Joint Clinical Research Board

Noon, Wednesday 7th June 2023
MS Teams

Present:

Amrita Ahluwalia (AA)
William Ajala
Sharon Barrett (SB)
Bryony Butland (BB)
Mark Caulfield (Chair) (MC)
Alistair Chesser (AC)
Mary Collins (MCO)
Steve Ford
Rhian Gabe (RG)
Hortensia Gimeno
Nick Good (NG)
Xavier Griffin (XG)
Ginette Hoare (GH)
Richard Hooper
Stamatina Iliodromiti
Mays Jawad (MJ)
Jamila Kassam (JK)
Hemant Kocher
Bryan Leventis
Kieran McCafferty
Jo Martin
Jo Morgan
Neeta Patel
James Patterson (JP)
Rupert Pearse (RP)
Caspar Ridley (CR)
Julie Sanders
Manish Saxena
Klaus Schmierer (KS)
Ajay Sinha
Imogen Skene (IS)
Beth Stuart
Fiona Walter

Apologies:

Coleen Colechin
Nikolaos Donos
Deanna Gibbs
Nick Lemoine
Anthony Mathur
Arunthathi Mehandran
Mauro Perretti
Anju Sahdev

Agenda Item	Action
1. Minutes and Actions from the last meeting. MC welcomed everyone. The draft minutes of the last meeting in November were agreed with some comments noted. Apologies received were read out by NG. Actions from the last meeting were noted as follows: (i) NG to add the research misconduct policy review to JCRB agenda in June. On the Agenda. (ii) RP is to return to JCRB with a Clinical Director update at the next meeting. On the Agenda. (iii) GH/RP/SK to report back on non-recruitment to approved commercial studies to the June JCRB. RP said that this work is in hand and due to report back now in September. **Action**: NG to put non-recruitment to commercial studies on the September JCRB Agenda.	**NG**

(iv)	NG to note Precision Medicine/ data core update to JCRB in due course and discuss progress with SN. **Action rolls over** – possible September JCRB item.	**NG**
(v)	NG to ensure a CRF progress update returns to JCRB in due course in consultation with KM. **Action rolls over** – possible September JCRB item.	**NG/KM**
(vi)	MJ to return with further updated on this JRMO work on regulatory approval changes. Particularly 'CTU-lite'. On the Agenda.	
(vii)	NG to finalise the TORs and publish them on the JRMO webpage. Done.	
(viii)	CR to return to next JCRB with an update on future Trust IP management. On the Agenda.	
2. CRN Annual Report SB reported that the CRN Annual Report format had changed this year, so there is no need for the JCRB to approve a Report that then goes to the Trust Board, as in past years. She had circulated a report in the very abbreviated format as directed by the NIHR but said that a longer less formal report will be prepared later in the year, with stakeholders including Barts Health. That report will focus more on activity within organisations. KS asked about the format and onward links as the latter can be difficult to access. SB said this was a specific format and she recognised difficulties with onward links. The more detailed report being planned will be an opportunity to capture more detail on one place. MC thanked SB for this report. There were no further questions.		
3. Joint Research Misconduct Policy JP said that the paper that had been circulated was the product of a working group plus additional stakeholder comments. The key question the group had considered was how two organisations with separate procedures for resolving allegations of research misconduct can agree about the principle of working together. The policy as circulated is the output of that thinking. RP said that document was the result of constructive team working and hard work. Interaction is the key here and we will continue to have issues that we will need to make work across both organisations. The top priority is ensuring patient safety, limiting researchers from practicing in a way that impacts upon that, but also takes account of the privacy of employees. AC recognised that this had not been an easy task; it is essential that individuals are unable to hide in gaps between organisations and this policy will hopefully help prevent that. AA said that there is also additional protection around this in relation to whistle blowing. She hoped that QM can call in additional expertise, eg, from the Trust, for oversight panels, as necessary. The later point was discussed, and it was agreed that working in this and the additional QM policy (procedure) were sufficient to ensure that flexibility. AA further asked whether the partnership with UCLP and its bodies were subject to this policy. RP said that efforts to get UCLP to agree a joint MOU had stalled last year. SB said she and Gerry Leonard		

had taken the MOU to UCLP who had failed to grasp its importance. She was happy to work with RP to see how CRN could support this in terms of messaging and could take is matter to our RD Leadership Group meeting for information. In due course this would be something for Gerry's successor to take forward. NG commented that, for the record, he would redraft the SOP so that it represents only the Trust's investigation process, working with others to agree and republish it. MC said that as there was no dissent the new Research Misconduct Policy was agreed as drafted and JP could take this forward for approval by the relevant QM and BH bodies. **ACTION:** JP to take the agreed Research Misconduct Policy forward for agreement by both QM and BH.	**JP**
4. Distribution of CRN Funds GH explained that up to 2021 CRN funding had been allocated by the Network itself, then in that year it was devolved to organisations with a requirement to establish an allocation process. Since 2021 we have been managing this within the JRMO based on historical funding agreements with a general lack of transparency. Whilst no major problems have arisen there is no Trust oversight and a growing need to use this funding to support changing needs and potential new activity; continuing as we have been is becoming a block to growing new research. Developing a complete system from nothing has proved too big a leap so the proposal, set out in the paper circulated, is to pilot an Oversight Committee. IS then took over explain that the idea of an Oversight Committee came out of the working group. The current proposal is to have a monthly meeting, with ad-hoc meetings as required, plus an annual meeting as a next step once the funding committee is set up. The annual meeting to include other stakeholders and would work through needs and how that fits with planning, strategy, and funding available. The Committee would work to transparent rules and, where available, useful metrics. Transparency around metrics and methodology will be important, although pragmatic decision-making is vital too. RP thanked GH and IS for their work on this. It is a sensitive issue and he and the working group are open to feedback now or at any time. The important thing is to do something along these lines and then learn from that, rather than waiting until we have a 'perfect' answer. He said that at present senior JRMO staff are very exposed to criticism and we need to resolve that. XG welcomed this work and said a clear process was very important. He asked what the scope was for the short term, would this include moving people off short-term contracts? RP agreed that short-term contracts are counter-productive, and he would like to get rid of them too, but that is not within the scope of this work. The problem there is risk-aversion within finance teams and a lack of leadership. This is simply about a locating funding from an ad-hoc annual scheme in a way that best supports our strategy and needs. **ACTION**: RP to meet with Trust finance officers and other to review what practical measures can take place to move away from the short-term employment culture.	**RP**

AA agreed that transparency is the key here, in the longer term that benefits everyone. She asked if there would be an FMD representative on the Oversight Committee. RP said that there could well be, membership has yet to be decided but there definitely needs to be FMD involvement. SB said that continuing to roll-over the historic decisions is not viable indefinitely, this proposal seems a very positive move. Her only concern would be around communications as there is no new funding available, so expectations need to be managed. JK said it would be helpful if timeframes could be added to any communications to further manage expectations. GH thanked people for their support and said that the aim was to have a planning meeting to collaborate with teams to establish likely needs then launch the pilot, tweaking it as it goes, clarifying and developing guidance and managing expectations. AC expressed his support for this venture and asked if those involved felt sufficiently supported. RP said that the team was being deliberately careful to limit the pilot and remain open to further changes. In the first instance it will simply take on existing JRMO work, not lead any major changes; that will come as we develop metrics. Mc thanked the team for their work and it was agreed that a pilot Oversight Committee for the Distribution of CRN Funds be established MC said that its work would be undertaken in the name of the JCRB, with appeals firstly to RP then to himself or AC, finally referred to the JCRB itself if necessary. **ACTION**: once the Oversight Committee for the Distribution of CRN Funds pilot is established and operational it is to report back to JCRB.	**RP/ IS/ GH**
5. Clinical Director's Update RP started by saying this was a brief overview and he would be presenting a more detailed report to the Faculty Executive on 8th June. He reported that consequences arising from the pandemic are still apparent in research activity. The O'Shaughnessy review into UK clinical trials and Pharma criticism has some basis in fact. As a combination of arguably the largest NHS Trust combined with a major Russell Group University we are now working to establish infrastructure that will support first-class research with equable access and excellent delivery that also supports education at both the University and Trust. A successor to Gerry Leonard is due to be appointed imminently and the JRMO is working well to support RP. Build on the Royal London CRF begins soon and it is due to complete and open by September 2024. This will support the growth of both commercial and non-commercial activity. Continuing the magnificent work on vaccine trials is a key part of that work and it will be moving into the CRF. The Trust's PI/PA scheme is set to support 19 PAs for 11 people. The response from Newham was particularly exciting. That launch specifically learnt lessons from preacademic work. It is a major investment and a fantastic opportunity for the individuals involved – who are a mix of doctors and AHPs. This fits with both the CRN funding review work (see above)	

and increasing the recognition of NMAHP activity elsewhere. The Trust Exec is keen to ensure that all Trust staff can take part in research, irrespective of their academic background. This then links to Neeta Patel's work on community engagement and the success of the recent International Clinical Trials Day key event. Involving all our employees and our community in research activities will become normal and routine.
Barts Charity is supporting this growth in PPI engagement within a community context, and we can help further that work.

Finally, we are working with the Hospital Sites to establish site research leads. That will be an important vehicle to enable a greater focus on all types of research at all those sites.

MC thanked RP and asked if there were any questions.

MCO said it was exciting news that we plan to retain the vaccine activity within the CRF. She wondered if the CRF will be accepting studies other than from QM and BH leads?

RP said that the focus of the CRF's work will be benefit to BH and QM, but that includes reputational and financial benefit. It is therefore a qualified 'yes', although such studies would need to pay more for services than our own.

6. JRMO research governance development

MJ thanked the Board for its time and before going into the specific development activity MJ flagged up a few current highlights:

- A new QMERC application system launches later in June.
- The recent KMPG audit has flagged up several items including the need for this meeting to understand and approve the SOG minutes when it meets (see item 8 below).
- A statutory GCP inspection by the MHRA of clinical research at Queen Marry has been announced. The team is currently preparing the Dossier. MJ thanked all those who have been involved in preparing that. The MHRA site visit will be announced in due course.
- An NHS England audit is underway.
- Staffing levels in the JRMO have been low but this is improving, although new staff still of course need time to train up.

MJ then talked through the paper circulated, outlining research governance working group activity in the following categories:

(i) Approval & Timelines (A&T) Working Group – the aim is to standardise processes (including removing duplication and unnecessary steps), ensure processes are proportionate to risk but without reducing quality whilst taking into consideration researcher expectations. Improving timelines is the overall aim so each step in any process is being assessed to see if it remains necessary. A pilot of this has already launched.

(ii) Processes Working Group – aims to review principles of processes and procedures focusing on areas of overlap, duplicate and communication.

(iii) IT Systems Working Group - aiming to review the Governance IT systems used to support staff and researchers across both organisations.

(iv) Accessibility and Availability Working Group - the aim is to review how accessibility and communication with stakeholders can improve. These include

JRMO Website, use of SharePoint, current/future drop-in session; researcher access to Governance staff whether on site or virtual; communications via the R&D news bulletin and general email communication via generic mailboxes. (v) Staff induction, Training and Empowerment (SiTE) Working Group – this aims to focus on the competency and empowerment of staff to enable them to thrive in their roles whilst providing a seamless service to our stakeholder. (vi) Staff Interaction and Staff Hub Working Group – this aims to support and bring JRMO staff together. In addition, MJ reported that work to established PREP support in the JRMO ('CTU-lite') is developing, thanks to assistance from within BH and QM that will enable career and training support to exist for potential statisticians and data support staff. That follows on from a survey that explored what the potential demand was: support with methodology and statistics were seen as a real need; potentially across all studies; with a reasonably anticipated frequency of use. MC thanked MJ and asked if there were any questions. AA recognised that isolated workers could feel estranged and over-exposed so was glad to see this was being considered. KS agreed and asked if existing centres of such working could support the team. MJ said that this was what she is working to develop. RG reported that she had been involved in discussions with Barts Charity about supporting such activity. A trials manager forum has been created and that was well attended. New JRMO staff would be welcome at that. RP said that there are clear links to CRU work here, but the idea here is to create something less formal and more easily accessible in the JRMO, not a replacement for existing CTUs. MC asked if 3 staff members are enough to deal with all the planned PREP activities. He also wondered whether it is possible to deliver work with such low staffing levels generally. He suggested MJ look at other similar organisations to benchmark their workloads against staffing to establish whether we are on par with expectations, and she agreed that benchmarking could be useful in the context of further governance developmental activity.	
7. Barts Health IP changes CR said that further to the announcement at the last JCRB, oversight of Trust IP and its potential commercialisation was in process of being handed over by Gerry Leonard to his team, and would not be complete until relevant historic data was transferred. Unfortunately, a first attempt had failed to recruit an officer to look after this work and would try a different method of recruitment, using an external agency to fill the vacant post. Until such time as handover is complete and the vacancy is filled, oversight of Trust IP and its Commercialisation would be 'light-touch'. In due course CR anticipated reviewing a range of the Trust's IP Commercialisation processes, and he is working to undertake some UK benchmarking which will seek to learn from IP commercialisation practices across other NHS Trusts. There is work underway to update the existing IP Policy regarding inventor remuneration. He will also present a paper to Trust Board later in 2023 seeking approval to exercise a warrant to purchase shares for Rhythm AI should that opportunity arise.	

MC and BB offered CR assistance from QMI in the short-term, CR thanked them and said he may take that up.	
8. Sponsorship Oversight Group (SOG) minutes NG said that as noted above, from now on, following the KPMG audit the JCRB would need to acknowledge and agree SOG minutes that had previously been submitted simply for information. MC said this was reasonable and asked if anyone had not read the minutes or had any comments. There was no dissent or comments. The SOG minutes were therefore agreed.	
9. A.O.B. None.	
10. Next JCRB meeting: 15th September	
11. Summary of forward Actions	
(i) NG to put non-recruitment to commercial studies on the September JCRB Agenda.	**NG**
(ii) NG to note Precision Medicine/ data core update to JCRB as a possible September meeting item.	**NG**
(iii) NG to ensure a CRF progress update returns to JCRB in due course in consultation with KM – a possible September agenda item.	**NG/KM**
(iv) JP to take the agreed Research Misconduct Policy forward for agreement by both QM and BH.	**JP**
(v) RP to meet with Trust finance officers and other to review what practical measures can take place to move away from the short-term employment culture.	**RP**
(vi) Once the Oversight Committee for the Distribution of CRN Funds pilot is established and operational it is to report back to JCRB.	**RP/ IS/GH**

NG
9th June 2023