

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

Please circulate this to any appropriate colleagues.

### ***The changing regulatory landscape***

#### **EU Regulations**

**General Data Protection Regulation** - GDPR will come into force in the EU (which will include the UK) on 25 May 2018. Meanwhile the Data Protection Bill is continuing its progress through parliament, and was presented to the House of Lords for a third reading on 17 January 2018.

For further guidance on the relationship between GDPR and the Data Protection Bill and how these two pieces of legislation will form the UK's future Data Protection law, please see the [ICO's Data Protection Bill webpage](#). For further information on the research aspects of GDPR, please see the [HRA briefing notes](#).

**EU regulations on medical devices and in vitro diagnostic medical devices** – In November 2017, the European Commission announced implementing measures for the Regulations. For further details please see 'Implementing measures for Regulations' on the [EC website](#).

**Clinical Trials** – The EU Clinical Trial Regulation will now likely come into application in the second half of 2019. Development of the EU portal is progressing but still requires close monitoring. The EMA will provide further information on timelines after an audit which will be carried out in 2018. For further details, please see 'Update' on the [EMA website](#).

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

#### **Consultations**

[NHS England consultation: supporting research in the NHS](#) – Seeks views on excess treatment costs and commercial clinical research. The consultation runs until **1 February 2018**.

[ICO consultation on Children and the GDPR guidance](#) – This consultation will run until **28 February 2018**, once responses have been considered, ICO will produce final guidance.

[Government consultation on organ donation opt-out](#) – The consultation will run for twelve weeks concluding on **6 March 2018**, after which a Government response will be published.

[EU consultation on research and innovation funding](#) - The consultation runs until **8 March 2018**, responses are welcomed from organisations as well as members of the public.

#### **HRA News**

- [UK Policy Framework for Health and Social Care](#) now launched. The UK Policy Framework replaces the previous Research Governance Frameworks of the four nations.
- [Preparing the UK for the EU Clinical Trials Regulation post Brexit](#) – The HRA are working closely with the MHRA in preparation for **the live pilot, due to commence in April 2018**.
- The HRA has published a [joint statement with the MHRA](#) advocating a proportionate approach to the application of Good Clinical Practice to researcher training.
- **IRAS v5.7** – IRAS will be updated to version 5.7 on **30 January 2018**, please see [Updates](#) for full details of the version changes.
- [New e-learning modules](#) released.

## **Other News**

### **NHS Digital News:**

- [Hospital Episode Statistics \(HES\)](#) – In January 2017 HES data was released 44 days faster than the previous year. NHS Digital will continue work to reduce this timeline further.
- **DARS website survey** – Help NHS Digital improve the Data Access Request Service (DARS) by completing their [confidential survey](#).

### **HTA News:**

- [HTA announces licence fees for 2018/19](#)
- HTA have launched [guides for the public to the new Codes of Practice](#).
- [All HTA inspection reports](#) are now available by date order in one place, as well as by each establishment.
- HTA have published [guidance on the coding and import of tissues and cells for human application](#) and details of the [Government's response](#) to the consultation on Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017.

The **National Data Guardian** have published their [2017 report](#) and reports on two events exploring [sharing data in line with patients' reasonable expectations](#).

The **Academy of Medical Sciences** outline [next steps](#) for implementing 'Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines'.

The **Academy of Medical Sciences, NIHR and Faculty of Public Health** have published '[The future of public health research](#)'.

[ARSAC approvals process to change](#) in line with Government's [Response to the Consultation on the draft Ionising Radiation \(Medical Exposure\) Regulations 2018](#)

The **Department of Health** has published a [framework for mental health research](#).

**Health & Care Professionals Council (HCPC)** publish [Confidentiality – guidance for registrants](#).

The **Information Commissioner's Office** reports on an audit which found [privacy notices to be too vague and generally inadequate](#). Whilst an [ICO survey](#) shows one in five members of the UK public don't trust organisations with their data.

The **MHRA** have updated their news story [making a success of Brexit](#) with further guidance for pharmaceutical companies.

**Research Involvement and Engagement** publish research article: [Understanding Plain English summaries](#), exploring how these might be improved.

The **Royal Society** release a [statement on research integrity](#).

**Sense about science** publish [Public engagement: a practical guide](#).

The **UKCRC Tissue Directory and Coordination Centre** announces [refunding until 2020](#).

**UKCRC Tissue Directory & Coordination Centre and BC Platforms Collaboration** – The UKCRC TDCC and BC Platforms are [increasing access to data and samples for research](#).

[Wellcome joins ClinicalStudyDataRequest.com](#) - a data-sharing initiative for academic research funders and pharmaceutical companies.

**Welsh Government** have completed an [evaluation of the Human Transplantation \(Wales\) Act](#).

***Other training and conferences***

**2018 Annual NHS R&D Forum Conference**

**Date:** 14-15 May 2018

**Venue:** Celtic Manor, Newport Wales