

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

Please circulate this to any appropriate colleagues.

Regulatory Support Centre news:

Survey exploring regulatory and governance issues facing the research community

We will shortly release our online survey to explore regulatory and governance issues facing the research community and try to identify root causes. We will email you when the survey goes live, and post details on 'News' at: mrc.ukri.org.uk/regulatorysupportcentre.

Forum events

At our last Research Governance Forum and Translational Project Managers Forum events we discussed how we might potentially change running these events in future. We're currently considering options, and will be in touch shortly to outline our plans for these events in 2019.

General Data Protection Regulation (GDPR) – GDPR Resources

We have added some new frequently asked questions to our GDPR resources, available from 'News' at: mrc.ukri.org.uk/regulatorysupportcentre.

The changing regulatory landscape

Brexit guidance – Since our last update the [ICO](#) has released Brexit guidance; the [MHRA](#) updated their Brexit guidance for the regulation of medicines, medical devices and clinical trials and the [HRA](#) released a statement on no deal implications for health and social care research.

We'll keep you informed of further developments on the [RSC website](#).

Regulatory Support Centre training courses

To book a place on any of the following courses, please contact us on info@rsc.mrc.ac.uk.

Date	Course	Location
14 Mar 2019	Consent and Transparency	WTCRF, Edinburgh
19 Mar 2019	Consent and Transparency	Glasgow CRF, Glasgow
26 Mar 2019	GCP for non-trialists	WTCRF, Edinburgh
4 Jun 2019	Human Tissue workshop (Scotland)	WTCRF, Edinburgh

Engaging with the public

- [Cancer Research UK Patient Involvement Toolkit for Researchers](#) – new version released.
- [Wellcome Engaging the public](#) – Learn more about Wellcome's public engagement work.
- [Next steps for Understanding Patient Data](#).

HRA News

- [NHS Excess Treatment Costs](#) – NIHR has released a video explaining NHS Excess Treatment Costs for non-commercial research in England. A new system for managing NHS Excess Treatment costs is currently being trialled, with full roll out planned by **April 2019**.
- [Commercial research in the NHS in England](#) should now use an [unmodified model site agreement](#) and the [NIHR industry costing template](#). The HRA are asking companies to [contact them](#) where they feel changes to the agreement are necessary (the HRA can waive the use of the unmodified agreement, but only on a case by case basis).

- **Research involving ionising radiation**
 - Updated guidance and e-learning can be accessed from [HRA's ionising radiation page](#).
 - Radiation Assurance accepts cardiology, oncology, neurology and rheumatology studies, involving ionising radiation exposures, which will take place across the UK in the NHS (or HSC in Northern Ireland). Please note that a fee may be applicable for Radiation Assurance – see [applying for radiation assurance](#).
- HRA releases [bite size eLearning modules for student researchers](#).
- **IRAS v5.10** – IRAS was updated to version 5.10 on **13th December 2018**. For full details of the changes please see [Updates](#).
- HRA publishes a [customer charter](#).

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:

- [Guide to data protection](#) – ICO have updated their guide to data protection to include guidance on basic concepts and how UK data protection legislation works. You'll find full details of what's been added in '[What's New](#)' (including more guidance on contracts and new guidance on data controllers and data processors).
- [AI and data privacy](#) - ICO has appointed an in-house expert to research and investigate the impact of Artificial Intelligence on data privacy.
- ICO has been awarded a [£537,000 by government to establish a Regulators' Business and Privacy Innovation Hub](#). The hub will provide data privacy expertise to other UK regulators to ensure rules and regulations keep pace with technologies of the future.
- [Consultation workshop: regulatory sandbox](#) – ICO are now accepting expressions of interest at: sandbox@ico.org.uk. The workshop will take place on 6 February 2019 in London.
- [Consultation on Freedom of Information and Environmental Information](#) – ICO seek views on their strategy to allow future public access to official information in the UK. The consultation will run until **8 March 2019**.

Health data access and re-use

NHS Digital have joined forces with Health Data Research UK to create the Health Data Research Alliance. [Learn more about the plans of the Health Data Research Alliance](#).

On behalf of the National Cancer Registration and Analysis Service, Public Health England have released the following open data:

- [Cancer Registration: Epidemiology of Renal Cancer \(1985-2016\)](#)
- [Cancer Registration: Epidemiology of Non-Hodgkin's Lymphoma \(1985-2016\)](#).

[EMA has published guidance on the use of data from patient registries to replace clinical trials to support marketing authorisation applications for certain haemophilia medicines.](#)

AMRC have released the report [Saving lives with patient data registries](#).

AMS has published '[Our data-driven future in healthcare](#)' which reports on the cultural shift needed to keep trust in use of patient data by health technology.

[New Wellcome Data Re-use Prizes](#) – Registration is open, submission dates are Thursday 28 February 2019 (for AMR surveillance prize) and Friday 15 March 2019 (for Malaria prize).

Human Tissue Authority News and other human tissue items

- [HTA licence fees 2019/20](#) – Fees across all sectors will increase by 2.7% from April 2019.
- [Notification of changes to Designated Individuals and Named Contacts on your licence](#) – An application to vary the licence should be submitted at least two weeks prior to any change in personnel to allow the HTA to assess suitability of the proposed change.
- **Human Application sector** - The HTA are collecting annual activity data for the Human Application sector via the HTA Portal in early January.
- [Organ Donation \(Deemed Consent\) Bill](#) – Details on the proposal to introduce an opt-out system of organ and tissue donation in England in Spring 2020.
- HTA have revised [Guidance to bone marrow and Peripheral Blood Stem Cell \(PBSC\) Transplant Teams and Accredited Assessors in England, Wales, and Northern Ireland](#).

UKCRC Tissue Directory want to know whether their referrals lead to sample release and even better research. Please email contact@biobankinguk.org if you've had success via the directory.

[Organ donation consent rates in Wales highest in the UK](#).

Other news

[EMA gives guidance on safety monitoring of medicines used in children](#).

[HFEA launch the 9th edition of their Code of Practice](#).

[Wellcome is updating its open access policy](#) – The new policy will apply from 1 January 2020.

[NIHR gives support to international Open Access initiative](#).

[The Science and Technology Committee is calling for increased transparency in research](#).

Government released [Life Sciences Deal 2](#) at the end of 2018.

AMS has published '[Advancing research to tackle multimorbidity: the UK and LMIC perspectives workshop report](#)'.

Other training and conferences

EFGCP Annual Conference 2019

Making Clinical Research an Element of Better Healthcare

Date: 19-20 February 2019

Venue: University Foundation, Brussels, Belgium.

NHS Digital researcher roadshows

Registration for the first roadshow in Scotland on 7 February is now closed.

Further events are planned in February and March, with dates TBC in: London, Bristol, Manchester, Cambridge or Oxford. To register your interest please email the [relationship management team](#) stating which roadshow you are interested in.

NHS R&D Forum conference 2019

Date: 12 May 2019 (2 Days)

Venue: Hilton Metropole, Brighton.

CM-Path: Do we really need another Biobank?

Date: 14 May 2019

Venue: Francis Crick Institute, London.