair in Health Informatics (**Wyatt**), and chairs in Health Economics (**Hulme**), International Health (**Ensor**), Clinical Trials and Evaluation of Complex Interventions (**Farrin**), Statistics in Clinical Trials Research (**Sharples**), Primary Care Research (**Foy**) and Palliative Medicine (**Bennett**).
An integrated network of training and development services provides support for the academic and professional development needs of all staff and postgraduate research students (the **Staff and Departmental Development Unit**; the **Next Generation Researcher** programme, developed in line with the Concordat to Support the Career Development of Researchers and the Researcher Development Framework), providing training in research and innovation, student education, academic leadership and management, and personal and professional skills. Targeted training in Applied Health Research for research staff and postgraduate research (PGR) students is provided locally. We monitor staff progress and development needs through the annual **Staff Review and Development Scheme** (SRDS), which is a two-way process focused on review of progress against agreed objectives, providing constructive feedback, recognising success, and identifying and planning appropriate development, aligned with SoM and Applied Health Research strategies (and also NHS strategies for our clinical academics and other NHS-employed researchers in consultation with NHS employers). We actively participate in the SoM training scheme for clinical academics, providing training in Applied Health Research to NIHR Academic Clinical Fellows, NIHR Academic Clinical Lecturers and Clinician Scientists from across the School in order to build Applied Health Research capacity (thirty three NIHR academic trainees (ACFs, ACLs and CS) in post in 2013). We also provide research capacity development for partners in low-income countries. The university monitors its progress in training and other objectives through participation in the **Careers in Research Online Survey** and the **Principal Investigators & Research Leaders Survey**; it was one of the first UK HEIs to receive the prestigious **HR Excellence in Research Award**. The University of Leeds is committed to ensuring a supportive and professional environment for all staff, underpinned by its equality and diversity policy, promoting equality of opportunity for all staff. The SoM received a Bronze award under the **Athena SWAN Charter for Women in Science** in September 2013 and has developed an ambitious 3-year Action Plan aimed at supporting and developing the career advancement of female academics within the School with a view to achieving Silver status by 2015.

***Research students*:** 110 postgraduate researchers have been awarded doctoral degrees during the current REF period (71 FTE supervision within Applied Health Research). Research students are supported by a variety of funding streams including NIHR, Research Council and Cancer Research UK studentships. All our research students have 2 or 3 co-supervisors to represent the multidisciplinary nature of the topics researched. **Postgraduate Research Tutors** monitor progress to ensure provision of high quality supervision, adequate progress towards timely completion, and completion of 10 days of generic skills training per year, consistent with University policy. PGR progress monitoring is facilitated by the recent introduction of an online **Postgraduate Development Record System** to facilitate the recording of formal supervision meetings, student training, transfer from provisional registration and formal reports on student progress, which is readily available to students, supervisors, tutors and administrative teams. PGRs, both clinical and scientific, are fully integrated into our Applied Health Research activities, contributing to a lively and productive research environment. The research groupings in the School have excellent seminar series with international speakers and there are rigorous group meetings within each of the Applied Health Research themes where students regularly present and discuss their findings. All students are required to present at least annually at local and/or University postgraduate research symposia. PGRs have elected representation to the University via Faculty Graduate School committees and their respective research groups. The **Faculty Graduate School** ensures high quality financial, technical, infrastructural and academic support is available and monitors student satisfaction through participation in the **Postgraduate Research Experience Survey.** In the 2013 survey, students in the SoM indicated high levels of satisfaction with the quality of supervision, provision of resources, development of research skills and professional development, with 90% of students expressing overall satisfaction with their research degree experience.

Researcher career support is a strategic priority in advancing our Applied Health Research

strategy, with local Early Career Research Groups coordinating career advice and support, and providing networking opportunities for research staff and postgraduate students. In a more targeted approach, we identify and support high calibre researchers of all levels by encouraging personal and professional development and providing support for fellowship applications and career development awards. Successes within the current REF period include: Royal College of Physicians/Dunhill Medical Trust Research Fellowship (Clegg); Cancer Research UK (CRUK) Fellowship (Birch); NIHR Clinician Scientist Award (Gale); MRC Career Development Fellowship in Biostatistics (Cairns); Cancer Research UK Career Development Award (Morris); NIHR Research Methods Fellowships (Brown, Walwyn, Farrin); NIHR Senior Investigator Award (Brown).

d. Income, infrastructure and facilities

***Income*:** Research is supported through a broad portfolio of funding, including grants from Research Councils, UK and EU governments, NHS R&D, charities and overseas agencies, with research expenditure totalling £38.9 million during current REF period.

Infrastructure: A review of the infrastructure in the SoM led to an ongoing programme of refurbishment and reorganisation to enable co-localisation of Institutes with overlapping expertise in high quality adequately sized accommodation. Cancer and Genetic Epidemiology researchers are based in the Genomics Facility of the Cancer Research UK Centre, linked to St James's University Hospital. Co-localisation of Clinical Trials Research and Health Services Research with Child Health and Lifecourse Epidemiology is planned in newly-refurbished single-site accommodation within the Medical School (£13M University capital bid) directly linked to the Leeds General Infirmary. Co-localisation of Applied Health researchers and key LTHT hospitals will facilitate collaboration with clinical colleagues in the relevant specialties and maximise opportunities for delivering high quality, clinically relevant research that is responsive to the changing needs of our key end-users. The wide-ranging and innovative partnership between the University of Leeds and LTHT is essential for our Applied Health Research, and exemplified by the **Leeds Biomedical and Health Research Centre** (BHRC), which facilitates collaboration between Applied Health Research, basic sciences, and translational and clinical research to promote and enhance academic excellence, and research and innovation. Established in 2009, the BHRC is overseen by a **Joint Partnership Board** (JPB, co-chaired by the University Vice-Chancellor and the LTHT Chief Executive), which provides overall strategic direction and guidance for collaborative initiatives. Through an innovative use of its Research Capacity Funding, LTHT supports the **Applied Health Co-operative** involving staff from SoM and the NIHR Research Design Service. Research and innovation support is provided by the central **Research & Innovation Service**, and includes 4 core areas: (i) innovation services (largely addressing commercialisation opportunities); (ii) performance, governance and operations; (iii) funding development; (iv) good research practice and ethics. Review and reorganisation of the support infrastructure has provided more effective financial, HR and contract advice, a more flexible approach to research management, and improved communication with funding bodies. Effective communication between the Research & Innovation Service and LTHT Research Support, supports management of Intellectual Property Rights especially with public sector funding bodies. The Faculty of Medicine and Health provides central support for the University values-based ethics review policies and process (www.leeds.ac.uk/ethics) to ensure and assure these values, in compliance with the University's policy on ethics, the NHS framework for ethical research and the legislative requirements of the Human Tissue Act. The Head of Faculty Research Support manages a Quality Assurance team, jointly funded with LTHT, which provides a source of support, advice and QA for clinical trials governance, predominantly within UoAs 1 and 2.

IT Facilities: The SoM has a coordinated approach to data management, information governance and IT infrastructure in partnership with the **University's Information Systems Services** and LTHT. We have evolved a data linkage model to link clinical data in situ (e.g. primary care, secondary care, cancer registry, and the Northern Yorkshire Cancer Registry and Information Service [NYCRIS]) and export pseudonymised records to secure University servers. This project is multidisciplinary, bringing together Computer Science, Medicine, Geography and external partners. We have in development a JISC-funded virtual environment which will encapsulate these services in a secure 'Cloud-based' architecture providing researchers with access to the N8 High Performance Computing Facility to support such functions as network modelling and digital data

visualisation. These activities are underpinned by strategic partnerships with the HSCIC and TPP who have the largest clinical records system in the world, SystmOne. This now has a pseudonymised mirror database ResearchOne providing access to primary care data. These platforms are used extensively in teaching, PGR training, and NIHR and other funded projects and are supported using dedicated computer scientists. Similarly, our CTRU, which handles data from multicentre trials (many of which include Leeds patients), has dedicated clinical trial-specific facilities managed in a coordinated manner in line with regulatory requirements. Data Management Groups across the SoM provide additional data management support for the legacy systems which have underpinned a range of biomedical and Applied Health Research, linking with data management colleagues in NYCRIS.

Laboratory facilities are provided through extensive collaborations with UoA1 clinical research units fully equipped for volunteer recruitment, sample processing and storage, biomarker analysis and the recording and retaining of data according to Good Clinical and Laboratory Practice.

e. Collaboration or contribution to the discipline or research base

Advisory Committees

To ensure that our research remains responsive to the priorities of key end-users of our research and continues to achieve research with impact, we make important contributions to strategic developments in Applied Health Research through participation in national and international policy and advisory boards, funding committees, governance bodies and research networks.

International advisory board and funding committee membership, including: WCRF/AICR Continuous Update Project (Greenwood); Irish National Research Centre for Diet, Obesity and Diabetes, Scientific Advisory Board (Gilthorpe); South African Medical Research Council Biostatistics Unit Quinquennial Review (Gilthorpe, External Expert); Scientific Evaluation Committee for the European Research Area Network on Translational Cancer Research 2013 (Barrett, vice-chair).

National research priority setting group membership, including: NCRI Clinical Studies Groups on Psychosocial Oncology (Brown, Chair), Palliative Care (Bennett, Chair), Complementary Therapies (Hulme 2010-12), Rehabilitation (Farrin), and Teenagers and Young Adults (Feltbower); Paediatric Intensive Care Clinical Reference Group (Parslow); Paediatric Intensive Care Expert Working Group for England (Parslow); Development team for Arthritis Research UK's INBANK Adult Inflammatory Arthritis Hub (Barrett).

***National funding committee membership, including*:** CRUK Biomarkers and Imaging Discovery and Development statistics experts review panel (Barrett); CRUK Population Research Committee (Gilthorpe); BHF Project Grants Committee (Hall A); MRC Mathematics and Statistical Research Board (Gilthorpe); MRC Methodology Panel (Sharples); NIHR Clinical Trials Unit Standing Advisory Committee (Brown); NIHR Programme Grants for Applied Research expert panel (Hewison, Forster, Brown); NIHR Research for Patient Benefit Programme Regional Advisory Committee (Farrin, Gale); NIHR Senior Fellowship Awards panel (Hewison, Chair); NIHR Doctoral Fellowship Awards panel (Brown, panel Deputy Chair); NIHR HTA Clinical Evaluation and Trials board (Hewison, Brown 2006-12); HTA Primary Care board (Farrin); MRC/Wellcome/DFID Global Health Trials panel (Newell).

***National research network and centre leadership, including*:** NIHR Stroke West Yorks CLRN Executive (Forster, Foy); NIHR Clinical Research Network Coordinating Centre (Brown, Associate Director 2005-10); UKCRC Registered Trials Unit Network (Brown, Director); National Cancer Research Network Portfolio Balance and Delivery Working Group (Brown); Yorkshire and Humber Regional Stroke Network Lead (Forster).

***National methodology development groups, including*:** NIHR Stroke Research Network Biostatistics Group (Farrin); NIHR Dementias and Neurodegenerative Diseases Research Network Clinical Trial Methodology Special Interest Group (Farrin); Mental Health Research Network Methodology Research Group (Walwyn).

***National professional leadership, including*:** National Scientific Steering Committees for the Sheffield and Liverpool Clinical Trials Units, the North West MRC Methodology Hub and the ICR Cancer Trials Unit (Brown); National Clinical Director for Frailty and Integration, NHS Commissioning Board (Young); Co-Director Connecting for Health Evaluation Programme 2004-

2011 (Wyatt); North West Cancer Intelligence Service (Feltbower); National Teenage and Young Adult Cancer Advisory Group (Feltbower); Northern Region Children's Diabetes Register (Parslow, Feltbower); Health Services Research Unit for Chief Scientist Office, Aberdeen, peer review panel (Brown).

***National governance bodies, including*:** MRC/DoH/MHRA Working Party on Risk Based Approaches (Brown); NICE Implementation Strategy Group (Foy); Chair of NICE Guideline Development Group for Delirium (Young).

Collaborations

The distinctive multidisciplinary approach to Applied Health Research in Leeds includes strong and wide ranging collaborations with academics, clinicians, allied health professionals, governance bodies and key funding bodies, locally (spanning UoAs 1, 3, 4), nationally and internationally.

International collaborations: we maintain a strong and consistent track record of major contributions to international research consortia resulting in an extensive range of highly cited collaborative publications in leading international journals during the current REF period. Major collaborations include: International Barrett's and Esophageal Adenocarcinoma Consortium (Greenwood); INTERPHONE (McKinney); European Network of Cancer in Children and Adolescents (Feltbower); European Society of Paediatric and Neonatal Intensive Care (Parslow); European Diabetes network (Feltbower, McKinney, Parslow); Worldwide Universities Network (WUN; Gilthorpe); EnviroGenomarkers (Gilthorpe); NewGeneris (Feltbower, Greenwood, McKinney, Parslow); Danish Birth Cohort (Greenwood); International Collaboration for a Life Course Approach to Reproductive Health and Chronic Disease Events (Greenwood); Cardiogenics Consortium (Hall A); Coronary Artery Disease Genome-Wide Replication and Meta-analysis Consortium (Hall A); Myocardial Infarction Genetics Consortium (Hall A); Melanoma Genetics Consortium, GenoMEL (Barrett, Iles); BioGenoMEL Consortium (Barrett); patient reported outcome development with University of Sydney (Brown); efficient trial design with University of Hasselt and International Drug Development Institute Texas; BEATRICE, PICCOLO and AZURE international cancer clinical trials conducted through CTRU recruit from 12-36 countries including 30 centres across the USA; Quality Improvement Interventions Group, RAND Health, US (Foy); French National Authority for Health (Tubeuf); Inequalities of Opportunities in Health Paris-Dauphine University Health, Risk and Insurance Chair (Tubeuf); University of Sydney George Institute for Global Health (Forster); international CONSORT group complex interventions reporting guideline, 2013 (Wyatt); WHO eHealth evaluation group 2011 (Wyatt); COMDIS-HSD (Newell, Walley).

National collaborations: an essential part of our research activities involve major contributions to national collaborative research efforts in Applied Health Research, as clearly reflected in our research outputs. Major collaborations relate to trials conducted through our Clinical Trials Unit, involving more than 200 UK centres. Other key national collaborations include: MINAP (Gale, Gilthorpe, Greenwood, Hall A); PICANet (**Parslow, McKinney**); CHiP (Parslow); UK Dietary Cohort Consortium (Greenwood); Wellcome Trust Case Control Consortium (Barrett, Hall A, Iles); Maximising Therapeutic Utility for Rheumatoid Arthritis consortium (Barrett); National Cancer Intelligence Network (Morris); EMMACE-3 (Gale, Hall A); SPACE ROCKET Trial (Hall A); MRC-funded lifecourse methods development with Bristol (Gilthorpe); patient-reported outcome development with Universities of Bristol and Oxford (Brown); efficient trial design development with Universities of Manchester, Reading and MRC CTU (Walwyn, Brown).

Editorial Boards

We contribute extensively to the peer review process, including membership of various editorial boards, in particular as statistical experts, including: Journal of the Royal Statistical Society series A (Sharples, Editor); Implementation Science (Foy, Deputy Editor-in-chief); Developmental Origins of Health and Disease (Gilthorpe, Statistical Editor); British Journal of Nutrition (Greenwood, Statistical Editor); Journal of Nutrition Science (Greenwood, Statistical Editor); BMJ Supportive and Palliative Care (Brown, Statistical Editor).

Organisation of International and National Conferences

We make important contributions to the organisation of international and national conferences, including the following conferences organised by our researchers: WUN-RSS Conference on High-Dimensional Analysis in Bioinformatics 2012 (Gilthorpe); MRC Methodology Hubs Conference 2013 (Brown); MRC Specialist Surgical Trials Workshop 2013 (Brown).