The MRC Regulatory Support Centre mrc.ukri.org.uk/regulatorysupportcentre **has compiled the following update.**

Please circulate this to any appropriate colleagues.

Regulatory Support Centre news:

Health Data Access Tool Kit
Built in collaboration with multiple central health data providers, our Health Data Access Tool Kit will help you understand how to gain access to routinely collected NHS data. The Tool Kit tells you which approvals are required, and explores the issues that need to be considered within a successful application. You'll find a link to the Tool Kit in **'News'** at mrc.ukri.org.uk/regulatorysupportcentre.

Guidance notes – finalised and coming soon…
We've finalised Guidance Note 5 on Identifiability, anonymisation and pseudonymisation. A key message is that anonymisation relies on control of both the **content** (of the data) and the **context** (within which it is viewed). One way context can be controlled between organisations is by putting a legal agreement in place. This guidance applies to genetic data just as it does to any other data (i.e. not all genetic data is personal data). You'll find a link to Guidance Note 5 in **'News'** at mrc.ukri.org.uk/regulatorysupportcentre.

Guidance Note 6 on Controllers and Processors will be published later this month. We're also developing guidance to support the roll-out of the National Data Opt-out to all NHS organisations in England. Once finalised you'll find these in **'News'** at mrc.ukri.org.uk/regulatorysupportcentre.

Survey exploring regulatory and governance issues facing the research community
We'd like to say a big thank you to all who completed our survey to tell us about your regulatory and governance experiences within the last year. We've heard from almost 400 of you and we're currently analysing your responses. We'll keep you posted on the results of the survey and our plans to address your feedback in future quarterly updates.

The changing regulatory landscape

Brexit guidance – Since our last update the HRA have linked to the latest 'no deal' guidance relevant for health and social care research. (This includes links to updated guidance from the MHRA on medicines, medical devices and CTIMPs). In addition the HTA and ICO have also been updating their Brexit guidance pages.

ABPI are hosting a number of Brexit and Clinical Trial webinars for the Department of Health and Social Care. The webinars will give an update on DHSC's contingency planning for 'no deal' and provide an opportunity for you to ask questions and raise any concerns.

EU regulations on medical devices – The following guidance is available:
- EMA has published draft quality requirements for drug-device combination products.
- The European Commission has published some FAQs on the Unique Device Identification (UDI) system under the new EU Medical Devices Regulations.

Open Access Government are currently running The Brexit Scientific Collaboration Survey.

We'll signpost further updates from the RSC website.

UKRI website development project
UKRI are developing a single website to replace the existing websites of the Research Councils, Research England, Innovate UK and UKRI. They're looking for users to test the developments. To volunteer please complete their survey (adding reference code **'RSC'** to register your interest in testing the MRC Regulatory Support Centre section of the site).

HRA News

- Make it public – HRA's consultation on improving research transparency in health and social care research is now closed. We'll keep you updated on progress in future updates.
- Research transparency and me: a blog by patient advocate Margaret Grayson.
- Patients aren't always against their data being used by commercial organisations, according to research conducted by the HRA and the University of Sheffield.
- HRA launch new best practice guidance for public involvement.
- **UK Local Information Pack** - Participant Identification Centres model agreements have been added and the HRA highlight the email templates for sharing the UK Local Information Pack with participating NHS/HSC Organisations.
- **IRAS v5.13** – IRAS was updated to version 5.13 on 22nd July 2019. There were two minor updates: 1) An addition to the REC Form checklist and 2) Question wording when a study involves adults with incapacity in Northern Ireland. For full details please see Updates.
- Next phase of Pharmacy Assurance roll-out – From 30th September, all phase III non-oncology CTIMPs led from England or Wales will be accepted for Pharmacy Assurance review. Guidance on which studies will be accepted and submission can be found on IRAS.
- The HRA have updated guidance for research involving radiation.
- The HRA have updated their GDPR transparency wording.
- Find out more about Excess Treatment Costs (if your research involves the NHS/HSC or if your research involves public health in organisations in England).

Human Tissue Authority News and other human tissue items

- In collaboration with the HRA, HTA has published a set of FAQs on research tissue banks.
- **HTA conference update:** The event (which will take place on Wednesday 6 November) is now sold out but it will be live streamed and you can join the debate at #HTAConf19.
- Code of Practice F: Donation of solid organs and tissue for transplantation – The consultation is now closed. HTA will publish their response and revised Code of Practice by Spring 2020.
- Establishments licensed under the Human Tissue Act and the Transplantation Regulations must send a compliance update by **18th October 2019**.
- From 1st October HTA's inspection reports will be shorter and inspection findings will be set out in a clearer way.
- Common shortfalls in the Human Application sector – guidance on independent audits.
- Test your knowledge on HTA legislation.
- New content added to HTA Blog.
- MRC UK Brain Banks Network enhances human tissue database.

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***:**

- People care how their personal data is used, but what causes most concern? – find out in ICO's annual track survey.
- ICO publishes annual report covering 'unprecedented year'.
- ICO consulted on their draft data sharing code of practice over the summer. (The code is a practical guide for organisations on how to share **personal data**). The consultation has now closed but you can access the updated draft code.
- ICO's blog: Protecting children online provides an update on progress of their Age appropriate design code of practice for online services.
- New blogs added to the AI Auditing Framework.
- First participants selected for the ICO regulatory sandbox.
- **Data Protection Officers:** In August the ICO updated their guidance on calculating time limits for responding to requests (in relation to Individual rights).

Other news

NHS Digital launch the Virtual Data Assistant (ViDA) – you can ask ViDA questions about data and information held by NHS Digital.

ABPI has launched new guidance to help the NHS and industry work together.

MHRA blog post on Electronic Health Records (EHRs) and Inspection findings where the conversion of paper to electronic records did not meet the requirements of Good Clinical Practice.

EU and US reach a milestone in mutual recognition of inspections of medicines manufacturers – The European Union and the United States have now fully implemented the mutual recognition agreement (MRA) for inspections of manufacturing sites for certain human medicines.

Training and conferences

3rd European Quality Assurance Conference
Date: 6th-8th November 2019 (2.5 Days)
Venue: The Convention Centre (The CCD), Dublin.

Edinburgh Clinical Research Methodology Course (for all health research practitioners)
Date: 11th-12th November 2019 (2 Days)
Venue: John McIntyre Conference Centre, Pollock Halls, Edinburgh.

Edinburgh Clinical Trials Management Course (for Trial Managers, Data Managers, etc.)
Date: 14th-15th November 2019 (2 Days)
Venue: John McIntyre Conference Centre, Pollock Halls, Edinburgh.

UK Biobanking Showcase 2019
Date: 18th-19th November 2019
Venue: East Midlands Conference Centre, Nottingham.

NHS R&D Forum Non-commercial sponsors symposium
Date: 19th November 2019
Venue: Birmingham NEC

Various NHS R&D Forum CPD and training events