

## **Health Research Authority Directorate Update 20 May 2020 Board meeting**

### **Part 1 - Public**

#### **Approvals Service update**

The COVID-19 lockdown arrangements have had a major impact on the way our staff and volunteers have had to work. We are hugely grateful to our volunteer members in our RECs and CAG who have swiftly adapted to working in online committee meetings with electronic access to all documents. We are further indebted to members who have also agreed to be co-opted to additional meetings or reviewed fast-track applications at very short notice.

#### **HRA Approval**

For our RECs, we have provided training and support to Chairs in moving to online meetings supplemented by support to members unfamiliar with the technology. Although we had made significant progress in supporting members to adopt electronic review through our member portal over the last year, a large number of members have had to move at short notice to online review since we are no longer able to print and post meeting papers. We continue to provide alternatives for those needing specific adjustments. We had already started piloting taking minutes remotely, so again were well placed to train staff to work with Chairs in this way.

Although we have remained open to non-COVID applications, we have had a reduction in total volumes which have allowed the workload to be spread across RECs and staff, which has created some capacity to process expedited studies. However, many REC members have gone the extra mile, supported by our staff to review COVID applications swiftly.

Our fast track process relies on high levels of operational support from senior managers in the team to support applicants, allocate applications to the appropriate review track, and work with the Support Division to slot applications at short notice into meetings or into additional ad hoc meetings. Senior managers have also put extra effort into supporting their teams with the move to home-based working, providing welfare support alongside the corporate support arrangements.

The median time in calendar days from submission to HRA Approval for COVID-19 applications is around 7 days for full REC applications and 3 days for proportionate review applications. This includes some applications assigned as Urgent Public Health studies by the Chief Medical Officer that have been reviewed by the REC within 24 hours of receipt and approved in as little as 3 days. We have also extended pharmacy and radiation technical assurances to COVID-19 studies, reducing

duplication at sites and supporting swift set-up and assisting with the addition of new arms to platform trials.

### **Confidentiality Advisory Group**

The Secretary of State for Health and Social Care has issued a general notice under the Health Service Control of Patient Information Regulations 2002 to support the response to COVID-19. This notice requires NHS Trusts, Local Authorities and others to process confidential patient information (CPI) without consent for COVID-19 public health, surveillance and research purposes. The notice is currently in force until 30 September 2020 and provides a temporary legal basis to avoid a breach of confidentiality for COVID-19 purposes.

This means that activities that normally require CAG support do not need to be reviewed in the usual way where they relate to a 'COVID purpose' and while the Notice is in force. However, to support research ethics committees the CAG is providing informal advice as part of the ethics review fast-track process.

### **Combined Ways of Working**

The Combined Ways of Working pilot with the Medicines and Healthcare products Regulatory Agency (MHRA) has continued, with reduced numbers reflecting the overall drop in study applications. Discussions around the roadmap for further technology developments are underway with MHRA and DHSC.

### **Guidance and Advice**

We have published guidance to support COVID-19 studies and other studies impacted by the effect of COVID-19 on sponsors and sites. This has included process arrangements to provide proportionate and pragmatic arrangements for handling changes to pausing studies, moving to remote contact with study participants or remote monitoring, as well as implementing COVID elements to existing studies. As many studies involve patients who are not able to consent or emergency situations, we have also published guidance on this area that draws together existing guidance in an accessible form.

Following the agreement on reciprocal arrangements for REC review of applications involving adults lacking capacity between Northern Ireland and England and Wales, we have nearly completed revisions to our guidance.

An update to 'Governance Arrangements for Research Ethics Committees' (GAfREC) was published in March. The online tool 'Do I need REC review' has been updated in parallel.

We had been working with MHRA Devices colleagues to prepare for the implementation of the EU Medical Devices Regulations, including some revision to the application form in IRAS and exploring the possibility of coordinated review of clinical investigations of medical devices. The implementation of the EU Medical Devices Regulation has been deferred for one year (now May 2021) because of COVID-19 pandemic and so work to revise the application form has been paused for now.

## **Programme activities**

The March 2020 versions of the commercial model Clinical Trial Agreement (mCTA) and Clinical Research Organisation model Clinical Trial Agreement (CRO-mCTA) have been published.

Agreed by the Association of the British Pharmaceutical Industry (ABPI), Health and Care Research Wales (HCRW), Health and Social Care Northern Ireland (HSC NI), the Health Research Authority (HRA, England) and NHS Research Scotland (NRS), the revised and updated templates reflect significant engagement with commercial research sponsors, CROs and the NHS. They provide GDPR and Data Protection Act 2018 compliant clauses for the processing and sharing of personal data. These documents are the culmination of extensive engagement and joint working, led by HRA, over a period of two years.

Two key developments to IRAS are scheduled for release in the coming weeks. These had been under development prior to the COVID pandemic. After discussion with stakeholders we have confirmed that we will release these to the research community as planned, as they will deliver benefits to users as well as freeing up staff capacity within the HRA.

It is anticipated that an online booking service will go live on 19 May 2020. External communication announcing this change was issued by email to specific stakeholder groups UK-wide on Monday 11 May 2020. This will be available to non-COVID applications and will be available 24/7, replacing the need to make phone bookings during working hours. This will release staff from our booking service to support the operational team. COVID applications will continue to receive bespoke and out of hours support.

Functionality for online submission of amendments will go live shortly after this. This will include a new amendment tool for applicants to ensure that amendments are submitted to the correct bodies and implemented in the right way. This will aid consistency and streamline the process for implementing amendments across the NHS. Initial communication on these changes was issued (as above) on Monday 11 May. This functionality will save considerable staff time, as amendments currently have to be uploaded manually from emails, with some amendments consisting of dozens of documents.

## **Learning and Development**

We have made significant advances in progressing online learning in the last few weeks. We have worked with external trainers to review the process of delivery and content.

We are working with others to produce a set of 8 podcasts for REC members and other stakeholders around Complex Innovative Design (CID) trials. These will compliment a parallel set of podcasts being produced by NIHR and other partners in the research environment.

We are putting together a series of resources which will be made available online as part of our micro workshop programme – short (one hour) packages of learning resources and questions to support in-committee learning opportunities. Initial topics will include: risk, public participation and research in emergency situations

As part of the development for micro workshops, we have produced a webinar with Katharine Wright, Associate Director for the Nuffield Council on Bioethics, introducing their report on 'Research in Global Health Emergencies: Ethical Issues' (2020).

Our normal schedule of face to face training for REC members has been revised. Live webinars will be recorded and edited, then made available on the Learning Management System (LMS).

For staff, the move of mandatory training to ESR has been completed. We are re-scheduling staff face to face training to online workshops where this is realistic. Working with staff representatives and HR, we have written a draft framework for staff mental wellbeing in the HRA, and taken this to the Staff Forum.

## **Policy and Partnerships update**

### **Supporting staff during lockdown**

The primary focus of the Communications team over the past two months has been on internal communications. With an overnight shift to 100% homeworking and significant pressures on staff with caring responsibilities, we have focussed our communications activity largely on ensuring that staff feel connected to the organisation, are aware of the support available to them and understand what the HRA is doing to support COVID-19 research.

A recent staff survey showed that 83% of staff are either satisfied (19%) or very satisfied (64%) with our communications to staff.

### **External communications**

Our external communications – through HRA Latest, the website and social media – has concentrated on COVID-19. We have used these channels to make researchers aware of our fast-track approvals and research support services, to thank our volunteers and to amplify COVID-19 related messages from our partners such as NIHR. Our external communications have performed very well compared to our normal activity.

### **Research transparency**

The planned launch of the Make it Public strategy for the end of March was postponed due to COVID-19. We are currently re-planning the project and hope to launch in the summer, depending on the volume of COVID-19 work at the HRA and across the research community.

In the meantime, the Policy and Engagement team has led on HRA work to ensure that COVID-19 research studies, approved in very short timelines, are made visible on our website in an equally fast-tracked way. In the interests of speed, we started this as a manual process to publish in a separate part of the website from other research studies. We are now exploring how this swift transparency could be incorporated into normal ways of working.

## **Working collaborative to promote public involvement**

The Public Involvement team has also reprioritised its work to focus on COVID-19. Following a successful workshop with public involvement leads and patient and public contributors, we published a statement to make it clear that public involvement is important, expected and achievable. The team is now working with partners to set up an early advice and signposting service to encourage public involvement in COVID-19 studies. It will involve advising researchers on suitable involvement methods and putting them in touch with groups across the UK who can organise patient and public review of studies speedily and at short notice.

## **Governance, Information, Finance & Technology update**

### **Finance**

#### **Year-end preparation and external audit**

All key milestones have been met in preparing for this year's annual report and accounts. This includes draft financials and majority of supporting information. Annual report draft presented to Audit and Risk Committee together with proposed new design for document which meets recently introduced government accessibility requirements.

#### **2020/21 budget setting**

2020/21 financial plan has been developed to support core service delivery and 13 priority transformation projects including both infrastructure and transformation work packages. Bridging funding for research systems transformation programme £2.6m has been confirmed by DHSC as well as 2-year funding from NHS X to support data driven technology programme £2.5m. Confirmation for core grant in aid funding including £2m increase to support widening role has yet to be confirmed but this is only a formality. Financial plan assumes this uplift.

#### **Member expenses**

Pilot project to understand benefits of rolling out electronic expenses to committee members is progressing although at a slower pace due to year-end pressures. Infrastructure configuration is now in place and live testing will begin in the next month.

### **Estates**

London office move. Programme has been delayed due to C19 supply chain issues. Whilst good progress continues on key delivery areas including facilities management planning, office fit out and agreement on technology networking solution, delays in securing a date for telecommunications' survey has pushed timelines out. London office staff have been informed of this delay and plans to start associated organisational change have been rescheduled. C19 impact (transition and long term) is also being considered by all parties in relation to design and ensuring a safe environment for all.

Bristol office move. Project team has been stood up and outline plans for space, shared with Care Quality Commission at Temple Quays House confirmed. Dilapidations report completed for existing property, Whitefriars and associated costs included within 2019/20 financial accounts.

## **Procurement**

Activity undertaken this period includes:

1. RS programme resources via Method (March – September 2020)
2. RS programme development resources (June – September 2020)
3. Contract change existing RS programme development resources (April – May 2020)
4. Pega licencing contract (2 years June 2020 to June 2022)
5. Executive recruitment
6. Cleaning contract – Manchester
7. Dilapidations review - Bristol

## **Corporate secretariat**

### **Business Continuity Planning**

C19 stand up meetings and associated planning have been introduced. Full details provided as part of Board update.

### **Data Security and Protection**

All mandatory requirements have been completed for Data Security and Protection tool kit except one – 95% completion of mandatory training. To date current compliance is 87%. Compliance is linked to salary progression and will be followed up as part of the Annual Appraisal process.

### **ICT infrastructure**

Zoom has been rolled out to support virtual committee meetings and office meetings. Guidance has been provided to staff based on Cabinet Office advice to ensure security concerns relating to Zoom have been addressed.

Microsoft Teams roll out is now in train and is expected to be complete by the end of June. This includes moving all HRA external phone numbers to a new supplier. Teams will be our main collaboration tool for the HRA, replacing Skype and Lync. Workshops are planned for staff to start to understand Teams functionality and what the package is capable of.

The HRA continues to be an active participant in the Future Services Programme. As part of the twin track approach, we are working closely with NHS E and I to drive improvements and create value. Our new mobile phone contract is currently being rolled out, using NHS E&I existing contract with replacement of existing service desk planned for later this calendar year.

## **Corporate Services update**

### **Research Systems**

The Business Case for further funding to support the Research Systems Programme gained approval to go to market from DHSC Investment Committee ahead of full approval. NHS X has also approved spend for bridging funding. The new Programme Manager started on 11 May 2020 and the recruitment of Chief Transformation Digital Officer has begun with interviews set for the end of July

Release of on-line booking remains scheduled for deployment into production on 18 June. Functionality will be available to users from that date and release of on-line submission of non-CWOW amendments remains scheduled for deployment into production on 18 June. Functionality will be available to users from early June to allow for communication to users and to facilitate stakeholders to make the required changes to their internal standard operating procedures or work instructions.

## **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. The planned workshop in March had to be adapted to a shorter virtual session with break-out sessions within each of the staff-led interest groups. The first session covered the theme 'awareness' for the groups to develop ideas on what the work for this theme would need to involve.

The plenary session was held on 12 May to share the ideas across the groups and set them the task of discussing the activities needed to support the next theme of 'Respect'. The steering group is assimilating the ideas and will develop a plan for delivering the work over the next few years.

In addition, the steering group agreed our Head of Learning and Development could make a proposal for the training and development theme, integrating into existing learning opportunities planned for the year as far as possible, based on discussions to date. The work is progressing at a slower pace than originally envisaged but the engagement of staff with lived experiences is crucial to the development and delivery of activity together that will ultimately make a difference to our staff. Staff-led interest groups are continuing to meet regularly, providing a source of support in addition to developing the detail of our plans.

Also participated in the cross-ALB group on Equality, Diversity & Inclusion to share ideas and best practice across our organisations.

## **Programme Management Office**

The PMO has contributed to the annual report process and has created the Quarter 4 performance report. Support has been provided to SLT as part of the 2020/21 business planning process and the new portfolio has been created with the agreed programmes for 2020/21 that will be reviewed at the Transformation Board. 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.

During this period the PMO has provided Programme Management support to the Research Systems Programme including planning the procurement activity, planning the programme, producing a regular highlight report of progress and putting in place a lessons learned log. 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.



## **Staff survey**

A full report of the 2020 staff survey results is now available. The report has been shared with the senior team and key findings are to be presented at the Board's meeting on 20 May. The main findings are to be shared through an All Staff VC later on the same day. Following reflection on this year's results the proposed next step is to develop an action plan, focusing on areas to improve and progress any outstanding actions from last year's plan that remain relevant.

## **Chief Executive recruitment**

Preparatory work continues to support recruitment of our new Chief Executive. The job description is in final draft following input from the Board and progress continues to identify our preferred search firm with a supplier to be identified by end May.

## **Policy review and development**

A number of new HR policies have been reviewed and approved by Leadership Team and our Joint Negotiating Committee: Probationary, Lone Worker and Home Working Flex policies. These were identified for action through the Audit & Risk Committee.

## **Death in service protocol**

A communications protocol has been developed by HR and Communications in the event of the death of a member of staff or a committee member during the current pandemic. The protocol aims to help us manage what would be very difficult circumstances in a sensitive and compassionate way.

## **HRA Mainline**

Lockdown has not had any negative impact on the service provision of the mainline. There have been a large proportion of calls to the mainline regarding around Covid19 studies and fast tracking. Some 40-45% of all calls to the mainline are around Covid19.

## **Corporate Travel Management (CTM)**

Steps have been taken to mitigate against losses for travel and accommodation booked for part of March and for April and May. The Corporate Services Business Manager has liaised with the account manager at CTM and bookers have been updated as to the necessary steps to be taken. The situation will be reviewed again in mid-May following latest government announcements. Withstanding any losses, there will likely be a significant underspend in the travel and accommodation budget organisationally.

## **HRA Unison Partnership**

The quarterly JNC meeting took place in late April and it was a productive and positive meeting. There has also been a number of joint activities where the Union reps have been able to contribute and collaborate.

- Joint working on the Equality, Diversity & Inclusivity (ED&I)
- Joint working on staff survey particularly ED&I aspects
- Joint working on the new Employee break scheme policy, and several existing policies recently revised.