Minutes of the meeting held on 7 June 2007, The Himsworth and Fletcher Rooms, UKCRC, 20 Park Crescent, London W1B 1AL

Present

Members

Professor Sally Davies – Department of Health (DH) (Chair)
Peter Arnold – The Association of the British Healthcare Industries (ABHI)
Aisling Burnand – BioIndustry Association (BIA)
Professor Iain Cameron – Universities Representative
Simon Denegri – Association of Medical Research Charities (AMRC)
Dr Russell Hamilton – Department of Health (DH)
Paul Hubbard – UK Higher Education Funding Councils
Professor Patrick Maxwell – The Academy of Medical Sciences (AMS)
Candy Morris – Strategic Health Authorities (SHAs)
Dr Declan Mulkeen – Medical Research Council (MRC)
Dr Liam O’Ttoole – UK Clinical Research Collaboration (UKCRC)
Ron Kerr – NHS Confederation
Nick Partridge – INVOLVE
Catriona McMahon – Senior Representative from the Pharmaceutical Industry
Peter Littlejohns – National Institute for Health and Clinical Excellence (NICE)
Dr Alison Spaull – Scottish Executive Health Department
Professor Bob Stout – Research and Development Department for the Northern Ireland Health and Personal Social Services
Richard Tiner – The Association of the British Pharmaceutical Industry (ABPI)
Professor John Williams – Welsh Assembly Government

Observers/Invited

Jenny McKibben – Patient/Public Representative
Sarah Dickson – MRC Regulatory Support Unit, Edinburgh (item 7 only)
Steve Walker – National Institute for Health Research IS Programme Director (item 8 & 9a)
Marc Taylor – Department of Health (DH)
Louise Wood – Department of Health (DH)
Dr Helen Campbell – Department of Health (DH)
Peter Selby – UK Clinical Research Network (UKCRN)
Roger Wilson – UKCRC Public and Patient Involvement Project Group (Chair)
Catherine Johns – Department of Health R&D (DH)
Sarah Fox – Department of Health R&D (DH)
UKCRC Secretariat

Dr Janet Valentine     Dr Andrew Speakman
Dr Sue Bourne         Dr Matthew Hallsworth
Samia Majid          Sarah Harrop
Dr Ngozi Okwudili-Ince Dominique Capostagno
Phillipa Yeeles      Katie Gale
Dr Rebecca Hodges

Announcements and Apologies

Apologies
Adrian Newland, AOMRC
Sir Alasdair Breckenridge, MHRA
Mark Walport, WT
Harpal Kumar, CRUK
John Neilson, OSI/DTI
John Bell; Chair of OSCHR

Announcements
The Chair welcomed everyone to the twelfth meeting of the UKCRC Board.

Attending the UKCRC Board for the first time were:

- Ron Kerr who had replaced Jonathan Michaels as the NHS Confederation representative on the Board.
- Catriona McMahon (AstraZeneca alternate) having replaced Allan Baxter (GSK) as the senior R&D Pharmaceutical Industry representative on the Board.
- Iain Cameron (Head of School of Medicine at the University of Southampton) who was attending in place of John Tooke as the representative from the University sector.

1. Minutes of the Eleventh UKCRC Board Meeting   UKCRC/07/12

The minutes were accepted as a correct record of the meeting held on 14 March 2007.

Matters Arising

Research Assessment Exercise (RAE)

Paul Hubbard updated the Board on progress with the RAE. It was noted that 2008 RAE would go ahead as planned and the outcomes would have implications for research funding from 2009/10. The introduction of the new framework for the assessment and funding of research would be phased in from 2010/11 and would be fully in place by 2014. A progress report to the Secretary of State on the development of the framework was due by 30 September and would be followed by consultations with HE institutions and other stakeholders.

Quantitative evaluation indicators would be used for science-based subjects. Expert advice was currently being sought on the use of bibliometric data as a research quality indicator. The overall funding and assessment package would also employ indicators of external research income and postgraduate student numbers.
Research quality in other subjects, such as the arts and humanities would be assessed through a light-touch process based on peer review and informed by statistical indicators in common with the science-based subjects. This process would take place in 2013 to inform funding allocations from 2014.

It was noted that this was a UK-wide initiative in terms of the changes to quality assessment; however the funding arrangements would continue to be determined individually by the funding bodies for England, Scotland, Wales and Northern Ireland.

**UKCRC General**

**2. Chief Executive’s Report**  
**UKCRC/07/13**

**Update on Staff Appointments**

The Board welcomed Dr Rebecca Hodges who replaces Mags Sara as Programme Manager working in the areas of Research Workforce, UK-wide working and lead liaison with the UKCRN. Dr Janet Valentine had been officially appointed deputy to the Chief Executive. The UKCRC Secretariat was now fully staffed with 13 members.

**Longer-term role of the UKCRC**

The Board agreed in March that, in view of the recent changes in the UK health research environment, it would be timely to have an early discussion of the 2008/09 Workplan and to consider the longer term role of the UKCRC, at the September Board meeting. The Board noted that Dr Liam O’Toole and Dr Janet Valentine would be meeting with members of the Board during the summer to discuss these issues.

It was noted that the UKCRC Budget Committee would meet in advance of the September Board to discuss financial implications associated with potential changes in activity levels and staffing arrangements.

**Communication**

A new communications strategy to support delivery of the Workplan through 2007-2008 had been developed. The strategy was designed to move the communications messages used over the first two years of UKCRC activity from ‘..this is what we are trying to achieve’ to a more customised engagement with stakeholders through ‘…this is the new environment and what it means for you’. The Board highlighted the importance of engaging with Industry and raising the international profile of the UK as an improving research environment.

**Industry**

The UKCRC had been working closely with UK Trade and Investment to promote UK plc internationally. The Board noted UKCRC representation at recent key Industry conferences.

**UKCRC Budget Report**

The Secretariat had provided the Budget Committee with a detailed final budget report for 2006/07 and an updated 2007/08 budget forecast in advance of the Board meeting. Nick Partridge, chair of the Committee, reported that the budget for 2006/2007 was under spent
and as agreed at the December Board meeting the balance had been carried forward to 2007/08. He also reported that the May 2007 forecast was in line with the 2007/08 agreed budget. It was noted that Partner contributions for 2007/08 would remain at a similar amount to 2006/2007.

3. Office for Strategic Co-ordination of Health Research (OSCHR) update

Liam O’Toole was invited to update the Board on the progress with the establishment of OSCHR. He highlighted the following issues:

- Two meetings of the Interim Oversight Group had taken place.
- Initial priority had been to establish the Translational Medicine Board
- For the Translational Medicine Board the membership and terms of reference were currently being finalised.
- A number of joint MRC/NIHR working groups were being established develop plans to implement the new institutional arrangements.
- The Comprehensive Spending review bid had been submitted and the results should be known in October.
- The OSCHR office had now been set up in the Treasury building.
- A stakeholder meeting was planned for the 19 June 2007.
- A communication plan would be formulated shortly.

The Board welcomed the degree to which the MRC and the NIHR were working together and how quickly the new working arrangements were being put in place. The Board also welcomed receiving a regular update on OSCHR and a more in-depth discussion on the implications for the UKCRC’s work at a future Board meeting.

In discussion the Board raised the question of how patients and the public, as a key stakeholder group, were going to be involved in the new structures being established, particularly in the set up of the boards focusing on clinical trials and methodology. The Board noted that both the MRC and NIHR had well developed approaches to patient and public involvement and this should flow through the joint working being established under OSCHR.


Professor Bob Stout presented Northern Ireland’s new R&D Strategy Research for Health and Wellbeing 2007-2012 to the Board. The Board noted that Health and Personal Social Services (HPSS), which was the Northern Ireland equivalent of the NHS in England, would become “Health and Social Care” (HSC). Also the Board noted that as Northern Ireland was small compared to its UK counterparts and so it had concentrated on prioritising and delivering on a small number of key issues. Specifically, the strategic priorities include:

- Developing an enabling infrastructure, including the Clinical Research Support Centre which was established in 2002 and had a similar function to the UKCRN Coordinating Centre and the Comprehensive Research Network. The Board noted that the considerable success resulting from pump priming activities and the significant returns HPSS had seen in terms of subsequent grants received.
- Building research capacity through a portfolio of schemes and initiatives including bursaries and continuing professional research
- Funding HSC R&D
• Supporting innovation through dissemination activities and Health and Personal Social Services Innovations
• Ensuring patient and public involvement (PPI) in HSC R&D through UKCRC PPI activities, committee training and workshops
• Building links and collaborations, including those with the Republic of Ireland and internationally
• Prioritising work on clinical and translational research, HSC Services Research, Primary Care, Allied Health Professionals, Nursing, Pharmacy and Social Care

The Board noted that the strategy had developed from the initial R&D strategy published 7 years ago and discussed the funding opportunities open to universities in Northern Ireland. They welcomed the formal and informal links that were being successfully forged across the UK and Ireland. Nick Partridge offered INVOLVE’s support to the programme of work.

5. Development of a UK Brain Banking Framework  UKCRC/07/16

Declan Mulkeen, MRC, outlined the importance of the use of human brain tissue in research. He reported that although there were a number of Brain Banks in existence throughout the UK, funding was not generally secure or sustainable with most longer-term funding being provided by the MRC or charities. Many banks had evolved to meet local research needs and consequently there was little co-ordination between banks and no overarching national strategy for the collection of human tissue was in place. For users in the research community, this had raised questions regarding accessibility, utility and comparability of tissue and data from different banks.

In response to the concerns raised by the research community, MRC had held a workshop in October 2006, chaired by Professor Chris Kennard from Imperial College, involving a wide variety of interested stakeholders. The main recommendation from the workshop was that a national brain banking strategy should be developed. In February 2007, a meeting of UK funders was convened to discuss mechanisms by which this could be taken forward. In principle, funders were willing to consider contributing additional funds (without commitment) to achieve collective goals. It had been agreed at this meeting that MRC would take the lead and that the initiative would be jointly owned by participating organisations and would ideally be carried out under the umbrella of the UKCRC.

There was general agreement and support from the Board to establishing a national network of brain banks to improve coordination and efficiency and the Board endorsed the initiative as a UKCRC activity. There were several existing platforms on which to build, including the MRC existing banks, the Brains for Dementia Research Network, the clinical research networks and banks funded by other organisations. In addition there was the opportunity to work closer with UKCRN (Dendron).

An expert Strategy Advisory Committee was currently in the process of being established with an independent chair, Professor Jonathan Montgomery, University of Southampton. The Board were pleased to note that the NHS R&D, Industry and Charity sectors were represented on the Committee and that patient and public involvement strategy would be taken on board to ensure due consideration was given to patients and their families. It was noted that there was scope to expand the membership as appropriate.

Activities

6. Public Awareness and Patient and Public Involvement  UKCRC/07/17
a) Patient and Public Involvement – update

Roger Wilson, Chair of the UKCRC’s Patient and Public Involvement Project Group, reminded the Board of its commitment to pursue a joint strategy to promote patient and public involvement in research. He acknowledged the expertise and leadership in this area already being provided by organisations such as INVOLVE. He summarised the work that the UKCRC has undertaken to date, identified current challenges and outlined the focus of future work.

A number of posts have already been created across the 4 health administrations in the networks with specific responsibility for leading on and supporting patient and public involvement activities. Working groups had been formed across the networks and in the UKCRC to agree on and prioritise activities, share learning and providing support. Patients and the public were being recruited and were involved in steering groups, oversight committees, study adoption panels, clinical studies groups, commissioning boards and other groups. A number of resources were being developed to support people in these activities such as the generic and topic specific courses organised by the UKCRN Training and Education team. It will be important to evaluate the impact of patient and public involvement in the UKCRC both to capture the learning and to develop future activities.

There were a number of current challenges that included:- developing and supporting patient and public involvement in the Primary Care Research Network and the 25 Comprehensive Local Research Networks, continuing developments in the topic specific networks and ensuring that the impact of patient and public involvement in the UKCRC and the networks was both monitored and evaluated.

The Board has previously agreed to develop a patient and public involvement strategy and this forms part of the 2007/2008 Workplan. A small working group has been established to agree upon and oversee the process of developing the strategy. This will be supported by the UKCRC Patient and Public Involvement Project Group and has been endorsed by Sally Davies, as Chair of the UKCRC. An update on progress will be made at the Board meeting in September with a full report and draft strategy expected by the end of the year.

The strategy will be developed in response to a number of key questions. How can patient and public involvement enable the UKCRC to achieve its strategic aims? With reference to the UKCRC’s agreed work plan, where will PPI make the most difference? What role should the UKCRC play in promoting and supporting PPI across the wider clinical research environment? What are the opportunities and challenges in fulfilling these roles?

The Board noted that although a project-based approach had been appropriate to the UKCRC’s developing needs over the previous two years it was now timely for the UKCRC to develop a coherent strategy on PPI in support of the implementation programme in its key work streams.

b) Public Awareness – update

The Board received an update paper on the UKCRC’s public awareness work and Matthew Hallsworth, the UKCRC Head of Communications, highlighted two items for the Board:

- The progress of the project to signpost to currently available educational resources on clinical research to support the teaching of the science curriculum in the UK. The team at the Centre of the Cell, working on behalf of the UKCRC, have scoped resources currently available in this area, examined the requirements of the science curriculum and the different science syllabuses, investigated what students already know about
clinical research, and worked with teachers to find out the types of materials they like to use and what they need to meet the demands of the curriculum. The next step will be to identify any unmet needs. In parallel the team are developing the web module that will sign post to resources that are currently available in this area.

- A diary note for a stakeholder event to jointly launch the MRC and Wellcome Trust studies on public perspectives on research governance and the use of personal health information for research. The event will take place on Tuesday 26 June at the Wellcome Collection, Euston Road starting at 6.30pm.

7. Streamlining the Regulatory and Governance Environment

a) Regulatory and Governance – update  

The UKCRC Board noted progress being made on work to streamline the regulatory and governance environment.

b) UKCRC Regulatory and Governance Advice Service  

Dr Sarah Dickson presented an update on the development and UK-wide roll out of the UKCRC Regulatory and Governance Advice Service, which is funded by NIHR and coordinated by the UKCRN Coordinating Centre and the MRC Regulatory Support Unit. In particular the Board noted that the Advice Service:

- Was developed in response to complex and changing regulatory and governance environment
- Is built around the NIHR Advice Service announced in the DH Strategy Best Research for Best Health on a UK-wide basis
- Provides support for local advice providers, such as staff in health service or university R&D departments
- Covers all aspects of health research and regulation
- Is supported by a network of regulators, governance bodies and policy makers such as the Medicines and Healthcare products Regulatory Agency, Human Tissue Authority, National Research Ethics Service and the UK Health Departments
- Was piloted at a number of sites across the UK between September 2006 and March 2007 in order to evaluate and improve query handling processes, response times and resource requirements. A report of the pilot project is publicly available on the UKCRC website
- Is being rolled out across the UK through a series of regional roadshows for local advice providers accompanied by publicity
- Has a dedicated website, which provides a route for submitting queries and accessing online resources including toolkits and a question and answer resource.

The Board welcomed this very important initiative and agreed the importance of highlighting the availability of resources such as this to the research community.

8. NIHR Information Systems update  

The Board heard an oral report of progress from Steve Walker of the NIHR Information Systems Programme. During the presentation the following points were made:

- UKCRN and NIHR IS activities have been combined in a single programme
- A number of robust governance and stakeholder mechanisms are being established
• A strong team has been created to implement the programme
• The Portal will be launched within the next few weeks. The intention is to present a single point of entry to all the underlying services for all users and groups
• A number of risks were highlighted, particularly those associated with rapid change and communications/public relations
• Operational relationships have been established with the UK administrations. To promote systems integration across the UK, the intention is to openly publish all documents and to build generic solutions available for use by a number of different user groups.

The Board noted and approved the establishment of the governance arrangements for this work.

During the subsequent discussion the importance of harmonisation with external resources and websites was raised. Steve Walker noted that the portal was already intended to present several different data sources through a common interface and agreed that a priority should be to eliminate duplication of effort or information. He further reported that a meeting had been instigated to discuss common data standards with the Research Councils.

The Board thanked Steve Walker for his presentation.

9. Building up the Infrastructure in the NHS

a) UKCRN – update paper UKCRC/07/19

Russell Hamilton reported that the Board Sub Group for the UKCRN wished to raise the issue of data standards with the Board. At the recent Board Sub Group meeting, members emphasised the importance of unifying data definition and standards across services and research. There was concern that there is currently no specific forum for discussion and activity towards this crucial goal.

The Board noted the importance of developing data standards across services and research and it was noted that the existing NHS data dictionary and SNOWMED CT (recommended for use by CfH) are not sufficiently detailed enough for both the purposes of clinical data capture and the needs of research. Furthermore, the current NHS Information Standards Board approves data standards but does not develop new standards and a strategic approach to developing data standards is needed.

John Williams agreed to prepare a paper for the next Board meeting identifying what is needed and who are the relevant partners.

b) Update on the Comprehensive Research Network Oral

The Board received a report from Professor Peter Selby, Joint Director of the UKCRN, in which he updated the Board on the progress being made in establishing the Comprehensive Research Network (CRN) in England. He explained that the CRN is being implemented quickly to enable a more rapid introduction of better treatments and care for patients and to minimise disruption for staff.

Professor Selby reminded the Board that the CRN is the third phase of the introduction of clinical research networks to provide the NHS with infrastructure to support clinical research. The CRN is composed of 25 Comprehensive Local Research Networks (CLRNs)
which will streamline the research management function and reduce bureaucracy where possible. The CLRNs are inclusive of all healthcare, and from April 2009 will be the main route for NHS service support for clinical research.

The Networks are lead by a Clinical Director, Network Manager and core team. Each CLRN reports to a Network Board and the CLRN Host Organisation is responsible for services such as finance and Human Resources. Through these structures it is hoped that the CLRN will achieve a balance between national standards and consistency, and local ownership and control. The implementation of the management structures should be completed by October 2007.

The resources for the CLRN are being rolled out in two stages. Stage one (2007/08) will be allocated to all networks as soon as possible and is based on a per capita allocation. From April 2008 resources in Stage 2 will be activity based rising to £90 million per annum.

Professor Selby reminded the Board that the UKCRN Portfolio is a national register of all eligible studies including multi-centre and single centre studies, and commercial and non-commercial ones. In England, DH has defined ‘eligible’ for the NIHR portfolio, and there are also Portfolios in Northern Ireland, Scotland and Wales with an aim of UK-wide working within portfolios.

The current UKCRN Portfolio is based on the Topic–Specific Clinical Research Networks (TCRN) and the Primary care Research Network. The provisional NIHR Portfolio for CRN has been developed using the UKCRC research categories. It is currently being refined and further study information will be added for identified studies by September 2007. It is hoped to be able to obtain a picture of accrual data by October 2007.

Other work in progress includes further discussions on Network Groups to provide subject-specific portfolio development and a framework for UK-wide collaboration between Networks. Strong UK-wide links exist between the TCRNs and their counterparts and these must be maintained and strengthened, and other links must be formalised where necessary.

In discussion, several issues were clarified: Patient/Public Involvement (PPI) in the networks is being developed in parallel with the management structures and a PPI representative will be included on the UKCRN Board; peer review is the responsibility of the funders and not the UKCRN; the balance of clinical trials and other well designed studies in the portfolio is not directive and is currently one third trials and two thirds other well designed studies.

c) Experimental Medicine – update paper

The Board noted that work was continuing with the Experimental Medicine database project – with UKCRN working on behalf of the UKCRC Partners to develop a UK-wide database of expertise and capability in Experimental Medicine.

It was reported that the project management group had recently met, with representatives from the MRC, Department of Health, Cancer Research UK and Wellcome Trust. At the meeting, the project timetable had been revised to incorporate a new launch date of autumn 2007. It had been agreed that the initial launch (Phase 1) would include details of NIHR Biomedical Research Centres, CRUK Experimental Cancer Medicine Centre, MRC Translational Medicine Centres, Wellcome Trust CRFs and the CRFs established under the UKCRC Coordinated Initiative. A subsequent Phase 2 version would include details of industry and other Experiment Medicine facilities.
10. Building up the Research Workforce

a) Building up the Research Workforce – Update Paper UKCRC/07/21

The Board was asked to note progress with the implementation of the Integrated Academic Training Programme for doctors and dentists. Thanks were given to Paul Hubbard for HEFCE’s funding of the Clinical Senior Lectureships. The Board acknowledged that there have been issues with MTAS, but the effects on the quantity and quality of trainees is yet to be determined. It was agreed that the Board would feed back on this to John Took.

(b) Report of the UKCRC Sub Committee for Nurses in Clinical Research Oral

Dr Liam O’Toole reported to the Board that the response to the public consultation of the nurses’ report had been overwhelmingly positive, and that the Finch Committee had met to consider the responses and had amended the draft report in light of the responses.

The Board gave its endorsement to the report, but raised the following issues:

The Department of Health (DH) welcomed the report and supported Christine Beasley and the other Chief Nursing Officers, in applying for funding of the implementation of the recommendations under the Government’s Comprehensive Spending Review (CSR). However, with respect to recommendation 4, NIHR would only be able to fund the research content part of the training programmes.

In summary, the Board welcomed and endorsed the report and supported the Chief Nursing Officers in their bid to secure CSR funding for implementation of the recommendations.

The Board was asked if it was content for the report’s recommendations to apply to Allied Health Professionals as well as nurses, or whether a new, similar piece of work should be done for them. The Board gave its support for application of the recommendations made within the Nurses’ report to the Allied Health Professions, but acknowledged that while the principles of the report could be applied to the Allied Health Professionals, the numbers quoted in the report may differ. The Board agreed that another large consultation process would not be necessary for the Allied Health Professions.

11. NHS IT Systems UKCRC/07/22

The Board was asked to note progress in this area. In particular that since they last met:

- The report of the R&D Advisory Group to Connecting for Health had been published on the UKCRC website on 7 June along with a letter of support from Lord Hunt, Minister for State for Quality at the Department of Health

- The Office for Strategic Co-ordination of Health Research (OSCHR) has proposed an E-Health funding stream as part of the current CSR Bid. In parallel, CfH have made a complementary bid for Capital expenditure via CSR. The results of these bids will not be known until the final CSR settlement is announced

- Discussion is ongoing in the Department of Health, England regarding the appropriate governance and structure for a programme of work. In order to keep the momentum going, following the publication of the report, the UKCRC is developing an interim programme of work
• The report of the research simulations had been shared with members of the House of Commons health select committee who were seeing evidence on the Electronic Health Record. The Board received a summary of proceedings of the 7th June 2007 evidence session where members of the UKCRC R&D Advisory Group to CfH and one of the simulation leads presented the case for research

In discussion Board Members stressed the importance of public involvement in future activities. Industry representatives stressed the importance of rapid progress in this area – in light of the advances being made abroad.

The Board noted that there are essentially two elements of work to be taken forward: the NHS CfH project managed activity with NHS CfH and the federation of databases which would offer an opportunity to ensure that UK-wide aspects of this initiative be actively pursued. They noted that a “Next Steps Working Group” would be established to contribute to future work in this area.

12. Coordinating Research Funding - update paper  UKCRC/07/23

It was reported that the analysis of the research portfolios of medium and smaller AMRC medical charities was well advanced and that results would be presented at the September Board meeting.

13. Developing Incentives for Research in the NHS  UKCRC/07/24

The Chief Scientist Office wished to inform the Board of the changes in the provision of Excess Treatment Cost in Scotland and that these changes were at present experimental. The Health Departments for England, Northern Ireland and Wales also provided an overview of their current Excess Treatment Cost arrangements for information.

14. Any other business

No issues were raised.

Next Meeting: 14:00 - 17:00, 20 September 2007, Himsworth and Fletcher Rooms, UKCRC, 20 Park Crescent, London, W1B 1AL