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:

Retention framework for research data and records
The MRC Regulatory Support Centre has published the Retention framework for research data and records. Developed in collaboration with the Research Governance forum, this guidance is designed to help MRC funded researchers make risk proportionate decisions about retention. It is *not* designed for researchers to make these decisions alone; but rather for these decisions to be made in partnership, with the involvement of both the researcher and their organisation.

General Data Protection Regulation (GDPR) – Preparations for implementation
The MRC Regulatory Support Centre are working with stakeholders to develop guidance to help the research community prepare for the implementation of GDPR. Please check **'News'** at: http://www.mrc.ac.uk/regulatorysupportcentre for its release.

Research Governance Forum - save the date!
The Research Governance forum will meet again on **Wednesday 27th September 2017**. The Agenda has yet to be finalised but is likely to include preparation for implementation of the General Data Protection Regulation and potential implications of Brexit. We will release further details in due course. In the meantime, to register your interest please email: info@rsc.mrc.ac.uk.

The changing regulatory landscape and consultations

Understanding Patient Data has been set up to support conversations with the public, patients and healthcare professionals about how health and care data is used.

EU Regulations

General Data Protection Regulation - The new regulation will come into force in the UK on 25 May 2018. The Department for Culture, Media and Sport recently held a consultation seeking views on the derogations (exemptions) contained within the GDPR. The ICO's response reflects their view which favours replicating existing arrangements under the DPA where experience shows that the exemptions work satisfactorily. The ICO support the introduction of new derogations only where there is a clear need. The ICO's full response is on their website. Members of the Regulatory Support Centre are currently taking part in discussions on the derogations.

EU regulations on medical devices and in vitro diagnostic medical devices – On 5 April 2017 the new regulations were adopted by the EU. As yet, there is no official position on the extent of UK implementation although the Wellcome plan policy work in this area. Guidance on current legislation can be found on the MHRA website.

Clinical Trials – Due to technical difficulties, the go-live date for the EU portal and database has been postponed. The EMA will discuss a new delivery time frame in October 2017. Due to these delays, the **EU Clinical Trial Regulation** will not come into application until **2019** instead of October 2018, as previously scheduled. For further details, please see the EMA website.

Evaluation of the EU blood and tissues and cells legislation – The EU are consulting on whether the legislation has achieved its original objectives and whether it is still fit for purpose. Comments are invited until 31 August 2017. See the EC website for full details.

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
7 Sept 2017	Human Tissue workshop	MRC EWL, Cambridge
14 Sept 2017	Handling Health-related findings	Royal Station, Newcastle
12 Oct 2017	Research data and confidentiality	WIMM, University of Oxford
18 Oct 2017	Human Tissue workshop	University of Cambridge

HRA News

- **Confidentiality Advisory Group: understanding public views on using personal data**: The HRA's Confidentiality Advisory Group held two workshops in February exploring, with members of the public, the circumstances under which it is acceptable to use confidential patient information without consent for purposes beyond direct patient care.
- **Improving consistency for cross-border research within the UK**: The Four Nations Policy Group has agreed four priority areas to align processes for cross-border research in the UK. The first change, effective from 28 June 2017, is use of the combined IRAS form (to replace separate ethics and R&D forms) for studies involving the NHS/HSC in the UK.
- **UK-wide guidance on submitting amendments:** Guidance on submitting amendments to projects involving the NHS/HSC has been agreed and is available on IRAS help pages.
- **#HRAtips**: The HRA's guide to applying for HRA Approval for Twitter users.
- **New eLearning modules from the HRA** available in July, NHS R&D Forum report.

Other News

HTA News:

- **HTA Codes of Practice and Standards**: Published in April 2017, these are now in force.
- **Compliance updates** will be requested in September-October 2017. These need to be submitted via the HTA Portal. For help with registration please contact the HTA.
- **Human Application sector – Coding and Import update:** The HTA have consulted on the draft regulations which will transpose these two new EU Directives into UK law. If you have any questions about the Directives, please contact the HTA.
- **Consent for transplantation research where donors are deceased**: Guidance and a flowchart have been produced to provide clarity on consent issues under the Human Tissue Act 2004 for research relating to transplantation where donors are deceased.
- **Triennnial Review**: The HTA's Triennial Review was published in April 2017. The report contains 12 recommendations for the HTA and the Department of Health.

ICO News:

- **The ICO has published its updated paper on big data and data protection** and their AI, machine learning and personal data blog introduces the paper.
- **New resources launched to help health sector**: A blog and press release provide more detail, while the Health sector resources themselves are on the ICO website.
- **Information Rights Strategic Plan 2017-2021** published.
- **Grants programme**: The ICO have introduced their grants programme to support independent research into privacy and data protection issues and develop privacy enhancing solutions.

NHS Digital News:

- **Improving access to HES data**: NHS Digital have improved processes, enabling Hospital Episode Statistics data to be published sooner.
- **Privacy Notices**: In collaboration with the ICO and the HRA, NHS Digital is revising its policy on Privacy Notices. The new policy will specify criteria that must be in a Privacy Notice before NHS Digital will release data. Once issued, we will circulate the new policy.

AMS publish Regulation and governance of health research: five years on and **Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines**.

GMC update Confidentiality: good practice in handling patient information (2017).

Common issues identified during clinical trial applications: This MHRA guidance identifies common issues with validation and assessment of clinical trial applications and how to avoid them.

Green light given for new EudraVigilance system for collection and monitoring of suspected adverse reactions: The European Medicines Agency (EMA) will launch a new version of EudraVigilance, the European information system of suspected adverse reactions to medicines that are authorised or being studied in clinical trials in the EEA. The new version will go live on 22 November 2017.

EMA guidance on the United Kingdom's withdrawal from the European Union: The EMA have published Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use.

EMA and heads of national competent authorities discuss consequences of Brexit: The EMA held a meeting to discuss how the evaluation and monitoring of medicines will be shared between Member States following the UK's withdrawal from the European Union. For full details please see the EMA website.

UK-EU research partnerships benefit patients across Europe: A report commissioned by eight leading UK medical organisations highlights how partnerships between UK and EU medical researchers have increased the value of research, benefiting patients across Europe.

ALLEA publishes a revised edition of The European Code of Conduct for Research Integrity.

European Network of Research Integrity Offices (ENRIO) launches a new website: This Europe-wide resource details the work of ENRIO and its member organisations.

UKRIO publishes Good practice in research: Authorship.

NHS R&D Forum publish Research Indemnity and GP practices Advice Sheet, written for GPs by Rachel Illingworth, Head of Research at Nottingham City CCG.

US National Institutes of Health, the Food and Drug Administration and others, hope to create a committee to review and evaluate feedback of health-related findings from research laboratories. The National Academies of Sciences, Engineering, and Medicine will conduct the study.

Other training and conferences

Assessing the Consequences (benefits and harms) of Research: a HRA workshop
Date: 26 September 2017
Venue: Manchester HRA Office

UK Biobanking Annual Meeting
Date: 18 October 2017
Venue: The Oval, London

2017 NCRI Cancer Conference
Date: 5-8 November 2017
Venue: BT Convention Centre, Liverpool

INVOLVE at 21
Date: 28 November 2017
Venue: Church House Westminster, London