HRA & NHS current progress against the recommendations outlined in the recent report from the Academy of Medical Sciences (AMS), Cancer Research UK (CRUK) and the Wellcome Trust on the *'Regulation and governance of health research: five years on'*

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| **Recommendation** | **Current status – October 2017** |
| HRA should work with funders and sponsors to develop **effective end-to-end trial timelines** that include metrics which span the whole system and start from the moment of grant award. | *HRA, NIHR, DH and the Devolved Administrations are collectively reviewing the way in which information about site set-up is measured, working to agree common definitions and efficient reporting arrangements. We are liaising with Cancer Research UK to explore data they have collected from grant funding to study delivery.*  *We have initiated work on business intelligence as part of the Service Improvement Programme.* |
| The sector should work together to support the HRA in **development and uptake of model contracts** and if necessary advocate for the HRA to receive additional resource to complete this vital task. | *The revised model Clinical Trial Agreement (mCTA) and associated guidance is nearing publication, following collaboration with the Devolved Administrations and the Association of the British Pharmaceutical Industry (ABPI). We have agreement from the Devolved Administrations (DAs) for a single UK agreement.*  *We are also making good progress on the revision to the model Non Commercial Agreement (mNCA), with the aim to publish in early 2018.* |
| NHS Trusts should ensure that R&D Offices are not duplicating the review carried out under HRA Approval. | *Within our Service Improvement Programme we are ensuring that we work collaboratively so that R&D offices do not need to duplicate the review.*  *Where we become aware that this is happening we have been meeting with the R&D office to understand any concerns that they may have and to share information so that they understand the new process and can alter their own practice.*  *We are exploring, with others in the research community, the concept of an NHS concordat.* |
| R&D Offices should work with the HRA to establish clear escalation pathways for researchers so that delayed studies can be expedited. | *We have provided a range of escalation routes through individuals who engage with the research community and via a generic email address.*  *We are also actively reviewing feedback to avoid any issues.*  *Dedicated assessors are now assigned to studies at the outset to ensure that researchers have a named contact.* |
| The HRA should establish a centralised repository for documents such as NHS staff CVs, Good Clinical Practice (GCP) certificates and other standard documentation necessary for study set-up. | *This will be a key user requirement as part of the specification for a new IRAS.* |
| NHS Trusts and R&D Offices should ensure that staff are **trained and supported to make risk-proportionate decisions** and avoid overly risk-averse behaviour, with senior managers helping to effect such culture change. A risk proportionate approach should also be encouraged by sponsors. | *We encourage this approach in our regular engagement with NHS organisations and sponsors. We work closely with the NHS R&D Forum that provides training and resource exchanges to support this. We also issued guidance on proportionate approaches to consent in January 2017.*  *The HRA’s assessment is designed to be proportionate in itself, but also to set out expected proportionate site arrangements in the information for sites.*  *HRA has recently launched a number of e-learning modules to assist the research community in understanding the principles of the regulatory system, and in developing a level of expertise that supports effective decision-making.* |
| The UK should maintain and support a strong national regulator for clinical trials | *HRA works closely with the Medicines and Healthcare Products Regulatory Agency (MHRA) to maintain an efficient regulatory system for clinical trials.* |
| In preparing for the UK’s exit from the EU, the MHRA, HRA and other stakeholders in the UK health research ecosystem must prioritise continued harmonisation/compatibility with the EU regulatory/clinical trials system and access to the EU portal and database. | *We are working closely with MHRA to implement the necessary business processes, integrated arrangements and IT to support implementation of the EU Clinical Trials Regulation. In addition we are undertaking equivalent work for alternative scenarios if we do not or cannot access the EU portal with the MHRA.* |
| The potential for establishing further regulatory flexibility for single state trials in the UK should be explored, whilst continuing to ensure compatibility with EU regulation. | *The scenarios that we are exploring with MHRA include potential arrangements for single state trials.* |
| Clear communication is needed from regulators on how the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines should be implemented – including highlighting that these are not a legal requirement – to ensure that they are not over-interpreted. R&D offices to also ensure that staff are aware of these expectations. | *We published the joint HRA/MHRA statement on GCP in the Proportionate consent guidance from January 2017 and we have now sent this out as a separate statement asking organisations to sign up in support. AMS amongst many others has signed up to this and this will shortly be placed on our website.*  *We are working with others (MHRA and NIHR) to clarify when ICH GCP is or is not applicable.*  *(The possibilities for influencing future ICH GCP guidelines are not clear as this has previously been through the EU).* |
| Patient involvement or input in clinical trials and associated regulation should be ensured where possible | *We continue to support this, including providing good practice information, and signposting. We are undertaking a project to explore the role of RECs in considering patient involvement as part of their review. The HRA Public Involvement in Ethical Research (PIER) project has been embedded in our Service Improvement Programme to ensure that HRA approval processes and guidance take account of the importance and benefits of this involvement.* |
| The research community and patient groups should be given an opportunity to input towards Government’s plans for implementation of the General Data Protection Regulation (GDPR), in order to ensure that it is implemented effectively. | *We submitted a bid to the Commissioner’s Office (ICO) to undertake a project on this topic and we are currently working with others to develop guidance and communications.* |
| With the implementation of the GDPR, Government should use this opportunity to further simplify and provide clarification on the data governance landscape | *We are collaborating with NHS Digital, Medical Research Council (MRC) and others to streamline systems for approval and access to data, and provide a route map for researchers. We are working to provide consistent language and consistent standards e.g. for consent. This work is reported regularly through the NHS Digital Research Advisory Group.* |
| Clarity is needed on the implementation of the new opt-outs (and what will happen to existing opt-outs for patients) that will be proposed in response to the Caldicott Review, and Government needs to work with all stakeholders including the research community on implementation and delivery of these opt-outs. | *We maintain good relationships with NHS Digital and the National Data Guardian. The HRA is represented on the National Data Opt-out Programme Board.* |
| All stakeholders must recognise the importance of building and maintaining public trust in the use of patient data, and support this wherever possible. The Understanding Patient Data initiative is working to develop tools and resources to support this. | *We have completed the CAG public engagement work on the factors to be taken into account by CAG in reviewing studies where identifiable data is used in commercial research.*  *We are now working on the joint HRA/Human Tissue Authority (HTA) public dialogue project on sharing patient data with tissue for research which is part-funded by Sciencewise. Workshops have started and we expect this work to report their findings later this year. We are building on Wellcome’s ‘Understanding Patient Data’ work and Wellcome are represented on the HRA Oversight Group for this project.*  *Through the NHS Digital Research Advisory Group we are influencing effective regulatory and oversight arrangements that will command public support.* |