

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

The Research Governance forum will meet again on **Wednesday 5th April 2017** in **MRC Head Office, London**. The Agenda will focus heavily on data with sessions from the ICO, NHS Digital and the Wellcome Trust. NHS Digital will discuss, and perhaps test, the replacement Information Governance Toolkit (IGTK). A pilot of the new IGTK is due for launch in April ahead of a formal roll out in spring 2018. To register your interest, please email: info@rsc.mrc.ac.uk.

Devices and In vitro Diagnostics workshop with the MHRA

Taking place on **Wednesday 3rd May 2017** in the **Academy of Medical Sciences, 41 Portland Place, London**. This workshop will take the place of the next Translational Project Manager's Forum. We currently have a waiting list, so if you cannot attend please email: info@rsc.mrc.ac.uk.

Funding call reminder: Capital investment in human tissue banking and linked data

The Deadline is **27 March 2017**. [The call](#) will support establishment of world-class human tissue banks with associated linked-data repositories to work in close partnership with research charities.

The changing regulatory landscape and consultations

National Data Guardian for Health and Care Review of Data Security, Consent and Opt-Outs (Caldicott 3) – Nothing new to report. Consultation on Dame Fiona Caldicott's report, including face-to-face consultation sessions with health and care professionals and the public, concluded mid-October 2016. The MRC responded via RCUK. All feedback is currently being analysed.

EU Regulations

General Data Protection Regulation - The new regulation is on track to come into force in the UK on 25 May 2018. [ICO guidance](#) is available on what to expect and when. Members of the Regulatory Support Centre are taking part in discussions on implementation.

The ICO is currently [consulting on GDPR consent guidance](#), the deadline for comments 31st March. The MRC will be responding, please email info@rsc.mrc.ac.uk to contribute.

EU regulations on medical devices and in vitro diagnostic medical devices – [Final formal EU adoption](#) of these regulations is expected during the first semester of 2017. As yet, there is no official position on the extent of UK implementation.

Clinical Trials – It's expected that the Clinical Trials Regulation will take effect by October 2018, dependent on the successful development and audit of the EU Portal and database. For further details, please see the [EMA website](#).

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.

Date	Course	Location
28 Mar 2017	GCP for non-trialists	WTCRF, Edinburgh
7 Sept 2017	Human Tissue workshop	MRC EWL, Cambridge
12 Oct 2017	Research data and confidentiality	WIMM, University of Oxford
18 Oct 2017	Human Tissue workshop	University of Cambridge

HRA News

Change to Research Tissue Bank NHS REC ethics review

The UK Ethics Committee Authority (UKECA) now require research tissue banks (RTB) applying or renewing NHS REC RTB ethics, to be [registered in the UKCRC Tissue Directory](#) in order to receive a favourable opinion.

HRA Approval – hints and tips for applicants

Approximately 40% of applications for HRA Approval are deemed incomplete by the HRA. The following are provided as tips to help avoid an incomplete application:

Applications for commercially sponsored studies should include:

- an [Industry Costing Template](#) validated by the Lead NIHR Local Clinical Research Network
- a template of the agreement the sponsor proposes to use with sites. Where at all possible this should be the [appropriate model agreement](#).

Applications for non-commercially sponsored studies should include:

- a template [Statement of Activities and Schedule of Events](#) for each site type in the study. Please seek advice from your sponsor or Lead NHS R&D office about attributing costs.
- a template site agreement – if one is going to be used in the study.

Other News

HTA News:

- **Codes of Practice and Standard:** These will come into force in April 2017. Supporting the release are a series of [Codes and Standards Newsletters and webinars](#).
- **HTA Fees:** Effective from April 2017 have been published on the HTA website.
- **MHRA & HTA sign partnership agreement:** to strengthen their commitment to work together regulating innovative treatments for patient benefit.
- **Human Application sector – Coding and Import update:** The HTA continue to work with the Department of Health to implement these two new EU Directives. These are due to come into force throughout the EU on or before 29 April 2017.
- **Should I donate my body to medical science?** The HTA, BBC iWonder and Queen's University, Belfast have produced an interactive online guide to body donation.

ICO News:

- [Data sharing case studies](#) have been added to support the Data sharing code of practice.
- [Data Protection on the Move again](#) considers the issues of working from home or on the move with personal data. Tips are provided to avoid mistakes in these circumstances.

NHS Digital News:

- **IGARD formally launched:** A new independent group to review applications for sensitive NHS Digital data formally launched in February. [IGARD](#) considers applications through the [Data Access Request Service](#) and replaces the Data Access Advisory Group (DAAG).
- **DARS Online improvements:** If you have any comments about DARS Online, please contact Data.Applications@nhs.net referencing 'Website Feedback' in the subject line.
- **DARS webinars:** NHS Digital is hosting a series of webinars covering the next phase of improvements to DARS online as well as a walkthrough of changes already made. A full programme of webinars is yet to be published but will start at the end of March.
- **New IG Toolkit on the way:** A new set of mandatory requirements are being introduced to the Information Governance Toolkit to support the [Review of data-security, consent and opt-outs](#). An early adopter pilot of the new Toolkit is due for launch in April ahead of formal roll out in spring 2018. Transitional arrangements will be in place from April 2017 – spring 2018. In the meantime, requirements remain unchanged and all organisations handling patient data must continue to implement requirements in the current IG toolkit.
- **Research Advisory Group (RAG):** NHS Digital, the MRC and the Department of Health are working together to simplify the research process where data is required. More details on RAG and its work will be made available on the NHS Digital website. (The Regulatory

Support Centre is represented on this group, to feed in comments on data access please email: info@rsc.mrc.ac.uk).

- **Can you help to transform data collection?** NHS Digital is exploring opportunities to transform the way in which data for secondary uses is collected from the NHS. To provide your views, ideas and feedback please email datacontent.pmo@nhs.net.

Office for National Statistics

[Approved researcher scheme changes](#) mean that new applicants need to complete SURE training. Existing Approved researchers can transition to new requirements by declaring they've read the Transitional training PDF and signing the accredited research declaration, until 12th July 2017. We're consulting ONS to find out more about SURE training.

Article on reasonable expectations

The National Data Guardian's Panel has been discussing [people's expectations about how health and care data is used](#).

Developing national standards for public involvement in research

Health and Care Research in Wales, NIHR in England, the Chief Scientist Office in Scotland and the Public Health Agency in Northern Ireland are developing a set of [national, self-assessment standards for public involvement in research for the UK](#).

Involvement 'What you need to know about payments' guide updated in Nov 2016

UKCRC Registered Clinical Trials Units – 2017 Registration

The network invites applications from all currently registered Clinical Trials Units and new units aspiring for registration. Deadline for all submissions is **Friday 7 April 2017**.

ARMA and the Association for Research Ethics

The Association for Research Ethics (AfRE) is amalgamating with ARMA (UK) in 2017. For more please see the [ARMA website](#).

Other training and conferences

UKCRC Tissue Directory Roadshow (Sheffield)

Date: 3 April 2017

Venue: University of Sheffield

UKCRC Tissue Directory Roadshow (Leeds)

Date: 25 April 2017

Venue: University of Leeds

2017 Annual NHS R&D Forum Conference: Adding value together

Date: 15-16 May 2017

Venue: Hilton Deansgate Hotel, Manchester

ARMA Annual Conference

Date: 5-7 June 2017

Venue: The ACC Liverpool

2017 NCRI Cancer Conference

Date: 5-8 November 2017

Venue: BT Convention Centre, Liverpool