

The MRC Regulatory Support Centre mrc.ukri.org/regulatorysupportcentre has compiled the following update.

Please circulate this to any appropriate colleagues.

Regulatory Support Centre news:

New contact details

The Regulatory Support Centre emails have changed. If you have a regulatory or governance question, you can now reach us on: rsc@mrc.ukri.org. The format of our personal email addresses is now firstname.surname, followed by @mrc.ukri.org. We've redirected email from our old addresses, so if you have emailed us there, we should receive it.

Guidance notes – finalised and coming soon...

Guidance Note 6 on Controllers and Processors is now published on [GDPR Resources](#). We've also finalised guidance to support the roll-out of the National Data Opt-out to all NHS organisations in England. We'll publish a link to this guidance shortly in 'News' at mrc.ukri.org/regulatorysupportcentre.

Survey exploring regulatory and governance issues facing the research community

Since our last update, we've been busy analysing almost 400 responses to our survey. In terms of the results a few key themes have emerged: GCP training - there's wide variation in terms of both the requirement for, and frequency of, GCP training in the UK; issues with health data access and linkage; and the need for more training and/or guidance in GDPR and confidentiality. Over the coming months we'll explore what our role could be in addressing these issues and we'll keep you posted on progress in future updates.

The changing regulatory landscape

Brexit update – If we leave the EU with a deal, the associated transition period means we will adopt EU Regulations where implementation is before 31st December 2020 (see [implementing the transition period](#)). The UK is therefore likely to adopt the new EU Medical Devices Regulation. The EU Clinical Trials Regulation is less certain (at the end of last year, EMA agreed to begin audit of the [Clinical Trials Information system](#) in December 2020).

A new UK Medicines and Medical Devices Bill 2019-20 is being drafted. The bill aims to keep UK regulatory regimes in line with international and scientific standards as they develop.

No-deal guidance was updated in October by [HRA](#) (this includes guidance on [medical devices](#) and [CTIMPs](#)). MHRA have released a webinar: [Preparing to make submissions to the MHRA after Brexit](#) – explaining the new MHRA systems that will need to be used if there were a no-deal Brexit. [ICO](#) have also updated their no-deal guidance.

We'll signpost further updates from the [RSC website](#).

Engaging the public

- **Wellcome Trust** – [Discuss the independent report from Demos](#) which explores how best to talk to the public about research online. Whilst [redefining public engagement with science](#) looks at how to actively engage the public in research.
- [UK standards for Public Involvement in research](#) now available.
- [Be Part of Research can promote your study](#) - NIHR launched [Be Part of Research](#) last May. Designed for the public, it makes information about research available to anyone who wants it.
- [NIHR launches free online course aimed at the public: What is Health Research?](#)
- [EMA launch infographic](#) which illustrates the journey of a medicine 'From lab to patient' and the EMA's role in authorisation.
- [Biobanking consent game for patients](#) is a free, customisable biobanking game for patients.

HRA News

- [Make it public](#) – Last year more than 700 individuals and organisations responded to the Make it public consultation. The consultation informed development of a strategy, which was agreed in principle in December. In early February 2020, the strategy will be formally approved and an implementation plan agreed.
- [Complex innovative trials](#) – Calls for 10 recommendations to be implemented to get innovative treatments to patients with cancer faster.
- Read about the HRA's and MHRA's [‘combined ways of working’ pilot](#). The scheme aims to streamline the approval and management of CTIMPs.
- **UK Local Information Pack** - the **non-commercial** [Organisation Information Document](#) and guidance have been updated to clarify the authorisation section.
- Learn more about [NHS England’s standardised approach to costing and contracting for commercial research](#) (see also [NIHR’s interactive Costing Tool \(iCT\)](#)).
- **Pharmacy Assurance** - From 1st April 2020, all phase I-III oncology trials and all phase III non-oncology trials led from England or Wales are expected to submit their studies for review through the [Pharmacy Assurance self-managed process](#). The technical assurances team are running a [series of face to face workshops](#) to support this.
- [Technical Assurance](#) - From 1 April 2020, the HRA expect submissions to Technical Assurance (i.e. Pharmacy Assurance and/or Radiation Assurance) to include review fees in their budget where these are applicable. You'll can find out when review fees apply on [IRAS](#).
- In collaboration with the HTA, the HRA have released two [e-learning modules about Research Tissue Banks](#).

Human Tissue Authority News

- HTA has published [Our year in numbers 2018/19](#) and the [HTA Annual Report 2018/19](#).
- [HTA licence fees 2020/21](#) – Fees across all sectors will increase by 4% from April 2020.
- **Human Application sector** - Compliance reporting is due in January 2020. For further information, please email enquiries@hta.gov.uk or call 020 7269 1900.
- [Test your knowledge on HTA legislation](#).
- Since our last update the HTA has added new content to the [HTA Blog](#).

Information Commissioner’s Office News

Please note that the ICO provide generic guidance for all organisations who hold personal data, these news items are not necessarily research specific:

- ICO announce their next steps in developing an [Auditing Framework for AI](#). This includes [consultation on first piece of AI guidance](#) (the consultation closes on **24th January 2020**).
- ICO are consulting on [draft right of access guidance](#) ('right of access' is also known as 'subject access'). The consultation closes on **12th February 2020**.
- ICO are also consulting on the [draft direct marketing code of practice](#). This consultation closes on **4th March 2020**.
- [Read about the ICO’s work in Data ethics and the digital economy](#).
- [ICO to chair OECD working party and develop international standards](#).

Other news items

Public Health England’s Office for Data Release (ODR) will offer the webinar **ODR Approval: how to submit a successful application for PHE data** on [24 Apr 2020, 10:30-11:30](#) and [24 July 2020, 10:30-11:30](#).

[NHS Digital report](#) – NHS Digital have published a clinical review exploring the use of patient-level data released through [Data Access Request Service \(DARS\)](#).

[Survey on novel trials and MHRA advice services](#) – As part of their work to implement the Life Sciences Industrial Strategy (LSIS) and Sector Deals, the MHRA have released [a survey](#). This will feed into an upcoming workshop, possible guidance, and will help shape future services.

AMS publish [Transforming health through innovation: Integrating the NHS and academia](#).

[ARMA Framework of Policies and Procedures for University Research Ethics Committees](#)

The Association of Research Managers and Administrators (ARMA) are revising this framework in partnership with the UK Research Integrity Office.

[Assessing a national service for international due diligence](#) - A consortium led by ARMA will explore the feasibility of a national service for due diligence in UK-funded international research.

Learn about Wellcome's campaign to [build a better research culture](#).

The Research Quality Association (RQA) are offering a free [Data Integrity](#) e-learning.

[Risk Management Standard for Medical Devices ISO 14971:2019](#) – Replaces 14971 of 2007. The 14971 standard can be applied to all phases of a medical device's life-cycle.

Training and conferences

[Research but not as we know it: Managing novel methods in research](#)

Date: 2nd March 2020

Venue: London

[NHS R&D Forum Annual Conference \(RDF20\)](#)

Date: 10-12th May 2020

Venue: Newcastle