

**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:***

**MRC Regulatory Support Centre - Christmas closure dates**

We will be closed for the holidays from Friday 18 December 2015, opening again on Tuesday 5 January 2016.

**Guidance on obtaining data from the HSCIC for health research**

We have released practical guidance on accessing data from the HSCIC. The process is undergoing a period of rapid change and so this guidance will be reviewed on a continuous basis. The most recent edition was released on 04-11-15 and is available from the [MRC RSC website](#).

**New HRA Approval guidance tool**

We are developing a tool to help guide researchers through the process of applying for HRA Approval. The tool will be available before Christmas from **News** on [MRC RSC website](#). We'll email you when the guidance is live.

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

The Research Governance forum will meet again on **Tuesday 5th April 2016** in MRC Head Office, London. To register your interest, please contact us on: [info@rsc.mrc.ac.uk](mailto:info@rsc.mrc.ac.uk).

**Translational Project Managers Forum – [save the date!](#)**

The Translational Project Managers forum will meet again on **Thursday 19th May 2016** in London (venue tbc). To register your interest, please contact us on: [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 for 2016. To book a place or to discuss the potential of holding training within your Unit or University, please contact us on [info@rsc.mrc.ac.uk](mailto:info@rsc.mrc.ac.uk).

<b>Date</b>	<b>Course</b>	<b>Location</b>
3 Feb 2016	Health Related Findings	Gibbs Building, London
4 Feb 2016	Consent: How can we do it better?	1 Victoria Street, London
24 Feb 2016	Good Clinical Practice for non-trialists	Toxicology, Leicester
16 Mar 2016	Good Clinical Practice for non-trialists	Epidemiology, Cambridge
16 Mar 2016	Good Clinical Practice for GLINT	Epidemiology, Cambridge
17 Mar 2016	Research Data and Confidentiality: What you really need to know	University of Cambridge
6 Apr 2016	Health Related Findings	University of Cambridge
28 Apr 2016	Research Data and Confidentiality: What you really need to know	CTSU, Oxford
10 May 2016	Health Related Findings	WTCRF, Edinburgh
17 May 2016	Research Data and Confidentiality: What you really need to know	WTCRF, Edinburgh
9 Jun 2016	Consent, payments and voluntariness	Homerton College, Cambridge

## **The changing regulatory landscape**

**EU Clinical Trials Regulation** – Implementation is dependent on the EU portal being fully functional. A press release from the EMA in October stated that the timetable for development of the EU portal was by the third quarter of 2016. If deemed fully functional at that time, then the Regulation will apply by the end of 2017. For full details please see the [EMA website](#).

**EU Data Protection Regulation** – Representatives from the three EU institutions – the European Parliament, European Commission and the Council of Ministers – are working together to agree a final text of the draft law. Further details can be found at: <http://www.datasaveslives.eu/>.

**Mitochondrial transfer regulations** – On 29 October 2015, the UK became the first country to license ground breaking mitochondrial donation regulations to legalise mitochondrial DNA transfer. For full details please see the [HFEA website](#).

The MRC recently responded to an **evidence gathering exercise from the National Data Guardian on data security and consent issues in research**. A copy of MRC's written evidence can be obtained from [Corporate@headoffice.mrc.ac.uk](mailto:Corporate@headoffice.mrc.ac.uk).

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

## **Consultations**

### **Call for comments - Site Specific Information (SSI) for NHS/HSC Sites**

The UK Four Nations Group is seeking views on the content and format of Site Specific Information (SSI) provided for NHS/HSC permission of research. Further details of the call including email addresses for the four nations, where responses should be sent, can be found within the [Call for comments document](#). The call closes on **18 December 2015**.

### **ICH consultation on good clinical practice guidance**

The European Medicines Agency is consulting on a new ICH guidance document on GCP to provide a unified standard in the EU, Japan and US. More information is available from the [MHRA website](#). The deadline for comments is **31 January 2016**.

### **GMC consultation on Confidentiality guidance**

The General Medical Council are holding a public consultation on a revised draft of their guidance for doctors on confidentiality. As part of that consultation, the GMC would welcome the views of doctors and other healthcare professionals on the issues covered by the guidance. For more details please see the [GMC website](#). Responses are invited by **10 February 2016**.

### **EU Public consultation on orphan medicinal products**

The European Commission is proposing to review the 2003 Communication on orphan medicinal products and streamline the regulatory framework. Full details of the consultation can be found on the [EC website](#). The deadline for comments is **15 February 2016**.

### **Public consultation on the UK Policy Framework for Health and Social Care Research**

The HRA is seeking comments on the Policy Framework following consultation on a draft version earlier this year. The consultation will open on 18 December 2015 and further details will be available from the [HRA website](#). Responses are invited by **end of March 2016**.

## **Other News**

### **HRA News**

#### **Implementation of HRA Approval**

Cohort 3 rolled out on 30 November 2015 making HRA Approval available to non-interventional studies in secondary care. This means that approximately half of all studies taking place in the NHS in England are now eligible for HRA Approval. The tool we are developing, mentioned above, will explain more.

## **Implementation of HRA Approval (ctnd)**

Work on standardising the information governance review within HRA Approval is ongoing. This review must assess studies for legal compliance as well as provide assurance and information to NHS sites. It is hoped that updated information governance questions will be available for 'testing in use' during cohort 4, before being incorporated into IRAS.

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

- **2015/16 Licence fees** - The research sector licence fee is to decrease by £850. For further details please see the [HTA website](#).
- **Licensing and inspection review** – The HTA have identified several opportunities for efficiencies in their licensing and inspection processes. They now seek stakeholder feedback on these areas. To get involved, please email: [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk).
- **EU Import and Coding Directives** - The Directives for Import and Coding of tissues and cells for human application are due to come into force throughout the EU, on or before 29 April 2017. The HTA is helping the Department of Health to transpose these directives into UK law. For further details please see the [HTA website](#).
- **Code of practice 10 - Human Transplantation (Wales) Act** – The Act came into force on 1 December 2015 and with it the Human Tissue Authority has launched the new Code of Practice. For full details please see the [HTA website](#).

## ***News from the Health and Social Care Information Centre (HSCIC)***

- **Patient Objections (type 2)** – The HSCIC has been working with the Department of Health on how to manage type 2 patient objections (i.e. where patients can opt out of their identifiable information leaving the HSCIC for purposes beyond direct care - this would include research). HSCIC are holding a webinar on **Thursday 17 December** to discuss this topic. To book a place at this event please see the [HSCIC website](#).
- **HSCIC Data Sharing Audits** - The HSCIC has carried out a number of audits to check compliance with [Data Sharing Contracts and Data Sharing Agreements](#). For further details please see the [HSCIC website](#).
- **Online application system to be implemented** – The HSCIC Data Access Request Service are to implement an online application system. An implementation date is yet to be confirmed. For latest news please see the [HSCIC website](#).

## **MHRA Position Statement on Electronic Health Records**

The MHRA GCP Inspectorate has developed a position statement to provide clarity on how Electronic Health Records systems can meet regulatory requirements and be GCP compliant. For full details please see the [MHRA website](#).

## **Royal College of Nursing updates 'Managing the Disposal of Pregnancy Remains'**

For full details of the updated guidance please see the [RCN website](#).

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

### **Archiving Master Class**

**Date:** 2 February 2016

**Venue:** Birmingham

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

### **2016 Annual NHS R&D Forum**

**Date:** 23-24 May 2016

**Venue:** Stratford upon Avon

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