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| **Agenda item:** | **7** |
| **Attachment:** | **B** |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 20 January 2016 |

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| **Title of Paper:** | HRA Approval – Brief progress report 2016 01 12 |
| **Purpose of Paper:** | To provide the HRA Board with a latest position statement on HRA Approval as we approach critical decision making for promoting cohort 3 and confirming arrangements for cohort 4 |
| **Reason for Submission:** | Information and discussion |
| **Details:** | The paper provides a summary of activity across all work streams of the HRA Approval Programme |
| **Suitable for wider circulation?** | **Yes** |

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| **Recommendation / Proposed Actions:** | **To Note** | |
| **Comments** |  |

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| **Name:** | Mary Cubitt and Janet Messer |
| **Job Title:** | HRA Approval Programme |
| **Date:** | 12 January 2016 |

HRA Approval – Brief Progress Report for HRA Board

# Introduction

1. The HRA Approval Programme Board, and associated project boards, receive regular highlight reports of progress against the HRA Approval Programme Plan. These are supported by detailed programme plans and critical paths. In addition the HRA Approval Programme Board receives regular Assurance Reports evidencing progress and identifying areas where work remains.
2. As the HRA Approval Programme is approaching key decisions about completing full implementation and UK-wide decisions around the local information package to be provided by sponsors/CIs to research site are in progress, it may be helpful to the HRA Board to have to hand a brief progress report on what has been achieved so far in the HRA Approval Programme.
3. Please note that the HRA Approval Programme is both accepting feedback and proactively seeking feedback in order to continue to refine and develop the processes.
4. The programme has been subject to three Gateway / Healthcheck reviews.

# High level summary of progress

1. The phased roll out approach and the definitions of the phases was published in Jan 2015.
2. Agreement has been reached with NIHR CRN about interim and long-term interactions to support Portfolio eligibility decisions.
3. The majority of staff have been recruited and ongoing volume of work and capacity will continue to be tracked.
4. Proactive engagement of REC chairs and members in England as well as RES staff has been undertaken.
5. For studies that require REC review, if the REC is an English REC, the committee is provided with an initial assessment summary of compliance or outstanding issues.
6. HRA Approval is operational for
   1. NHS staff studies in England not requiring REC review from 11 May 2015
   2. All studies taking place in primary care settings only in England from 10 August 2015.
   3. Studies other than clinical trials and investigations with sites across the UK from 30 November 2014
7. First test commercial CTIMP (with a site in Northern Ireland) accepted Dec 2015.
8. As of 8 January 2016 62 studies have received HRA Approval with 23 applications in progress.

# External Communications and Training

1. Communication
   1. The HRA website and HRA Latest have been key vehicles to provide updates and applicant guidance.
   2. An email cascade mechanism to NHS R&D has been in place through change leads (see below)
   3. For cohort 2 – messages sent specifically to primary care contacts across universities and a briefing paper for practices developed and communications through RCGP.
   4. For cohort 3 – targeted messages to non-commercial sponsor list held by HRA and targeted email cascade. Non-commercial sponsor training targeted.
   5. Continuous engagement with ABPI, CREN, cCOG and others.
   6. Champions for Research Support updated and engaged on quarterly basis.
   7. Change Leads (see below)
   8. MRC Regulatory Support Centre developing materials to support communication to their community
   9. Engagement log of speaking engagements maintained.
2. External Training
   1. Included in HRA Researcher Training days from Sept 2015
   2. Non-commercial sponsor training piloted Oct 2015
   3. Commercial sponsor training – EMIG Jan 2016, ABPI supported train the trainer Jan and Feb 2016
   4. Large event planned with ICR for Feb 2016.
   5. Materials to be made available on HRA website when tried and tested.

# Change across the NHS

1. In Oct 2014 the HRA published a document which clearly laid out the continuing role of NHS R&D management functions once HRA Approval would be in place. A companion document for primary care was developed collaboratively with and published by the NHS R&D Forum.
2. Regional change leads have identified change contacts in R&D offices supporting all NHS organisations in England and these have been the key routes for dissemination of information to NHS R&D management teams.
3. Regional change leads have held meetings and workshops across all regional to not only describe change but to work collaboratively to consider what process changes are needed.
4. Regional change leads linking with NIHR CRN Research Management and Study Support Service Leads to encourage consistent communications.
5. Support provided to CRN to develop good practice guidelines for local confirmation of capacity and capability.
6. Template email for confirmation of capacity and capability provided in response to feedback.
7. Change readiness assessments across NHS R&D management in England currently that the majority of people are now actively waiting to receive their first studies to test and refine their processes.

# Cross-border arrangements

1. Agreement has been reached across the 4 nations for compatible arrangements for studies with cross-border sites. The process will be reviewed and refined through testing on cross-border studies.
2. HRA assessment has its origins in the previously agreed UK-wide study wide review criteria.
3. The HRA acknowledges that the move in England to address issues specifically for the NHS in England have presented challenges to the other countries, not least because of the pace of change, and careful handling has been required to ensure continued UK-wide operation of RECs and broader arrangements for compatibility.
4. A number of workstreams are being pursued on a UK-wide basis:
   1. Model commercial trial agreement (mCTA) – ABPI has initiated a review of the existing agreement. HRA has sought views from NHS organisations in England on the first draft, and liaised with colleagues in the devolved administrations. Further discussion with ABPI will be taken forward to achieve a revised mCTA for the UK (retaining the existing nation-specific legal references).
   2. Model non-commercial agreement (nMCA) – HRA has worked collaboratively with representatives from sponsors and sites across the UK to review the existing agreement. Following a review by HRA lawyers, a final version is under preparation for formal review by the devolved administrations.
   3. The practical implementation of the UK guidance on Attribution of Costs of R&D (AcoRD) is informing the development of costing and attribution processes for non-commercial studies in HRA Approval. These discussions are included in a DH-convened group with UK-wide representation.
   4. HRA Approval uses the Industry Costing Template which is used across the UK.
   5. The use of the IRAS number as a universal identifier on participant facing information has been agreed UK-wide
   6. Pharmacy and radiation technical assurances have been developed and tested through the UK-wide Experimental Cancer Medicine Centres. Decisions about wider roll-out will be taken in discussion with the devolved nations.
5. These and other issues related to the use of SSI Forms in England led to proposals that were tested in the early cohorts of HRA Approval. This led to the UK-wide call for comments on site specific information issued on 20 November 2015

# Information Systems

1. Historically there have been differences in the mechanisms for submission of the R&D application for study-wide review across the UK, with only CSP having e-submission. E-submission for R&D has therefore been a high priority for the IRAS Partners, but achieving it has been complex due to different IT systems in each nation.
2. A combined REC and R&D Form has been developed in IRAS to allow one application for REC and HRA assessment in England. Making use of the existing e-submission for REC applications to HARP, the combined form provides a simple mechanism to achieve e-submission for R&D across the UK. The Devolved Administrations have agreed to adopt the combined REC and R&D Form from 1 April 2016.
3. A portal has been developed in HARP so that NHS organisations can confirm for themselves the status of a HRA Approval study. The development of this portal, and the role-based access to HARP for assessors, has demonstrated the potential for other parties to securely access relevant information in HARP, and work is now underway to allow Devolved Administrations R&D coordinating functions to have relevant role-based access to HARP and therefore allow the combined REC and R&D form to be used across the UK.
4. E-submission of amendments UK-wide, which would have been extremely complex if there had been separate e-submission routes for R&D across all 4 nations can now be scoped.

Mary Cubitt and Janet Messer

HRA Approval Programme

12 January 2016