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OFFICE FOR STRATEGIC COORDINATION
OF HEALTH RESEARCH

# CHAIRMAN'S FIRST PROGRESS REPORT

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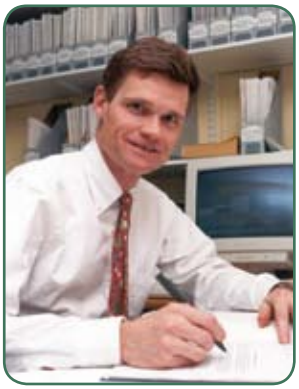

## Summary Letter from the OSCHR Chairman Professor Sir John Bell

The last thirty years of discovery in biomedical science have laid the foundations for a revolution in translational research. New tools and knowledge of disease pathways will greatly facilitate research to develop new therapies and diagnostics. The fruits of basic science advances in genetics, cell and molecular biology and the physical sciences are now available to drive this translational research agenda.

Sir David Cooksey's report, *A review of UK health research funding*, laid out a bold vision for invigorating translational biomedical research in the United Kingdom. The report argued that the coordination of health research activities in the UK could lead to substantial benefits for the country. These included more efficient use of public funds, an improved environment for commercial health sector research and development (R&D) and, importantly, benefits to patients and the NHS as basic knowledge about disease was converted into benefits for patients and the health care system. Government was quick to recognise the importance of this report and to decisively support its recommendations. The Office for Strategic Coordination of Health Research (OSCHR) was established to forge the cross-departmental coordination that would be essential if the UK were to benefit from the translational research agenda.

OSCHR has been in place for twenty-two months and, in that short time, it is apparent that the scope, depth and nature of translational research in the UK have all benefited dramatically from the coordination of strategies for its delivery. As an organisation, we are now well established with a strong Board greatly enhanced by three non-executive directors, Mark Walport (Director of the Wellcome Trust), Alan Langlands (Principal of the University of Dundee) and Andrew Witty (Chief Executive of GlaxoSmithKline plc). The Board is supported by a small but effective staff led by Dr Liam O'Toole, the Head of the OSCHR Office.

A significant development in 2008 has been the agreement of the Scottish Government and Welsh Assembly Government to participate as full partners in OSCHR and to contribute their share of funding to the agenda. The commitment of Scotland and Wales to participate in OSCHR has been made at the highest level. This gives us the potential to work towards a truly UK-wide vision for health research.

As part of the 2007 Comprehensive Spending Review (CSR) process, a coordinated bid for health research was submitted by OSCHR to HM Treasury through the Department of Health (DH) and the Department for Innovation, Universities and Skills (DIUS). In a significant change in policy, the resultant settlement to both departments not only specified the amounts of new funding that should go towards meeting the Cooksey agenda, but also incorporated both budgets into a single health research fund.

The successful CSR bid was based around a new model for leadership and coordination agreed with the Medical Research Council (MRC) and National Institute for Health Research (NIHR). Since then we have seen a significant number of new translational programmes announced by both agencies to support the translational strategy in three research areas – translational medicine, E-health and public health.

The new resource provided by the CSR will allow UK Government health research funding to exceed £1.7 billion per annum by 2010. It has provided ample opportunities to expand our activities in all three areas of translation without damaging the basic science base. The "rising tide" has allowed the research funders to alter their balance of activities without disrupting existing strengths. Changes in organisational structure and focus at the MRC have facilitated this process, as has the continued expansion and restructuring of R&D in the NHS through the NIHR. Together with the Departments of Health in Scotland and Wales, I believe the OSCHR Partners are together making very real progress in developing and implementing a coordinated translational programme that, globally, is unequalled.

The Translational Medicine Board (TMB), under Sir Alex Markham's chairmanship, has provided a crucial forum for the agencies to coordinate their strategies in this area of clinical research. New programmes in drug discovery and early development, diagnostics, methodology, experimental medicine, large clinical trials and health technology assessment have now been initiated. Funding is now available for support across the developmental pathway of new therapeutics, an area of research historically inaccessible to academic investigators due to paucity of funding. The programmes complement the powerful structures already developed by the NIHR to support experimental medicine infrastructure (Biomedical Research Centres and Units) and large-scale trials (UK Clinical Research Network). A network of Clinical Research Facilities has also been funded by a range of stakeholders to support the translational research agenda.

The E-health research agenda has also been defined and substantially progressed through the establishment of a Research Capability Programme within the National Programme for Information Technology (NPfIT) of the Department of Health, in England. This represents a collaboration between the NIHR and NHS Connecting for Health. Scotland and Wales both have existing electronic patient record systems that will also prove powerful for research purposes in this context. Progress in this area has been more rapid than might have been anticipated. There appear to be real prospects that this unique aspect of health research will soon be more widely undertaken in the UK, taking full advantage of one of our major competitive assets for research, the National Health Service.

I welcome the decision of the MRC and NIHR to focus their public health research efforts on four major current problems – obesity, addiction and mental health, ageing, and infections. Public health remains one of the most challenging areas of medical research, but one with enormous potential for translation and benefits to the population of the UK. We hope the new OSCHR Public Health Research Board can provide much-needed monitoring of activity across this crucial area.

All these new activities build on existing strengths in basic and translational science across the UK that have laid the foundations of our understanding of disease mechanisms. Strengthening our ability to move from targets to therapy, to diagnose and better classify disease, and to evaluate treatment responses puts us in a powerful position to reap the benefits of previous research for the benefit of patients and the economy.

Non-programmatic activities ascribed to OSCHR in the Cooksey Report have also progressed well. We are initiating an important staged process of considering the health research opportunities for the UK, starting with the burden of disease data recently published by the Department of Health and moving on to consider the unique opportunities for advancing particular areas of research within the UK. Industry's views will be particularly helpful in prioritising these UK Research Opportunities. In addition, the Prime Minister has now asked OSCHR to work with DH and DIUS, through the MRC, NIHR and the research community, to identify a set of National Ambitions for Translational Health Research which we hope will build on the UK Research Opportunities.

Through the Ministerial Industry Strategy Group, there are ongoing discussions on mechanisms for improving the development pathway for new drugs. We will attempt to facilitate the development of innovative new therapies, to provide early access to significant numbers of patients within the UK and to minimise the limitations of the classical late-stage drug development pathway.

The Cooksey agenda has now been transformed into reality, with the OSCHR Partners working closely together to enhance the activities in all these areas of translational research. I recognise how difficult it can be for different agencies to genuinely commit to the notion that the success of other agencies and the entire programme is as important as their own agenda, and for them to work seamlessly to ensure efforts by all funders are properly recognised and supported. A reasonable expectation and key performance indicator for OSCHR is that the OSCHR Partners, working closely together, should function as effectively as if they were a single entity. Together we need to continue to work to achieve this level of coordination and to monitor progress toward Sir David's ambitious goals.

Despite the considerable successes noted above and elsewhere in this report, there are clearly areas that need more work and attention in the immediate future. They are all well recognised by the OSCHR Partners and will be a major focus over the coming year. They include:

- **Communication.** Explaining our whole programme to the outside world was inevitably going to require time, and considerable effort and focus. Many of our stakeholders remain uncertain about what the OSCHR process has been about since its inception. We will correct this with a powerful and broad communication strategy aimed at describing the scope and importance of the translational agenda to the widest possible audience.

- **Commercial Interactions.** We will focus in the coming year on further extending engagement with the commercial sector in the work of the OSCHR Partners. The MRC and NIHR are already establishing new interactions with industry – in pharmaceuticals, biotech, devices, diagnostics, informatics and services. We will work with all the OSCHR Partners to complement and reinforce their work, and ensure the commercial sector is fully engaged in developing joint programmes. Many such programmes are new and will take time to cement their industrial links. There are already important successes to celebrate: the clinical trial networks are being increasingly accessed by industry; there are new initiatives targeting the diagnostics industry; discussions are

being held with the Technology Strategy Board (TSB) about new collaborative programmes; and we welcome the establishment of the Health Innovation Challenge Fund, a new partnership between the Wellcome Trust and the Department of Health.

- **Public Health.** Research in this area remains a significant challenge. It will take time to resuscitate public health research, which has been under-resourced for many years, with limited capacity and a wide and heterogeneous research community. Cross-departmental working across Government, crucial for success in this area, remains challenging. But without it, Government is unlikely to make real advances in the disease prevention arena. The research capabilities of the scientific community in the Devolved Administrations as well as England will be crucial for this agenda, as will access to electronic records, which will allow health outcomes to be measured more systematically. We still have a long way to go.

- **E-Health Records Research.** The Research Capability Programme and similar initiatives in Scotland and Wales have done much to ensure the capacity will exist to use electronic patient records in a research setting. Failure to agree the governance arrangements that will both preserve patients' confidentiality and also allow health research professionals to access data for the public good, represents a significant risk for this entire programme. Enormous opportunities for improvements in public health and patient safety will be lost if this issue is not resolved. We will continue to advocate a rational governance structure that facilitates legitimate research programmes.

- **Capacity Building.** This ambitious agenda will demand significant growth in the number of those capable of undertaking translational and public health research. From methodologists to clinician scientists, the UK will need to train many more people to compete globally and to succeed with this programme. This area has recently become the focus for much more activity by the OSCHR Partners. The lag-phase between training and delivery of productive scientists is long and the partners recognise the need to address the increasing gap between our ambitions and the capacity of the research community to tackle these challenges. This is a major priority for the coming year.

- **NHS.** The most critical partner for this translational research agenda remains the NHS. Much progress has been made through the NIHR in developing and funding research programmes and infrastructure in the NHS. To realise our objectives, however, this will not be sufficient to ensure that translational research, with all its benefits, thrives in the UK, and delivers all its benefits. Real commitment to research is still lacking in most NHS Trusts and this must be changed if the culture of innovation that the Health Service needs so badly is to develop. I would expect that this will change if the right incentive structure is in place within the NHS. Targets relating to research, such as increasing the number of patients participating in clinical trials, should be included in any future NHS Operating Framework or equivalent. Providing hospital management with such incentives could rapidly convert the NHS into the greatest UK asset in translational research, concordant with all our ambitions.

The next year presents many challenges. The partners in OSCHR have made an excellent start with their work over the last 22 months. Much overlap of remits has been eliminated, there is better coordination between funders, and translational science is beginning to receive a large boost from the new programmes and funding. OSCHR is also now preparing to carefully evaluate the success of the new programmes to ensure that the resources provided by the last CSR produce the intended outputs and benefits.

OSCHR is keen to encourage ongoing dialogue with its stakeholders across all sectors. If you have any comments about this progress report and/or on OSCHR's strategic direction more generally, please contact the OSCHR Office at the address given in Annex 4. We look forward to hearing from you.

The UK and the world at large have been surprised by the stunning success of Great Britain in the 2008 Olympics. Such achievement has required the participation of multiple stakeholders, meticulous coordination of activities, focus on areas where the country could most successfully compete, monitoring progress against tangible milestones and, importantly, significant additional resources. This formula for success is not unique to sport but applies to most areas of human endeavour. With a similar structure and approach we should be capable of outperforming all others globally in health research, with the expected benefits to patients, economic growth and the NHS. Cooksey-specified Government investments have provided the necessary resources.

Together, the OSCHR Partners now need to deliver the environment that will produce the gold medals. I believe that we have made an encouraging start.

Professor Sir John Bell
Chairman of OSCHR

CHAPTER 1

# INTRODUCTION

### 1.1 Purpose of this Document

This document provides a report of progress for the period January 2007 to September 2008 in the establishment and operation of the Office for Strategic Coordination of Health Research (OSCHR).

### 1.2 Status of this Document

This Report is submitted to the Secretary of State for Innovation, Universities and Skills, the Secretary of State for Health, and to Parliament by the Chairman of OSCHR, Professor Sir John Bell. It has been prepared with advice from the three independent members of the OSCHR Board (see Annex 2 for full membership). Board members representing the Department for Innovation, Universities and Skills (DIUS), the Department of Health (DH), the Medical Research Council (MRC), the National Institute for Health Research (England) (NIHR), the Chief Scientist Office (CSO) (part of the Scottish Government Health Directorates) and the Wales Office for Research and Development (WORD) (of the Welsh Assembly Government, WAG) have also provided advice on the report.

### 1.3 Background

On 31 March 2006, the then Chancellor of the Exchequer, Gordon Brown, appointed Sir David Cooksey to lead a review to build agreement on the best institutional arrangements for a new single fund for health research announced in the budget. The report of the review, *A review of UK health research funding*, was published in December 2006.

The review concluded that, although good progress had been made in some areas, further work was needed to ensure that publicly funded health research was carried out in the most effective and efficient way, and to facilitate rapid translation of research findings into health and economic benefits. The report recommended specific actions for the Government to take to achieve this. In his Pre-Budget Report on 6 December 2006, the Chancellor announced that he and the Secretaries of State for Health and for Trade and Industry (now Innovation, Universities and Skills) welcomed the report and would take forward its recommendations.

A key recommendation of the review was the establishment of a new Office for Strategic Coordination of Health Research (OSCHR) that would take an overview of the budgetary division and research strategies of both the MRC and NIHR.

CHAPTER 2

# OSCHR AND THE OSCHR PARTNERS

## 2.1 Establishment of OSCHR

OSCHR was initially set up in January 2007 following the blueprint laid out in Sir David Cooksey's review. Over the past 22 months, the role of OSCHR has evolved in order to maximise its impact on UK health research. This evolution has had the full agreement of the Government Departments and the independent experts on the OSCHR Board.

OSCHR was created in order to develop a more coherent strategic approach to health research in England. This role has now been extended to two of the Devolved Administrations (Scotland and Wales). This change reflects the collaborative, multi-disciplinary, multi-centre nature of much health research, and the need to maximise UK competitiveness in a global health research environment.

As recommended by the Cooksey Review, OSCHR was created as a jointly-staffed and funded office of the Department of Health and the Office of Science and Innovation (OSI) (now DIUS). OSCHR is headed by a non-executive Chair who is appointed by, and reports to, the Secretaries of State for Health and for Innovation, Universities and Skills. Professor Sir John Bell, Regius Professor of Medicine at Oxford University and President of the Academy of Medical Sciences (AMS), was appointed as the first Chair of OSCHR.

The work of OSCHR is overseen by the OSCHR Board, which first met in January 2007. The Board has three non-executive members recruited through the Appointments Commission in accordance with the procedures set by the Office of the Commissioner for Public Appointments and appointed by Ministers. Initially there was representation on the Board from DIUS, DH England, the MRC and the NIHR, with a single representative for the Devolved Administrations. Following discussions with the Scottish Government and the Welsh Assembly Government, Scotland and Wales agreed to become full partners in OSCHR in 2008 and now have full representation on the OSCHR Board. Discussions with Northern Ireland are ongoing. The research funders – the MRC, the NIHR (for England), CSO (for Scotland) and WORD (for Wales) – are now referred to as "the OSCHR Partners".

By September 2008, the Board had met seven times since January 2007. Membership, key functions and meeting dates of the OSCHR Board are listed in Annex 2.

## 2.2 The OSCHR Office

The Office is administered by DH England under an agreement between DH and DIUS, and is funded jointly by DH and DIUS. The Head of the OSCHR Office is Dr Liam O'Toole, and it has four members of staff. Details can be found at Annex 4.

## 2.3 The Roles of the OSCHR Partners

The key messages emerging from the Cooksey Review were that there was the need to:

- ensure a more strategically coherent approach to publicly-funded health research;
- create a step-change improvement in the translation of basic research into health and economic benefits; and
- encourage a stronger partnership with the health industries and charities.

The OSCHR Partners are responding to these challenges by developing a shared Vision for UK Health Research. The Partners are working together to realise this Vision through the development of an integrated plan to deliver the Vision supported by five key areas of

work: translational research, public health research, E-health records research, research methodology and human capital. The Vision for UK Health Research will be published as part of OSCHR's wider communication plans (see also Section 4.2).

All the OSCHR Partners remain the direct funders of research with their own budgets and lines of accountability. Each has, and continues to develop, its own strategy. The major difference since the Cooksey Review is that, under the oversight of the OSCHR Board(s), the OSCHR Partners are now coordinating their strategies to deliver the shared Vision for UK Health Research.

### 2.4 The Roles of the OSCHR Board and OSCHR Office

The role of the OSCHR Board and OSCHR Office is a) to forge agreement between the OSCHR Partners on the UK Health Research Vision and their integrated plan to deliver the Vision, and b) to monitor the coordination and implementation of the OSCHR Partners' delivery of the Vision.

Since the establishment of OSCHR in 2007, the OSCHR Partners have worked to coordinate their strategies in specific areas such as translational medicine, and have then brought these to the OSCHR Board for discussion and agreement.

OSCHR has the additional role of submitting a single funding bid to the Treasury covering the activities of the MRC (UK-wide) and the NIHR in England, and the allocation to the MRC and NIHR of Government funding, rising to over £1.7 billion per annum (p.a.), needed to deliver the Vision for UK Health Research.

### 2.5 The OSCHR Boards

The OSCHR Partners fund research that covers a very broad spectrum of activity. In order to help OSCHR fulfil its facilitation and monitoring roles, three Boards – a Translational Medicine Board (TMB), an E-Health Records Research Board (EHRRB) and a Public Health Research Board (PHRB) – have been established to provide strategic oversight in these areas. It has been agreed that these Boards do not have a direct funding role.

The roles of these Boards echo that of the main OSCHR Board in that they advise and monitor the coordination and implementation of the OSCHR Partners' delivery of the Vision according to their Terms of Reference (see Annex 2 for details). The Chairs of the Boards attend OSCHR Board meetings and report on progress to OSCHR Board members. The three Boards are at different stages of development, and Chapter 3 gives a summary of what has been achieved in each area.

Figure 1 is a schematic diagram depicting the key tasks of the OSCHR Partners and the OSCHR Board.

### 2.6 The UK-wide Dimension

Scotland and Wales agreed to become full Partners in OSCHR in 2008. Since then, WORD, the body that coordinates research and development (R&D) in Wales, and the CSO in Scotland have been working with the MRC and NIHR to coordinate their strategies.

*Welsh Approach*

The Welsh Assembly Government has acknowledged the contributions that researchers in Wales already make to UK activity and wishes to expand that potential; the decision to become an OSCHR Partner is a central element of this approach. A key objective of the Welsh R&D strategy (currently being updated) is the development of a Welsh National Institute for Social Care and Health Research (NISCHR), combining

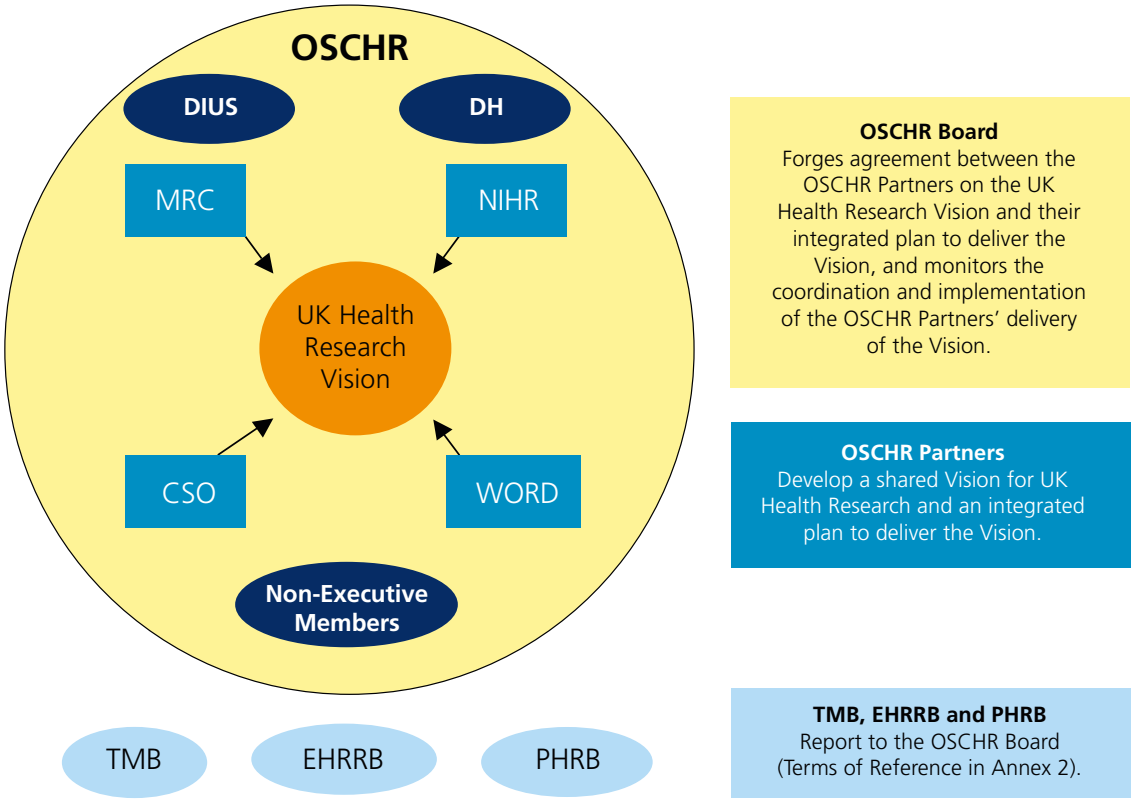


***Figure 1:*** *Schematic diagram depicting the key tasks of the OSCHR Partners and the OSCHR Board. For more details on the OSCHR Board, as well as the TMB, EHRRB and PHRB, such as Terms of Reference and Membership, see Annex 2.*

health-related areas with social care. The commitment to that objective has been reiterated by the provision of an escalating funding stream over the forthcoming years for R&D. This support will allow both development within Wales and wider participation in UK research activities, in association with the other OSCHR Partners.

### *Scottish Approach*

The Scottish Government Health Directorates have made it clear that they support participation as an OSCHR Partner. The health sciences community in Scotland brings a strong collaborative ethos to work with other OSCHR Partners that will drive forward a UK-wide response to the Cooksey Report.

The Chief Scientist Office (CSO), established as long ago as 1973, has frequently been the catalyst in research collaborations aimed at building research capacity, improving health and fuelling the economy. For example, CSO has recently worked with Scottish Enterprise to bring Wyeth Pharmaceuticals together with four University/NHS Health Board partnerships to form the £50 million Translational Medicine Research Collaboration. This aims to speed up the development of new, personalised medicine through a programme of biomarker discovery and experimental medicine. CSO has also invested heavily in the Scotland-wide phenotyping/genotyping project Generation Scotland that will build on local strengths in health informatics to recruit

50,000 volunteers from families in which common disorders are clustered, providing a participatory resource for predictive research that will complement UK Biobank. There is also a strong track record in working with other OSCHR Partners, for example in public health research, where CSO has built on its successful partnership with the MRC in the MRC Social and Public Health Sciences Unit to establish the MRC/CSO Scottish Collaboration for Public Health Research and Policy (SCPHRP) in 2007. A new research strategy for CSO is being developed for publication in 2009; a key feature will be the development of a single point of access to five million inhabitants registered with NHS Scotland. The new strategy also affords a timely opportunity for coordination and collaboration with other OSCHR Partners, particularly in areas being led by the NIHR.

CHAPTER 3

# ACTIVITIES TO DATE

### 3.1 The 2007 Comprehensive Spending Review Bid

In March 2007, in line with Sir David Cooksey's recommendations, DH and DIUS submitted their bids to the Treasury for health research funding. These were integrated together in a single "OSCHR Comprehensive Spending Review (CSR) Submission" that outlined an ambitious programme of coordinated work to enhance translational research and to begin building activity in E-health records and public health research.

This was the first time that a single bid for health research crossing Government Departments had been submitted to the Treasury, and the requests were funded in full. As a result of this bid, the total uplift for health research was £300 million p.a., creating total funds for health research that will rise to more than £1.7 billion p.a. by the end of the current CSR period.

This settlement means that the MRC budget will grow from £543 million p.a. to £707 million p.a. over the next three years, enough to ensure that the MRC's basic medical research does not suffer at the expense of growth in its translational activity. Growth at the NIHR will take its annual spend to £992 million p.a. by 2010/11. The level of planned contributions to OSCHR objectives from the MRC and NIHR was stated explicitly in the CSR settlement. See Figure 2 for more details.

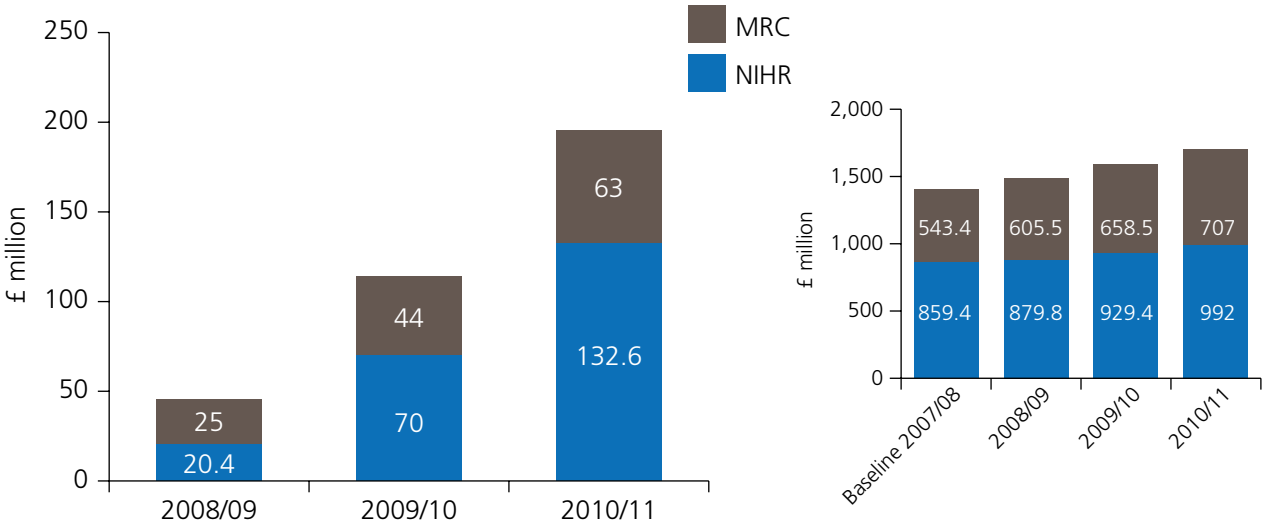


***Figure 2:*** *Increase of funding for the MRC/NIHR from the Cooksey uplift in the CSR 2007 (main graph) and MRC/NIHR budgets after the CSR 2007 (insert) over the current CSR period (£ million).*

## 3.2 Translational Medicine

**Box 1:** A note from the Chairman of the Translational Medicine Board, **Professor Sir Alex Markham**

*It is a privilege to report on progress achieved to date by the Translational Medicine Board (TMB) of OSCHR. Since the publication of Sir David's report in December 2006, I believe we have come a long way in a very short time. I hope that both Sir David and attendees at the July 2006 meeting of the Academy of Medical Sciences and the Royal Society, entitled Lost in Translation, will feel that the challenge they laid down has been taken up enthusiastically.*

*However, we have by no means yet completed all our tasks and the TMB is not complacent in the least. The vitally important issues of training the future workforce in translational medicine (human capital) and of coordinating infrastructure to deliver this activity (provided independently by the NIHR and MRC) are only now receiving our full attention. We are also working carefully to define the metrics by which the impact and ultimate success of this substantial additional investment of public money will be judged.*

*I am, of course, eternally grateful to all my TMB colleagues for their contributions and to the staff in the OSCHR Office who support us so well. Colleagues have made enormous sacrifices of their valuable time in order to achieve the progress in translational medicine made so far. They deserve the gratitude of the whole medical research community. It is important to note that progress since December 2006 has been achieved without any detrimental effects on the UK's basic biomedical research activity. The fact that our translational medicine machinery is starting to function nicely ought to be a source of encouragement for all for the challenges ahead.*

The Translational Medicine Board (TMB) is chaired by Professor Sir Alex Markham and has met eight times. The role of the TMB has evolved, originally working with the MRC and NIHR to develop a fully aligned approach in translational research. The emphasis of the TMB is now increasingly on monitoring the coordination and implementation of the OSCHR Partners' coordinated approach to translational research on behalf of OSCHR.

The Cooksey Review called for "a step-change improvement in the translation of basic research into health and economic benefit". Although the OSCHR Partners had previously provided funding in this area, there was incomplete coverage across the research spectrum, and duplication of activity between funders. Building up translational research was a major focus of the integrated CSR bid and has been a major area of joint planning for the OSCHR Partners (initially the MRC and NIHR). Since the Cooksey Review, and enabled by the CSR settlement, the OSCHR Partners have significantly increased their commitment to fund clinical and translational research.

*Joint Working and Potential for Commercialisation*

During 2007/08 the MRC and NIHR have, under the oversight of the TMB, jointly developed an ambitious new approach to translational medicine research.

By working closely together, a coherent approach to public funding of translational medicine research has been developed that will provide ample opportunities for those choosing to move basic medical research discoveries towards commercialisation and clinical use. It is also intended that these programmes will be developed with significant industrial input from the healthcare industries associated with pharmaceuticals, diagnostics and medical devices, and that the platforms, products and skills associated with this programme will be helpful in attracting research activities in the healthcare industries to the UK.

A key step in this process was forging agreement between the MRC and NIHR for new institutional arrangements for funding translational research. This involved a re-focusing of responsibilities through the concept of "Lead Organisation". This means that in some areas the Lead Organisation will administer funding for both organisations.

For instance, in large-scale clinical trials and evaluative studies, which all organisations have historically supported, the NIHR is now the Lead Organisation. The MRC's funding in this area will therefore, in future, be managed by the NIHR on behalf of the MRC. In the same way, the MRC is now the Lead Organisation for the early development of new opportunities, from discovery R&D to early-stage clinical trials. The MRC also leads on methodology, and the NIHR's investment in methodology research is now managed by the MRC on behalf of the NIHR.

The benefits of this joint approach to planning include:

- a strong focus on areas that are already successful;
- reduced overlaps in the system;
- single administrative leadership and shared resources where necessary;
- a range of funding and management approaches across the translational research landscape;
- procedures for managing and facilitating movement of projects between organisations as they progress along the development pathway;
- input from the healthcare industries to help bring innovative products to market and attract industry R&D to the UK; and
- clarity for the research community about areas of responsibility.

*Major Elements of the New Approach*

Coordinated strategies have been created that are designed to increase translational research activity and capacity. To achieve this, a system has been created which is designed to swiftly identify the latest advances in basic science, develop their potential into promising interventions, and evaluate effectiveness, value for money and broader impact for use in the NHS. For the first time, the "development gaps" where support was not consistently available have been addressed. The major elements in this new combined approach are further described below and form part of

Table 1 (see Annex 1). This is further illustrated in a number of boxes where examples of funded projects or initiatives are given.[1]

It should be noted that the purpose of this Progress Report is to highlight the major changes the OSCHR Partners have put in place since the Cooksey Review. This means that the Report focuses on new strategic elements, and expanded existing programmes in translational research developed and put in place over the last 22 months using new CSR funding. These elements should not be seen in isolation – they are designed to complement and build on other activities that the NIHR is delivering through *Best Research for Best Health* (BRfBH) and that the MRC delivers through its existing funding programmes.

### *The Developmental Pathway Funding Scheme*

The MRC Developmental Pathway Funding Scheme (DPFS) is designed to directly support work which has a clear goal of delivering fundamental research towards the clinic. Investment is aimed at projects that target significant and unmet health needs by improving prevention, diagnosis, prognosis, or treatment of patients, or by developing the relevant research tools.

The scheme is designed to support proposals, including those aimed at:

- target validation;
- developing candidate therapies – from discovery up to early evaluation in humans;
- developing candidate diagnostic or medical devices – from prototype design to early evaluation in humans; and
- developing new research tools that might overcome significant bottlenecks in the development of therapies or diagnostics.

The projects will be tightly managed with progression milestones. This continuous monitoring will allow support for innovative, high-potential but risky projects, with rapid redeployment of funds to other lines of work when necessary. Funds will ensure that projects shift to (or from) commercial funding of development, or co-funding, where appropriate.

The scheme was launched in April 2008. More than 70 outline proposals were received for the first submission deadline, with 24 full applications subsequently being invited after consideration. The applications covered a wide range of potential interventions, including pharmaceuticals (New Chemical Entities (NCEs) and new indications), biological/immune interventions, surgical and psychological interventions, and devices. Similarly, there was a wide spectrum of clinical conditions being addressed, with – for example – diseases such as diabetes, Alzheimer's and glaucoma, as well as scarring, fracture and wound repair.

In addition, universities were invited to apply for limited prospective DPFS resources to pump-prime their activities under this scheme. Decisions were taken in early August 2008 to support 13 universities, at a total cost of almost £3 million.

[1] The boxes are colour coded – warm grey for the MRC and blue for the NIHR and in places a combination of the two – to indicate the Lead Organisation and/or where the initiatives are jointly funded or managed.

*Experimental Medicine*

There will also be an expansion of the MRC's support for early-stage clinical trials (phase I/II) and "first into man" studies. Funding rounds were previously biennial; from 2008, projects will be assessed throughout the year, and projects with high scientific or clinical potential but significant project risks will be developed iteratively with the research community (see Box 2 for an example).

**Box 2: Exploratory Clinical Studies**

Researchers at University College London are investigating a novel way of helping patients with cancers of the blood and bone marrow to stay healthy after bone marrow transplants. Cytomegalovirus (CMV) reactivation in immuno-suppressed patients can lead to progressive infection and even death. The study proposes to take the T cells of CMV negative donors and genetically modify them so that they are able to recognise and kill CMV-infected cells. The proposed Phase I/II proof of concept pilot study will test the feasibility of generating donor-derived CMV-specific T cells, and also determine safety, toxicity and efficacy. The CMV T cell receptor gene-modified T cells will be infused into patients when they reactivate CMV, as part of this Phase I/II clinical trial.

*Engaging Universities and Creating the Translational Research Infrastructure*

Delivering the Vision calls for organisational and cultural change in universities, research institutions and NHS organisations, as well as change within the Partner organisations. To facilitate this, the MRC undertook a series of visits to major recipients of funding by senior research management staff. The purpose of these visits was to explain the translational research strategy and discuss the university's own vision, existing capacity, and capability for translational research. As a follow-up to this, the MRC launched a £15 million initiative to pump-prime translational research in the university sector and to provide resources to help each university's vision. Decisions were taken in July 2008 to support a variety of pump-priming activities in 14 universities across the UK. These included strategic appointments for senior researchers from overseas (or from industry) who would strengthen the university's translational strategy, expansion of capital necessary for translational programmes, and the appointment of scientists or support staff who would underpin growth in translational research.

The NIHR has provided extensive NHS infrastructure support for translational and clinical research through its Biomedical Research Centres, Units, Clinical Research Facilities and the NIHR Research Networks. This infrastructure has been supplemented with the new CSR resources and will provide a powerful asset to underpin MRC and NIHR programmes in translational research (see Box 3 for an example).

**Box 3: NIHR Biomedical Research Unit in Nutrition, Diet and Lifestyle at Southampton**

The NIHR Biomedical Research Unit in Nutrition, Diet and Lifestyle at Southampton (one of 15 Biomedical Research Units) is exploring barriers to healthy eating in women with lower levels of educational attainment, who are known to eat a poor quality diet. The Unit will trial a toolkit, focusing on behaviour change to alter food choices, to improve the balance and variety of young women's diets (both before and during pregnancy), with anticipated benefits for the health of the women and their families.

Meanwhile, the MRC will coordinate its support for infrastructure and training in universities and institutes/units with the NIHR's existing support in the NHS (especially Biomedical Research Centres and Units) – focusing on early-stage discovery and development – and with the Devolved Administrations in Scotland, Wales and Northern Ireland.

*Joint Efficacy and Mechanisms Evaluation Programme*

Launched in April 2008, the Efficacy and Mechanisms Evaluation (EME) programme was created as part of the joint arrangements for later-stage clinical trials. Funded by the MRC, and administered by the NIHR, the aim of the EME is to support later-phase "science driven" clinical trials and evaluative studies which:

- evaluate clinical efficacy of interventions (where proof of concept in humans has already been achieved);
- add significantly to our understanding of biological or behavioural mechanisms and processes;
- explore new scientific or clinical principles; and
- include the development or testing of new methodologies.

The EME programme's first call for proposals closed on 1 March 2008, prior to the programme's official launch on 1 April 2008 (see Box 4 for an example). The following activities took place during the period from April to September 2008:

- The EME Board has been established and held an inaugural meeting in June 2008. The Board membership comprises 21 senior, experienced clinicians and methodologists who are all active researchers in their fields. Professor Rajesh Thakker (University of Oxford) was appointed Chair. A new team has been established within the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC) to provide the secretariat management function for the programme (NETSCC, EME).
- The first submission deadline for applications was 31 March 2008. A total of 61 applications were received (total potential R&D costs requested £78.6 million), 51 of which were within remit. After consideration by referees and by the Board, 19 applicants have been invited to submit a full proposal for consideration at the March 2009 meeting (total potential R&D costs £16.7 million).
- Research applications are considered by the most suitable funding body, and transferred quickly to other funding committees where appropriate.

**Box 4: Efficacy and Mechanisms Evaluation (EME) Programme**

The EME programme has already considered many proposals which seek to translate basic or early clinical research into improvements in health or patient care. The following studies are examples that will soon be considered for funding:

- A study seeking to examine the use of metformin in obese insulin-resistant pubertal adolescents. Although already used in this situation, there is little evidence for its safety or efficacy.
- A trial examining whether drug pregabalin given pre-operatively can prevent long-term pain following thoracotomy, as well as investigating its possible mechanisms of action.
- A study investigating the diagnostic efficacy of a specific biomarker (CRP-VLDL) which seeks to improve the prediction and treatment of sepsis in children in intensive care units.

*Expanded NIHR Health Technology Assessment (HTA) Programme*

Additional CSR funding is also being used to expand the successful NIHR Health Technology Assessment (HTA) Programme in order to:

- increase funding for randomised controlled trials through expansion of the HTA Clinical Trials Programme;
- support additional HTA-commissioned research – primary studies and themed calls;
- increase the systematic evaluation of diagnostic tests through expansion of the HTA-commissioned programme;
- increase the assessment of medical devices through expansion of the HTA-commissioned programme; and
- increase commissioned research to follow up on National Institute for Health and Clinical Excellence (NICE) research recommendations through the expansion of the HTA programme to support NICE.

The NIHR HTA programme commissions research for the NHS where there is an important gap in current knowledge about healthcare interventions. The research commissioned uses a variety of methods, as appropriate, to determine the effectiveness, costs and broader health impact of health technologies. It has commissioned 770 research studies to date and has invested more than £160 million in NHS research. Closer working of the NIHR and MRC through coordinated strategies is aimed at speeding up the translation of advances in basic science into applied research with benefits to patients. The HTA programme will be a key part of this and is working closely alongside the new EME programme. The overall HTA programme budget is to rise to more than £80 million by 2010/11 (see Box 5 for an example).

Taken together, the EME and the expanded HTA Programme provide major new opportunities for large-scale healthcare evaluations in the UK.

**Box 5: Large-scale Evaluation and Trials Including HTA**

The HTA Programme has extended its role in funding major trials which address questions of major importance to patients. Recent examples include:

- CRASH-2 – a UK-coordinated international clinical trial testing tranexamic acid as a means to reduce blood loss in patients who have suffered a major trauma, the second biggest cause of death in young people worldwide. The trial involves more than 140 hospitals in 42 countries. Over 7,000 patients have been recruited already and the research team aims to recruit 20,000 patients to the trial by 2010.
- PERSEPHONE – this trial investigates the optimum duration of treatment with trastuzumab (Herceptin) for HER-2-positive early breast cancer. Current treatment is for 12 months but there is evidence supporting a shorter duration, with fewer adverse effects and costs. A parallel study is underway in France and it will be possible to analyse the results of both together, speeding the delivery of results.
- ACST-2 – this international trial compares two different interventions to reduce the risk of stroke: the standard operation, carotid endarterectomy, and the newer technique of carotid artery stenting. Immediate and long-term (up to 10-year) outcomes will be measured in more than 5,000 patients worldwide.

*Methodology*

The MRC and NIHR share a vision that the UK should lead the world in the development of pioneering research methodologies. A programme of research, developed jointly and led by the MRC, with co-funding from the NIHR, now supports this aim. It is hoped that research in universities and the NHS will benefit from new and improved ways of designing and conducting clinical research, and translation into patient benefit will be supported by better tools to inform regulatory and adoption decisions and to support industry R&D needs.

The new Methodology work stream now supports:

- a jointly funded Methodology Research Programme which provides:
  - response-mode funding for research methodology, from pre-clinical research through to public health and health services research; and
  - commissioned (or targeted) calls to address the needs of regulators, health departments, industry, and specific research programmes – especially EME and HTA (see Box 6 for an example);
- strategic initiatives around identified areas of need; for example, NICE methodological research needs and patient-reported outcomes;
- support for methodology research in "Hubs" geographically spread across the UK, to link innovation in new methods and trials conduct intimately with the expanded clinical trials programmes (see Box 7 for details);

- additional support to underpin Clinical Trials Unit capacity (see Box 8 for details); and

- new MRC Methodology Research Fellowships for specialist training in methods development research, and NIHR training and capacity development schemes, which both underpin the methodology strategy.

**Box 6: Methodology Research Programme**

This is a new funding scheme. Only a few awards have been made to date. An example award is a mapping project, commissioned by the Methodology Research Programme, which is focused on NICE's requirements for methodological research.

The project, awarded to Professor M Sculpher, aims to map and analyse the mechanisms by which methodological research priorities are identified within NICE. By examining the processes that contribute to the identification and evolution of research priorities within NICE, the project should identify areas and make recommendations about how these processes might be improved. The project will also identify a set of research priorities that would meet NICE and its stakeholders' needs to improve the methodologies underpinning evidence syntheses, and systematic appraisals of health interventions and technologies.

**Box 7: Methodology Hubs**

The MRC has awarded £16 million to establish a new national network of hubs to develop new and improved methods to design, conduct and analyse clinical trials. The hubs will be linked, and will bolster the national methodological platform underpinning clinical trials research by providing expertise in a wide variety of research issues across a broad range of therapeutic areas. Each hub is made up of a core team undertaking high-quality research in trials methodology. As well as undertaking research, each hub also has a role in providing support and advice to the clinical trials research community on methodological issues. Examples of the expertise offered by hubs in the national network include:

- **London** (led by Professor Max Parmar, MRC Clinical Trials Unit). Methods expertise – statistical methodology, trial conduct and meta-analysis. Clinical expertise – cancer, HIV and musculo-skeletal disease.

- **North-West** (led by Professor Paula Williamson, University of Liverpool). Methods expertise – design and analysis of early-phase trials, design and analysis of late-phase trials and patients' perspectives in trials. Clinical expertise – drug safety, medicines for children, epilepsy and cancer.

- **Scotland** (led by Professor Gordon Murray, University of Edinburgh). Methods expertise – systematic appraisals and synthesis of individual patient data, simulation. Clinical expertise – clinical neuroscience and mental health, cancer and cardiology.

**Box 8: Additional Support to Underpin Clinical Trials Unit Capacity**

To provide stability and ensure sufficient research capacity to support a major expansion in clinical trials, the NIHR has provided additional underpinning funding to the following UK Clinical Research Collaboration (UKCRC) registered clinical trials units:

- University of Birmingham Clinical Trials Unit;
- Primary Care Clinical Sciences, University of Birmingham;
- Bristol Heart Institute, Clinical Trials and Evaluation Unit;
- Community Based Medicine, Bristol Randomised Trials Collaboration;
- Leeds Clinical Trials Research Unit;
- Clinical Trials Research Centre, University of Liverpool;
- Centre for Health Sciences, Barts and The London;
- Primary Care and Population Health, UCL Medical School, London;
- Newcastle Clinical Trials Unit;
- Clinical Research and Trials Unit, Norfolk and Norwich University Hospital;
- Clinical Trials Unit, University of Nottingham;
- National Perinatal and Epidemiology Unit, University of Oxford;
- Clinical Neurology Research Group, Peninsula Medical School;
- Sheffield Clinical Trials Research Unit; University of Sheffield;
- University of Southampton Clinical Trials Unit;
- Warwick Clinical Trials Unit, Warwick Medical School; and
- York Trials Unit, Department of Health Sciences, University of York.

*Joint Patient Research Cohort Initiative*

More than £7 million of funding has been awarded to researchers in a programme coordinated by the MRC with participation from all the UK Health Departments. This programme will create small, extensively defined groups of patients to help detect, treat or prevent disease. The cohorts in this pilot study are in areas of high unmet need or where there are bottlenecks in turning research into therapies. It will set up the infrastructure to look closely at groups of patients with a particular disease whose symptoms are closely matched. This approach is aimed at providing new insights into disease processes and fostering early exploratory trials – involving the pharmaceutical and biotechnology industry – of new and promising treatments (see Box 9 for examples of projects funded).

**Box 9: Joint Patient Research Cohort Initiative**

Examples of projects funded:

- Wessex Severe Asthma Cohort;
- Pathobiology of Early Arthritis Cohort (PEAC);
- MRC Centre for Translational Research in Neuromuscular Disease Mitochondrial Disease Patient Cohort (UK);
- Refractory Juvenile Myoclonic Epilepsy Cohort (ReJuMEC);
- Paediatric-Onset Inflammatory Bowel Disease Cohort and Treatment Study (PICTS);
- Bipolar-II Disorder;
- Characterisation of the United Kingdom Thrombotic Thrombocytopenic Purpura (TTP) Patient Cohort;
- Type 2 diabetes in childhood: building a platform to support novel intervention strategies;
- United Kingdom Primary Sjögren's Syndrome Registry (UKPSSR);
- Rapidly evolving multiple sclerosis: opening the window of therapeutic opportunity; and
- National studies of kidney disease in childhood and adolescence.

*Strategic Initiatives Targeted at Bottlenecks in Translational Research*

- In order to support and underpin the UK effort in experimental medicine, the MRC is pursuing a series of strategic initiatives, targeted at the identified "bottlenecks", including models of human disease and biomarkers. A call on *Models of Human Disease* was issued in February 2008, focusing on the evaluation and validation of human and animal models of disease, *in vivo*, *in vitro* and *in silico*. £10.6 million was committed in June, to support 20 awards. The projects are based in universities from across the UK and look at a wide range of diseases – including diabetes, stroke, heart disease and age-related macular degeneration (see Box 10 for an example).

- In March 2008, a call for proposals in *Biomarkers* was announced by the MRC, with a planned £10 million budget. The purpose of the call was to support the further development of potential biomarkers and/or to evaluate potential biomarkers for their predictive and prognostic capability for the diagnosis of disease, disease heterogeneity and underlying mechanisms, susceptibility, exposure or response to interventions. Funding decisions will be taken in early October 2008.

**Box 10: Validation of Models of Human Disease**

At the Institute of Ophthalmology a new study focusing on progressive age-related macular degeneration (AMD) has been funded.

AMD is a chronic, progressive disease of the central retina, called the macula, which results in the loss of central vision. Progress is hampered by the lack of qualified, validated animal models that enable credible comparative studies to pinpoint a therapeutic window for the application of complement antagonists in clinical trials. In collaboration with a small ophthalmic biotech company, the investigators propose to evaluate and qualify the suitability of two mouse genetic models which together appear to demonstrate most of the pathologies associated with the progression of AMD, and to determine the comparative efficacy of novel treatments (VEGF and complement antagonism) on disease progression.

### 3.3 E-Health Records Research

**Box 11:** A note from the Chairman of the E-Health Records Research Board, **Professor Ian Diamond**

*I am delighted to have chaired the Board this year. We have made great progress in providing external input into the Research Capability Programme of Connecting for Health and in starting to identify the important areas in E-patient record research in which early research funding can enhance the UK effort in this expanding and exciting area of research. I must extend my huge thanks to the Board members, a splendid mix of all relevant areas of academia, industry and others, who have worked incredibly hard, often to short deadlines, to support the challenging timetables of the Board's work.*

The OSCHR Board has identified E-health records research, and particularly the research potential of large electronic patient record databases, as a major opportunity for UK biomedical science, patient safety and public health. These opportunities were clearly identified in the Cooksey Report and were highlighted as an area where OSCHR should promote development.

The NHS's array of patient information held electronically, under provisions that maintain patient confidentiality, provides invaluable opportunities to reveal untapped knowledge for the benefit of patients. Linked electronic patient data, as used by the NHS, can be harnessed to monitor patterns of disease, help discover more about the effectiveness and safety of medicines and other interventions, and help researchers to identify possible recruits to clinical trials. This can become a unique selling point for the UK. With proper safeguards to ensure patient confidentiality, and rigorous information governance, the strong science base and world-leading epidemiologists, from the public and charity sectors as well as industry, can make best use of the NHS's unrivalled databases to develop safer and better medicines and so contribute to improved patient management, patient safety and public health (see Box 12 for an example).

**Box 12: Research Capability Programme of Connecting for Health**

Although the Research Capability Programme itself is just entering its full "implementation phase", there are already several examples of what it will achieve from pilot studies by partners undertaking confidential linkage of electronic patient records. For example, researchers at the University of Leeds have used this approach to study the variation across England in the use of specific surgical procedures for rectal cancer and determine if any variation could be explained by differences in patient characteristics such as stage of disease, age, gender or socioeconomic deprivation.[1] They concluded that reducing the observed variation in the use of abdominoperineal excision would remove inequalities, reduce colostomy rates, and improve outcomes in rectal cancer.

[1] http://gut.bmj.com/cgi/content/abstract/gut.2007.137877v1

NHS Connecting for Health (CfH) has now established the Research Capability Programme (RCP), funded through the NIHR. This programme is a long-term initiative designed to make research capability an integral part of the NHS National Programme for IT in England. It will achieve this by:

- enabling research to achieve its full potential as a "core" activity for healthcare; and

- facilitating uses of NHS data to lead to improvements in the quality and safety of care of patients and the public.

The Research Capability Programme was established in September 2007 and Professor Sir Alex Markham was appointed as Chair of the Programme in January 2008. The enabling phase for the Programme is complete. The first Gateway 0 Review has concluded that the Programme is on target and that it should progress through the next stages. The Strategic Outline Case (SOC) has been approved. The SOC sets out a major programme of investment over the next three years, drawing on funds earmarked in the Spending Review. Work on the Outline Business Case and procurement strategy has begun.

The OSCHR E-health records research Board (EHRRB) functions as the External Reference Group (ERG) for the Research Capability Programme in England and in addition provides strategic oversight of E-health records research in the UK. The Board is chaired by Professor Ian Diamond. It has met frequently (nine times) since December 2007 and input to the Research Capability Programme has been intensive and highly influential. An E-health records research mapping project, coordinated by the OSCHR Office, has been initiated to inform strategic discussions on gaps and opportunities for leveraging the UK's advantage in this field. The EHRRB has membership from across the UK – full membership is given in Annex 2.

A Funders' Group, with membership from Cancer Research UK, EPSRC, ESRC, the MRC, the NIHR and the Wellcome Trust, has been established to facilitate coordination of funders' strategies in the area of E-health records research in order to maximise preparedness of the research community for exploitation of the RCP's Health Records Research Service when it is launched. The Group, which has met three times to date, will report to the EHRRB in November with a draft paper outlining the strategic implications of the Research Capability Programme for E-health records research in the UK. It has begun to identify the major issues that will need to be addressed if the research community is to make the most out of the Research Capability Programme in England and related activities in Scotland and Wales. Issues that will be considered include the possible need for additional infrastructure, stakeholder communication, training, and funding of novel E-health records research.

To stimulate research in this area, a call for funding was launched in September 2007 by the Wellcome Trust in partnership with the ESRC, the EPSRC and the MRC for health research using electronic patient records.

### 3.4 Public Health Research

Terms of reference and membership for the OSCHR Partners' Public Health Research Board have recently been agreed. It is chaired by Professor Ray Fitzpatrick and is due to hold its first meeting in late 2008.

The OSCHR Partners' shared ambition is to prevent ill health, provide effective interventions against disease, and promote good health by exploiting public health research to the full. The potential for health gain through public health research is enormous. In order to make swift and tangible progress in this complex area, the

MRC and NIHR have recognised the need for focus and have agreed that each should take a strategic lead on two major areas of public health need. The MRC is leading on Ageing and on Addiction and Mental Health. The NIHR is leading on Obesity and on Infection. Strategic planning in other areas may be led by other OSCHR Partners.

A key part of this strategic leadership role will be to draw together the wider group of partners and stakeholders that will be necessary to make concerted progress in the area. Key outputs will be to strengthen research coordination, develop a critical mass of researchers in the area, engage with appropriate stakeholders in the public and private sectors, and translate research into policy and practice. This will involve collaborative funding between the MRC and NIHR, and other partners including other Government Departments and Research Councils.

*Obesity*

Recognising the need for other Government Departments to contribute to research into this health problem, the Department of Health, in support of the NIHR as the strategic lead for Obesity, has convened high-level, cross-Government meetings of Chief Scientific Advisers to Government Departments and Research Councils UK (RCUK) on 17 January 2008 to discuss how to take forward a research agenda on Obesity using the Foresight report *Tackling Obesities: Future Choices* (October 2007) as a starting point. The discussion included the need to:

- work collaboratively on key policy interventions;
- share data; and
- develop measures and indicators to use across Government.

A strategy for action in this area is being prepared for autumn 2008. The delivery of this strategy will require the engagement and involvement of other funders and other OSCHR Partners – early thinking was shared with the MRC for the recent strategic review of nutrition.

*Addiction*

The MRC is developing a two-phase strategy to strengthen addiction research and networking, and address issues identified in recent Foresight and AMS reports in this area (*Drugs Futures 2025*, Foresight, 2005; *Brain Sciences Addiction and Drugs,* AMS, May 2008). The initiative covers illicit drug use, addiction to nicotine, abuse of alcohol and problem gambling. Strategy development is being undertaken in consultation with a range of key stakeholders including the ESRC and the Home Office, who are leading the implementation of the cross-Government drug strategy.

A total of £6 million has been allocated towards this initiative, which aims to:

- make better use of existing expertise and infrastructure;
- build research capacity in the UK;
- increase coordination and connectivity; and
- carry out innovative, cross-disciplinary studies that will lead to improved public health.

An initial call for proposals has been issued under phase 1 of the initiative to fund pilot projects that will exploit existing research activity/infrastructure to support innovative addiction research. Funding decisions will be taken in February 2009.

Phase 2 of the initiative will develop a limited number of thematic research clusters, which will act as foci for future interdisciplinary research in Addiction. The process of facilitating cluster development and identifying the research priorities to be addressed will be discussed at a stakeholder workshop in November 2008. A second call for proposals, for research to be performed within the new research clusters, will be launched in 2009. This call will provide funding of at least £4 million.

### *Ageing and Lifelong Health and Wellbeing*

The MRC leads on Ageing research on behalf of the OSCHR Partners and also leads on the cross-Research Council initiative Lifelong Health and Wellbeing (LLHW) (MRC, BBSRC, ESRC and EPSRC). In phase 1 of the initiative, a total of £10 million was awarded in April 2008 to three new centres investigating the ageing brain, frailty and quality of life.

Plans for the development of phase 2 of LLHW are underway and will involve a multi-funder partnership between the Research Councils, Health Departments, the NIHR and charities. The focus of phase 2 will be multi-disciplinary working and will include schemes to promote multi-disciplinary team building. Knowledge transfer and engagement with user communities such as industry, policy makers and the public will be a key priority for the initiative. The call will be launched later in 2008.

The AMS is carrying out a review of needs and opportunities in biomedical-related ageing research on behalf of the MRC. The report is due to be published in late 2008.

### *Infection*

The NIHR expects to launch a time-limited group this winter (2008/09) to advise on the research landscape in this field.

### *New NIHR Public Health Research Programme (PHR)*

On 23 May 2008, the Department of Health announced the launch of a new Public Health Research (PHR) Programme. The PHR Programme is being established by the NIHR and will evaluate a wide range of public health interventions. The funding will rise over each of the next three years to reach £10 million p.a. It will have two modes of operation. Most funding is likely to be in response to applicants' proposals, but there will also be commissioning capacity to advertise prioritised topics, themed calls and linked research projects (see Box 13 for an example).

**Box 13: NIHR Public Health Research Programme**

The new Public Health Research Programme will release its first call for proposals in October 2008. Examples of studies that it could fund (with a particular focus on interventions not directly involving the NHS) are:

- Trials of interventions to prevent obesity in primary school aged children. Preventing obesity in children is a national priority but we know very little about what really makes a difference. These studies should make a major difference in improving both practice and the underlying knowledge base.
- A review of what is known about health-related lifestyle advisers and the impact they can have on health and health inequalities.

### 3.5 Human Capital

The OSCHR Partners will work in partnership with the other organisations involved in training and employment of health researchers to deliver the highest quality research workforce.

This ambitious agenda will demand significant growth in the number of those capable of undertaking translational, clinical and public health research. It will cover the full spectrum of recruitment, training, retention and personal development. This is a major priority for the coming year.

In delivering this agenda, the MRC will remain focused mainly on the basic research workforce, and the NIHR, CSO and WORD will remain focused mainly on the applied research workforce in their respective countries, with coordination to ensure effective delivery and clarity for stakeholders (see Box 14 for an example).

**Box 14: NIHR Doctoral Research Fellowships for Academic Clinical Fellows**

The University of Birmingham is using an NIHR Doctoral Research Fellowship to successfully support a trainee doctor in the early stages of his specialty training in diabetes/endocrinology to research the epidemiology of diabetes in South Asians and compare its complications with Caucasian populations. This will inform the provision of high quality, culturally sensitive care in this patient group. The Fellowship will allow the completion of a higher research degree and will fast-track the trainee through a customised research training programme in an environment reflecting his individual talents and training needs. It is anticipated that the trainee will become an independent research leader within six years of completing his Fellowship.

Figure 3 illustrates how OSCHR's work has progressed in the five key areas of work – translational research, public health research, E-health records research, research methodology and human capital – since January 2007.

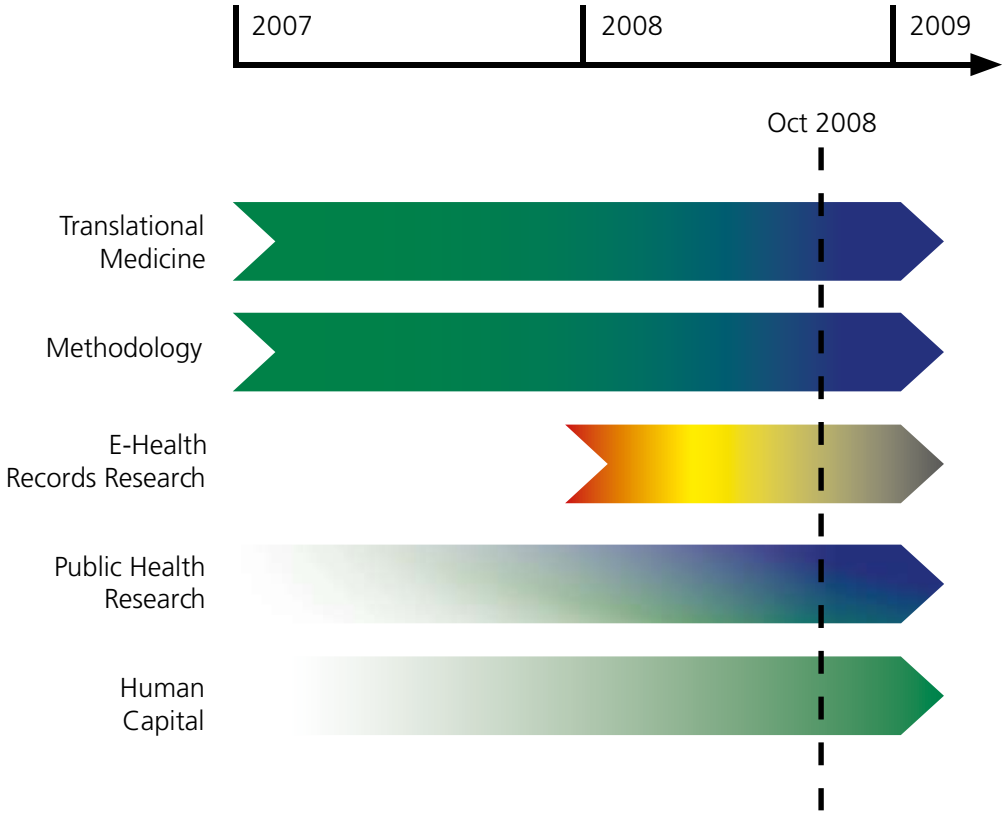


***Figure 3:*** *Time lines describing the work of the OSCHR Partners and OSCHR Boards, identifying the following phases:*

- ***Green:*** *Development of coordinated strategies by the OSCHR Partners*
- ***Blue:*** *Implementation by the OSCHR Partners and monitoring by the OSCHR Board(s)*
- ***Red:*** *Mapping of the E-health records research landscape by the EHRRB*
- ***Yellow:*** *Development of coordinated strategies by E-health records research funders*
- ***Grey:*** *Implementation by E-health records research funders and monitoring by the EHRRB*

*For public health research, in order to make swift and tangible progress, the MRC and NIHR have agreed that each should take a strategic lead on two major areas of public health need with the MRC leading on Ageing and on Addiction and Mental Health, and the NIHR leading on Obesity and on Infection. The PHRB will have its first meeting in December 2008. The figure is an approximation to show progress. For more details on the Boards' Terms of Reference, see Annex 2.*

### 3.6 Monitoring Against the UK Health Research Vision

Since OSCHR came into existence, work has concentrated on reaching agreement on a set of coordinated strategies that will deliver the UK Health Research Vision. In the case of the TMB, this work has been largely completed and the Board is moving into a monitoring function. The other two Boards are at a different stage of development but it is envisaged that this transition will also occur over the next year to 18 months.

To facilitate monitoring of the coordination and implementation of the OSCHR Partners' coordinated approaches to health research on behalf of OSCHR, the MRC and NIHR have agreed to develop an aligned MRC–NIHR Reporting Framework. In developing this Framework, the MRC and NIHR are working together to develop aligned metrics for reporting on delivery. This will include a "Themed Report" to cover translational medicine research in the first instance.

### 3.7 Monitoring the Broader Recommendations of the Cooksey Review

The Cooksey Review contained many recommendations, some of them central to the delivery of the health research vision and the role of OSCHR, and some peripheral. The OSCHR Board has monitored, and continues to monitor, activity in response to these recommendations focusing on those issues that are likely to have a high impact on the single health research fund.

*A New Drug Development Pathway*

The Cooksey Report discussed the possibility of establishing a new drug development pathway in the UK that would facilitate the development of novel innovative therapies.

The Ministerial Industry Strategy Group (MISG) provides the coordination mechanism proposed by Cooksey to take forward his vision of a new pathway. Responsibility for this programme falls within the remit of the MISG, although OSCHR is closely involved as it is taking forward issues that relate to translational research. It was suggested that improvements to the pathway would reduce the time taken for new medicines to reach patients. To help achieve this, Cooksey proposed the development of a process for "conditional licensing". However, as all of the regulations governing the development and assessment of new medicines derive from European legislation, any fundamental change to the current development pathway will need – at least – EU agreement. This is therefore a long-term objective, but the UK is well placed to lead the debate. An MISG-sponsored Forum debate on earlier access to medicines was held in September 2007. This recommended that the UK should explore further how new medicines might be made available sooner to patients in the UK.

As agreed by the MISG, an initiative is now underway to consider all the issues associated with this proposal and is expected to make significant progress within the year. More immediately, NICE has developed a process for early dialogue with pharmaceutical companies. NICE will be able to provide companies with early scientific advice on what information it may need for its technology appraisals so that this can be included in Phase III trials. Meanwhile, OSCHR has begun a dialogue with the medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), and the pharmaceutical industry aimed at exploring other approaches to late-stage drug development.

CHAPTER 4

# NEXT STEPS

### 4.1 UK Health Research Opportunities and National Ambitions for Translational Health Research

The OSCHR Board has agreed an approach to identifying UK Health Research Opportunities. This will be done using a modular approach, with different OSCHR Partners responsible for different elements of the process.

The Department of Health has fulfilled the Cooksey Report recommendation to undertake a review to understand the impact of diseases and illnesses on the UK population and economy. The review took place in 2007 and was published on the DH website in June 2008 (*The Burden of Disease and Illness in the UK,* June 2008).

The MRC has agreed to follow this up by bringing together a group of key academics and users of research to discuss scientific opportunities – both across disease areas and across a number of cross-cutting themes such as regenerative medicine, surgery or diagnostics. Consideration of scientific opportunities will be informed by the health need and by the state of the UK science base in each area, and will be based on systematic and consistent criteria. The MRC will then synthesise this information and make it available for spring 2009.

The OSCHR Office will then undertake further consultation with other stakeholder groups before using the information collected to identify a series of UK Health Research Opportunities. The outcome is the potential identification of areas of scientific opportunity in which the UK is strongly placed to make a major impact internationally.

On 4 November 2008, the Prime Minister wrote to the Departments of Health and Innovation, Universities and Skills and asked for the development of a new overarching set of national objectives to encourage the translation of major research breakthroughs into new NHS treatments and services within a decade. These will be articulated as a set of "National Ambitions for Translational Health Research".

The "National Ambitions" will be developed independently of Government by the research funding bodies, working collaboratively with the medical and wider research communities (including the Wellcome Trust and Cancer Research UK) and with industry, under the auspices of OSCHR. The approach taken will combine an assessment of clinical need with opportunity assessment based on the state of science internationally and in the UK. This will be informed in part by the work on UK Health Research Opportunities.

### 4.2 A Comprehensive Communication Strategy

The emphasis in the first 22 months has been on forging agreement and implementing new strategies. The OSCHR Board has now agreed that there was an urgent need to communicate how all the new initiatives fit together to deliver the shared Vision and to emphasise the substantial progress that has been made since the establishment of OSCHR. During September and October 2008 the OSCHR Office has been working with the OSCHR Partners to develop a coordinated communication strategy to explain, and publicise, the UK Health Research Vision and integrated delivery plan.

### 4.3 Focus on Stakeholder Engagement and Partnership Working

Good progress is being made to deliver Cooksey's recommendations for a more strategically coherent approach to publicly funded health research and to create a step-change improvement in the translation of basic research into health and economic benefit. Focus in the coming months will be for the OSCHR Board and Partners to discuss ongoing and planned activities aimed at achieving Cooksey's third aim of building stronger partnerships with health industries and charities.

# ANNEXES

# Annex 1: Summary Table

**Table 1** provides a summary of the new initiatives described in Chapter 3, including the aims and intended impact of each initiative. The table also includes financial information on the planned commitment at the end of the current CSR period of funds provided to the MRC and NIHR through the Cooksey uplift (£63 million and £132.6 million respectively) (see also Section 3.1 and Figure 2, p22). Many of these initiatives build on existing programmes and initiatives where significant funding is already provided from core (baseline) NIHR/MRC budgets as specified in BRfBH and MRC's existing funding programmes (see footnotes, p51). The table is colour coded – warm grey for the MRC and blue for the NIHR and in places a combination of the two – to indicate the Lead Organisation and/or where the initiatives are jointly funded or managed.

Table 1 does not include commitments made by the Scottish Government and Welsh Assembly Government to increase health research funding.

***Table 1:*** *A summary of the new initiatives described in Chapter 3 together with information on the planned commitment of funds from the Cooksey uplift at the end of the current CSR period.*

| Key initiative | Aims | Intended impact | Planned commitment at the end of 2010/11 |
|---|---|---|---|
| **Translational Medicine Research** ***Supporting Developmental Research*** | | | |
| **Developmental Pathway Funding Scheme** | To support the development of novel therapies, interventions and diagnostics, and the research tools used to achieve this development. | Scientific advances are progressed more quickly from discovery to early evaluation. | £10.1 million |
| **Early Clinical Studies** | To strengthen support for exploratory "first into man" studies and early-stage clinical trials (Phase I/II trials). | Increased volume of high-quality exploratory clinical studies being undertaken in the UK. | £6 million[1] |
| ***Targeted Initiatives against Identified Bottlenecks in Translational Research*** | | | |
| **Models of Disease** | To validate and qualify potential *in vivo*, *in vitro* and *in silico* models of human disease. | Robust models of disease allowing the faster identification of targets and development of novel therapies. | £3.3 million |
| **Biomarkers** | To support the further development of potential biomarkers and/or to evaluate potential biomarkers for their predictive and prognostic capability for the diagnosis of disease, disease heterogeneity and underlying mechanisms, susceptibility, exposure or response to interventions. | Robust biomarkers of disease allowing the faster identification of targets, development and evaluation of novel therapies. | £3.2 million |

| Key initiative | Aims | Intended impact | Planned commitment at the end of 2010/11 |
|---|---|---|---|
| **Patient Research Cohort Initiative** | To support the creation or further development of small cohorts of individuals who have been precisely defined in terms of their phenotype and medical history.<br><br>To enable novel interventions to be tested more swiftly through exploratory trials in small groups of carefully-characterised patients, using relevant clinical endpoints or well-validated proxy measures for those end-points. | To fill a key translational gap (Cooksey's "first translational gap") by taking novel interventions swiftly from the laboratory into early-stage clinical studies.<br><br>To speed up the development of more targeted therapies, new diagnostics and novel preventative measures in areas of high health need – bringing benefits for patients and encouraging companies to innovate in the UK. | £1.1 million[2] |
| **Underpinning Infrastructure Initiative** | To help universities to quickly develop their translational research activities, supporting the recruitment of key research leaders to the UK, making substantial investments in the UK's research infrastructure, and supporting staff to deliver translational programmes. | Increased capacity and capability for the UK academic sector to undertake world-leading and cutting-edge translational research. | £8.3 million |
| **Stem Cells and Regenerative Medicine** | To support fundamental stem cell research, furthering translation towards application and therapeutic development, and building further capacity in stem cell research. | Maximising the competitiveness and impact of UK stem cell research, with world-class tools, resources and skills. | £8.1 million[3] |

| Key initiative | Aims | Intended impact | Planned commitment at the end of 2010/11 |
|---|---|---|---|
| ***Large-Scale Evaluations*** | | | |
| **Efficacy and Mechanisms Evaluation (EME) Programme** | To support clinical trials and other well-designed studies which are focused on adding to our understanding of mechanisms and efficacy of interventions. | To fill a key translational gap by taking promising interventions swiftly from early-stage clinical studies into larger clinical studies designed to provide greater understanding of an intervention's efficacy or mechanism of action. | No specific funding from CSR uplift[4] |
| **Programme of Large-Scale Evaluation and Trials** | To provide reliable, relevant research evidence on the effectiveness, costs, and broader impact of promising health interventions. | To fill a key translational gap by evaluating the performance of a promising intervention in a real health service setting. | £67 million[5] |
| **Centres for Leadership in Applied Health Research and Care** | To develop an innovative model for conducting applied health research and translating research findings into improved outcomes for patients. | To fill a key translational gap (Cooksey's "second translational gap") by identifying and evaluating those new interventions that are effective and appropriate for everyday use in the NHS, and establishing effective processes to implement them in routine clinical practice. | £20 million |

| Key initiative | Aims | Intended impact | Planned commitment at the end of 2010/11 |
|---|---|---|---|
| **Methodology** | | | |
| **Methodology Research Programme** | To support methods research in all areas of health research. | New and better methods and approaches in health research. | £4.0 million[6] |
| **Hubs for Trials Methodology Research** | To strengthen the methodological research platform underpinning clinical trials research. | Increased national capacity and centres of excellence in clinical trials methodology research. | £3.7 million |
| **Clinical Trials Unit Infrastructure Awards** | To provide stability to clinical trials units. | To ensure sufficient research capacity to support a major expansion in clinical trials funded by the NIHR. | £3.7 million |
| **Capacity Building/Human Capital** | | | |
| **Translational Training Awards** | To increase the number of training awards to scientists engaged in pre-clinical and clinical translational research, population health sciences, translational public health research and the underpinning methodologies. | To train the translational research leaders of tomorrow. | £8.8 million |

| Key initiative | Aims | Intended impact | Planned commitment at the end of 2010/11 |
|---|---|---|---|
| **Methodology Research Fellowships** | To support the development of individuals with expertise in research methods including health statistics, health economics, clinical trial design, and operational research and modelling.<br>The scheme is aimed at the most talented individuals, especially those who are not currently working in a health-related field. These individuals will be provided with the necessary support and training to become specialist methodologists in areas relevant to applied health research, or to expand their research interests into areas relevant to applied health research. | To address the relative shortage of individuals with the necessary training and expertise in key areas of research methods to support the volume of applied health research that is needed. | £2 million[7] |
| **Applied Clinical Research Training Fellowships** | To provide individuals of outstanding potential early in their research careers with 3 years' full-time funding to undertake a PhD. It aims to fast-track them through a customised research training programme in an environment reflecting their individual talents and training needs. | To increase the numbers of researchers who will lead and conduct high-quality clinical and applied health research focused on the needs of patients and the public. This meets a specific need identified by Cooksey for additional PhD training fellowships aimed at Academic Clinical Training Fellows. | £3.7 million[8] |

| Key initiative | Aims | Intended impact | Planned commitment at the end of 2010/11 |
|---|---|---|---|
| **Public Health Research** | | | |
| **Public Health Research Programme** | To evaluate interventions to improve public health. It will provide new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme will be multi-disciplinary and broad. | To fill a key translational gap by evaluating the performance of a promising public health intervention in a real-world setting. | £10 million[9] |
| **Public Health Initiatives** | To support public health research in prevention, ageing and addiction. | To respond to major challenges in public health research. | £5.9 million[10] |
| **Initiatives in E-Health** | | | |
| **Research Capability Programme of Connecting for Health in England** | To enable research to achieve its full potential as a "core" activity for healthcare, and to facilitate uses of NHS data to lead to improvements in the quality and safety of care of patients and the public. | To harness the invaluable opportunities provided by the NHS's electronically held patient information. With proper safeguards to ensure patient confidentiality, this can become a unique selling point for the UK. | £18 million |
| **E-Health Initiatives** | To support, in partnership with other funders, research on the use of electronic datasets. | To enable electronic records to be used as resources for researchers investigating human health and disease. | £0.6 million |

| Key initiative | Aims | Intended impact | Planned commitment at the end of 2010/11 |
|---|---|---|---|
| NHS Research Infrastructure | | | |
| **Biomedical Research Units** | To support the NHS infrastructure for translational clinical research in priority areas of high disease burden and clinical need, which are currently under-represented in the existing NIHR Biomedical Research Centres, and in which the country has identified research strengths. | To meet Cooksey's suggestion that there needs to be scope for other NHS/university partnerships to develop, in order to provide a challenge to the established Biomedical Research Centres in future funding competitions, and thus helping to drive excellence in the system. To respond to Cooksey's suggestion that greater priority should be given to supporting medicines and therapies that tackle unmet health needs in the UK. | £8.2 million[11] |
| | | | **Overall commitment: NIHR: £132.6 million; MRC: £63.1 million** |

[1] Together with investment from MRC baseline.

[2] From MRC Cooksey uplift. An additional £1 million is provided from the NIHR baseline.

[3] Together with investment from MRC baseline.

[4] Funded to approximately £15 million from MRC baseline.

[5] Direct costs of research and NHS Service Support Costs required for delivery in England. This is in addition to the substantial existing NIHR funding for large-scale evaluation and trials.

[6] From MRC Cooksey uplift plus £1 million from NIHR baseline.

[7] This is in addition to the existing NIHR funding for training in research methods.

[8] This is in addition to the substantial existing NIHR funding for research training.

[9] This is in addition to the existing NIHR funding for research on public health, especially through the NIHR HTA Disease Prevention Panel.

[10] In addition to MRC baseline and Partners' funding.

[11] From NIHR Cooksey uplift plus £6.8 million from NIHR baseline. This is in addition to the substantial existing NIHR funding for Biomedical Research Centres.

# Annex 2: Board Membership and Terms of Reference

## 1. The OSCHR Board

### OSCHR Board and Key Functions

OSCHR's mission is to facilitate more efficient translation of health research into health and economic benefits in the UK through better coordination of health research and more coherent funding arrangements to support translation.

The key functions of OSCHR are to:

- work with officials from DH, DIUS and the Devolved Administrations to set the Government's health research strategy, taking into account the advice, priorities and needs set out by the NIHR and its equivalents in the Devolved Countries, the MRC and NHS;
- set the budget required to deliver this strategy and submit a single Spending Review bid to the Treasury;
- communicate the UK's health research opportunities to major stakeholder groups;
- monitor delivery of the strategy against objectives and report to Parliament on progress; and
- encourage a stronger partnership between Government, health industries and charities.

OSCHR's role is a) to forge agreement between the OSCHR Partners on the UK Health Research Vision and their integrated plan to deliver the Vision, and b) to monitor the coordination and implementation of the OSCHR Partners' delivery of the Vision.

### Membership of the OSCHR Board

- Professor Sir John Bell – Chair OSCHR
- Professor Sir Leszek Borysiewicz – CEO MRC
- Dr Harry Burns – CMO for Scotland, on behalf of the Devolved Administrations (January 2007 to February 2008)
- Professor Sally Davies – Director General R&D, DH, England
- Mr Alun Evans – Interim Director General, Science and Research, DIUS (April to August 2008)
- Dr Russell Hamilton – In lieu of CEO NIHR
- Professor Mike Harmer – Acting Director WORD, DCMO Welsh Assembly Government (since February 2008)
- Mr Robert Hudson – Director of Strategy, Direction and Planning, Health and Social Services, WAG (December 2007 to February 2008)
- Professor Sir Alan Langlands – Principal, University of Dundee (Non-Executive member)
- Sir Keith O'Nions – Director General of Science and Innovation, DIUS (until March 2008)
- Professor Sir John Savill – Chief Scientist, Scottish Government (since May 2008)
- Professor Adrian Smith – Director General of Science and Research, DIUS (from September 2008)
- Dr Mark Walport – Director of the Wellcome Trust (Non-Executive member)
- Mr Andrew Witty – CEO GlaxoSmithKline plc (Non-Executive member)

In attendance: Professor Sir Alex Markham (Chair TMB), Professor Ian Diamond (Chair EHRRB), OSCHR Office lead officials.

During the reporting period, the OSCHR Board has met eight times: 7 January 2007, 16 April 2007, 3 July 2007, 16 October 2007, 12 December 2007, 11 February 2008, 1 May 2008 and 21 July 2008.

The OSCHR Board as of August 2008:

**Professor Sir John Bell, OSCHR Chair**

Sir John Bell is Regius Professor of Medicine at Oxford University and President of the Academy of Medical Sciences. Sir John undertook his medical training in the UK and at Stanford University, USA, returning to the UK in 1987. His research interests are in the area of autoimmune disease and immunology, where he has contributed to the understanding of immune activation in a range of autoimmune diseases. In 1993, he founded the Wellcome Trust Centre for Human Genetics, one of the world's leading centres for complex trait common disease genetics. Sir John was responsible for the working party that produced the highly influential Academy of Medical Sciences *Strengthening Clinical Research* report, which highlighted the need for the UK to focus some of its attention on developing expertise in translational research. In January 2007, he became the first Chairman of the Office for the Strategic Coordination of Health Research.

**Professor Sir Leszek Borysiewicz**, PhD, FRS, FRCP, FRCPath, FMedSci

Sir Leszek Borysiewicz has been Chief Executive of the Medical Research Council since October 2007. Prior to the MRC, Sir Leszek was Deputy Rector at Imperial College London. He was knighted in 2001 for his research into developing vaccines, including a vaccine to prevent the development of cervical cancer.

A physician by training, Sir Leszek specialises in viral immunology, infectious diseases, cell-mediated immunity, virus-associated malignancy and vaccine development.

He has held a number of high-profile posts, including Governor of the Wellcome Trust, Chair of the Higher Education Funding Council for England Research Assessment Exercise (RAE) Main Panel A, council member of Cancer Research UK and a trustee of the Nuffield Trust.

Sir Leszek was a founding Fellow of the Academy of Medical Sciences, and is a Fellow of Cardiff University. He holds honorary degrees from the Universities of Southampton and Hull.

**Professor Sally C Davies**, Director General of Research and Development, Department of Health

Professor Sally Davies is the Director General (DG) of Research and Development and Chief Scientific Advisor for the Department of Health and NHS. As DG she developed the new Government research strategy, *Best Research for Best Health*, with a budget rising to £1 billion, and is now responsible for implementation of the National Institute for Health Research. She also chairs the UK Clinical Research Collaboration (UKCRC). She was a member of the steering groups for the Biotechnology Innovation and Growth Team, chaired by Sir David Cooksey, and its "Refresh" the Health Care Industry Task Force and is a member of the Health Innovation Council.

She is a member of the World Health Organization (WHO) Global Advisory Committee on Health Research (ACHR) and is currently chairing the Expert Advisory Committee for the development of the WHO research strategy. She is a member of the International Advisory Committee for A*STAR Singapore (the Agency for Science, Technology and Research) and the Caribbean Health Research Council.

**Dr Russell Hamilton**, PhD, MBA, BSc(Hons), DipM, FFPH

Russell Hamilton is Director for Research and Development at the Department of Health. His work is focused on the development and implementation of policies and strategies to harness the potential of research to improve health and healthcare. He played a central role in the development of the Government's strategy *Best Research for Best Health* and in the creation of the National Institute for Health Research and is now engaged in delivering the strategy to establish a research system in the NHS that supports world-class research focused on the needs of patients and the public.

Russell was previously Regional Director of NHS R&D for the South of England and Director of three National NHS R&D Programmes (Cancer, Asthma, and Physical and Complex Disability). He has a scientific background in physiology and has held clinical, research, and management appointments in teaching hospitals, universities, and government organisations in Australia and the UK.

He is a Board member of the Office for Strategic Coordination of Health Research, the UK Clinical Research Collaboration, the National Institute for Health Research and the National Cancer Research Institute. He is a member of the Scientific Advisory Committee of the Association of Medical Research Charities, the Universities UK Health and Social Care Policy Committee, the OSCHR Translational Medicine Board, and RAE 2008 Main Panel A.

**Professor Mike Harmer**

Professor Michael Harmer graduated from St Bartholomew's Hospital Medical School in 1974. Following early posts in Winchester, he undertook speciality training in anaesthesia in Cardiff. He was appointed Consultant Anaesthetist at the University Hospital of Wales in 1982 and remained in that post until 1996, when he moved into an academic appointment. He was appointed Professor in the Department of Anaesthetics and Intensive Care Medicine in 1997 and during that post served on the Council of the Royal College of Anaesthetists as well as being President of the Association of Anaesthetists of Great Britain and Ireland (AAGBI) from 2004 to 2006. He moved to take up the post of Deputy Chief Medical Officer for Wales in June 2007. With the shift of the Wales Office for Research and Development into the Chief Medical Officer's department early in 2008, he took over the Acting Director role.

**Professor Sir Alan Langlands**, FRSE

Alan Langlands is the Principal and Vice Chancellor of the University of Dundee. The University is a world-ranking research institute and provides a broad range of undergraduate and postgraduate teaching programmes. It plays an important role in the economic, social and cultural development of Scotland. Alan is also the Chairman of UK Biobank, a joint venture set up by the Wellcome Trust and the Medical Research Council to oversee one of the world's largest genetic epidemiology studies, and a Non-Executive Director of the Office for the Strategic Coordination of Health Research and the UK Statistics Authority.

Alan was the Chief Executive of the National Health Service in England from 1994 to 2000. He has an international reputation in the development of healthcare policy and as a strategic manager of health services, and has advised in many countries including Russia, the USA, Canada and China. He received a knighthood in the Queen's Birthday Honours list (1998) for his services to the NHS and is a Fellow of the Royal Society of Edinburgh.

Alan is a science graduate of the University of Glasgow and was conferred Doctor of the University in October 2001. He is an Honorary Professor at the University of Warwick Business School. He has been awarded Honorary Fellowships by the Royal College of Physicians, the Royal College of General Practitioners, the Royal College of Surgeons of Edinburgh, the Royal College of Physicians and Surgeons (Glasgow), the Faculty of Public Health Medicine, the Institute of Actuaries and the Chartered Institute of Public Finance. He is a trustee of The Nuffield Trust and Chairman-designate of the Health Foundation.

**Professor Sir John Savill**, Chief Scientist, Scottish Government Health Directorates

John Savill graduated in Physiological Sciences from Oxford in 1978 and in Medicine from Sheffield in 1981 and received a PhD (London) in 1989. After junior hospital appointments in Sheffield, Nottingham and London, he spent seven years in the Department of Medicine at the Royal Postgraduate Medical School, Hammersmith Hospital, with spells as an MRC Clinical Training Fellow and a Wellcome Trust Senior Clinical Research Fellow. In 1993, he moved to the Chair of Medicine at Nottingham, then to Edinburgh as Professor of Medicine in 1998 where he set up and became the first Director of the University of Edinburgh/MRC Centre for Inflammation Research. In 2002, he became the first Vice-Principal and Head of the College of Medicine and Veterinary Medicine; he moved to the Chair of Experimental Medicine in 2006. On 1 June 2008, he was appointed Chief Scientist for the Scottish Government Health Directorates (part-time).

His work has been recognised by fellowships of the Royal Colleges of Physicians of London and Edinburgh, the Academy of Medical Sciences, the American Society of Nephrology and the Royal Society of Edinburgh. He was a member of the Medical Research Council from 2002 to 2008 and chaired two Research Boards during this period. He was knighted in the 2008 New Year's Honours List for services to clinical science.

**Professor Adrian Smith**, FRS

Professor Smith is joining DIUS after ten years as Principal of Queen Mary, University of London. Prior to being Principal of Queen Mary, Professor Smith was at Imperial College, London, where he held a number of posts over an eight-year period. These included: Professor of Statistics, Head of the Department of Mathematics, Member of the Management and Planning Group and Company Director of ICON (Imperial Consultancy). From 1977 to 1990, he was Professor of Statistics at Nottingham, Head of the Department of Mathematics and a member of the University Council. Professor Smith has also held posts at the University of Oxford and University College, London. He read undergraduate mathematics at Cambridge University.

Professor Smith has recently been the Treasurer of Universities UK, a member of the governing body of the London Business School and a past Chair of London Higher, the regional umbrella body representing London's 42 universities and higher education colleges. He served on the Advisory Committee to the UK Government Office for National Statistics from 1996 to 1998, worked for the UK Government Department of the Environment from 1991 to 1998 as a Statistical Advisor to the Nuclear Waste Inspectorate, and for the Ministry of Defence from 1982 to 1987 as advisor on Operational Analysis. Professor Smith has also worked with the UK Higher Education Funding and Research Councils.

Professor Smith has held numerous statistical consultancies in the private sector, in business and finance, the pharmaceutical industry and the communications and power industries.

Professor Smith is a past President of the Royal Statistical Society and was elected a Fellow of the Royal Society in 2001 in recognition of his contribution to statistics. He is currently a member of the Council of the Royal Society. In 2003/04 he undertook an Inquiry into Post-14 Mathematics Education for the UK Secretary of State for Education and Skills. In 2006 he completed a report for the UK Home Secretary on the issue of public trust in Crime Statistics.

**Dr Mark Walport**

Mark Walport is Director of the Wellcome Trust, which funds innovative biomedical research, in the UK and internationally, spending over £600 million each year to support the brightest scientists with the best ideas. Before joining the Trust he was Professor of Medicine and Head of the Division of Medicine at Imperial College London. His own research career focused on the immunology and genetics of rheumatic diseases.

He is a board member of the UK Clinical Research Collaboration (UKCRC), the UK Research Base Funder's Forum, the Health Innovation Council and the Prime Minister's Council for Science and Technology. He is also a member of a number of international advisory bodies, including the Grand Challenges in Global Health Scientific Board and the Council of the Global HIV Vaccine Enterprise.

He chaired the Academic Careers Sub-Committee of the UKCRC and Modernising Medical Careers, which reported in 2005. More recently, at the request of the Prime Minister and the Secretary of State for Justice, he co-chaired with the Information Commissioner an independent review on the use and sharing of personal information in the public and private sectors.

Mark is a founder Fellow, and was the first Registrar, of the Academy of Medical Sciences and an Honorary Member of the American Association of Physicians.

**Mr Andrew Witty**

Andrew Witty became CEO of GlaxoSmithKline on 21 May 2008.

Andrew joined Glaxo in 1985 and held a variety of roles in the UK business. He was a Sales Representative for the respiratory business, held a variety of marketing roles and was Director of Pharmacy and Distribution.

He has worked in the Company's International New Products groups, both in the Respiratory and HIV/Infectious disease fields, and has been involved in multiple new product development programmes.

In 1993, Andrew was appointed Managing Director of Glaxo South Africa and later Area Director for GlaxoWellcome, South and East Africa. Subsequently he moved to North Carolina as Vice President and General Manager, Marketing for GlaxoWellcome Inc, the group's US subsidiary.

Andrew then moved to Singapore and led the Group's operations in Asia as Senior Vice President, Asia Pacific. While in Singapore he was a Board Member of the Singapore Economic Development Board and the Singapore Land Authority and in 2003 was awarded the Public Service Medal by the Government of Singapore.

In 2003 Andrew was appointed President of GSK Europe and joined GSK's Corporate Executive Team.

Andrew has served in numerous advisory roles to Governments around the world, including South Africa, Singapore, Guangzhou China and the UK.

Andrew has a Joint Honours BA in Economics from the University of Nottingham.

## 2. OSCHR Partners Translational Medicine Board (TMB)

### The TMB Terms of Reference

The role of the Translational Medicine Board is to work with the OSCHR Partners to develop a coordinated, coherent, fully aligned research strategy in translational research. This includes carrying out the following functions:

- to work with the OSCHR Partners to develop Delivery Plans to meet this strategy;
- to advise OSCHR on suitability of the delivery plans;
- to advise OSCHR on funding priorities;
- to monitor implementation and progress, providing OSCHR with regular reports and opinion, incorporating feedback from the research community, industry and Government; and
- to advise on appropriate mechanisms for engagement with the needs of patients, industry and the charity sector.

The Chair of the TMB attends OSCHR Board meetings in order to:

- advise OSCHR on suitability of delivery plans;
- advise OSCHR on funding levels for different activities under the Strategic Plan for Health Research Coordination; and
- advise OSCHR should any change in Lead Organisation be required.

The TMB's responsibility is therefore to:

- develop with the OSCHR Partners a coordinated strategy for each of the major activities in translational medicine;
- agree with the OSCHR Partners the mechanisms for allocating resources in each activity area (i.e. define the review process, agree the Board structure, establish the criteria for successful applications);
- oversee the Lead Organisation as it implements the plans for funding activity in each area;
- ensure adequate input into plans from industry;
- review outcome of funding decisions on a regular basis to ensure they align with strategic plans; and
- report progress and outcomes through the Chairman of the TMB to OSCHR.

### Membership of the TMB

- Professor Sir Alex Markham – Professor of Medicine, University of Leeds (Chair)
- Professor Sir Philip Cohen – Director, MRC Protein Phosphorylation Unit, University of Dundee (Expert Advisor)
- Dr Sue Denman – Head of WORD (from September 2008)
- Dr Diana Dunstan – Director, Research Management Group, MRC (until November 2007)
- Dr Jim Elliott – Patient and Public Involvement member (from October 2008)
- Professor Adrian Grant – Professor of Health Services Research, University of Aberdeen (Expert Advisor)
- Dr Russell Hamilton – Director, Research and Development, DH
- Professor Stephen Holgate – MRC Clinical Professor of Immunopharmacology, University of Southampton (Expert Advisor)
- Dr Declan Mulkeen – Director, Research & Training, MRC (from November 2007)
- Professor Jon Nicholl – Director, Medical Care Research Unit, University of Sheffield (Expert Advisor)

- Dr Richard Peck – Director, European Exploratory Medicine, Eli Lilly and Co Ltd. (Expert Advisor) (to September 2008), Global Head of Clinical Pharmacology, Roche Products Ltd. (from September 2008)
- Dr Alison Spaull, Director, CSO, Scottish Government Health Directorates (from September 2008)
- Mr Jon Sussex – Deputy Director of the Office of Health Economics (Patient and Public Involvement member) (from August 2008)
- Professor Tom Walley – Director, NIHR HTA programme
- Dr Neil Weir – Senior Vice President, Research, UCB Group (Expert Advisor)
- Mr Paul Williams – Head of Research Councils Unit, DIUS

In attendance: OSCHR Office lead official.

During the reporting period, the TMB has met eight times: 18 July 2007, 17 September 2007, 10 October 2007, 23 November 2007, 28 January 2008, 19 March 2008, 22 May 2008 and 24 September 2008.

## 3. OSCHR Partners E-Health Records Research Board

### The EHRRB Terms of Reference

The OSCHR Partners E-Health Records Research Board (EHRRB) fulfils two main roles:

- it provides strategic oversight of E-health records research in the UK; and
- it acts as the External Reference Group (ERG) for the NHS Connecting for Health (CfH) Research Capability Programme (England).

The membership is the same for both the External Reference Group and Strategic Oversight functions.

The Terms of Reference for the ERG can be found on the NHS CfH Research Capability Programme website. The Terms of Reference for the EHRRB in its Strategic Oversight function are:

- to maintain strategic oversight of the E-health records research agenda in the UK and ensure that there is connectivity between a range of different funding initiatives across the UK. This includes the NHS CfH Research Capability Programme and federating existing databases;
- specifically to:
  - provide strategic oversight of E-health records research relating to all aspects of the use of electronic databases for research;
  - advise on the appropriate alignment between all the different Government-funded elements of the E-health records research agenda;
  - develop a strategic framework for E-health records research in the UK;
  - promote interconnectivity with non-government activities;
  - identify gaps and opportunities in activity and funding for E-health records research; and
  - provide strategic input to ongoing discussions on information governance as it relates to research uses of electronic databases.

**Membership of the EHRRB/ERG**

- Professor Ian Diamond – CEO Economic and Social Research Council (ESRC) (Chair)
- Professor Tony Avery – Professor of Primary Health Care, University of Nottingham
- Dr Richard Barker – Director General, Association of British Pharmaceutical Industries (ABPI)
- Dr Charles Brigden – Medical Director, Amgen
- Dr Paul Cload – GE Healthcare
- Professor Rory Collins – Chief Executive and Principal Investigator of UK Biobank, University of Oxford
- Professor Carol Dezateux – Professor of Paediatric Epidemiology, Institute of Child Health, University College London
- Professor Paul Elliott – Chair, Epidemiology and Public Health Medicine, Imperial College London
- Dr Cathy Emmas – Clinical Effectiveness Manager, AstraZeneca (from July 2008)
- Dr Tim Hubbard – Head of Informatics, Wellcome Trust Sanger Institute
- Professor Ronan Lyons – Professor of Public Health and Co-Director of the Health Information Research Unit (HIRU), Swansea University
- Dr Alan McDougall – Head of Medical, Primary Care, AstraZeneca (until July 2008)
- Dr John Parkinson – Group Head, GP Research Database (GPRD), MHRA
- Mr Nick Partridge – Chair of INVOLVE
- Dr David Roblin – Vice President and Head of Clinical R&D, Pfizer R&D
- Mr Tony Sargeant – Patient and Public Involvement member
- Dr George Sarna – Assistant Director: Strategy, Research Management Group, MRC (until July 2008)
- Professor Frank Sullivan – NHS Tayside Professor of R&D in General Practice and Primary Care, University of Dundee
- Mr Rob Thwaites – Director, Healthcare Information Factory, GlaxoSmithKline plc
- Dr Janet Valentine – Head of Partnership Initiatives, MRC (from July 2008)
- Ms Christine Vial – Patient and Public Involvement member
- Professor John G Williams – Professor of Health Services Research, Swansea University
- Dr Louise Wood – Deputy Director, Head of Innovation and Industry R&D Relations, DH

In attendance: Professor Sir Alex Markham (Chair, CfH RCP Board), Mr Peter Knight (NHS CfH RCP), Mr Marc Taylor (Deputy Director for R&D Systems and Governance, DH), OSCHR Office lead official.

During the reporting period, the ERG has met nine times and the EHRRB has met five times in its strategic oversight function: 29 November 2007, 13 February 2008, 28 March 2008, 5 June 2008 and 18 September 2008.

# 4. OSCHR Partners Public Health Research Board (PHRB)

### The PHRB Terms of Reference

The role of the PHRB is to provide advice jointly to the OSCHR Partners on their coordinated approach to public health research and to facilitate the monitoring role of OSCHR. Its key tasks are:

- to monitor the coordination and implementation of the OSCHR Partners' coordinated approach to public health research on behalf of OSCHR;
- to provide advice to the OSCHR Partners on the issues that should be addressed by the Partners through their coordinated approach to public health research;
- to provide advice on the on the ways in which the OSCHR Partners could address these issues; and
- to advise the OSCHR Partners on areas where a wider partnership of funders and other stakeholders is desirable, and to suggest ways in which such partnership could be achieved.

The OSCHR Public Health Research Board will report jointly to the OSCHR Partners and, for the purposes of monitoring, will report to the OSCHR Board.

### Membership of the PHRB (with effect from October 2008)

- Professor Ray Fitzpatrick – Professor of Public Health and Primary Care, Division of Public Health and Primary Health Care, University of Oxford (Chair)
- Professor Brian Duerden – Inspector of Microbiology and Infection Control, DH
- Professor John Frank – Director, Scottish Collaboration for Public Health Research and Policy, MRC Unit Building, Western General Hospital, Edinburgh
- Dr Tony Jewell – CMO Wales
- Professor Laurence Moore – Director, Cardiff Institute of Society, Health and Ethics, Cardiff University
- Professor Nick Wareham – Director, MRC Epidemiology Unit, Cambridge
- To be appointed – Patient and Public Involvement member

In attendance: Mr Michael Bowdery (Senior Project Manager, WORD); Dr Peter Craig (Research Manager, CSO); Dr Russell Hamilton (Director, Research and Development, DH), alternate: Dr Ruairidh Milne (Director of NETSCC PHR, NIHR Evaluation, Trials and Studies Coordinating Centre, University of Southampton); Dr Declan Mulkeen (Director, Research & Training, MRC), alternate: Dr Wendy Ewart (Director of Strategy, MRC); OSCHR Office lead official.

The Chair and members of the PHRB were appointed with effect from 1 October 2008. The first meeting of the PHRB will take place in December 2008.

# Annex 3: Terms of Appointment and Register of Interests

## Terms of Appointment

The OSCHR Chair was appointed for a period of two years in the first instance by the Secretaries of State for Health and for Trade and Industry (now Innovation, Universities & Skills). The three independent members of the OSCHR Board were recruited through a public process conducted by the Appointments Commission, and appointed by the Minister of State for Public Health and the Minister of State for Science & Innovation for an initial period of three years. The Chair and the independent members are eligible to receive a remuneration, set by DIUS, of £15,410 p,a. in 2007 (£15,780 p.a. in 2008) and £6,410 p.a. in 2007 (£6,570 p.a. in 2008) respectively, as well as allowances for travel and subsistence costs incurred on OSCHR business.

The chairs of the TMB, EHRRB and PHRB were agreed by the OSCHR Board, and the members selected jointly by the OSCHR Partners. The members and chairs were all appointed for an initial period of three years and are eligible to claim allowances for travel and subsistence costs necessarily incurred on Board business. Patient and Public Involvement members may also claim a fee of £150 per meeting day.

To ensure that public service values are maintained, the Chairs and members are required, on appointment, to act in accordance with the seven principles recommended by the Committee on Standards in Public Life:

- Selflessness: Holders of public office should act solely in terms of the public interest. They should not do so in order to gain financial or other benefits for themselves, their family or their friends.
- Integrity: Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.
- Objectivity: In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.
- Accountability: Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.
- Openness: Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands this.
- Honesty: Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.
- Leadership: Holders of public office should promote and support these principles by leadership and example.

## Register of Interests

Board members and Chairs are required to declare any relevant business interests, positions of authority or other connections with commercial, public or voluntary bodies; to declare any conflict of interest that arises in the course of Board business; and to take any action necessary to avoid any such conflict making a material difference to the work of the Boards.

The full registers of interests for members of the TMB, EHRRB and PHRB are available on request from the OSCHR Office. The register of interest for members of the OSCHR Board is given below, and further details can be obtained on request from the OSCHR Office.

The following interests have been declared by current OSCHR Board members (as of September 2008):

| | |
|---|---|
| Professor Sir John Bell | • Regius Professor of Medicine, University of Oxford (since 2002)<br>• President of the Academy of Medical Sciences (since 2006)<br>• Member, Board of Directors, Roche Holding AG (since 2001)<br>• Non-Executive Director, Oxagen Ltd (since 1997)<br>• Trustee, Rhodes Trust (since 2002)<br>• Master, Ewelme Almshouse Charity (since 2002)<br>• Member, Biomedical Sciences International Advisory Council of Singapore (since 2002)<br>• Chairman, Oxford Health Alliance (since 2004)<br>• Member, Board of Directors, UK Biobank Ltd (since 2004)<br>• Non-Executive Director, Isis Innovation Ltd (University of Oxford) (since 1996)<br>• Non-Executive Director, The Edward Jenner Institute for Vaccine Research (since 2005)<br>• Non-Executive Director, Gray Laboratory Cancer Research Trust (since 2006)<br>• Scientific Advisor, Advent Venture Partners<br>• Scientific Advisor, Life Science Capital LLP |
| Professor Sir Leszek Borysiewicz | • Member of Oxxon Pharmaccines Ltd Scientific Advisory Board (2002–04)<br>• Member of the Scientific Advisory Board for Cancer Research Ventures Ltd (2000–02)<br>• Consultant to Cantab Pharmaceuticals plc (1991–2000)<br>• Consultant to SmithKline Beecham RIT (Belgium) in cell-mediated anti-viral immune responses and vaccine development (1998)<br>• Family members employed by the Chelsea and Westminster NHS Trust and the University of Kent<br>• Declared a number of past and present chair and membership affiliations with a range of (national and international) advisory committees, research and grant awarding organisations, universities, clinical and other advisory organisations, and editorial boards* |

* Details available on request

| | |
|---|---|
| Professor Sally Davies | • Member of the MRC Council<br>• Member of the International Advisory Board of Singapore A* STAR<br>• Member of the Caribbean Health Research Council<br>• Family member employed by Cambridge University |
| Dr Russell Hamilton | • Family member employed by Exeter University |
| Professor Mike Harmer | • Through role as DCMO, close links with politicians within WAG<br>• No other relevant interests, including no financial interests in companies or bodies that might relate to OSCHR activities |
| Professor Sir Alan Langlands | • Principal and Vice Chancellor, University of Dundee (since 2000)<br>• Chairman, UK Biobank (since 2004)<br>• Non-Executive Director, UK Statistics Authority (since 2007)<br>• Trustee, Nuffield Trust (since 2006)<br>• Chairman Designate, The Health Foundation (from 2009) |
| Professor Sir John Savill | • Post in Edinburgh (Vice Principal and Head of the College of Medicine and Veterinary Medicine) (since 2002)<br>• Part-time Chief Scientist post in the Scottish Government Health Directorates (since 2008)<br>• Governorship of the Health Foundation (unpaid) (since 2001)<br>• Chairmanship of Programmes and Chairs Committee, British Heart Foundation (unpaid) (since 2007) |
| Professor Adrian Smith | • Remunerated employment: Editorial advisor, John Wiley and Sons<br>• Miscellaneous and unremunerated interests: Trustee, Biometrica Trust; Council Member, Royal Society (until 1 December 2008); Ex-Principal (until 21 August 2008), Queen Mary University of London |
| Dr Mark Walport | • Director, Wellcome Trust<br>• Member, Council for Science and Technology<br>• Member, Health Innovation Council<br>• Member, Scottish Executive Chief Scientist Committee<br>• Member, Department for Business, Enterprise and Regulatory Reform (BERR) Funders' Forum<br>• Directorship and Council membership, Association of Medical Research Charities<br>• Directorship and Council membership, Foundation for Science and Technology<br>• Fellow, Academy of Medical Sciences |

| | |
|---|---|
| Mr Andrew Witty | • Member, Business Council for Britain<br>• Board Member, British Pharma Group<br>• Board Member, PhRMA (trade association of the US pharmaceutical industry)<br>• Vice-President, European Federation of Pharmaceutical Industries and Associations (EFPIA)<br>• Member, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Council<br>• Board Member, Imperial College Commercialisation Advisory Board<br>• Member, INSEAD UK Council<br>• Member, Health Innovation Council<br>• Member, Singapore Economic Development Board's International Advisory Council<br>• Member, Corporate Advisory Board, Global Business Coalition on HIV/AIDS<br>• Member, International Business Advisory Council of the London Mayor |

# Annex 4: OSCHR Office Staff

The OSCHR Office currently has four members of staff:

- Dr Liam O'Toole (Head of Office, since January 2007);
- Dr Monika Preuss (Programme Manager, since April 2008);
- Mrs Karen Todd (Programme Manager, since April 2008); and
- Mr Adam Storring (Support Officer, since June 2008).

Between January 2007 and April 2008, the OSCHR Office was also supported by Dr Alison Austin (DIUS) and staff from the UKCRC office. We would like to thank Dr Austin, Ms Katie Gale, Ms Hannah Brown and Ms Ngozi Okwudili-Ince for all their support and hard work.

The OSCHR Office is based at:

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Room G-41
1 Horse Guards Road
London SW1A 2HQ

Tel: 020 7270 5075

# Annex 5: Glossary of Terms

| | |
|---|---|
| ABPI | Association of British Pharmaceutical Industries |
| Aligned MRC–NIHR Reporting Framework | MRC and NIHR's aligned metrics for measuring delivery |
| AMD | Age-related macular degeneration |
| AMS | Academy of Medical Sciences |
| BBSRC | Biotechnology and Biological Sciences Research Council |
| Biomarker | A biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment |
| BRfBH | *Best Research for Best Health: A new national health research strategy*, Department of Health, January 2006 |
| BRU | Biomedical Research Unit |
| CfH | Connecting for Health |
| CLAHRC | Collaboration for Leadership in Applied Health Research and Care |
| CMO | Chief Medical Officer |
| CMV | Cytomegalovirus |
| CRP-VLDL | A complex of C-reactive protein (CRP) and very low-density lipoprotein (VLDL) in plasma |
| CRUK | Cancer Research UK |
| CSO | Chief Scientist Office (part of the Scottish Government Health Directorates) |
| CSR | Comprehensive Spending Review |
| CTU | Clinical trials unit |
| DCMO | Deputy Chief Medical Officer |
| DH | Department of Health |
| DIUS | Department for Innovation, Universities & Skills |
| DPFS | Developmental Pathway Funding Scheme |
| EHRRB | OSCHR Partners' E-Health Records Research Board |
| EME | Efficacy and Mechanisms Evaluation Programme |
| EPSRC | Engineering and Physical Sciences Research Council |

| | |
|---|---|
| ERG | External Reference Group for the NHS CfH Research Capability Programme (England) |
| ESRC | Economic and Social Research Council |
| HER-2 | Human Epidermal growth factor Receptor 2; a protein present on the surface of some breast cancer cells |
| HIV | Human Immunodeficiency Virus, the virus that can cause AIDS (Acquired Immunodeficiency Syndrome) |
| HRSS | Health Research Support Service (to be built by the RCP) |
| HTA | Health Technology Assessment |
| HTMR | Hubs for Trials Methodology Research |
| IC | Information Centre for Health and Social Care |
| Integrated Plan to Deliver a Vision for UK Health Research | This sets out how the OSCHR Partners will deliver the UK Health Research Vision together. It describes how this will be achieved within the strategies of the OSCHR Partners, with delivery coordinated to achieve the outcomes for health research recommended by Cooksey |
| IT | Information Technology |
| KPI | Key Performance Indicator |
| LLHW | Lifelong Health and Wellbeing |
| Metformin | An anti-diabetic drug |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| MISG | Ministerial Industry Strategy Group |
| MRC | Medical Research Council |
| MRP | Methodology Research Programme |
| NCE | New Chemical Entity |
| NETSCC | National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre |
| NHS | National Health Service |
| NHS CRS | NHS Care Record Service (part of NHS CfH) |
| NICE | National Institute for Health and Clinical Excellence |
| NIHR | National Institute for Health Research (England) |
| OSCHR | Office for Strategic Coordination of Health Research. OSCHR has been established as part of the Department of Health (DH) under an agreement between DH and the Department for Innovation, Universities and Skills (DIUS), and is funded jointly by DH and DIUS |

| | |
|---|---|
| OSCHR Board | All Board members, including representatives from the OSCHR Partners |
| OSCHR Office | The OSCHR Office staff |
| OSCHR Partners | The health research funding bodies represented at the OSCHR Board (NIHR, MRC, CSO and WORD) |
| OSI | Office of Science and Innovation |
| p.a. | Per annum |
| PHR | Public Health Research programme |
| PHRB | OSCHR Partners Public Health Research Board |
| R&D | Research and Development |
| RCP | Research Capability Programme |
| RCUK | Research Councils UK, the strategic partnership of the UK's seven Research Councils |
| SOC | Strategic Outline Case |
| SUS | Secondary Uses Service; being delivered as part of the National Programme for IT by NHS Connecting for Health in partnership with the NHS Information Centre for Health and Social Care (IC) |
| T cells | A group of white blood cells, known as lymphocytes, which play a central role in cell-mediated immunity |
| TMB | OSCHR Partners Translational Medicine Board |
| TSB | Technology Strategy Board |
| UK Health Research Vision | The OSCHR Partners' joint vision for health research |
| UKCRC | UK Clinical Research Collaboration |
| UKCRN | UK Clinical Research Network |
| USP | Unique selling point |
| VEGF | Vascular endothelial growth factor, a sub-family of growth factors |
| WAG | Welsh Assembly Government |
| WORD | Wales Office of Research and Development for Health and Social Care |

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DH Department of Health

Department for **Innovation, Universities** & **Skills**

The OSCHR Partners are the Medical Research Council, the National Institute for Health Research in England, the Chief Scientist Office (part of the Scottish Government Health Directorates) and the Wales Office for Research and Development (of the Welsh Assembly Government, WAG).

Llywodraeth Cynulliad Cymru
Welsh Assembly Government

CHIEF SCIENTIST OFFICE

MRC Medical Research Council

NHS National Institute for Health Research

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