

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:**

#### **General Data Protection Regulation (GDPR) – GDPR Resources**

The MRC Regulatory Support Centre has created a GDPR resources page, available from 'News' at: <http://www.mrc.ac.uk/regulatorysupportcentre>. This is the new home for our GDPR Guidance Notes (created in consultation with the Information Commissioners Office and others) as well as the place to find links to other GDPR resources relevant for research. We'll be adding new resources over the coming weeks and months – so please watch this space!

**[GDPR: What researchers need to know](#)** – The MRC Regulatory Support Centre have written a blog on GDPR, aimed at researchers. We'll link to the blog from GDPR resources soon.

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

#### **EU Regulations**

**General Data Protection Regulation** - GDPR and the new Data Protection Act 2018 (currently the Data Protection Bill) will come into force in the UK on 25 May 2018. These pieces of legislation will together form the UK's new Data Protection law.

The UK Information Commissioner has urged organisations not to view the 25th May as a deadline: *'GDPR is an evolution which requires change over time.'*

**EU regulations on medical devices and in vitro diagnostic medical devices** – The new regulations will apply in Spring 2020 (medical devices) and Spring 2022 (in vitro diagnostic medical devices). The MHRA has produced [guidance](#) to help companies understand the new requirements. *Implementation in the UK is subject to Brexit negotiations.*

**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 under close monitoring and a version should be available for audit in early 2019. For further details, please see 'Update' on the [EMA website](#). *Implementation in the UK is subject to Brexit negotiations.*

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](mailto:info@rsc.mrc.ac.uk).

<b>Date</b>	<b>Course</b>	<b>Location</b>
8 May 2018	Health Related Findings workshop	WTCRF, Edinburgh
10 May 2018	Research Data and Confidentiality	SPHSU, Glasgow
14 Jun 2018	Human Tissue workshop	WIMM, Oxford
14 Jun 2018	Consent and Transparency	WIMM, Oxford
12 Sept 2018	GCP for non-trialists	WTCRF, Edinburgh
25 Sept 2018	Human Tissue workshop	University of Cambridge

#### **Consultations**

**[Scottish Government: Adults with incapacity reform](#)** – Seeks views on reform to the Adults with Incapacity (Scotland) Act 2000 (AWI). The consultation runs until **30 April 2018**.

## HRA News

- Ten [top tips for public involvement](#) in your research application.
- Survey investigates [public support for health research](#).
- [Change to HRA Approval process: Sponsors to pass on 'no formal confirmation required' decision instead of the HRA](#) – The 'No formal confirmation required' decision is based on the assumption that an NHS organisation in England will have the capacity and capability to take part in certain types of research.
- [Radiation Assurance](#) is a UK-wide process which aims to streamline review and approval of studies involving ionising radiation in the NHS. The process rolled out on **16 April 2018**.
- [Updated model agreements for commercial research in the NHS/HSC](#) have been published.
- **IRAS v5.8** – IRAS was updated to version 5.8 on **18 April 2018**, please see [Updates](#) for full details of the version changes.
- [Health and Care Research Wales align processes across England and Wales](#) – from **16 April 2018** new applications in IRAS will not use SSI forms for NHS sites in Wales.

## Engaging with the public

- [Understanding Patient Data](#) have created a series of animations for the public to help explain how data saves lives. They show how patient data is used to improve care, and the safeguards in place to protect confidentiality. **The Farr Institute** have also produced the animation [#datasaveslives](#).
- [New Public Involvement Standards](#) developed by a UK wide partnership.
- **Involve** publish [Guidance on co-producing a research project](#).

## Other News

**ICO 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 the GDPR** has been updated to include more guidance on the lawful basis of public task, children and rights. [What's new](#) provides a full list of changes.
- ICO release the first in a series of Podcasts [answering questions about GDPR myths](#).
- **New Data Protection Fee model announced** – ICO produces a [Guide to the fees](#).
- The ICO have consulted on what would be viewed as 'high risk' processing and so require a [Data protection impact assessment](#). Further guidance is likely to be published there.
- [GDPR myth-busting videos for in-house lawyers](#).
- **Network and Information Systems (NIS) Directive** comes into force in May 2018 and aims to protect essential UK services from cyber attacks. ICO is the proposed competent authority and [NCSC guidance](#) has been produced to help with compliance.

## HTA News:

- If you are an HTA-licence holder and would like to demonstrate your working relationship with the HTA more clearly, you can now add [Establishment button\(s\)](#) to your website.
- The HTA has responded to [public consultations on organ donation and transplantation](#).
- **Human Application sector**
  - **Coding and Import regulations** came into force on **1 April 2018** via the [Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018](#) and the HTA has provided guidance on [changes to licences for the human application sector](#).
  - The reporting of SAEs and SARs was highlighted as an area for improvement for the sector. For guidance see [Human application adverse event and reaction reporting](#).
  - The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) have updated their [Microbiology Safety Guidelines](#).
- [Guidance for transplant teams and independent assessors updated](#). (The [Scottish guidance document](#) was published in August 2017).

- The HRA, in collaboration with the HTA, have released a free e-learning module for the research sector on '[research using human tissue.](#)'

### **NHS Digital**

- [Remote Data Access Environment \(RDAE\)](#) - NHS Digital are looking for researchers to user test their new RDAE system. RDAE will provide researchers who have Data Sharing Agreements in place with secure remote access to their datasets, from December 2018.
- **Data Access Request Service (DARS) webinar** available for [sign up](#).
- [National Data Opt-out](#) – NHS Digital will provide an online service to allow patients and the public to opt out of their personally identifiable data being used for planning and research.
- [Deal to protect against cyber attacks](#) – NHS Digital's deal with Microsoft aims to protect IT systems within health and care settings in England against cyber security threats.
- [NHS and social care data: off-shoring and the use of public cloud services guidance](#) for health and care organisations on the use of these services for storing patient data.
- [Clinical safety guidance](#) on the governance and regulatory requirements for software algorithms and applications used in the NHS and Adult Social Care.

[ARSAC update approvals process](#) in line with the new Ionising Radiation (Medical Exposure) Regulations which came into force on 6 February 2018.

[Research to be recognised by regulators for its role in improving patient care](#) – a partnership between the NIHR, HRA, MHRA and the Care Quality Commission (CQC) aims to develop new research indicators for use in the CQC's monitoring and inspection programme.

The MHRA guide [Marketing Authorisation Holders on considerations for agreements with Pharmacovigilance System Service Providers](#).

The MHRA release [Guidance on GxP data integrity](#).

Industry release [Brexit Life Science Industry Coalition Position Paper](#) and back [findings of new Health and Social Care Committee report](#).

The UKCRC Tissue directory and Coordination centre will be embedded within one of the new UK Health Data Research centres. For more please see the [UKCRC TDCC website](#).

### ***Other training and conferences***

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

**Date:** 14-15 May 2018

**Venue:** Celtic Manor, Newport Wales

#### **UKRIO 2018 annual conference**

**Date:** 23 May 2018

**Venue:** Congress Centre, London

#### **RQA 2018 Annual Conference: Data and Quality – is the tail wagging the dog?**

**Date:** 31 October – 2 November 2018

**Venue:** Manchester Central