**HEALTH RESEARCH AUTHORITY**

**BOARD MEETING**

**PART 1 – PUBLIC SESSION**

**Minutes of the Health Research Authority (HRA) Board meeting, held on 20th May 2016 from 1.00pm – 3.00pm via teleconference / London HRA Centre**

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| **Present** | | **Initials** |
| *HRA Non-Executive and Executive Directors*  Graham Clarke Non-Executive Director  Ian Cook Director of Corporate Services  Debbie Corrigan Director of Finance, Procurement and Estates  Allison Jeynes-Ellis Non-Executive Director  Deirdre Kelly Non-Executive Director  Jonathan Montgomery Chair  Nalin Thakker Non-Executive Director  Janet Wisely Chief Executive  *HRA Directors who attend the Board*  Janet Messer Director of Research Systems, Standards and HRA Approval Programme  Tom Smith Director of Quality, Guidance and Learning | | GC  IC  DC  AJE  DK  JMo  NT  JW  JMe  TS |
| **In attendance** | |  |
| Sheila Oliver Head of Research Ethics Service (England)  Stephen Tebbutt Head of Corporate Governance | | SO  ST |
| **Observers** | | |
| Sylvia Hazard Health Research Authority  Amanda Hunn Health Research Authority | | |
| **Item** | **Item details** | **Action** |
|  | **Apologies**  Joan Kirkbride, Director of Operations |  |
|  | **Conflicts of interest**  None to note |  |
|  | **Minutes of last meeting**  The Board agreed the minutes of the last meeting were a true and accurate representation of the matters discussed without amendment. |  |
|  | **Matters arising**  *Risk discussion*  The Board noted the Audit & Risk Committee had discussed at its April meeting the recommendations from the recent Board effectiveness and governance review. The Board noted the Committee confirmed it was content to suggest items relating to risk to be consider at each Board meeting for a ‘deep dive’. |  |
|  | **Update from Chair**  *All Staff day*  The Board agreed the All Staff day had been excellent and thanked all those involved in delivering a successful event.  *NIHR at 10 event*  The Board noted the National Institute for Health Research (NIHR) at 10 event had been held on 18th May 2016 with keynote speeches by the Secretary of State for Health, Jeremy Hunt MP, the Minister for Life Sciences, George Freeman MP, the Chief Scientific Adviser, Professor Chris Whitty and the Chief Medical Officer, Professor Dame Sally Davies with final words provided by Lord Howe, Deputy Leader for the House of Lords and Minister of State (Ministry of Defence).  *NREAP Hosted Chairs’ Meeting*  DK advised she had recently attended a National Research Ethics Advisors’ Panel (NREAP) hosted Chair’s Meeting which the Operations team had supported excellently. DK however questioned the value of the NREAP involvement at the meeting which GC agreed with following attendance at a different meeting. The Board noted a new model for NREAP is currently being developed and it may be appropriate at that time to move the meetings to be run solely by Operations.  *Audit and Risk Committee member recruitment*  The Board noted the closing date for applications had now passed with shortlisting completed. An interview date is in the process of being confirmed for end of June. |  |
|  | **Update from Chief Executive**  ***HRA Approval Programme***  HRA Approval is now receiving a very high volume of activity. The number of applications for HRA Approval for new studies is as anticipated. However, the volume of requests for HRA Approval for ongoing studies and for review of amendments is considerably higher than planned. In both cases, there appear to be a number of factors driving these numbers and further analysis is underway so that we can determine what the stable state might look like. A range of interventions are being put in place to manage the volume of activity, in addition to communications to encourage more efficient handling of amendments by the community. It is likely that these volumes will also impact on timelines for HRA Approval over this period and we will need to manage expectations.  The Board noted confusion amongst researchers regarding the need to request HRA Approval. The Board noted HRA Approval of pre-approval studies was only required for studies which require a new site and not any other amendment. The Board noted the communications had been made clearer with HRA Latest to be released detailing updated guidance. The Association of British Pharmaceutical Industry (ABPI) and Ethical Medicines Industry Group (EMIG) had agreed to escalate with a further update to be provided at the NHS R & D Forum next week.  The Board noted staff had been reassigned and were working overtime to address the backlog of amendments (approximately 2000, although some of these may be duplicate).  The Board was assured urgent safety measures could be implemented without amendment as per normal process and there was therefore no significant patient safety risk.  The Board expressed its gratitude and thanks to the staff undertaking additional work to address the backlog and managing the concern. The Board was pleased to note that new applications were being managed appropriately with good feedback received.  We continue to actively seek feedback to maintain early awareness of issues. The NHS R&D Forum Annual Conference takes place in May and provides an opportunity to share information and hear feedback with a key audience of over 400 people.  ***Research Systems***  HARP and IRAS  HARP 2.7 was released on 11 May 2016 and went smoothly. It incorporates a number of enhancements for REC and assessment purposes.  IRAS 5.3.1 will be released week commencing 8 June and is more of a maintenance release  Staffing  The following permanent HRA posts were advertised and successfully recruited to, to replace the contractor roles, with staff expected to join in late June:   * Research Systems Quality Manager * Technical Documentation Specialist * Business Analyst   Contract management – software development for HARP and IRAS  The first formal contract management review with BGO Software as part of the new arrangements will take place on 20 July. This will look at performance over the first quarter of the new arrangements.  ***Collaboration & Development***  DH SMT met in May to consider the paper developed jointly by HRA with the two NIHR funding coordination centres, NETSCC and CCF, on the timing of release of NIHR funding. We had collectively noted that the current DH contractual arrangements meant that funding was normally not released until after ethical approval, which did not allow researchers to undertake activities in preparation for HRA Approval and study set-up in the most efficient way. DH SMT discussed the paper and agreed with the proposal to change the arrangements to permit earlier funding release. This is a significant change that will benefit many research groups , resulting from effective partnership working.  ***Confidentiality Advice Service***  This team have now moved line management to the Systems Directorate. Work continues to address the backlog of amendments. A process for managing annual reviews has been developed and a note has been added to the relevant section of the website to clarify that there is no requirement for the annual review to be completed in order for approval for the activity to continue.  ***Finance***  Financial position – March position in line with updated expectations. March year end closed within 19 calendar days compared to an NHS benchmark of 25. Next target will be to reduce the % difference between forecast outturn at month 6 and the final outturn.  Draft annual report and accounts reported to audit committee. External audit nearing completion. Comments received on the draft annual report and being reviewed.  Budget setting complete and all budgets on the financial reporting system and reported as part of month 1 soft close.  Finance meeting held with DH colleagues from sponsor and finance teams. Awaiting final confirmation of grant in aid but expectation is that it will be as expected. Further focus required on savings for future years.  Cycle to work scheme launched.  ***Estates***  Flexible working roll out – Rollout completed. Draft report received. Over 100 staff attended awareness and training sessions provided and over 50 attended the Lync training sessions. The project was used as a vehicle to formalise flexible home working arrangements for all staff. A total of 50 applications were received with half from the Operations directorate. The highest proportionate uptake was in Bristol where a third of staff submitted an application. At the end of the project 116 staff had engaged in home working with 68 staff being identified as office based.  London property update – we continue to await further information on progress regarding a new lease for Skipton House.  Nottingham – final lease nearing completion.  ***Procurement***  Procurement audit completed with moderate rating and actions agreed. Contract management audit due to start.  Procurement strategy and annual procurement plan reviewed.  ***Operations***  Jersey Research Ethics Service  We have been approached to provide training to the Jersey research ethics service. David Carpenter, REC Chair and Charlotte Allen from the operations will undertake this work.  Appeals against REC unfavourable opinion 2015-2016  A total of 12 requests were received to appeal an unfavourable opinion for a new application. Of the total requests received, 6 were allowed, 1 did not proceed and 5 were resubmitted as a new application. On receipt of the appeal request, consideration is given to the various options available to proceed and the applicant is advised. Where it is clear that the applicant is able to make the changes requested as part of the unfavourable opinion, the applicant is advised that resubmission to the same REC after making the changes is advisable. All 5 applications which were resubmitted to the same REC instead of proceeding as an appeal received a favourable opinion from the REC after the second submission.  Of the 6 applications which went to appeal, 3 received a further unfavourable opinion, one received a further information favourable opinion and two have not yet received a final opinion and currently have a provisional opinion. An analysis was carried out on the application which received a favourable opinion to check for consistency of decision making. The application had previously received an unfavourable opinion prior to the unfavourable opinion on appeal. Both unfavourable opinions related to the lack of informed consent on behalf of some of the research participants. The same issue was raised by the appeal REC and the researchers agreed to change the study to recruit only those participants who had given fully informed consent.  REC Performance 2015-16  The workload data for submission to RECs in 2015-16 showed that 4994 applications were submitted to RECs in England and 6220 across the UK. This figure has been consistent now for a number of years.  Of the 68 RECs in England the following performance targets were achieved with 100% compliance.  Statutory  Full Applications – 48 RECs  Proportionate Review – 46 RECs  Stretch target  Full Applications - 30 RECs  Proportionate Review – 32 RECs  Amendments – 38 RECs  MI data per Centre  *Full Applications*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Jarrow | Bristol | Nottingham | London | Manchester | | % in Statutory target (60 days) | 99.8% | 99.6% | 99.4% | 99.1% | 99.6% | | % in KPI (40 days) | 95.6% | 88.2% | 90.5% | 79.1% | 92.3% |   *Proportionate Review Applications*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Jarrow | Bristol | Nottingham | London | Manchester | | % reviewed in 14 calendar days | 97.7% | 93.2% | 98.0% | 82.7% | 93.1% |   *Substantial Amendments*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Jarrow | Bristol | Nottingham | London | Manchester | | % in Statutory target (35 days) | 100.0% | 99.5% | 99.9% | 98.8% | 98.6% | | % in KPI (28 days) | 97.3% | 92.7% | 96.6% | 86.6% | 91.9% |   ***HRA Queries Line service***  As reported in the last CE update, during the last quarter of 2015-16 there was a steady increase in the number of queries received by the HRA Queries Line meaning that by the end of Q4 the number of queries received had increased by approximately 45% as compared to Q1-Q3 of 2015-16. However, despite this increase demand on the service it appears that it is continuing to rate well, with the most recent HRA User Satisfaction survey showing that during October 2015 – March 2016 an average of 87% of respondents to the survey rated the HRA Queries Line service as excellent or good. (This compares with an average of 92% rating it as good or excellent between April 2014 – March 2016). This increased demand on the service appears to be continuing in Q1 of 2016-17 and the Guidance & Advice team are continuing to carefully monitor the volume and nature of queries received to ensure current service levels continue to be maintained.  ***Updated IRAS E-learning module***  An updated version of the IRAS e-learning module has been prepared and will be published on the IRAS website in the coming weeks. This version, which replaces the original module that was published in 2009, has a revised layout as well as updating and expanding the content in response to common queries from IRAS users. The module continues to provide an online guide to IRAS and the functionality that the system offers. Users can still choose whether to work through the whole module or just specific sections of interest and it will remain free to use with no need to register prior to using.  ***Communications***  During the last month the Comms team have been supporting preparations for our attendance at the NHS R&D forum on 23 & 24 May and also for the ARMA conference in June. This has also involved working closely with the public involvement team to prepare for the launch of the joint HRA/INVOLVE statement on Public involvement in research and research ethics committee review and a  joint briefing from the Health Research Authority and INVOLVE on how public involvement can help in the ethical design and conduct of research.  They have continued to deliver Comms in support of HRA Approval which has been a key priority.  Work has been underway to develop the next issue of HRA Latest which will be due out shortly.  Progress in relation to the web redevelopment work has included recruitment activity for a product and delivery manager, development of the project documentation and taking forward discussions with finance and procurement for the hosting and maintenance contract. The existing programme of review and updates to the website has been maintained and the new section for the patients and public is close to being finalised in conjunction with the public involvement team.  Regular weekly newsletters and intranet updates have been made to keep staff aware of any key information and developments, including supporting staff in preparing for the new VC system and making training materials available for utilising Lync to enable homeworking as part of the estates strategy. Support has also been provided for the all staff VCs and for the organisation’s all staff day.  The team have been working alongside colleagues in the MHRA to develop some joint communications planning in relation to the EU Clinical Trials regulations.  The team has supported the training team with updating the e-learning management system branding and pictures in support of the work on the system.  Some initial discussions have taken place and agreement has been reached to deliver the Year in Review in the autumn, which will allow us to align timings with the planned AMS stakeholder event as well as having the opportunity to share in more detail how HRA Approval has embedded.  The team have been handling a number of media enquiries over the period, predominately linked to the role of CAG in relation to news reports about a hospital trust’s technical development in relation to patient data.  ***Stakeholder Management***  The stakeholder management group have continued to meet and have been reviewing both our attendance at, and co-ordination of, stakeholder meetings. The next quarterly planning session will take place in June when the group will give further consideration to its role and ways to evolve and build on its progress to date.  ***Business Unit***  Travel and Accommodation  Excellent efforts have been made by bookers and travellers in keeping accommodation costs down for the quarter: Average for London - £95: Average for regions - £61.95. Well below our upper limit rates on £115 and & £75 respectively. Consistently booking in rail tickets in advance has also generated ‘savings’ against those costs if booked on same day (See table below).  Average savings per ticket when booked in advance Qtr 4 2015/16  0-2 Days               237         £21.89 = £5,187.93  3-6 Days               402         £24.45 = £9,828.90  7-11 Days             337         £31.49 = £10,612.13  12+ Days              866         £35.55 = £30,786.30  Total ‘saved’                                      £56,415.26  ***PMO***  A comprehensive report on key project/activity progress was recently presented to EMT. This offers a high level view on significant deliverables planned for 16/17. A summary report is planned to come to the board in July which will cover progress against key programmes of work contained in the business plan as well as  consolidated view of progress against other projects or activities which are responsible for realising organisational and ‘system’ benefits  ***Training***  All Staff Day  Very positive feedback received regarding the All Staff Day held on 5th May.  Over 170 attended. Comments from staff included *‘A really good day - great to be able to get the whole organisation together’, ‘A very good atmosphere and working with people from other teams’, ‘It is great to have external speakers and remind us how important our work is in the wider world’* The session on Genomics was particularly well received with the speaker, Mark Caulfield receiving a satisfaction rating of 97%  ***Public Involvement*** The public involvement team will be publishing new HRA/INVOLVE joint guidance and a briefing on involving the public in health and social care research and the relevance of public involvement to the role of Research Ethics Committees. Both will be held in a new *public involvement in research* resources pages on the HRA website. We will be launching the guidance and briefing on 23rd May at the annual R&D Forum conference. Following publication, the public involvement team will be taking forward our wider programme of work on public involvement within ethical review, working closely with colleagues and external stakeholders.  Two public contributors were successfully involved in the interview process for the new HRA Director of Finance.  ***Human Resources***  An updated retirement policy has been provided to SEMT for consideration. Work has also been ongoing with BSA in developing an MOU for 16/17 (with agreed performance targets) and is now ready to sign off by respective organisational leads. More recently the HR Team has offered significant support to the Director of Finance recruitment process |  |
|  | **HRA Key Performance Indicators**  The Board received the KPIs for Quarter 4 2015/16 plus the Annual Summary Report. The Board agreed the dashboard was helpful. The Board noted the sickness absence rate and agreed to consider if there were any trends under part 2 of the meeting.  The Board noted some indicators showed the target had not been met for the whole year and were highlighted as red on the dashboard e.g. rail travel. The Board queried if the target is realistic and what is achievable linked to the needs of the organisation. IC clarified the indicator regarding rail travel did not reflect how well the HRA has done in comparison with the Department of Health and other Arm’s Length Bodies. The Board agreed the targets should be reflected upon for the future year.  The Board approved the report and was pleased to note the consistently impressive performance and achievements against stretched targets over the year. |  |
|  | **HRA Corporate Risk Register Q4 2015/16**  The Board reviewed and approved the risk overview summary and register for Q4 2015/16. The Board agreed the summary was a useful tool at providing a snapshot of risks faced by the organisation. ST highlighted a total of 7 new risks had been added in Quarter 4 with a further 2 ‘old’ risks raised to the Board which had not been considered in the previous quarter. The Board noted in Quarter 4 there continued to be movement in HRA Approval risks with the addition of new risks / closing or reduction of risks, as the programme moved through the final phases of roll out prior to 1st April 2016  The Board noted a discussion had already taken place under item 6 regarding the two new risks relating to HRA Approval and amendments (452 and 453).  The Board discussed the risk relating to a shift in financial position (471). DC flagged a number of mitigations had been put in place with an audit due to begin this week however the risk had been escalated to the corporate risk register to provide reassurance to the Board and allow a watching brief to be kept. DC advised a good meeting had been held with DH finance colleagues and the budget for this year is expected to be what was agreed. DC flagged a potential longer term risk regarding future years’ budgets being reduced.  The Board noted the risk relating to IRAS and the alignment of technical requirements in comparison with business requirements of the HRA, Devolved Administrations and other IRAS Partners (468). |  |
|  | **Finance report**  The Board received and approved the finance report for March 2016. DC advised the final under spend position stood at £931k (£489k February 2016), largely increased due to the predicted release of reserves in month 12 (£557k).  The Board noted the underspend of £122k within the Operations Directorate and mostly due to the unique number of vacancies that have arisen either because of successful applications for roles linked to HRA Approval or due to the move of Research Ethics Committees (RECs) between HRA Offices in order to spread the support more equitably. These vacancies have taken longer than expected to fill due to the knock on vacancies that have resulted from successful internal candidates. The Board noted work with the Business Services Authority (BSA), improvements to the Vacancy Control Form plus organisational learning has helped reduced timelines for recruitment over the last quarter. IC flagged BSA had been through a significant organisation change however the HRA had managed to retain a dedicated named contact.  The Board noted the unprecedented levels of recruitment within the organisation over the last 12 months with 167 VCFs raised compared with 92 the previous year. 46% of these relate to the Operations Directorate. Whilst the volume was expected within the Research Systems Directorate, the extent of the knock on recruitment in Operations was not.  DC advised the final capital underspend position was £190k, which is in line with the upper range underspend of the forecast. The Board noted the capital budget available for the forthcoming year had not been impacted upon with DH confirming the budget to match the capital plan as previously agreed. The Board was pleased to note the contract with BGOmedia was operating smoothly and productively.  DC advised a revised report with minor narrative changes would be circulated for information to the Board. |  |
|  | **Management response to staff survey**  The Board noted the full presentation of staff survey results had taken place at the February Board meeting which had highlighted very encouraging feedback which compared favourable against benchmarks. IC presented a paper which focused on areas of the survey which required further action from management.  The Board noted, following detailed analysis by the survey provider, an outlier with the results from one regional office being noticeably lower than other areas of the organisation. The Board noted interventions had taken pace with the Operations staff based in the office which had been welcomed by some.  The Board discussed the findings for new starters in comparison with existing staff. The Board noted new starters were in general more positive than existing staff however this was very similar to the benchmark figures. The Board was assured this aspect had been appropriately explored.  The Board discussed whether it was possible to capture all concerns raised by staff. The Board however noted the variety of means by which staff can raise a concern and agreed would not be possible to capture all concerns. IC advised the written comments from the staff survey had been considered and no specific theme of concern had been identified. The Board discussed the importance of the culture of the organisation and ensuring staff feel able to raise concerns and speak their minds.  The Board agreed succession planning regarding staff forum membership was an important consideration and was pleased to hear discussions regarding encouraging others to join the forum to replace outgoing members were taking place.  The Board approved the response and was pleased to see the findings from the survey were being utilised efficiently to help improve the service provided by the HRA. |  |
|  | **Audit and Risk Committee minutes (2016.01.20)**  The Board noted the Audit and Risk Committee minutes. |  |
|  | **Any other business**  None to note |  |
|  | **Questions from the public**  None to note |  |
|  | **Date of next meeting**  20th July 2016, to include a seminar on strategy with PEST analysis, facilitated by Adrienne Fresko, Foresight Partnership |  |