# NHS Health Research Authority LogoHealth Research Authority Directorate Update 18 March 2020 Board meeting

# Part 1 - Public

## Approvals Service update

**Combined Ways of Working**

The Combined Ways of Working programme with the Medicines and Healthcare products Regulatory Agency (MHRA) has reached two significant milestones: the 100th application has now been approved, and the process is now being managed on new digital technology. New functionality in the Integrated Research Application System (IRAS) has been released to those taking part in the pilot, allowing them to submit new applications and amendments to existing studies in the pilot. The case management systems for MHRA and the UK Research Ethics Service (hosted by HRA) have been enhanced with electronic interfaces to allow integrated review of the applications. This new functionality will remain limited to the existing pilot group initially in order to gain feedback. Further development by HRA and MHRA is planned, pending financial agreement, and plans for wider roll-out are under discussion.

Alongside this, the HRA is contributing to wider discussions about the future arrangements for clinical trials in the context of future EU trade arrangements.

**HRA Approval**

The emergence of Covid-19 means that the HRA’s standard procedures for managing expedited applications is underway. As expected, early requests have related to amendments to existing studies established to analyse such outbreaks. We are providing advice to those preparing new studies and are starting to receive these. We are grateful to our volunteer members who are prepared to attend additional meetings, or be co-opted across committees in order to meet expedited timelines.

Appointments to the team are now over agreed establishment to ensure there is capacity to support subject matter input into the development of our Research Systems. Staff are now working with our interim, short-term procured resources to implement functionality to develop electronic self-booking of applications and electronic submission of amendments. This will provide interim improvements to user experience and reduce burden on staff, although the functionality will be relatively simple and limited. Timelines for release of this new functionality will be published in due course.

In the Approvals Support Division, work to support volunteer members in the continued move towards review via the HRA Assessment Review Portal (HARP) Member Portal is progressing well with 45% of members are now using the portal instead of requiring paper copies (up from 33% in November). A number of committees are now solely reviewing applications electronically. This is more environmentally sustainable, significantly reduces costs of copying and postage, reduces staff burden and gets applications to reviewers quicker. We continue to provide for specific needs of individual members as needed.

We are also seeing the benefits of the new staffing model and support to committees, with positive feedback from Chairs, and early signs of improvement in performance metrics.

Work to revamp the recruitment and induction of new volunteer members is underway. A new induction webinar ‘How to prepare for your first Research Ethics Committee (REC) meeting’ will go live this month.  This is in response to a survey of newly appointed REC members which identified the need for more help and support in their first few weeks / months of appointment.  Work will commence on a second tier of induction training. The face to face induction course that members attend within their first few months has been revised recently and continues to be adapted in response to feedback from delegates.

**Guidance and Advice**

Following the implementation of the Mental Capacity Act (Northern Ireland) on 1 October 2019 with little advance notice, we have now agreed reciprocal arrangements for REC review of applications involving adults lacking capacity between England/Wales and Northern Ireland. This is a significant step of increased consistency for researchers, simplifying the study paperwork for researchers, as previously different documents were needed for participants in Northern Ireland and liaison between RECs was needed for studies involving more than one nation. We are now progressing revisions that are required to guidance.

Work to update the “Do I need REC review” decision tool so that it is in alignment with a number of minor revisions to the Governance Arrangements for Research Ethics Committees (GAfREC) is due to be completed later this month, and will then be published alongside the revised GAfREC.

Preparation for the implementation of changes to legislation for devices continues with the MHRA. Over time this will include increased liaison between RECs and the MHRA in reviewing applications.

**HRA Approval** **Programme Activities**

With agreement from the Association of the British Pharmaceutical Industry (ABPI) the final stages of work to publish the revised (General Data Protection Regulation GDPR) compliant) model Clinical Trial Agreement (mCTA), Clinical Research Organisation (CRO)-mCTA and Primary care mCTA are now underway.

To align with the work on electronic submission of amendments, work is ongoing to make the necessary changes to the functionality of the amendment tool so that it can be submitted as part of the amendment package. Testing will then be undertaken and release is planned for later in the spring.

**Learning and Development**

Activities relating to learning and development for volunteer committees includes:

* The first wave of five new regional REC Member Training Days have been completed with approximately 300 members attending. Feedback to date has been very positive.  The programme for next year is already under development.
* With the Cancer Research UK Experimental Cancer Medicine Centres we are developing a range of podcasts on complex innovative trial designs, to enhance member’s understanding of the issues these present.
* The Nuffield Council on Bioethics have kindly agreed to record a short webinar within the next few weeks introducing their report on emergency research.  We are planning to use this as a ‘micro’ learning package for RECs to discuss at a meeting.  This model of micro learning packages within REC meetings is one that we will be testing across a range of topics, to make learning more interactive and accessible.
* A review of learning support for REC Chairs is in progress.

Activities relating to learning and development for staff includes:

* Transfer of staff mandatory training to our Electronic Staff Record (ESR) system is almost complete. We have clear reporting and visibility of staff uptake of training for the first time.
* The first of three two-day leadership programmes has started for new and inexperienced line managers. This is being made available alongside the roll out of line management to a new tier of staff within the Approvals Operations team to strengthen individual support and development for staff. We have received positive initial feedback.
* A Staff mental health and wellbeing framework is under preparation.

## Policy and Partnerships update

##### Research transparency

Our Make it Public strategy is ready for public launch. We have continued with our stakeholder engagement activities in preparation for this and continue to receive support for the strategy commitments. Detailed planning is underway for the implementation phase, the start of which will be marked with a workshop with the academic community and an event to thank those who contributed to the development of the strategy. An internal Project Board will be convened to oversee the programme of work to take forward the strategy and we are also exploring the establishment of an Oversight Group with members drawn from the external community.

We have written to the new Chair of the House of Commons Science & Technology Committee, Greg Clark MP, to describe progress with the strategy.

##### Stakeholder engagement

We have now completed the series of interviews with our strategic leadership team and other key staff, as well as our non-executive directors, to map and record current external engagement activities to support the development of an engagement plan. A report will be submitted to the strategic leadership team summarising the findings of this exercise and outlining the proposed next steps.

##### Working collaborative to promote public involvement

One of the priorities for the Public Involvement team over the next year is to work more closely with other organisations which champion the involvement of patients and the public in research. This will help us to make a wider group of researchers aware of our guidance and resources about public involvement. Recent contact has included the UK Standards for Public Involvement Partnership (bringing together senior staff responsible for public involvement across the UK to set and maintain standards for public involvement), the Commercial Clinical Operations Group (made up of senior staff responsible for the setting up and running of commercial clinical trials) and Patient Focused Medicines Development (an international partnership between the pharmaceutical industry and patient advocacy organisation that is working to involve patients in the development of all medicines).

##### Ethical issues in involving patients and the public

Our Public Involvement Lead has been working with a team of public involvement advisers from the National Institute for Health Research (NIHR) Research Design Service and two patient advocates to develop guidance for researchers on how to avoid potential ethical issues when they involve the public in their research. The team is working on a simple version of this guidance to be published on our website.

##### Research related to COVID-19

The communications team has updated our website to ensure that it’s easier to find [information about our fast-track process](https://www.hra.nhs.uk/about-us/news-updates/research-public-health-emergency/) for reviewing research approval applications in a public health emergency.

##### Understanding how applicants use our guidance

The communications team has begun a user research project to identify opportunities in how the organisation presents its guidance and advice to those making an application for HRA Approval. The project, conducted by an external research organisation, will work with HRA staff, stakeholders, partners and the research community to test the most effective means of sharing the information needed to produce high-quality health and social care research studies.

## Governance, Information, Finance & Technology update

**Finance**

**Year-end preparation and external audit**

Preparations are progressing well. Project team is in place, timetable agreed, and report design brief has been developed with a focus on accessibility, infographics and more professional layout. KPMG have performed their interim audit and the finance team are working hard to meet all key milestones.

**2020/21 budget setting**

2020/21 budget set has focused on 100% review of all non-pay expenditure following extensive organisational change processes in recent years. Outline funding for 2020/21 (including indicative increase to fund increased activity and digital transformation) has yet to be confirmed by Department of Health & Social Care (DHSC) due to recent departmental review of all non-NHS funding. We expect funding to confirmed after HM Treasury’s budget on 11 March 2020.

Detailed financial planning work continues based on seven work-packages identified as part of the planning process as well as agreed investment in government priority areas such as ICT infrastructure and estates strategy. Structural changes have been agreed such as reduced vacancy factor managed centrally and backfill funding ring-fenced to continue to improve capacity and ensure operational performance meets target.

**Member expenses**

Discovery work continues to understand benefits of rolling out electronic expenses to committee members. This follows the successful roll out of electronic expenses to staff members April 2019.

**Estates**

London office move. Good progress continues. Office fit out is on track to be delivered by the summer. Facilities management and Technology working groups have developed detailed work plans and are progressing core functions – meeting room booking software, storage requirements, networking, work-station standardisation.

Bristol office move. Project team to be stood up in coming weeks. Discussions continuing with Care Quality Commission and Government Property Agency re: space at Temple Quays House.

**Corporate secretariat**

**Incident management**

A staff communication cascade has been tested for each directorate using data included in ESR. The exercise showed the vast majority of staff contact numbers held on ESR are up-to-date and a message can be quickly communicated to staff in the event of an emergency. A reminder has since been circulated reminding staff to update their contact details and next of kin details when any changes are made.

##### Covid 19 business continuity planning

The business continuity plan for pandemic diseases has been reviewed and updated to ensure our processes and plans are appropriate to manage the Coronavirus outbreak. The HRA continues to follow Government guidance and has published internal guidance for staff and volunteer members. Weekly meetings have been scheduled to review the situation and ensure business priorities are addressed however urgent meetings will be held as and when Government guidance changes. A consideration of staff home working requirements is currently underway.

**Data Security and Protection**

Work is almost complete on the annual submission of the Data Security and Protection Toolkit for the HRA. This is the second year that the HRA has been mandated to complete the online self-assessment tool, provided by NHS Digital, that allows organisations to measure their performance against the National Data Guardian’s 10 data security standards. In addition, the annual information asset review has taken place and the results of this are currently being reviewed.

**Governance**

The HRA’s Standing Financial Instructions, Standing Orders and Scheme of Delegation have been reviewed to ensure they reflect best practice and the HRA’s current organisational structure. The proposed changes have been reviewed by Audit and Risk Committee and are presented to the Board for approval in March 2020.

**Quality**

**Streamline of accreditation action plan**

Audit checklist/report documentation has been amended to streamline the process for distribution of action plans and recommendations for the Support Quality and Performance team.

**Quality Control**

Completed a repeat quality control check on the use of validation under consideration and PR suitability and report findings to the HRA Approval team and member of UKREDG. Subsequent actions to be taken forward by the approval teams.

**Records Retention**

Additional resource has been secured to transfer REC minutes predating 2000 to the National Archive, in line with the Information Governance Alliance guidance (2016).

**Accreditation Audits completed**

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| **REC Name** | **Decision** |
| East Midlands - Derby | Full accreditation |
| London - Surrey Borders | Provisional accreditation |
| North East - Newcastle & North Tyneside 2 | Provisional accreditation |
| London - Chelsea | Provisional accreditation |
| West Midlands - Coventry & Warwickshire | Provisional accreditation |
| London - Westminster | Provisional accreditation |
| Wales REC 2 | Accreditation with conditions |
| Wales REC 4 | Accreditation with conditions |
| Wales REC 3 | Accreditation with conditions |

**ICT infrastructure**

Two major projects have been undertaken by the ICT team over the past few months. The most notable is the move to Exchange On-Line from NHS Mail. The move has enabled the HRA to make the most of the functionality Office 365 offers, reducing compatibility issues, improving self-service and security and enables the roll out of MS collaboration software Teams (planned for Q1 2020/21). The migration was completed for all staff by 28th February. The project was managed manually with all staff extracting their existing email files and migrating them to Exchange On Line. This was necessary due to configuration set-up in NHS Mail. The project was phased over several weeks to enable sufficient support to be available to staff as they migrated. This phased approach provided the support needed although created some challenges with working across two systems. We anticipate closing our NHS Mail email at the end of April 2020.

Windows 10 v1809 has also been rolled in this period, providing additional security features and some extra functionality. Currently 95% of the estate has been updated to this version of the software.

The HRA continues to be an active participant in the Future Services Programme (FSP) and are working closely with DHSC, NHS England and NHS Improvement I to drive improvements and create value. We will be rolling out new mobile phone April 2020 to support improved collaboration and enable better virtual attendance at meetings. We are also working on other projects – unstructured storage, service desk, end user compute which we anticipate will all be implemented in 2020/21. HRA is represented on the FSP Board and on the various governance groups – including finance, commercial and technology.

## Corporate Services update

**2020 staff survey**

The survey launched on 24 February and is due to close on 20 March. Top line findings are expected on 31 March and the full narrative report on 20 April. The content of this year’s questionnaire was developed with a working group comprising Equality & Diversity steering group, Staff Forum, Unison, management and HR representatives

**London relocation (to Stratford)**

Preparatory work being undertaken ahead of formal staff consultation due to begin on 27 April (involves c30 staff).

**HR policies**

A number of policies identified for action through the Audit Committee are being revised – at final draft stage following input from management, staff and Joint Negotiating Committee (JNC) and to go to Leadership Team in April and ratified at JNC end of April.

**Equality, Diversity & Inclusion**

The steering group has agreed a set of priorities for the work to focus on respect, awareness, training and development, social inclusion and recruitment. We are holding a workshop in March for interested staff to develop more detailed work plans for the coming year focussed on these priority areas. The staff-led interest groups are meeting regularly, providing a source of support as well as developing thoughts and ideas to direct our planned activity.

**Smarter Working**

Sub-groups of the project team held workshops in February to develop some best practice/ top tips guides for line management (with a particular focus on good practices when you’re not co-located with your staff) and working well from homes and offices (e.g. taking breaks, staying connected with colleagues, etc). These aim to address some of the themes that came out from work we did with staff in our office locations. Work is underway to develop the outputs of these workshops into resources in conjunction with the communications team.

**Programme Management Office (PMO)**

The PMO has continued to focus on embedding the updated benefits management process. The benefits register is being populated and is being reviewed at the Transformation Board. The Quarter 3 performance report has been created and support has been provided to SLT as part of the 2020/21 business planning process.

The PMO has produced the portfolio dashboard that provides a monthly update on the progress of programmes and projects and is used by the Transformation Board and Leadership Team meeting to review progress. Support has been provided to project managers in the use of the project management process, feedback given on project documentation as well as ongoing support with KPI analysis, HRA Hub, Excel etc. The PMO is contributing to work led by Health Education England to develop some training modules on project management methodologies.