

## Joint Clinical Research Board

Monday 18<sup>th</sup> June 2017

BCI Boardroom, Charterhouse Square

**Present:** Sally Burtles (SB), Mark Caulfield (MC), Jack Cuzick (JC), Sandra Eldridge (SE), Nick Lemoine (NL), Gerry Leonard (GL), Jo Martin (JM) (Chair), Mauro Perretti (MP), Steffen Petersen (SP), Steve Thornton (ST)

**By telephone:** Nick Croft (NC), Deanna Gibbs (DG), Anju Sahdev (AS)

**In attendance:** Sharon Barrett (SBA), Heather Clarke (HC), Elizabeth Clough (EC), Nick Good (NG), Neeta Patel (NP)

**Apologies:** Alistair Chesser, Khalid Khan, Jo Morgan, Costantino Pitzalis, Rakesh Uppal

Agenda Item	Action
<p><b>1. Minutes and actions from the last meeting</b></p> <p>JM opened the meeting. The minutes of the March meeting were agreed. The following actions were addressed:</p> <ul style="list-style-type: none"> <li>(i) NG to include a paper from EC on the June JCRB Agenda. Done – see 3 below.</li> <li>(ii) SB to ensure that Task and Finish Group implementation, including specifically a review of clinical groups and Institute compliance with recommendations such as reporting to JCRB, is undertaken by the JRMO in autumn 2017 and a paper of this brought to the December JCRB 2017 meeting for consideration. JM suggested that if areas refuse to disclose minutes that could be raised as a formal Risk. <b>Ongoing action.</b></li> <li>(iii) GL to prepare a paper for the next JCRB on the overhead policy and principles. GL reported that, in the light of Trust changes (see 4 below) it had not been possible to produce but he would now do so for the next meeting (September). <b>Action.</b></li> <li>(iv) Mike Curtis and JM to agree a joint communication on outcomes of the Task and Finish Joint Implementation Group and to send this round to CAG, Institute and CTU Directors as soon as possible. This was done shortly after the March JRCB.</li> </ul>	<p>SB</p> <p>GL</p>

<p>(v) Any views on matters arising from the proposed Research Misconduct Policy, including points of detail, to SB as soon as possible. SB reported that none had been received.</p> <p>(vi) A meeting to discuss CRF development with relevant stakeholders was to be arranged. SB reported that a meeting of key players on the Whitechapel site had taken place and there was an in principle appetite for a more co-ordinated facility and therefore for making an NIHR funding bid.</p> <p>(vii) NG to add Strategic R&amp;D Risks to the Agenda for the next meeting. Done – see 9 below.</p>	
<p><b>2. Study Metrics</b></p> <p>GL presented a paper ‘R&amp;D Outturn’ with year-end detail for the Trust and outline of a School of Medicine and Dentistry (SMD) dashboard.</p> <p><b>SMD dashboard:</b> GL presented a table summing up SMD activity and asked whether this was helpful? He said there are anomalies in the report but this is intended as a draft.</p> <p><b>Action:</b> Steve Thornton (ST) said he would review this, specifically suggesting targets that JRMO could work to. Others undertook to comment on structure</p> <p><b>Action:</b> A full, end of QMUL FY dashboard for SMD to be produced to the next JCRB meeting in September.</p> <p><b>Trust dashboard:</b> GL went through the detail and the various graphs. It was agreed that tracking to target graphs is helpful. JM congratulated those involved in meeting NIHR targets and said there had been clear progress on this.</p> <p>It was noted that whilst recruitment and retention in NIHR funded posts was up overall there remain issues in JRMO around this.</p>	<p><b>ST and others</b></p> <p><b>GL/ SB</b></p>
<p><b>3. Research portfolio report</b></p> <p>EC presented a paper along the lines of previous discussions. This was warmly welcomed and the board expressed a wish that this full report be presented again in a year’s time, with quarterly 1 page, high-level reports: <b>Action.</b></p> <p>Headline messages: The breadth of research activity is being maintained by volumes are up; commercial activity is up; approvals are up. One concern is that we may be focussing on a comparably small number of individual researchers.</p>	<p><b>EC, HC and successor.</b></p>

<p>EC clarified that the categories used are the IRAS ones and follow what clinical group or Institute the lead researcher is in (ie, they are self-selecting). She said that we, along with many other Trusts, CRN etc, would like to report at a more granular level but DH wants to keep categories high-level; That is an ongoing tension.</p> <p>ST asked how we compare with other NHS Trusts and Universities. EC said that is difficult to determine as data of this sort is neither published nationally nor available in comparable formats. The NIHR and its Networks probably have the best current overview.</p> <p>There was discussion around funding allocations and transparency models.</p> <p>JM thanked EC for her work and, as this would be her last JCRB, wished her a happy early retirement. The board echoed this and hoped that EC’s successor could continue with this work.</p>	
<p><b>4. Trust restructuring</b></p> <p>GL reported that whilst CAGs are no longer formally part of the Trust’s structure the Clinical Boards that will oversee activity, including research, are yet to become operational. Cancer and Surgery have split, as have Women’s and Children’s. It is also as yet unclear how the replacement people for CAG RDs will be selected. This all has oversight and financial consequences. He said he had discussed this with Alistair Chesser and believed that the intention was to move financial responsibility, including for research, back to clinical areas, away from sites. This will mean that reporting to the JCRB will make more sense and that a redistribution policy can be worked out. However it is all work in progress and much of the detail has yet to be resolved.</p> <p>JM said that she will keep the group up to date with decisions. Leaving both RD and Education off the draft structure that has been published serves to illustrate how green much of this thinking is. She said that there are logistical issues around research oversight to be worked through and there needs to be clarity about the local leads for both research and education; who appoints them, how and when.</p> <p>MC commented that research and education need to be seen as core to the business model, not an add-on, if there is to be any hope for transformation. This was agreed by the Board.</p> <p><b>Action:</b> JM will feed back to the Trust that research and education need to be embedded in the structure.</p>	<p><b>JM</b></p>
<p><b>5. LCRN report</b></p> <p>SBA presented the latest report to the Board. She thanked those who had worked with the Network to achieve time to target delivery. The Trust needs to continue to invest in support target delivery. Q1 data suggests that we are currently just over the 80% threshold but efforts need to be kept up.</p>	

<p>SBA reported that the Partnership Board did not approve the Network’s Financial Plan for 17-18 as it involved greater than anticipated cuts. It is being redrafted to move cuts from the generic/ high-level into specific details.</p> <p>NL said that he hoped there would be a study quality metric introduced soon. He felt that would support work at Barts and QMUL where we tend to run more complex studies. There was wide agreement on this point.</p> <p><b>Action:</b> SBA to circulate the revised year-end paper as soon as possible.</p>	<p><b>SBA</b></p>
<p><b>6. Sponsor oversight report</b></p> <p>SB talked to the papers that had been circulated. Overall sponsored and hosted studies seem to be going well but there are some issues:</p> <ul style="list-style-type: none"> <li>• Studies are having to be entered onto 2 systems and the JRMO is helping research teams expedite that.</li> <li>• SB needs to discuss one particular example, where there has apparently been no upload, with JC (<b>Action</b>).</li> <li>• A Freedom of Information request from a journalist, relating to study results being published, has made senior managers realise there a considerable amount of research never reaches the public domain. That was disappointing although, now we have seen the comparative data, it appears that we are no worse than other Trusts and Universities.</li> <li>• All information re last year’s Serious Breach (no stem cell licence) has now been supplied to MHRA.</li> <li>• The database IP issue is now being resolved with a post-award access agreement. JM commented that instances of inappropriate downloading of data have exposed incomplete audit trails. Security of databases is a live issue. She said that research leads need to ensure that databases throughout the College and Trust are managed in accordance with the relevant regulations.</li> <li>• The clinical trials pharmacy at the Royal London Hospital is being evicted and need a home. This is a high risk to research activity.</li> </ul> <p><b>Action:</b> JM agreed to escalate this matter with Estates.</p> <p>NL commented that there is now a risk that we will be unable to undertake research relating to local stem cell storage, owing to the lack of a related licence.</p>	<p><b>SB &amp; JC</b></p> <p><b>JM</b></p>

<p>SE reported that the PCTU MHRA inspection led to no serious findings. This was welcomed.</p> <p>Finally EC reported that the HTA are undertaking an inspection in July. JM asked SB to inform site management team of this.</p> <p><b>Action:</b> SB to inform site management team of the HTA inspection.</p>	<b>SB</b>
<p><b>7. JRMO report</b></p> <p>SB had circulated a report. Key points were:</p> <ul style="list-style-type: none"> <li>• The Trust cyber-attack had a significant negative impact on JRMO performance.</li> <li>• She SB introduced HC who would be covering some of EC’s work for the next few months, whilst undertaking a review of research governance processes. HC will be meeting most key players over the next few weeks.</li> <li>• Our sponsorship processes have been externally reviewed and found to be comparable to those at KCL and Oxford. JM commented that the JRMO is working hard to address concerns that have been expressed about researcher-support.</li> <li>• Research Matters went well, thanks to NP and her team, particularly as they organised the event in the aftermath of the cyber-attack, without the usual IT infrastructure and communications back-up.</li> </ul>	
<p><b>8. CRF update</b></p> <p>SB said that the team were still struggling with site local management and Estates issues. Currently they are waiting for the RLH site team to sign-off on CRF SOPs. Issues of concern include oversight and accountability around out-of-hours working.</p>	
<p><b>9. Strategic R&amp;D risks</b></p> <p>NG had circulated a report that recently went to the Trust’s Risk Management Committee (RMC). Existing risks, ratings and ongoing mitigation were discussed and agreed. This included that a risk around time to targets (see 5 above) was now as low as possible and can therefore be closed.</p> <p><b>Action:</b> NG to update the risk register to move forward review dates and close the named risk</p> <p>Concern was expressed that a risk proposed by the JCRB in September 2016 around provision of imaging facilities had someone been rejected. NG explained that it had not been rejected by the RMC but had somehow been passed to the CSS Board who</p>	<b>NG</b>

<p>had rejected it for lack of information. JCRB directed that the risk should be reinstated on the Trust's DATIX risk management system, to be owned by GL and JM on behalf of the JCRB.</p> <p><b>Action:</b> NG to set up a new risk and to ensure timely review of this.</p>	<p><b>NG</b></p>
<p><b>10. BRU capital</b></p> <p>JM reported that £1m awarded to the Trust by the NIHR to pay for a new CT scanner for the Biomedical Research Unit (BRU), now Biomedical Research Centre (BRC), was no longer needed for that purpose. The Trust had 3 options:</p> <ul style="list-style-type: none"> <li>(i) Buy another CT scanner (unnecessary);</li> <li>(ii) Absorb funds back into the Trust; or</li> <li>(iii) Use that money to support research.</li> </ul> <p>There was a full discussion of this. The Board was unanimous in its request to the Trust that the money be used to support research. They agreed that the priorities are cardiac and imaging, since these are BRU elements and the Trusts BRU (not QMULs) was the origin of the fund, with the BRU now upgraded to the BRC. The current ask against this fund, should it be possible, was for £250k for 2 years in a row to support the BRC devices theme, and we can provide more information about this. The success of the BRC at review in 18 months' time is a strategic priority. The Board also recognises the shortage of MRI capacity to support research.</p> <p>It was felt that, should the Trust agree to keep this fund ring fenced for research, it can be used not only for the 'research purchases' but will be badged as 'matched funding' for external income which gives us additional firepower with the NIHR since it demonstrates the Trust's ongoing commitment to research.</p>	
<p><b>11. A.O.B.</b></p> <p>Following on from the discussion on the new Misconduct Policy (Actions, item 1(v)) ST revealed that QMUL are now trialling misconduct training. JM said she would liaise with Rob Bennett to see if the Trust could use that training or run something similar. NL commented that the time investment in this training is not trivial, but it is worthwhile.</p>	
<p><b>12. Next meeting</b></p> <p>18<sup>th</sup> September, Garrod Building, Whitechapel.</p>	

NG  
27<sup>th</sup> June 2017

