

The MRC Regulatory Support Centre <http://www.mrc.ac.uk/regulatorysupportcentre> has compiled the following update.

Please circulate this to any appropriate colleagues.

Regulatory Support Centre news:

Research, GDPR and Confidentiality e-learning: interim replacement

We released our interim replacement for the Research, Data and Confidentiality e-learning module in the summer. 'Research, GDPR and Confidentiality – what you need to know' consists of 10 bite-sized modules and an independent quiz. We intend to develop a full e-learning replacement in the longer-term and will keep you posted on progress in future updates.

Translational Project Managers Forum - Wednesday 14th November 2018

The next forum meeting will focus on the new Devices and IVD Regs (MHRA will be presenting), overcoming challenges of diverse stakeholder working, quality and accreditation, and evidence of regulatory barriers to research. Places are limited, if you are interested in learning more or registering for this event please email: info@rsc.mrc.ac.uk.

General Data Protection Regulation (GDPR) – GDPR Resources

We will be adding a new animation and other resources to our GDPR resources page, available from 'News' at: <http://www.mrc.ac.uk/regulatorysupportcentre>. We are aiming to release the new resources before Christmas – so please watch this space!

The changing regulatory landscape

Brexit guidance - The Department of Health and Social Care and the MHRA have issued [technical information on what the implementation period means for the life science sector](#), including implementation of the [Clinical Trial and Devices regulations](#).

Government has published a suite of guidance notes on [how to prepare if the UK leaves the EU with no deal](#). You can find the most relevant notes for research under the headings 'Personal data and consumer rights' and 'Regulating medicines and medical equipment'.

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
6 Nov 2018	Research, GDPR and Confidentiality	SPHSU, Glasgow
15 Nov 2018	Human Tissue workshop	Harwell, Oxford
15 Nov 2018	Research governance, ethics and oversight: what do you need?	Harwell, Oxford
4 Dec 2018	Human Tissue workshop	WTCRF, Edinburgh

Consultations

[MHRA to consult on EU exit no-deal legislative proposals](#) - The MHRA are consulting on how its legislation and regulatory processes would have to be modified in the event of a no deal Brexit, with no Implementation Period. The consultation runs until 11:45pm on **1st November 2018**.

[EU Public consultation for the evaluation of the EU drug precursors regulations](#) - Seeks views on the effectiveness of these regulations. The consultation runs until **2nd November 2018**.

Engaging with the public

- [Public engagement: it's fantastic for research, but how feasible is it for you?](#) – The third blog post from Wellcome's Public Engagement team.
- [The European Patients' Academy \(EUPATI\) Guidance](#) – EUPATI has developed guidance on the involvement of patients in the design and conduct of clinical trials.

HRA News

- [HRA seek 'test beds' to evaluate their public involvement guidance.](#)
- [NHS Excess Treatment Costs and Commercial Study Setup](#)
 - A new system for managing NHS Excess Treatment Costs for non-commercial research in England will be trialled from **1st October 2018** with full roll out by **April 2019**.
 - Commercial study set up in England to be streamlined by: establishing standards for contract values; reaffirming the importance of transparency in research and using the [unmodified model agreements](#), unless otherwise specified.
- [Pharmacy Assurance roll-out](#) - This process coordinates a single technical pharmacy review for all participating NHS/HSC sites in the UK. Available from **15th October 2018** in England, Scotland and Wales, it will open in Northern Ireland following roll-out in England and Wales.
- [Radiation Assurance phase two roll-out](#) - Radiation Assurance is for studies with ionising radiation research exposures taking place in the NHS/HSC. Currently available for cancer studies, the system will roll out to cardiology, neurology and rheumatology studies from **12th November 2018**. Please note that a fee may be applicable for both Pharmacy Assurance and Radiation Assurance – see [HRA Payments Framework Guidance](#).
- [Public support for greater data sharing with biobanks](#) - Findings showed that the public expect a clear explanation of what they're consenting to, and who their data will – and won't – be shared with.
- [HRA and MHRA integrated approval process for Clinical Trials of Medicinal Products](#) – An update on the [combined ways of working pilot](#) and testing of the approvals process.
- [HRA and MHRA publish joint statement on seeking and documenting consent using electronic methods \(eConsent\).](#)
- [New version of UK-wide model Non-Commercial Agreement \(mNCA\) published.](#)
- [Updated HRA and HCRW Statement of Activities and Schedule of Events published](#) - (HRA and HCRW Approval applies in England and Wales; this supersedes HRA Approval).
- [GAfREC revised](#) - Revised Governance Arrangements for Research Ethics Committees (GAfREC) have been implemented across the UK.
- [Teresa Allen appointed HRA Chief Executive](#) – following her term as HRA Interim CEO.

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's public research](#) – Finds one in three people have trust and confidence in companies and organisations storing and using their personal information (up from one in five people in 2017). The ICO said 'It's certainly positive news... However, there is still a long way to go'.
- [GDPR guidance](#) – ICO have expanded their GDPR guidance on exemptions and international data transfers.
- [Regulatory Action Policy](#) – Following consultation, ICO's policy on when and how they will use their various regulatory powers has been laid in parliament.
- [Your views on a regulatory sandbox](#) – The ICO are consulting on the feasibility, scope and demand for a 'regulatory sandbox' – a place where organisations are supported to develop innovative products and services using personal data in different ways.
- [Data Breach Reporting webinar](#) - provides data controllers with advice and guidance on how and when to report security breaches to the ICO.
- [ICO Annual Report 2017-18 published.](#)

Human Tissue News

- [What do the HTA's four guiding principles mean to you?](#) – Complete the HTA's questionnaire and let them know what you think about **consent, quality, dignity, and honesty and openness**.
- **Human Application sector** - The HTA has a [position on the procurement of tumour material being used as a starting material for an ATMP](#). This guidance sets out a number of scenarios to explain the licensing requirements for tumour materials when used in the manufacture of an Advanced Therapy Medicinal Product (ATMP). For further advice please [contact the HTA](#).
- [HTA publish 2017/18 Annual Review](#).

[The UKCRC TDCC](#) – Have improved the UKCRC Tissue Directory as a result of feedback from researchers and biobank staff.

[CM-Path Biobanking Sample Quality Improvement Tool](#) - This free, confidential self-assessment tool has been designed for biobank staff to review how their practices impact on sample quality.

Other news

[UKRIO and the Royal Society launch Integrity in Practice toolkit](#) – a series of case studies and positive interventions to improve research culture and integrity.

[Article by Andrew Boyd, University of Bristol](#) - shows the threat to research from misconceptions about data protection, and the importance of retaining personal data for research ([ICO allow indefinite retention for research](#)).

[Medical Devices US Food and Drug Administration \(FDA\) News: Quality in 510\(k\) 'Quik' Review Programme Pilot](#) - The pilot aims to simplify premarket notification (510(k)) submission for certain moderate risk medical devices, and evaluate the FDA's free eSubmitter software.

Other training and conferences

[Public Health England Introduction to the Office for Data Release \(ODR\) webinar](#)

Date: 26 October from 10:30am to 11:30am

Venue: N/A

[UK Biobanking Showcase 2018](#)

Date: 27 November 2018

Venue: Prospero House, London

[Improving lives through research conference \(NHS Digital, NIHR and Health Data Research UK\)](#)

Date: 3 December 2018

Venue: Queen's Hotel, Leeds

[NHS Digital researcher roadshows](#) – NHS Digital will run more researcher roadshows in the New Year. These will be advertised in due course on [NHS Digital's News and Events](#).

[NHS R&D Forum conference 2019](#)

Date: 12 May 2019 (2 Days)

Venue: Hilton Metropole, Brighton