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:

General Data Protection Regulation (GDPR) – GDPR Resources
Since our last quarterly update, we've added the following new GDPR resources:

- GDPR and Data Protection Act 2018: Key facts for research: to dispel some misconceptions.
- GDPR: What do I need to do? - Answers to some frequently asked questions.
- Guidance note 4: Public interest, approvals and 'technical and organisational measures'.
- GDPR animation: Likely lawful basis for research.

Access our GDPR resources from **'News'** at: http://www.mrc.ac.uk/regulatorysupportcentre.
Please watch this space for new resources over the coming weeks and months.

Research, Data and Confidentiality e-learning withdrawn
Due to the new data protection legislation, we have withdrawn our Research, Data and Confidentiality e-learning as it no longer reflects current legal requirements. We aim to upload some new learning resources over the summer. We will also develop replacement e-learning, although this will be a longer-term project. We'll keep you posted on progress in future updates.

The changing regulatory landscape

EU Regulations

General Data Protection Regulation - GDPR and new Data Protection Act 2018 came into force in the UK on 25th May 2018. Together these now form the UK's new Data Protection law. The UK Information Commissioner saw 25th May not as an end point, but the beginning of a journey of improvement.

EU regulations on medical devices and in vitro diagnostic medical devices – Nothing new to report. *Implementation in the UK is subject to Brexit negotiations.*

Clinical Trial Regulation – The EU Clinical Trial Regulation is on track for application in the second half of 2019. Development of the EU portal continues to be prioritised and progress is being closely monitored. For more please see 'Update' on the EMA website. EMA has also updated their guidance for pharmaceutical companies on Brexit. *UK Government has made a commitment to implement the regulation subject to Brexit negotiations.*

Government have responded to the Brexit, medicines, medical devices and substances of human origin inquiry.

We'll keep you informed of further developments on the RSC website.

Consultations

The Department for Digital, Culture, Media and Sport (DCMS) – is consulting on data protection fees exemptions. The consultation runs until **1st August 2018**.

The European Medicines Agency (EMA) – Seeks views on their draft guideline on sponsor responsibilities when shipping investigational medicinal products for human use. The consultation runs until **31st August 2018**.

Information Commissioner's Office – is calling for evidence and views on the Age Appropriate Design Code (the Code). The consultation runs until **19th September 2018**.

Engaging with the public

- Involve, Understanding Patient Data and Carnegie UK Trust launch Data for Public Benefit.
- It's not what you do in public engagement, it's who you do it for – Wellcome's first in a new series of blog posts from their Public Engagement team.

HRA News

- New public involvement guidance for research applicants – aims to help researchers better identify where they've involved the public in an IRAS application.
- Updated Governance arrangements for Research Ethics Committees (GafREC) – The new version of GafREC will be implemented on 17th September 2018. This means there will be some slight changes to when NHS REC approval is needed.
- In our April update we reported on Health and Care Research Wales, this aligned processes for NHS R&D and NHS REC review in England and Wales. HRA Approval became HRA and Health and Care Research Wales (HCRW) Approval as a result.
- **Changes to IRAS submissions for NHS/HSC studies** – Any NHS/HSC study, whether it is led from England, Wales, Scotland or Northern Ireland, now only requires a single form (the IRAS form) and associated documents to be submitted in IRAS. There is no change to how participating organisations are set up. For further details please see the NRS website.
- **IRAS v5.9** – IRAS was updated to version 5.9 on **28th June 2018**. UK-wide use of the single IRAS form was one of the main changes, for others please see Updates.
- IRAS Verification tool – Checks before submission of the IRAS form that key information has been entered, mandatory documents are uploaded and there are valid authorisations.
- HRA Training and events – Webinars on HRA approval and managing your approvals.
- HRA guidance on the General Data Protection Regulation – access to streamlined technical guidance for managers updated on the 8th May, and HRA's operational guidance for studies.

Information Commissioner's Office News

***Please note that the ICO provide generic guidance for all organisations who hold personal data, these news items are not necessarily research specific*:**

- **ICO policy line on genetic data**
  - Not all data about genetics is 'personal data'. The GDPR definition of 'genetic data' includes the data being 'personal data' as a prerequisite.
  - This means it firstly has to fall under the definition of 'personal data' - it has to identify an individual directly or indirectly and it has to relate to them, in particular, by reference to an identifier. Then it has to meet the criteria in the definition of 'genetic data' in Article 4(13).
  - This means that there can be data about genetics that does not meet the definition of 'genetic data' and falls outside of the scope of the GDPR, as it will not be 'personal data'.
- **ICO Guide to the GDPR** is regularly updated. What's new provides a full list of changes.
- **ICO podcasts** – The ICO has released further podcasts to address questions about Data Protection Impact Assessments (DPIAs) and lawful basis.
- **European Data Protection Board** - The Article 29 Working Party was replaced by the European Data Protection Board (EDPB) on the 25th May. The EDPB will be a stronger, independent body responsible for ensuring data protection rights are upheld across the EU.
- **Grants programme** – The ICO have launched a second round of funding for independent, innovative research and solutions focused on privacy and data protection issues. There was a webinar for potential applicants on Tuesday 17th July, you can view the webinar here.
- **Data Breach Reporting webinar** – Aimed at data controllers this webinar was hosted by the ICO on Thursday 19th July. You can view the webinar here.

Human Tissue News

- **Human Tissue Authority's 2017 public evaluation** – Ensuring individuals' wishes were respected was a strong theme of the focus group discussions. Full findings are summarised on the HTA website.
- **England's opt-out system for organ donation: consultation update** - The consultation received just over 17,000 responses, including one from the HTA. The Department of Health and Social Care are now analysing feedback and a response is expected in July.

- **Coding and Import regulations** came into force in April. All establishments in the Human Application sector should now be working to the most recent version of the HTA's Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment.

The UKCRC TDCC is carrying out research on how researchers access human samples. They need volunteers who will tell them about their experiences of locating samples. For more please visit: https://www.biobankinguk.org/finding-out-what-makes-researchers-tick/.

CM-Path (Cellular Molecular Pathology Initiative) launch their Biobanking Sample Quality Improvement Tool, a free confidential self-assessment tool for biobank staff.

NHS Digital News

- **England's national data opt-out** – This won't apply to the majority of research (e.g. where consent is in place) but does impact on research with Section 251 support from HRA CAG.
- **Data Security and Protection Toolkit** replaces the Information Governance Toolkit.
- **NHS Digital to deliver new patient de-identification solution**.
- **Processing of patient (Type 2) objections** – NHS Digital have written to researchers who have received datasets which mistakenly included Type 2 objections.
- **Data access research** – NHS Digital are seeking volunteers to take part in user research for their new Data Access Environment, by phone on 25 July. If you are interested in taking part, please contact: dataservicesplatform@nhs.net.

Other news

Call for volunteers - The University of Aberdeen are looking for sponsor representatives to take part in research aiming to develop recommendations for researchers on feeding back trial results to trial participants. To register your interest in taking part please contact: info@rsc.mrc.ac.uk.

UKRIO welcomes House of Commons Science and Technology Committee's report on research integrity – The report has urged ministers to set up a new watchdog which would be run by UK Research and Innovation (UKRI).

Brunswick agreements updated – includes confidentiality agreements, research collaboration agreements, human tissue agreements, amongst others.

The National Institute of Health Research (NIHR) launch social media toolkit.

Other training and conferences

ABHI Annual Regulatory Conference 2018
Date: 18 October 2018
Venue: Euston Square, London

RQA Annual Conference 2018
Data and Quality: is the tail wagging the dog
Date: 31 October - 2 November 2018
Venue: Central Manchester

NHS R&D Forum Non-Commercial Research Sponsors Symposium for Health & Care
Date: 8 November 2018
Venue: London

UK Biobanking Showcase 2018
Date: 27 November 2018
Venue: Prospero House, London