

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:

Non-commercial sponsor workshop – adapting to HRA Approval

We are pleased to confirm that this workshop is now fully booked and will take place in The Light, Friends Meeting House, London on **Wednesday 9th November**.

Translational Project Managers Forum

The Translational Project Managers Forum will meet again on **Thursday 17th November 2016** in the **Academy of Medical Sciences, 41 Portland Place, London**. The Agenda will include sessions on the project start-up timeline and human tissue training. To register your interest please email: info@rsc.mrc.ac.uk

UPDATED – Guidance on Type 2 patient opt-outs and obtaining data for health research

These guidance documents were updated in October to reflect the name change for the Health and Social Care Information Centre (HSCIC). HSCIC is now known as NHS Digital. You can download both of these documents from the [RSC website](#).

Regulatory Support Centre training courses

We are currently arranging training dates for 2017. To discuss the potential of holding training within your Unit or University, please contact us on info@rsc.mrc.ac.uk.

The changing regulatory landscape and consultations

National Data Guardian for Health and Care Review of Data Security, Consent and Opt-Outs (Caldicott 3)

– The consultation on Dame Fiona Caldicott's report closed on 7 September and the Department of Health are analysing the feedback. RCUK submitted a response to this consultation which we fed in to.

EU Regulations

On 2 October Government announced plans to repeal the 1972 European Communities Act (ECA). The Act gives direct effect to all EU law and the introduction of a new Bill to repeal it will mean the Act ceases to apply from the day the UK leaves the EU. At the same time the new Bill will convert existing EU law into domestic law, which will allow Parliament to make changes to these laws in the longer term. Timing of the implementation of the following EU Regulations will be critical to what becomes domestic law when the UK leaves the EU. Full details can be found on the [Gov.UK website](#).

General Data Protection Regulation - The European Commission (Article 29 Working Party) held a workshop to discuss priorities for the new General Data Protection Regulation. The new data portability right, the use of Data Protection Impact Assessments (DPIAs), the use of certification and codes of conduct and the role of the data protection officer were all discussed. The new regulation is on track to come into force in the UK on 25 May 2018.

EU regulations on medical devices and in vitro diagnostic medical devices – It's expected that these regulations will be adopted by the EU Council and the Parliament towards the end of 2016. The new rules will apply 3 years after publication for medical devices and 5 years after publication for in vitro diagnostic medical devices.

Clinical Trials – It's expected that the Clinical Trials Regulation will take effect in 2017/18. Dependent on the European Medicines Agency's development of requisite information systems. We'll keep you informed of further developments on the [RSC website](#).

HRA News

HRA Approval

In their most recent update the HRA reported that they have cleared the backlog of amendments and HRA Approval (for existing studies). They thank you for your patience and confirm that numbers now being received are much closer to predicted levels. For the full performance update and details of how the HRA are acting on your feedback, please see the [HRA website](#).

Revised contract for National Institute for Health Research (NIHR) funded studies

The Department of Health (DH) and the Health Research Authority have reviewed the standard DH contract for NIHR funded research. From August 2016 research funded by NIHR will be able to receive payments for start-up in advance of ethical approval. For more see the [HRA website](#).

Update to Research Ethics Service (RES) Standard Operating Procedures (SOPs)

The Standard Operating Procedures for Research Ethics Committees were updated in October. For full details please see the [HRA website](#).

Other News

Transferring data to the USA

The EU-US Privacy Shield began operating on 1 August 2016. The European Commission issued a formal decision stating that the Privacy Shield provides adequate protection for personal data to be transferred to the US (replacing the Safe Harbor scheme). For more please see [ICO's website](#).

News from the Human Tissue Authority

- **Codes of Practice and Standards implementation** - The new Codes of Practice and Standards are available in draft on the [HTA website](#). They are due to come into force in April 2017. The HTA will hold webinars in early 2017 to help you prepare for implementation. If you are interested in attending a webinar, please [register your interest](#). In addition the HTA will publish further guidance and training materials over the next few months. If you are interested in reviewing these to make sure they're fit for purpose, please email enquiries@hta.gov.uk.
- **HTA Fees** – The consultation on proposed changes to the fee structure has now closed. The HTA will publish fees in December, these will then come into effect in April 2017. For full details please see the [HTA website](#).
- **Research sector: Review of compliance updates 2015/16** is available from the [HTA website](#).
- **Research sector review** – A summary of inspection findings and compliance with HTA standards is also available on the [HTA website](#).
- **Reminder: Designated Individual (DI) information** – It is important that you notify the HTA of any changes to the DI for your licence. For example, if the previous DI has changed roles or moved to another organisation. Failure to do so breaches licence conditions. You can check who the DI for your licence is on the [HTA website](#). If your DI is incorrect, you will need to vary your licence. For more, please refer to the [HTA website](#).
- **Human Application sector:**
 - **Coding and Import update** – The HTA continue to work with the Department of Health (DH) to implement these two new EU Directives. Although consultation on these draft Regulations has been delayed, a formal consultation is still planned.
 - **New EU Coding Platform** is now available from the [HTA website](#).
 - **HTLV-1 Policy** has been published on the [HTA website](#).
 - **HTA Compliance Resource for US Imports guidance** on the [HTA website](#).
- **Post Mortem sector: List of Mortuaries happy to be contacted regarding Brain and Spine removals** – Available from the [Post Mortem Sector page](#) (see '[here](#)' at end of third paragraph).

The UKCRC Tissue Directory is now Live

The Directory is now open for researchers who want to locate tissue samples. On behalf of the UKCRC funders, Dr Claire Newland (MRC) has urged, "those responsible for biobanks/collections of human tissue and biosamples to work with the Centre to ensure their collections are visible in the tissue directory." For more see the [UKCRC Tissue Directory and Coordination Centre website](#).

ICO Guidance

The ICO has published the following guidance:

- NEW [Privacy notices, transparency and control: A code of practice on communicating privacy information to individuals](#) [released October 2016]

MHRA Medical devices (apps) guidance

The following MHRA guidance was updated in August 2016:

- [Medical device stand-alone software including apps \(including IVDMDs\)](#)

MRC, MHRA and HRA respond to Innovative Medicines Initiative (IMI) consultation

Working with the MHRA and HRA, the MRC have responded to IMI's consultation on Advanced Therapies Concept Paper. For more please see the [MRC website](#).

HFEA reconvenes independent expert panel and launches call for evidence

The HFEA have reconvened an independent scientific panel to consider the safety and efficacy of mitochondrial donation techniques. For full details please see the [HFEA website](#).

NHS Digital (formerly HSCIC) launch new cyber security services

NHS Digital have added new services to complement the CareCERT scheme which they launched in late 2015. For further details please see the [NHS Digital website](#).

Nuffield Council on Bioethics Statement of aspiration: improving research by involving children and young people is available from the [Nuffield Council on Bioethics website](#).

Other training and conferences:

UKCRC Tissue Directory and Coordination Centre: Annual Biobanking Showcase

Date: 16 November 2016

Venue: The Oval, London

For further details please see the [Eventbrite website](#).

UKCRC Tissue Directory Roadshow (Exeter)

Date: 22 November 2016

Venue: University of Exeter

For further details please see the [UKCRC website](#).

UKCRC Tissue Directory Roadshow (Manchester)

Date: 24 November 2016

Venue: University of Manchester

For further details please see the [UKCRC website](#).

EFGCP Annual Conference 2017 on

Meeting the Ethical Standards under the Clinical Trials Regulation: the Burning Questions (and Answers) for Researchers, Sponsors and Patients

Date: 21-22 February 2017

Venue: Diamant Conference Centre, Brussels, Belgium

For further details please see the [EFGCP website](#).

Data Protection Practitioner Conference 2017

Date: 6 March 2017

Venue: Manchester Central Convention Complex

If you are interested in attending this conference [please register your interest](#).

Registration closes on **30 November 2016**.