Joint Clinical Research Board

Monday 18th September 2017
Room 2.48 Garrod Building, Whitechapel

Present: Sally Burtles (SB), Nick Croft, Sandra Eldridge (SE), Gerry Leonard (GL), Jo Martin (JM), (MP), Rupert Pearse (RP), Steffen Petersen (SP), Anju Sahdev (AS), Steve Thornton (ST) (Chair)

By telephone: Deanna Gibbs (DG), Costantino Pitzalis (CP), Peter Sasieni (PS)

In attendance: Paul Astin (PA), Sharon Barrett (SBA), Heather Clarke (HC), Coleen Colechin (CC), Nick Good (NG), Jo Morgan (JMO), Anh Nguyen (AN), Neeta Patel (NP)

Apologies: Neil Ashman, Rob Bennett, Mark Caulfield, Jack Cuzick, Nick Lemoine, Mauro Perretti,

Agenda Item	Action
1. Minutes and Actions from the last meeting ST opened the meeting. The minutes of the March meeting were agreed. The following actions were addressed:	
(i) 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. ***Ongoing action.***	**SB**
NG commented that at present very few minutes were coming through. ***Action***: ST reminded all clinical leads that minutes of any research boards/ committees that meet should be forwarded to NG.	**All RDs**
(ii) 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).	
GL reported that this cannot happen due to the high-level re-organisation. ***Action***: He will discuss with Neil Ashman, JM and RP and report back to the next JCRB.	**GL**
(iii) ST and others to review the proposed QM-SMD study metrics table. This review happened and table presented (see Item 7 below).	
(iv) CC to produce a full, end of QM-SMD FY dashboard to the next JCRB meeting in September. Done, see Item 7 below.	
(v) JRMO Research Governance to produce a brief quarterly activity report. Done see Item 6 below.	
(vi) In relation to Trust restructuring, JM will feed back to the Trust that research and	

education need to be embedded in the structure. Confirmed that this has happened. (vii) SBA to circulate the revised year-end LCRN report. This has not yet happened but will happen as soon as possible. SBA said that the LCRN will submit its annual report to the Trust Board shortly. (viii) Sponsor oversight issue - SB needs to discuss one particular example, where there has apparently been no upload, with JC. SB confirmed that this discussion has taken place. (ix) The clinical trials pharmacy at the Royal London Hospital is being evicted and need a home. This is a high risk to research activity. JM agreed to escalate this matter with Estates. This matter is subject to discussion today – Item 2, below. (x) SB to inform site management team of the HTA inspection. Completed. (xi) NG to update the Trust's risk register, moving forward review dates and closing the named risk. Completed. (xii) NG to set up a new risk re Imaging facilities issues and to ensure timely review of this. Completed.	
2. Research Pharmacy issues AN presented three papers on related research pharmacy: **(i) Deterioration of existing RLH pharmacy accommodation** ST said that the risk the deterioration of the current location presented was obvious but asked how this should be progressed. AN said that her team had identified a possible area on 5th floor of RLH that they could move into but are unclear how to get that approved. ST asked what the cost of this was. AS and JM suggested it could be approx. £40k to scope the work and perhaps £1.2m to complete a suitable refit, move in, etc. GL said that the cost of the CRC Skanska scoping was £20-30k but the key thing here is putting together a business case. JM asked if a business case has been prepared. AN reported that Shok and Simon are working on that. JM said that housing the research pharmacy in this decayed building is unacceptable in the longer term but that any move needs Trust agreement and support. There may be other options to 5th floor RLH. There was a consensus around the ongoing unsuitability of the current situation. ST said that a meeting to work out a way forward should take place ASAP. He should attend. It should also be discussed at the next QAC. ***Action***: JM to arrange a meeting to work out concrete ways forward with respect to RLH pharmacy accomodation. **(ii) Backlog of studies** AN presented a second paper proposing a methodology to work out how many staff would be	**JM**

needed to address the current backlog of pharmacy actions by Christmas. Following discussion the JCRB agreed this methodology. There was discussion around the cost of this. SB said that the JCRB is working with Pharmacy and the CRN to arrange payment for temporary staff for this, as well as additional resources to cover research imaging issues. Quite how much would be needed depends on the result of the methodology being put into practice. SB and GL will continue to work with Pharmacy and CRN on this. There was a discussion around the need for greater transparency of both research income and expenditure. **(iii) Review of ongoing Pharmacy staffing** GL said that the resources for staffing are there already but are not all being used for research. JM suggested that Pharmacy should develop a detailed action plan for this. ***Action***: JMO will work with pharmacy to develop a complete action plan.	**JMO**
3. Research Misconduct Policy SB presented the new Draft Misconduct Policy. This has been agreed as a high level policy for both organisations and is due to go to the Senate in October and the Trust's Policy Committee quite possibly also in October. Detail procedures will follow and they should be ready for the next JCRB in December. SB asked if any comments on this could be sent to her ASAP (***Action***). SE said she had some suggestions on wording around the scope of the policy and will send to SB. SP asked how this would affect people employed by UCL but working with QM or BH. SB said those individuals would probably be covered by a UCL policy.	**All**
4. LCRN report SBA introduced the latest Network report. A new structure for this report is being developed. Year to date re use of Edge is very good – clear improvement. Patient numbers are high due to the Genes and Health project. ***Action***: Future reports should separate out Genes and Health as this is swamping other studies. BH is mid-range on commercial activity. Data cleansing activity is ongoing. RP expressed concern that PIs are not being involved sufficiently in keeping this figures up-to-date. JMO said that efforts have and are being made by the JRMO and LCRN to ensure researchers keep data updated. The balance of opened and closed studies seems consistent and BH leads in terms of volume. SBA said that the Annual Report letter from the NIHR, circulated, shows that we are largest area in terms of activity. We should be very pleased with the NIHR's comments. JM said that the Network's performance is good and the improving activity in BH needs noting.	**SBA**

NC asked whether more training on Edge is available, given that it is the way recruitment now needs to be recorded. SBA and HC confirmed that more training is being rolled out for researchers with Network support.	
5. Sponsor oversight report SB presented the latest minutes of the Sponsor Oversight Group on 4th September. RP had attended for the first time. Work to update studies onto EUDRACT is proceeding as anticipated. The audit programme is progressing well. Other matters were presented. There is nothing that needs to be escalated to JCRB this time – although the SOG also noted concerns/ risks around the RLH Clinical Pharmacy (see 2 above). Of general note is that the MHRA inspection is becoming imminent as it is now overdue by a year. RP said that it is useful to keep the focus on trial risks so that these can be escalated to JCRB as soon as necessary. GL agreed and said that we must continue to focus resources onto risk assessment as we already know which study types are more high risk. RP suggested that we may wish to consider a strategic policy of not undertaking studies that are clearly high-risk. ST said that we must be open and flexible and proceed with proper risk-assessments; he was not keen on blanket bans of certain sorts of research.	
6. Research portfolio report HC presented a short report. The JRMO started 83 new studies and is averaging at 80-110 each quarter. A quarter of our studies relate to cancer and respiratory condition. Other matters were highlighted. HC asked for any views on this format. JM asked if working is growing. HC said yes, incrementally.AS asked how many CSS trials there are. ***Action***: HC said she would respond to AS (CSS work does not fit cleanly with the NHIR categories used for this report).	
7. Research finance report: QMUL FY-end report 2016-17 CC presented the first edition of a QMUL-SMD dashboard. Targets, if thought suitable, are still be added, subject to discussion with Rob Bennett and others. This is cumulative and will build up over the next FY. CC asked JCRB whether this was what they had been asking for. ST said that overall targets for SMD exist but he was not aware that these have ever been broken down into Institutes. CC said that the general value position is comparable to last year although the number of new awards is down. JM said that as a general comment Dentistry and William Harvey seem to have a higher "hit rate". CC that may be a seasonal matter. As the next year progresses we will be able to see a fuller picture. ***Action*:** This report to return quarterly. The Trust six monthly finance report is to return in December.	**CC and GL**

8. JRMO activity report SB presented this regular report. The number of new studies is consistent but there has been a huge growth in study amendments. Mays Jawad is joining the JRMO to replace Liz Clough in October. RP has started as R&D Clinical Director. Marie-Claire Good is being seconded one day a week to NIHR to develop a GCP training programme. The MHRA forum has demonstrated that the validation of data and trail oversight is increasingly important. E-health records must comply with MHRA requirements; our do not due to the Cerner system, but we are not alone. JM asked if the E-health non-compliance posed a risk to research. SBA said no as this is a general problem and only MHRA guidance rather than a legal requirement. SB reported that JRMO is working on improving local access: Juan-Carlos has been basing himself at the Barts' site regularly and the RSU held a drop-in session. There was a discussion around validating trial systems. SB said that the expertise for this often sites in CTUs. RP said that some systems, such as those used in commercial trials, sat outside of CTU ambit; that could pose a risk. GL suggested that he thought e-storage space was being developed at Mile End. SE said it was "being developed" but that had been ongoing for a while and never seems to get there. ***Action***: SB to look into the issues around trial systems and their validation and to develop a plan.	**SB**
9. AOB: (i) ***Research misconduct training*** – JM said that a shorter version of the BCI research integrity training pack had now been developed and uploaded to the ECPD App. She would welcome any feedback on this - ***Action*** (ii) ***UKCRC CTU accreditation*** – SE said that both our CTUs are now fully accredited. She also asked for it to be noted that she is not leaving (contrary to a rumour that has gone around!). (iii) ***Clinical Boards versus Sites issues update*** – GL said that this is progressing and the appointment of Directors of Research within the new Clinical Board (CB) structure will finish off one stage of the restructuring. Those people will replace the current CAG Directors as members of the JCRB. CSS remains unchanged and we will be reporting to CBs on the financial side (not to Sites). (iv) ***MR scanning*** – AS reported that this is now up to capacity at Mile End. The equipment upgrade has been successfully phased in.	**All**
1. Next meeting 11th December, BCI Charterhouse Square	

NG
27th September 2017