MINUTES
UK CLINICAL RESEARCH COLLABORATION
BOARD MEETING 20 September 2007

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

Present

Members

Professor Sally Davies – Department of Health (DH) (Chair)
Jane Austin – NHS Confederation
Richard Barker – The Association of the British Pharmaceutical Industry (ABPI)
Professor Sir Alasdair Breckenridge - Medicines and Healthcare products Regulatory Agency (MHRA)
Simon Denegri – Association of Medical Research Charities (AMRC)
Dr Diana Dunstan – Medical Research Council (MRC)
Glyn Edwards – BioIndustry Association (BIA)
Dr Kenneth Fleming – Universities Representative
Dr Russell Hamilton –Department of Health (DH)
Harpal Kumar – Cancer Research UK (CRUK)
Dr David Lynn – Wellcome Trust (WT)
Professor Patrick Maxwell – The Academy of Medical Sciences (AMS)
Dr Catriona McMahon – Senior Representative from the Pharmaceutical Industry
Professor Adrian Newland – Academy of Medical Royal Colleges (AOMRC)
Dr Liam O’Toole – UK Clinical Research Collaboration (UKCRC)
Nick Partridge – INVOLVE
Professor Peter Littlejohns – National Institute for Health and Clinical Excellence (NICE)
Andrew Russell - Patient/Public Member
Mike Stevens – Scottish Executive Health Department
Professor Bob Stout – Research and Development Department for the Northern Ireland Health and Personal Social Services
Professor John Williams – Welsh Assembly Government

Observers/Invited

Dr Louise Wood – Department of Health (DH)
Dr Helen Campbell – Department of Health (DH)
Sarah Fox – Department of Health (DH)
Catherine Johns – Department of Health R&D (DH)
Nancy Lester – UK Clinical Research Network (UKCRN)
Announcements and Apologies

Apologies
John Bell, Chair of OSCHR
Peter Arnold, ABHI
Candy Morris, SHA
John Neilson, DIUS
Paul Hubbard, HEFCE

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

Attending the UKCRC Board for the first time were:

- Harpal Kumar, in his capacity as Chief Executive of CRUK.
- Dr Kenneth Fleming (Medical Sciences Division, University of Oxford) who attended in place of Professor Sir John Tooke as the representative from the University sector.
- Andrew Russell, the alternate public/patient member attending in place of Jenny McKibben. This was the first meeting with formal patient/public representation.
- Mike Stevens, deputy director of the Chief Scientist Office in Scotland attending in place of Alison Spaull.

It was noted that this was Professor Patrick Maxwell’s last meeting. The Academy of Medical Sciences would appoint a successor in due course.

1. Minutes of the Twelfth UKCRC Board Meeting UKCRC/07/25

The minutes were approved as a correct record of the meeting held on 7 June 2007.

UKCRC General

2. Chief Executive’s Report UKCRC/07/26

Liam O’Toole reminded the Board that a key priority of the communication’s strategy is to raise awareness of emerging health research environment in the UK amongst different stakeholder groups. A number of activities were highlighted:

- As part of the communications cascade the UKCRC Secretariat had been meeting with the Partners’ communication teams to update them on issues that would affect their stakeholder groups.
The UKCRC had run a number of joint workshops with Partner organisations designed to promote practical ways for target groups to engage with the new infrastructure. In particular, workshops had been held with the AMRC and Contract Research Organisations focusing on understanding career structures and the UKCRNs.

A series of powerpoint slides were now available on the UKCRC website to download for stakeholders wishing to describe the activities of the Partnership.

As part of international profile raising the UKCRC had been invited to give the keynote speech at the 2007 Hong Kong Research Symposium. This was an outcome of the Secretariat assisting the Hong Kong Government Health Wealth and Food Bureau analyse their health research portfolio.

**UKCRC Budget Report**

As a matter of routine prior to the Board meeting the Secretariat had provided the Budget Committee with a financial report detailing spending in the first quarter of 2007/08 and a 2007/08 budget reforecast.

Nick Partridge, Chair of the Budget Committee, summarised the key points from the report. The August reforecast showed a revised projected spend for the 2007/08 financial year of 10% less than previously predicted. Many of the savings that had been made were due to an increased efficiency in the operation of the Secretariat and reflected effective joint working by Partners. It was noted that the under spend at the end of the financial year was projected to be at least £280k. The Budget Committee would consider options for this surplus following the Board discussions on the long-term role of the UKCRC.

### 3. Long term role of the UKCRC

The UKCRC has been operational for three years. It had previously been agreed that, following the initial change leadership phase, the Partnership would review its role to take into account changes in the health research environment. At the previous meeting the Board agreed that with the recent establishment of OSCHR it would be timely to consider the long term role of the UKCRC.

#### 3.1 Feedback from discussions with Board Members

Liam O’Toole summarised the main points that had been raised in discussions with Board members. Feedback was generally very positive on the Collaboration’s achievements to date and the majority of Board members highlighted the developing culture of joint working and shared ownership of the UKCRC agenda as being particularly important. Other areas highlighted as particularly important by members included:

- establishment of a forum with broad stakeholder engagement;
- establishment of the clinical research networks;
- new academic career structures;
- the UK Health Research Analysis;
- joint funding initiatives including in public health and microbiology and infectious diseases; and
- patient and public involvement (PPI) and engagement.

Areas where work was underway but significant progress was not yet visible were:

- incentives in the NHS;
• Regulation and Governance (R&G) where the work was ongoing, and
• the use and development of metrics to monitor and demonstrate changes in the clinical research environment.

There was general agreement amongst Board members on the following key elements needed for the future:
• The UKCRC workplan should be completed
• There was a need to measure and monitor performance and impact
• Overlap with other coordination bodies should be managed with efficient use of resources
• The UKCRC way of collaborative working needs to be maintained
• Changes in UKCRC and its ‘branding’ needs careful handling
• Continued need for some type of broad stakeholder strategic forum to -
  o major strategic issues
  o monitor the research environment
  o hold each other to account

Board members were keen to maintain the UKCRC way of joint working exemplified by a number of joint UKCRC funding initiatives. As a result of these experiences the Secretariat has developed guidance for establishing joint funding initiatives which have been published on the UKCRC website.

The Board agreed that the paper accurately reflected discussions with members.

3.2 Role of OSCHR

The roles of UKCRC and OSCHR were compared. It was highlighted that OSCHR’s role was the strategic coordination of government funding agencies, whereas UKCRC had a cross-sectoral coordination role. OSCHR was a Government Office jointly run and funded by DH England and the DIUS. The OSCHR Board had officers from DH, NIHR, DIUS, MRC, a single Devolved Administration representative and independent chair with three “non-executives”. These latter brought experiences from a range of different sectors but were not representative of them.

The major roles of OSCHR were:

• Alignment of MRC, NIHR and other government funded health research agencies with a single integrated strategy
• Effective cross working between government agencies, retaining clarity for the research community
• Elimination of unnecessary duplication and redundancy
• Enhancement of capacity for translational & public health research

The focus of OSCHR’s work will be to ensure alignment between Government funders in a single integrated strategy. However, in keeping with the Cooksey recommendations to “encourage a stronger partnership with the health industry and charities”, MRC, NIHR and members of the OSCHR Board were committed to partnership working and stakeholder engagement in the development and implementation of a single strategy. This engagement will more often than not be carried out by the funding bodies themselves rather than be a role of the OSCHR Office. Similarly, whilst the OSCHR Board and OSCHR Office will wish to encourage coordination and collaboration with non-government funders, the Office itself will not carry out this coordination role.
The areas of the UKCRC Workplan where OSCHR was likely to provide the focus of activity for government funding were highlighted:

- Strategic partnerships in research funding
- Research infrastructure
- Oversight of E-health
- Research careers

The areas of UKCRC activity that would not be provided by OSCHR were:

- The OSCHR Board will not provide a multi-stakeholder forum
- OSCHR will not play an active role in streamlining the regulatory and governance environment
- The OSCHR Office is unlikely to have a role in coordinating public awareness and public engagement activities

3.3 Model for long term role

The Board turned to the proposed models for the future role of the UKCRC. The two options were a synthesis of the views of the members:

- Option one - the UKCRC continues in its current form until the end of 2008 and then discontinues. Ongoing work would then be led by individual partners. Partners would continue to use the UKCRC way of working for joint initiatives.

- Option two - the UKCRC continues in its current form until the end of 2008. From 2009 the UKCRC should move into a second phase to review and monitor progress. It would continue to identify major new strategic issues and agree how they were tackled and hold each other to account. The Board would meet less often but continue to provide an umbrella for coordination of the agreed activities such as PPI or public awareness. The UKCRC would maintain a smaller secretariat dictated by the level of activity agreed by the Board. These arrangements should be reviewed after two years.

It was noted that the UKCRC was the only forum for addressing issues outside the remit of OSCHR and performed coordination roles that would not be addressed by OSCHR. There was concern that if UKCRC was discontinued immediately after 2008 it would send the wrong message to the clinical research community, both in the UK and internationally, suggesting that there was no longer Government backing or the UKCRC considered its job to be completed.

Other issues raised in discussion included:

- The importance of the UK-wide remit of the UKCRC was stressed
- Much of the work set out by the Research for Patient Benefit working party had yet to be completed
- Continued strategic oversight of the research networks was important
- The UKCRC had begun to affect cultural change but this process was not complete and required more than three years
- The role of the Secretariat would diminish with time, however the Partnership should remain and individual Partners would take on responsibility to lead on joint activities.

Industry Partners highlighted that whilst the long term competitiveness of UK industry was important, the short term must not be neglected as global companies were impatient to see improvements in the clinical research environment in the UK.
Sally Davies summarised that there was no support for option 1 but strong support amongst the Board for the continuation of UKCRC past 2008. After that time the UKCRC should evolve along the lines of option two although it was still too early to judge the exact size and nature of the activities that would continue. This would become clearer as the OSCHR strategy beds down. It was proposed that the long term role of the UKCRC should be a standing item on the Board Agenda and the exact nature of future activities should be discussed at the next Board meeting. A formal review of the long term role of the UKCRC should be conducted after two years in autumn 2009.

The Board devolved the responsibility for extending staff contracts in line with the agreed workplan to the Budget Committee.

4. OSCHR Update Paper UKCRC/07/28

Liam O’Toole presented an update on OSCHR activities and informed the Board that Professor John Bell had been formally appointed as Chair of OSCHR. The Appointments Commission were in the process of carrying out a recruitment exercise on behalf of DH/DIUS to appoint 3 Independent Members to the Board. It was anticipated that the interviews would be before the next meeting of the Board/Interim Oversight Group in October.

The main areas of OSCHR activity were:
- The Translational Medicine Board (TMB) which had met twice.
- Public Health - this would be overseen by the Public Health Research Board but was at a much earlier stage than the TMB and had not met yet.
- E-Health – this would follow later.

The priority for OSCHR was to progress the plans for the Translational Medicine Research Strategy. MRC and NIHR had been working together in 3 joint working groups: Experimental Medicine (MRC lead); Methodology (MRC lead) and Clinical Trials/Evaluation (NIHR lead) to achieve this. The TMB was responsible for the oversight of the strategy development and was currently drafting a Strategy Development Document which outlined the overall aims of TMB. The document would be sent to UKCRC Board members, in confidence, over the next month to give members a chance to provide feedback. OSCHR were keen to engage with stakeholders and a number of focused stakeholder engagement workshops, aimed at coal face Research Management groups had also been held.

The Board was informed that the level of funding for the single health research fund for the 2008-2011 period would not be known until the DH Comprehensive Spending Review (CSR) 2007 settlement and the MRC’s allocation from DIUS was announced.

The Board was updated on the OSCHR office arrangements. Recruitment of staff would take place shortly however it was unlikely staff would be in post before early 2008. It had been proposed that in the interim, if time was available, UKCRC staff could be contracted to assist in specific pieces of work for OSCHR. Nick Partridge, chair of the UKCRC Budget Committee, reported that the Budget Committee had discussed this and agreed that there was sufficient capacity within the Secretariat to resource OSCHR work without compromising the ability to deliver the UKCRC workplan. The DH, as host department, would reimburse UKCRC for any work undertaken by UKCRC staff on behalf of OSCHR.
5. Information Standards for Clinical Records  

John Williams presented a discussion paper on information standards in health research and healthcare that had been drafted in response to discussions at the previous Board meeting. The Board noted that:

- The paper focused on bringing operational data from clinical practice to support research from the information standard perspective and not from a technical perspective.
- The simulations conducted by the R&D Advisory Group to Connecting for Health (CfH) had demonstrated that the secondary use of data was very valuable at population level. However, data quality was not good enough at individual patient or practitioner level.
- Long term prospective studies would need agreed information standards that were applicable across the UK.
- There was a window of opportunity at the moment as CfH had engaged proactively with the professional bodies and had asked them to specify requirements.
- There was a plethora of data definitions that overlap so there was a need to develop agreed common definitions.

The Board thanked Professor Williams for preparing the paper and following discussions agreed that:

- This was an important issue and something needed to be done
- There was a role for the UKCRC in this issue but the UKCRC could not lead on it
- Developing and agreeing common data standards would need involvement from a range of organisations
- Ownership from the Academy of Medical Royal Colleges was crucial and they should be encouraged to take a lead.

It was agreed that a joint UKCRC and AMS approach would be made to the Academy of Medical Royal Colleges in collaboration with Connecting for Health. Adrian Newland would raise the issue with the Academy of Medical Royal Colleges.

6. The Use of Personal Health Information in Medical Research  

Nick Partridge briefly summarised the findings of two studies commissioned by the MRC and the Wellcome Trust, examining public perceptions on the use of personal health information. He highlighted that we now had empirical evidence that there was greater public support for medical research which was based on the two pillars of anonymity and consent.

The Board were asked to consider a number of questions:

- What do the findings of the two studies mean and how do they relate to the recommendations of the Academy of Medical Sciences report on Personal Data for Public Good?
- What do researchers/research managers/commissioners need to do differently?
- What do we now need to do to raise public awareness of clinical research?
- How can the Collaboration help to facilitate this work?

The following points were made in discussion:

- The Wellcome Trust, working with the MRC and other funders, had issued a funding call for proposals for the development and use of electronic resources in health research. This included an open stream on public engagement activities around this issue. A workshop was planned for November to bring interested parties together.
• There may be mileage in developing a research record guarantee that could sit alongside the Care Record Guarantee, although it would be important to ensure that this did not develop into something that was overly restrictive.
• Engaging with professional audiences was also felt to be important, in particular with GPs who were seen as the ‘gatekeepers’ to personal data. The need for a communications campaign targeted specifically at GPs, working closely with the GPRD and the primary care networks, was highlighted as an important step forward.
• It was noted that the engagement and communication issues being discussed are different to those being addressed by the ongoing UKCRC patient and public involvement strategy and that they required a distinct work stream.
• It was noted that results of the studies showed that low numbers of participants appeared to be supportive of the use of their personal data for commercial research. It was agreed that industry had an important role to play in providing the information to support engagement with, and assurances to, the public.

In summary the Board agreed that this area needs a joint approach in order to make a real difference. The use of personal health information for research would be one important focus of a restructured overall public awareness strategy for the Partnership, but it would be important to ensure that this included work with the research community to help them to engage with the public more effectively.

The MRC agreed that there was still much work to do in this area and were keen to play a role in taking this work forward.

It was agreed that Nick Partridge would work with the Secretariat to develop a public awareness strategy to take forward the issues discussed, alongside exploring ways of working with the research community to promote standards in the use of personal data.

Activities

7. Public Awareness and Patient and Public Involvement
   - Update Paper

The Board noted progress reported in the update paper.

Simon Denegri reminded Board members that work to develop a UKCRC patient and public involvement strategy was underway. In October, two workshops will take place to elicit views and ideas from patients and the public who have experience of public involvement in research. Simon Denegri would shortly be undertaking telephone interviews with Board members.

8. Streamlining the Regulatory and Governance Environment
   – Update Paper

The Board noted progress made in this area and Janet Valentine highlighted two developments in particular:
• A statement had been published on the UKCRC website stating the UK Health Departments’ commitment to harmonise their systems for streamlining R&D permission in the Health Service. This will be achieved through development of a way of working where there was mutual acceptance of each others systems so that activities were not duplicated.
An event, hosted by the UKCRC and Universities UK, will be held on 30th October to introduce the UK-wide adoption of the Research Passport as standard working practice between NHS organisations and non-NHS employees who were conducting research in the NHS.

9. **Building up the Research Workforce – Update Paper**  
**UKCRC/07/33**

It was noted that the report of the UKCRC Subcommittee for Nurses in Clinical Research (Workforce) ‘Developing the best research professionals’ was published in August. Implementation of the recommendations made in the report was dependent on the outcome of the Comprehensive Spending Review (CSR). Sally Davis advised that she had agreed to meet with the Chief Nursing Officer to discuss the implementation of the recommendations following the CSR settlement.

The Board noted updates on the proposals for the third round of Academic Clinical Fellowships and Clinical Lectureships for 2008 and the results of the 2007 In-Practice Fellowships. The Board welcomed the news that in 2008 clinical research positions would be appointed before the general tranche ensuring that the very best applicants could apply for academic positions.

10. **Building up the Infrastructure for Research in the NHS**

a) **UKCRN – Update Paper**  
**UKCRC/07/34**

The Board noted the update from the UKCRC Board Subgroup for the UKCRN which summarised progress.

Russell Hamilton reported that at the last meeting of the Board Subgroup it was noted that the networks were experiencing difficulties in obtaining comprehensive data on studies run through the networks. This information was crucial for measuring performance of the networks and providing service support costs.

The Board agreed that it was important for the funders to support the UKCRN in obtaining this data from the research they fund. This issue would be discussed further at the next meeting of the UKCRC Research Funders Liaison Group.

b) **Experimental Medicine - Update Paper**  
**UKCRC/07/35**

The Board noted the progress on Experimental Medicine reported in the update paper.

Russell Hamilton raised the issue of quality of local independent Clinical Research Facilities which had not been established through UKCRC Partners’ peer reviewed processes. It was agreed that it was important to raise standards, promote best practise and avoid duplication of effort in these facilities. The Board agreed that the Partners should work together to address this issue.

11. **Coordinating Research Funding**

a) **Coordinating Research Funding – Update Paper**  
**UKCRC/07/36**

The Board noted the activities reported in the Coordinating Research Funding update paper.
b) Analysis of medium and smaller sized AMRC research charities

Simon Denegri of the Association of Medical Research Charities (AMRC) presented a summary of the analysis of health research funded by medium and smaller sized medical research charities.

The Board was reminded of the preceding UK Health Research Analysis which was the first comprehensive national analysis of health research funding. It was published in May 2006 and encompassed the peer reviewed research of the 11 largest government and charity funders during the 2004/2005 financial year. It included the 3 largest medical research charities (Wellcome Trust, Cancer Research UK and the British Heart Foundation) accounting for over 80% of AMRC members’ research spend.

The new analysis was undertaken to provide a more comprehensive picture of charity sector research funding. For participating charities it offered the prospect of informing their strategy development process and enabling them to collaborate and participate in wider research coordination. It also allowed charities to show transparency and to maximise the impact of the research they fund.

The analysis included 29 medium and smaller sized members of the AMRC and together with the previous analysis extends coverage to 96% of AMRC members’ research spend. It employed the same classification system and robust methodology as the previous analysis and covered the same time period. It included 1496 peer reviewed awards and £64 million of funding.

The analysis presented an overview of the combined research portfolio as well as the profiles of individual participants.

It was noted that the results were already being used by the participating charities and that the analysis was a positive sign of wider engagement by AMRC members. The Board also noted that the results would be particularly useful for those looking for gaps in research funding and areas not covered by the medical research charity sector.

Richard Tiner stated that there was positive support from his members for a similar analysis of pharmaceutical industry research. Initial discussions with several members had taken place and the possibility of a pilot analysis involving one member was being investigated.

The Board agreed that the analysis was an impressive achievement and thanked the UKCRC Secretariat and the supporting teams at AMRC. The report would be launched on the 17th October at the AGM of the AMRC.

12. NHS IT Systems – Update Paper

Liam O’Toole informed the Board that the NHS Capability Programme was a major programme being developed in the Department of Health England, with the aim of addressing the recommendations of the UKCRC R&D Advisory Group to Connecting for Health. A Programme Board had now been put in place to ensure delivery. The Connecting for Health Research Capability Programme will have an External Reference Group chaired by Professor Ian Diamond. The aim was that this should also function as an OSCHR E-Health Advisory Group to provide strategic oversight of E-health research and deliver some “quick wins”. A decision on this would be taken at the OSCHR Interim Oversight Group meeting on 16 October.
The Programme Director and Project Manager were currently being recruited. The Board discussed the item and the research funders agreed to support this initiative and raise awareness within their communities.

13. Developing Incentives for Research in the NHS  Oral

Catherine Johns provided a verbal update in two main areas:

**Clinical Excellence Awards**

Research and Innovation had been included as a separate domain in the criteria for awards in the 2006 and 2007 award rounds and would continue as such for 2008. The award criteria had been reviewed and amended to ensure that they addressed all aspects of R&D appropriately as well as the traditional academic indicators. For example, the influence of research findings on health service practice or policy or on the development of health services was included together with significant participation in multicentre research studies. A specific reference to the use of research evidence was also included in the Developing a High Quality Service domain.

An online application form had been used for the 2007 award round allowing the data to be collected electronically. A formal request had been made to the Advisory Committee on the Clinical Excellence of Awards (ACCEA) secretariat to analyse the data to determine the success of applicants scoring highly in the Research Innovation domain. ACCEA secretariat confirmed that it was unable to analyse the 2006 data but agreed to analyse the data for 2007 and future years to enable trends to be identified.

**GP Quality and Outcomes Framework (QOF) Points**

A number of discussions about QOF points had taken place with the Primary Care community. The establishment of the primary care research network to cover the whole of England meant that every GP now had the opportunity to participate in research and the network had an important role in facilitating this development. It was now highly appropriated for QOF to include research indicators as a measurement of GP practice achievement.

Catherine Johns would be meeting with Professor Tony Kendrick (Academic GP at the University of Southampton), Dr David Colin-Thome (National Director for Primary Care, DH), Professor Paul Wallace (Assistant Director, UKCRNCC and Director of PCRN) and Professor Sally Davies to discuss how to take this forward.

14. Any Other Business

In view of the discussions held on the long term role of the UKCRC (item 3) it was agreed to cancel the December Board meeting. The Board would be kept updated separately on the outcome of the CSR bid and any progress from OSCHR. Additionally, the approval of the 2008/09 budget was delegated to the Budget Committee.

Next meeting: 14.00 –17.00, 27 March 2008, UKCRC, Himsworth and Fletcher Rooms, UKCRC, 20 Park Crescent, London, W1B 1AL