

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 Governance Forum – [save the date!](#)**

The Research Governance forum will meet again on **Tuesday 28th April 2015** in Head Office, London. We are currently approaching potential speakers and hope to be able to release a draft Agenda soon. To register your interest, please email: [info@rsc.mrc.ac.uk](mailto:info@rsc.mrc.ac.uk).

**Regulatory Support Centre training courses**

We are pleased to announce the following training courses. To book a place or to discuss the potential of holding training within your Unit or University, please contact us at [info@rsc.mrc.ac.uk](mailto:info@rsc.mrc.ac.uk).

Date	Course	Location
10 Mar 2015	Consent: how can we do it better?	HNR, Cambridge
15 Apr 2015	Research Data and Confidentiality Blended learning	University of Birmingham
16 Apr 2015	Submitting a successful ethics application & brief update on expected impact of new CT regulations	CTU, London

**The changing regulatory landscape**

**EU Clinical Trials Regulation** – Nothing new to report. Efforts are now focussed on preparing for implementation (see EMA consultation overleaf).

**European campaign on the EU Data Protection Regulation** – The European Data in Health Research Alliance has launched a digital campaign to inform the ongoing debate regarding the EU Data Protection Regulation. The campaign, established by the Wellcome Trust amongst others, provides a platform for researchers and patients to share their views on the value of using data in research. For more please see [www.datasaveslives.eu](http://www.datasaveslives.eu)

**Health Research Authority** – From 1 January 2015 the Health Research Authority was formally established as a Non-Departmental Public Body. In effect this means that the HRA has now extended its remit to include social care research and responsibility for the Research Governance Framework.

**Mitochondrial transfer regulations** – On 3rd February 2015, MPs voted in favour of amending the Human Fertilisation and Embryology Act 2008 to legalise mitochondrial DNA transfer. These regulations now need approval from the House of Lords before they can come into force.

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

**UKCRC establishes new National Tissue Directory and Research Collaboration**

A new National Tissue Directory and Coordination Centre will be established by the University College London in collaboration with Nottingham University. The new resource will enable researchers to search multiple collections through one system. For full details please see the [MRC website](#).

### ***Consultations:***

#### **EMA consult on application of transparency rules of EU Clinical Trial Regulation**

The European Medicines Agency (EMA) public consultation on what clinical trial information to make publicly available in the new clinical trial database is now open. For further details please see the [EMA website](#). Responses are invited by **18 February 2015**.

#### **HRA protocol template released for consultation in use**

In collaboration with a wide range of partners, the HRA has published a template and guidance for protocols for clinical trials of investigational medicinal products (CTIMPs). The aim is to provide clarity about the information that reviewers need to assess research projects, and that research teams need to conduct the project effectively. For further details please see the [HRA website](#). Responses are requested by **31 May 2015**.

#### **DH Release of a body from hospital: good practice form**

DH has developed a form to help hospitals have a more consistent, quality-controlled, and timely process to release bodies. For further details please see the [DH website](#). Responses are requested by **6 April 2015**.

### ***HRA news:***

#### **HRA updated Standard Operating Procedures**

A revised version of the NRES Standard Operating Procedures for Research Ethics Committees was released on 1st January 2015. Full details are available on the [HRA website](#).

#### **Revised Amendment Process: HRA handling of non-portfolio studies**

There are minor changes to how amendments to NHS R&D approval are handled. Full details are available from the [NHS R&D Forum website](#).

### ***Other news:***

#### **Nuffield Council on Bioethics – Report on the ethical use of data**

This report looks at the ethical issues of using patient data in biomedical research. It sets out key ethical principles for the design and governance of “big data” projects, and identifies examples of good practice relevant to anyone approaching a data initiative. For full report please see the [Nuffield Council on Bioethics website](#).

#### **News from the Human Tissue Authority**

- **New HTA website** – Launched this week, for details please visit the [HTA website](#).
- **DNA frequently asked questions** – The HTA have updated their FAQs on the analysis of DNA under the HT Act 2004. For more please see the [HTA website](#).
- **2015/16 fees announced** – Full details can be found on the [HTA website](#).
- **Compliance returns** – Directions will be issued in the summer, with the aim of collecting compliance updates from those licensed under the HT Act 2004 in September.
- **Pregnancy loss guidance** will be published soon. Interim guidance is available on the [HTA website](#).

#### **News from the Medicines and Healthcare Products Regulatory Agency**

- **New MHRA website** was launched 28 January 2015, please see the [MHRA website](#).
- **MHRA New Devices Online Registration System (DORS)** was launched on 11 February 2015. You can now register specified devices online and manage your details directly. For full details please see the [MHRA website](#).

***Other training and conferences:***

**2015 Annual NHS R&D Forum**

**Date:** 5-6 May 2015

**Venue:** Central London (venue to be confirmed)

For further details please see the [NHS R&D Forum website](#).

**UKRIO 2015 annual conference**

**Date:** 13 May 2015

**Venue:** Manchester

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

**MHRA conference: Pharmacovigilance Symposium**

**Date:** 6 November 2015

**Venue:** London

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