

The MRC Regulatory Support Centre [mrc.ukri.org.uk/regulatorysupportcentre](http://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 want to know about your regulatory and governance experiences in the last year. Let us know by completing our survey (coming soon to [mrc.ukri.org.uk/regulatorysupportcentre](http://mrc.ukri.org.uk/regulatorysupportcentre) - see 'News'). Please feel free to distribute the survey as widely as you feel appropriate.

#### **Identifiability, anonymisation and pseudonymisation guidance**

Following our workshop: Safe sharing of research data: The role of legal agreements when anonymising, we will be working stakeholders over the summer to revise our identifiability, anonymisation and pseudonymisation guidance and take forward next steps.

#### **Updated Research and Human Tissue Act 2004 summaries**

Our updated Research and Human Tissue Act 2004 summaries are now available from our [human tissue](#) page and from 'News' at: [mrc.ukri.org.uk/regulatorysupportcentre](http://mrc.ukri.org.uk/regulatorysupportcentre).

### **The changing regulatory landscape**

**Brexit guidance** – Since our last update there has been an [extension of the period under 'Article 50'](#) (to 31st October). The Department of Health and Social Care (DHSC) detail how they plan to support continuity of medicines, medical products and clinical trial supplies in the event of 'no deal' (full details at [NHS R&D Forum](#)). Whilst the European Commission released a notice on [the implications of withdrawal of the UK in the field of Good Laboratory Practice](#).

**EU regulations on medical devices** – A [joint statement](#) has been released highlighting the need for accelerated implementation of the Medical Device Regulation, to avoid disruption of product supply. *Implementation in the UK is subject to Brexit negotiations.*

**Clinical Trial Regulation** – The [EMA update](#) reports that the Clinical Trial Information System (database) is now in a phase of **agile, iterative delivery**, to prepare the system for audit. *Implementation in the UK is subject to Brexit negotiations.*

[EMA consult on revised guideline to evaluate new medicines in treatment of bacterial infections.](#)

Regulators in the EU, US and Japan have explored how to align their respective data requirements so that clinical trials can meet the evidence needs of multiple regulatory agencies. The revised guidance reflects these discussions. This consultation ends on **31st July 2019**.

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).

Date	Course	Location
16 Jul 2019	Research, GDPR and Confidentiality	Big Data Institute, Oxford
19 Sept 2019	Human Tissue workshop	Clifford Albutt, Cambridge
8 Oct 2019	Health Related Findings	WTCRF, Edinburgh
29 Oct 2019	GCP for non-trialists	SPHSU, Glasgow

## **HRA News**

- [Make it public](#) – The HRA and devolved administrations are consulting on how to increase public access to research findings, and improve transparency in health and social care research. The consultation is open until **6th September 2019**.
- **IRAS v5.12** – IRAS was updated to version 5.12 on 4th June 2019 to support changes to the site approvals process (see below). Site Specific Information (SSI) forms will no longer be used and so this functionality has been removed. For full details please see [Updates](#).
- [Changes to the approvals process for NHS/HSC sites](#) were implemented on 5 June with the introduction of the '**UK Local Information Pack**'. This contains an Organisation Information Document to replace the Statement of Activities in England and Wales and the Site-Specific Information form, in Northern Ireland and Scotland. To learn more please see [IRAS](#).
- [Changes to the approvals process for non-NHS/HSC sites](#) – From 5 June you will only need to submit the new site assessment form for non-NHS/HSC sites if your study is a CTIMP or clinical trial of a device (the form is not needed for any other type of research). In all cases, you should check with the non-NHS/HSC site whether any local sign offs are required.
- Model **Participant Identification Centre** (PIC) agreements are now available on [IRAS Help](#).
- Are you seeking approvals for a CTIMP? You can volunteer to test an integrated approach to approvals. For more please see the [combined ways of working pilot](#).
- NIHR launch [new research costing tool](#) for commercial collaborations in the NHS.
- The Administration of Radioactive Substances Advisory Committee (ARSAC) changed the way it grants approvals for research in February. For details please see the [ARSAC website](#).
- [What does AI mean for the HRA and health research in the UK?](#) – Blog by Dr Nicole Mather.
- [New e-learning module](#) to be released soon on ethical review of Research Tissue Banks.

## **Human Tissue Authority News and other human tissue items**

- HTA have amended the research online tests in light of feedback from the research community. If you haven't taken the tests yet you can at: [Test your knowledge](#).
- **Save the date!** – The HTA Conference will be held on 9th November in central London
- [Consultation on Code of Practice F: Donation of solid organs and tissue for transplantation](#). The code has been amended to reflect changes resulting from the Organ Donation (Deemed Consent) Act 2019. The consultation runs until **26th September 2019**.
- [The Department of Health and Social Care \(DHSC\)](#) are consulting on organs and tissues **excluded** from deemed consent (this includes use of organs and tissues in research where deemed consent will not apply).
- [HTA blog](#) launched.

## **Health data access and re-use**

- NHS Digital's [Data Access Environment \(DAE\)](#) went live in May. The DAE is a secure environment which provides access to NHS Digital data.
- The Open Data Institute has launched an [anonymisation project page](#) which provides practical guidance on anonymisation.
- [Wellcome updates open access policy](#) to align with cOAlition S.
- [Open access publishing under Plan S to start in 2021](#).

## **Engaging the public**

- Wellcome pilot new delegated decision-making approach to support researchers in delivering [public engagement](#) in the UK and Africa.

- ABPI has published the guide: [Working with patients and patient organisations - a sourcebook for industry](#).
- [Understanding Patient Data](#) – Find out more about Understanding Patient Data and how they are engaging the public.

### **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 has drafted [Age appropriate design: a code of practice for online services](#) (consultation on this is now closed). ICO will lay a final version of the code before Parliament, which they expect to come into effect before the end of the year.
- New blogs have been added to the [AI Auditing Framework](#) since its launch in April.
- ICO has published '[Openness by Design](#)'. The new strategy sets out five goals relating to the Freedom of Information Act (FOIA) 2000, the Environmental Information Regulations (EIR) 2004, and the Re-use of Public Sector Information Regulations 2015.

### **Other news**

[NIHR release health services research toolkit.](#)

ABPI and the AHSN Network publish a [new guide to cross-sector working](#) between NHS Sustainable Transformation Partnerships (STPs), Integrated Care Systems (ICSs) and industry.

[Medicine shortages: EU network takes steps to improve reporting and communication.](#)

[Call for all sponsors to publish clinical trial results in EU database.](#)

[The UKCRC Registered CTU Network](#) invites new registrations.

The Universities of Leeds, Birmingham and Bristol (with funding from NIHR) have developed an [International Surgical Trials Toolkit](#).

UK life sciences industry welcomes launch of [Health Innovation Research Alliance Northern Ireland \(HIRANI\)](#).

### **Other training and conferences**

#### **[Edinburgh Clinical Research Facility PPI Summer School](#)**

**Date:** 29th-30th August 2019 (2 Days)

**Venue:** WTCRF Western General Hospital, Edinburgh.

#### **[Edinburgh Clinical Research Methodology Course \(for PIs future research leaders\)](#)**

**Date:** 11th-12th November 2019 (2 Days)

**Venue:** John McIntyre Conference Centre, Pollock Halls, Edinburgh.

#### **[Edinburgh Clinical Trials Management Course \(for Trial Managers, Data Managers, etc.\)](#)**

**Date:** 14th-15th November 2019 (2 Days)

**Venue:** John McIntyre Conference Centre, Pollock Halls, Edinburgh.

#### **[UK Biobanking Showcase 2019](#)**

**Date:** 18th-19th November 2019

**Venue:** East Midlands Conference Centre, Nottingham.