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:

Identifiability, anonymisation and pseudonymisation guidance
The MRC Regulatory Support Centre has released a new guidance note, available from **'News'** at: mrc.ukri.org.uk/regulatorysupportcentre. This guidance was created in consultation with the ICO and others and will be further developed following our workshop: Safe sharing of research data: The role of legal agreements when anonymising.

Forum events
The MRC Regulatory Support Centre is planning a forum event in July to cover sustainability of Research Tissue Banks; some common consent issues and how to handle them. We will keep you informed of details, including date and venue, once these are confirmed.

Updated Research and Human Tissue Act 2004 summaries
We will shortly release our updated Research and Human Tissue Act 2004 summaries. They will be available from our human tissue page and **'News'** at: mrc.ukri.org.uk/regulatorysupportcentre.

The changing regulatory landscape

Brexit guidance – Since our last update the HRA has added additional guidance on the implications of 'no deal' for health and social care research. ICO has blogged about flows of personal data in the event of 'no deal'. ABPI has reacted to the Brexit extension (particularly on the position of stockpiling of medicines for 'no deal') and the HTA has published 'no deal' guidance for the human application sector.

Government debated a report on the implications of Brexit on EU student exchanges and funding for the Erasmus and Horizon programmes.

EU regulations on medical devices – EMA has published guidance on new rules for certain medical devices. *Implementation in the UK is subject to Brexit negotiations.*

EMA consult on revised guideline to evaluate new medicines in treatment of bacterial infections. Regulators in the EU, US and Japan have been exploring how to align their respective data requirements so that clinical trials can meet the evidence needs of multiple regulatory agencies. The revised guidance reflects these discussions. The consultation runs until **31st July 2019**.

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
9 May 2019	Research, GDPR and Confidentiality	WTCRF, Edinburgh
30 May 2019	Consent and Transparency	WIMM, Oxford
4 Jun 2019	Human Tissue workshop (Scotland)	WTCRF, Edinburgh
19 Jun 2019	Consent and Transparency	WTCRF, Edinburgh
27 Jun 2019	GCP for non-trialists	WTCRF, Edinburgh
16 Jul 2019	Research, GDPR and Confidentiality	Big Data Institute, Oxford

Engaging with the public

- Understanding Patient Data – Find out more about Understanding Patient Data's work in public engagement.
- Wellcome Engaging the public – Read about Wellcome's latest public engagement work.
- EMA booklet for patients and carers: 'The journey of a centrally authorised medicine' describes how medicines are authorised for human use by the EMA. This includes how the EMA supports medicine development and marketing authorisations.

HRA News

- HRA, NIHR-INVOLVE and the NHS R&D Forum have jointly developed new guidance to support the public as co-applicants in research.
- Read a patient and carer's perspective of the HRA's new public involvement guidance.
- **From 5th June 2019** the way to involve the NHS/HSC in your research will be changing. You can learn more about the UK Local Information Pack on the HRA website.
- The Human Resources Good Practice Resource Pack has been updated.
- Pharmacy Assurance roll-out – second phase – From 18th March 2019, the HRA are accepting phase III oncology CTIMPs for Pharmacy Assurance review in England and Wales. Detailed submission guidance can be found on IRAS.
- Ionising radiation exposures guidance has been released on IRAS.
- **IRAS v5.11** – IRAS was updated to version 5.11 on 19th February 2019 to enable electronic submission of applications to the MHRA for clinical investigations of medical devices. For full details of the changes please see Updates.
- HRA respond with recommendations to the House of Commons Science and Technology Committee report Research integrity: clinical trials transparency. You can learn more about the HRA research transparency agenda on their website.
- The HRA, NHS England, NIHR, Health and Care Research Wales and others are working together to simplify set up and reporting of commercial research in the NHS. You can learn more about the changes from NIHR.
- Clinical Negligence Scheme for General Practice (CNSGP) - From 1st April 2019 the new indemnity scheme for primary care, will cover research involving NHS patients in England.
- Dr Harriet Teare blogs about Dynamic eConsent in the RUDY study.

Human Tissue Authority News and other human tissue items

- HTA licence fees 2019/20 – Fees across all sectors will increase by 2.7% from April 2019.
- Notifying changes to Designated Individual (DI) and Named Contacts on your licence – An application to vary a licence should be submitted at least two weeks prior to any change in personnel to allow the HTA to assess suitability of the proposed change.
- Test yourself on the Human Tissue Act, the Organ Regulations, and the Q&S Regulations.
- **Compliance updates** – HTA will be requesting biennial compliance updates from a number of sectors (including research) in Autumn 2019.
- **Joint statement from the HTA and MHRA on the export of tissues and cells for use in Advanced Therapy Medicinal Product (ATMP) manufacture** – MHRA confirms that Good Manufacturing Practice does not apply to the donation, procurement, testing and export of starting materials for ATMP manufacture. The export of tissues and cells to third countries must be done by licensed establishments (i.e. an export licence from the HTA is required under the Q&S Regulations).
- **Organ Donation (Deemed Consent) in England** – From Spring 2020, adults in England will be considered potential organ donors unless they chose to opt out or are excluded. The only change to the Human Tissue Act is to consent for transplantation (i.e. appropriate and valid consent to use organs unsuitable for transplant in research is still required).
- The European Directorate for the Quality of Medicines & Healthcare (EDQM) publish the 7th edition of 'Guide to the quality and safety of organs for transplantation' (2018).

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*:**

- Case for reform to Freedom of Information and Environmental Information – ICO has laid a report in Parliament calling for change to Freedom of Information (FOI) and Environmental Information Regulations (EIR) to provide oversight for the 'outsourcing' of services.
- ICO releases new FOI guidance for public authorities.
- ICO response to government's Online Harms White Paper.
- New film sets out how organisations can benefit from ICO regulatory sandbox.
- ICO launches a new blog site to keep you informed about the developing auditing framework for Artificial Intelligence (AI).

Health data access and re-use

- **National Data Opt-out** - All health and care organisations in England must comply with the national data opt-out by March 2020. NHS Digital provide guidance to help organisations:
  - Compliance Implementation Guide,
  - Information Standard: DCB3058: Compliance with National Data Opt-outs,
  - Informing patients about the national data opt-out.
- Data Security and Protection Toolkit now includes compliance with the national data opt-out.
- GPs in England reminded that Type 2 opt-outs are no longer valid.
- NHS England has published its long term plan for the next 10 years. There's a key focus on research and innovation to drive future outcomes and improvement.

NHS England releases Code of conduct for data-driven health and care technology.

Learn more about Plan S and its aims to make open access to research publications a reality; and how Wellcome are tackling four key concerns.

Other news

New system to protect patients from fake medicines goes live across the UK and Europe.

Wellcome Trust Opinion Piece: Pivotal moment for clinical trial regulations.

AMS and the US National Academy of Medicine, US National Academy of Sciences, and Royal Society respond to a commentary in Nature, calling for a moratorium on clinical uses of heritable human genome editing and the establishment of an international governance framework.

Other training and conferences

NHS R&D Forum conference 2019
Date: 12th-14th May 2019 (2 Days)
Venue: Hilton Metropole, Brighton.

UKCRC Tissue Bank Conference - Save the date!
Date: 19th November 2019
Venue: East Midlands Conference Centre, Nottingham.