

HRA Directorate Update September 2019

Approvals

HRA Approval

The Board will receive an interim evaluation of the programme to implement significant workforce and process changes in the Approvals Operations and Support divisions over recent months.

We are beginning to see some settling down in terms of people's familiarity with processes and roles. Nevertheless, we recognise that many staff are coping with high workloads, and some are continuing to need ongoing support. We are grateful for the continued commitment shown by staff. Work is underway to improve the accessibility of staff to applicants as user feedback indicates that although our staff continue to be highly rated, our response rate to email and phones has decreased.

The Approval Support division continues to make progress on addressing issues relating to member recruitment and meeting quoracy that have been identified as a result of the new centralised systems.

Programme activities

UK Local Information Pack

We continue to support the implementation of the UK Local Information Pack - the processes and common document set for setting up research projects and NHS/HSC sites across the UK that went live on 5 June. This work has created greater consistency across the UK.

Excel Amendment Tool

Live piloting of the Amendment Tool is commencing across the UK with selected sponsors. The tool has been developed to guide sponsors in determining which review bodies need to see amendments (MHRA, REC, etc.) and to provide a categorisation of the amendment (relating to level of review required by local R&D offices) and a triage as to whether the amendment requires further review against the UK Study Wide criteria. Feedback will inform any further development and support wider roll out of the tool, with the intention of improving consistency in handling of amendments and reducing the time taken for processing of amendments.

Guidance

The volume of queries to the HRA queries line increased over the first 4 months of financial year (Apr – July) in response to difficulties applicants were having with contacting operational staff, and the implementation of the UK Local Information Pack. A slight reduction in queries was seen in August and we continue to monitor the situation.

We are currently working with public involvement colleagues to identify opportunities in guidance to help embed the public involvement principles, which were recently published.

In the coming months we will be working on updates to the "Do I need REC review" decision tool so that it is in alignment with minor revisions being made to the Governance Arrangements for Research Ethics Committees (GAfREC).

Work to review our wider Customer support is underway and requirements for a Customer Relationship Management (CRM) system are being defined.

Learning and Development

The HRA has been working with the HTA to develop two new eLearning modules on Research Tissue Banks (RTBs). These modules are now close to completion and will go live at the beginning of October. They will be disseminated under joint HRA/HTA branding.

The Learning Management System (LMS) has been live for 9 months and the number of users is exceeding our expectations and KPIs. We have been working with the developers to improve the layout of the LMS, based on feedback. The platform is an 'off the shelf' product and there are limits to the amount of change we can make. User panels have fed back positively to us on the proposed changes, which will be implemented in October.

The HRA's first podcasts are now live – hosted on a new SoundCloud platform procured by Comms. These first podcasts support the work which is being undertaken by the HRA and MHRA, in collaboration with the devolved administrations, to streamline clinical trial regulation. Listen by [clicking here](#).

New software is being used to enhance the production of recorded webinars etc. The L&D team is continuing to work with MRC and NIHR to build our in-house expertise. [Click here](#) to see the enhanced webinar recorded by Andrew George to support the transparency consultation.

Policy directorate

We have completed the final stage of the Policy directorate restructure, with the Communications and Public Involvement teams moving into the directorate on 2 September. The new Head of Policy and Engagement started on the same date.

Policy and Engagement

Our consultation on research transparency, Make it Public, concluded with a final workshop in Edinburgh on Friday 6 September and the survey closing at midnight on the same day. We are currently analysing the responses to feed into the development of the final strategy. A full report on the consultation is provided in the paper to the Board.

We are currently updating our joint guidance on the use of patient data in medical software development. A draft version was reviewed by the National Data Guardian (NDG) Panel which provided positive and constructive feedback. The NDG also agreed to consider becoming a co-signatory to the guidance. We will circulate an updated draft, reflecting the Panel's comments, to our original co-signatories (DHSC, NHS Digital, MHRA) and key internal and external stakeholders, including user representative organisations, for review. The final guidance is anticipated to be published by NHSX.

Public involvement

In July, we launched new Best Practice Guidance for public involvement in applications for Approvals. Since then, we have started working with colleagues in Approvals to help them in embedding the guidance in their processes. We have also started working with Member Support colleagues to develop learning and support for REC members.

We are also planning a project, working collaboratively both internally and externally, to improve the information commercial sponsors produce for participants in their studies. This was initiated in response to the high proportion of commercial study participant information sheets to which RECs request changes.

We are also finalising our membership of Patient Focused Medicines Development, which is an international partnership of pharmaceutical companies, patient advocates and advocacy organisations and other stakeholders with an interest in the involvement of patients in the development of medicines.

Communications

The Communications team has been supporting the Make it Public research transparency consultation, promoting the workshops and online survey and facilitating discussion during the workshops themselves. The consultation period showed a significant increase in engagement with the organisation via our social media channels, and we're working hard to ensure that we continue to offer our new audience information about the HRA and our work that is relevant and timely and helps them to continue their relationship with us.

Work continues to ensure that the HRA website complies with the accessibility regulation for public sector websites ahead of the first deadline this autumn. The team has devised a new policy for the website and has trained HRA staff who regularly upload content so that they can ensure that this is accessible. As the regulation means that pages on the HRA website are likely to contain more text in the future, in the coming months the team will develop new capacity to add page anchors to improve the user experience.

The team has started a piece of work to redevelop HRA Latest, our newsletter for external stakeholders.

Zoe Hegarty has joined the team as Communications Officer. Zoe has previously worked in the R&D department of a large NHS Foundation Trust and more recently at the General Medical Council.

Corporate Services

Deputy Director Portfolio

The Equality, Diversity & Inclusion steering group has been set up to direct our work in this area. The group has met twice and has produced principles to underpin our work that our staff have provided feedback on. The steering group has also reviewed HRA's workforce data relating to key areas and protected characteristics under the Equalities Act to help focus our attention on the areas where HRA could undertake work that would help to make us a more inclusive organisation. Our findings have been shared with our staff at an all staff VC. We have a number of staff who have volunteered to be the point of contact for staff-led interest groups around gender and the gender pay gap, disability, BAME and LGBTQ+ and allies. These groups will be a safe place for staff to discuss their experiences and from this make suggestions and ideas for the work that would make a difference that the HRA could undertake.

The smarter working project – a project strand under the estates strategy – has been established and is in its early stages. The draft PID was reviewed by workforce board who have agreed the work can commence. The project was discussed at the staff forum, and the project team have had their first meeting. Work is now underway to develop plans for wide engagement and dialogue with our staff to create a definition for smart working that works for

us and supports a positive, productive work culture that enables social connectivity to each other and supports well-being.

Programme Management Office

Continuing to maintain the 2019/2020 portfolio dashboard for the reporting of programmes and projects for use by the Transformation Board and Leadership Team Meeting and developing the performance scorecard to report on SIP benefits and progress against the 2019/20 business plan.

As well as work on the following;

1. options for project management maturity assessment.
2. Reviewing options for SRO training.
3. Further project management sessions have been planned for delivery by DHSC.

HR

Recently launched independent exit management service. The new service is run by NHS BSA with the first quarterly report due in October. Also delivered line manager workshops on Managing Sickness Absence in London and Manchester to support rollout of new sickness absence policy earlier this year. Continuing HR support and advice for recent organisational changes relating to the Approvals Programme Team and move of Communications and Public Involvement to the Policy directorate

Finance

Team

Finance team warmly welcome our new Finance trainee, Collin Sritharrathan, to the HRA who will work with the finance team supporting transactional processes.

Procurement - RS Programme

Dedicated commercial capacity to support the RS programme during the next key stage of the process has been approved internally and by DHSC's finance approval panel. Denise King will join the HRA from 23 September.

High-level commercial strategy has been developed, informed by our programme knowledge to date, and the frameworks available.

Facilities

Our facilities management procurement exercise did not generate the level of interest expected from the market. We are exploring options to ensure hard facilities management services are provided for our Bristol / Manchester and Nottingham offices.

Estates

London office move project delivery is being set up with a briefing for all staff planned for 17 September 2019. A programme project manager has been appointed to work across the 5 ALBs (NICE, CQC, HRA, HFEA, HTA) and DHSC / GPA (government property agency) and 5 workstreams have been defined (Culture; Communications; Finance & Commercial; Technology and Facilities Management).

Regional office meetings focusing on Health, Safety and Welfare, Facilities and ICT requirements have been held at all regional offices and will continue on a 6-monthly basis. Estates regional office guide has been launched for all staff to provide key information for staff across the HRA estate.

Corporate secretariat

Fraud, bribery and corruption

New functional standards have been produced by Cabinet Office for fraud, bribery and corruption. The HRA has implemented an action plan to meet these standards and this has been submitted to Cabinet Office to demonstrate our compliance following approval by Audit and Risk Committee at their meeting in August.

ICT infrastructure

Plans to implement WIFI across all our regional offices are being implemented. Work is now underway to roll out Exchange On Line across the HRA. This work will be delivered by the end of calendar year providing improved service performance and better tools to meet HRA requirements.

The HRA continues to be an active participant in the Future Services Programme which aims to replace our current out-sourced ICT infrastructure contract with a SIAM model (service integration and management) where the supplier management is bought back 'in house' to improve performance, value and control. It is anticipated that the service desk functionality will move to the new model early in 2020 with many of the other core functions transitioning during 2020. HRA is represented on the FSP Board and on the various governance groups – including finance, commercial and technology.

Accreditation update

Name of REC	Accreditation status as at 06 September 2019
RECs accredited under 2018 Accreditation Scheme	
West Midlands – Solihull	Full accreditation under 2018 scheme (after completion of action plan)
North West – Liverpool East	Full accreditation under 2018 scheme (after completion of action plan)
London - Harrow	Full accreditation under 2018 scheme (after completion of action plan)
West Midlands - Black Country	Full accreditation under 2018 scheme (after completion of action plan)
South Central - Berkshire B	Full accreditation under 2018 scheme (after completion of action plan)
South Central – Oxford B	Accreditation with conditions (action plan pending completion)
East Midlands – Nottingham 2	Accreditation with conditions (action plan pending completion)
London – City & East	Provisional (action plan pending completion)
North West – Liverpool Central	Provisional (action plan pending completion)
North West – Haydock	Provisional (action plan pending completion)
London – Fulham	Provisional (action plan pending completion)
London – Bloomsbury	Accreditation with conditions (action plan pending completion)
South Central – Berkshire	Provisional (action plan pending completion)
North East – York	Full accreditation under 2018 scheme
Yorkshire & the Humber – Leeds West	Provisional (action plan pending completion)

London – Brent	Provisional (action plan pending completion)
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