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

Please circulate this to any appropriate colleagues.

Later this month NIHR will publish a framework to restart paused non-COVID19 research and start new research in the NHS. NIHR have worked with funders, NHS R&D, regulators, and the devolved administrations to develop the framework. More to follow at NIHR news.

Regulatory Support Centre news:

Medical Devices Workshop – We ran our first virtual event on 2nd April exploring medical devices regulatory requirements and how research teams developing devices have overcome challenges. Oxford Global Guidance, which featured in the workshop, is now live. The tool helps you determine whether a product is a medical device and, if so, which class. If developing devices for the EU market, this is an essential first step. You can access recordings of this event (Part 1 and Part 2) with the password: MRCrsc159!

Global Health Research Oversight conference – We ran this virtual event on Wednesday 6th May, to highlight funders' expectations in global health research, to showcase resources and approaches in university governance departments and in MRC funded research. You can access the recording of this event with the password: MRCrsc159!

The changing regulatory landscape

EU Exit update – The UK left the EU on 31st January 2020. The UK is now in a transition period, where we can negotiate a future relationship with the EU. During the transition period (due to end on 31st December 2020) the UK must adopt any new EU regulation which comes into application. The EU and UK can jointly decide to extend the transition period by 1st July 2020. For more see the House of Commons Library, Insight.

In our last update we reported that the UK would adopt the new EU Medical Devices Regulation (as it was due to come into full application on 26 May 2020). The European Commission (EC) has since postponed this by one year, until 26 May 2021, to allow competent authorities to prioritise the fight against coronavirus. This means that the current devices regulation (Medical Devices Regulations 2002) will be in force in the UK on 31st December 2020. For more on the devices regulations please see MHRA's webpages.

Given the timescales for development of the Clinical Trial Information System, the new EU Clinical Trial Regulation is also unlikely to be in application. Therefore, the current Clinical Trials Regulations (Medicines for Human Use (*Clinical Trials*) *Regulations* 2004) are likely to be in force in the UK on 31st December 2020.

The new UK Medicines and Medical Devices Bill 2019-20 has been drafted to enable the existing regulatory frameworks to be updated at the end of the transition period. You can follow the progress of the bill.

The following links provide more guidance on the transition period and implementation of Brexit: UK Government, ICO's guidance on data protection, EC's guidance on medicinal products, EC's guidance on industrial products (to include medical devices), EMA's guidance for companies and the British Chamber of Commerce.

We'll signpost further updates from the RSC website.

Regulatory Support Centre training courses

Due to the current pandemic all our face-to-face training events have been cancelled. We'll bring you further details about our training programme in future updates. In the meantime, we have online training on: human tissue, Good Research Practice and GDPR and confidentiality.

Engaging the public

- AMS, Health Data Research UK (HDR UK) and the Collaboration for Advancement of Sustainable Medical Innovation (CASMI) publish Realising patient and NHS benefits from health and care data – From policy to practice.
- **Understanding Patient Data** published research on what the public thinks about third-party use of NHS data. Findings highlight that the public are supportive when the use of NHS data benefits patients (e.g. improves disease detection, develops new medicines/treatments, etc.).
- NCRI, HDR UK, DATA-CAN and use MY data are supporting Patient and Public Involvement and Engagement in research that uses patient health data.

HRA News

- HRA to launch a service to improve public involvement in Covid-19 research.
- Review of applications for student research (i.e. undergraduate and masters level) is suspended until further notice.
- The HRA and the Devolved Administrations are fast-tracking applications for COVID-19. Other applications are still being accepted for review but are likely to take longer.
- NIHR has paused progress on national contract review for commercial research in NHS England. (Roll-out of NIHR's interactive Costing Tool (iCT) went ahead on 1st April 2020).
- Governance Arrangements for Research Ethics Committees (GafREC) has been updated. This UK policy sets out when review by an NHS/HSC Research Ethics Committee is required.
- Revised (March 2020) commercial model Clinical Trial Agreement (mCTA) and Clinical Research Organisation model Clinical Trial Agreement (CRO-mCTA) have been published.

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*:**

- Two blogs by Elizabeth Denham: Priorities for UK data protection during COVID-19 and beyond; and combatting COVID-19 through data: some considerations for privacy.
- ICO detail how they will regulate freedom of information during the coronavirus pandemic.
- EU Data Protection Board releases guidelines (03/2020) on international data transfers for COVID-19 Research.
- Contracts between Controllers and Processors need to meet the requirements of Article 28. Standard Contractual Clauses (SCCs) which have been approved by the EU Data Protection Board meet these requirements if used without amendment. For more see the ICO website.
- ICO has published guidance on developing GDPR Codes of Conduct and Certification schemes (which help organisations demonstrate compliance with data protection legislation).
- Blog on the challenges of balancing innovation and privacy in the first six months of the ICO Regulatory Sandbox.
- ICO publish Age Appropriate Design Code to protect children's online privacy.
- ICO has released a statement on government's initial response to the Online Harms White Paper consultation.

Human Tissue Authority News

- HTA licence fees 2020/21 – Fees across all sectors increased by 4% from April 2020.
- Test your knowledge on HTA legislation.
- Since our last update the HTA has added a new Blog looking back on the last decade.
- use MY data, the Medicines Discovery Catapult (MDC) and Incisive Health publish The Issue with Tissue: Recommendations for improving the use of human tissue samples.

Other news items

Further Covid related updates
MHRA regulatory flexibilities resulting from coronavirus (COVID-19) – Dates have been added so it is easier to see which regulatory flexibilities have been added and when.

MHRA has launched a Coronavirus Yellow Card reporting site to report suspected side effects to medicines or medical device and diagnostic adverse incidents used in coronavirus treatment.

A number of regulators have announced changes to their inspection programmes due to the Covid-19 pandemic (see MHRA, HTA and HFEA (clinic inspections) for more).

The Research Quality Assurance (RQA) have recorded the free webinar COVID-19 GxP Insights on Building Resilience and Agility.

Our Special Covid-19 bulletin published on 17th April supplements the items above.

Good Clinical Trials Collaborative – The Wellcome Trust, African Academy of Sciences, and the Bill & Melinda Gates Foundation have launched a joint initiative to support improved practice in running Randomised Controlled Trials (RCTs). The work will engage patients, regulators, funders, and academic, clinical and commercial trialists. It will learn from the approaches and adjustments that COVID-19 has necessitated in trials management and launch a major survey of triallists next month. If you would like to learn more about this work, including how you can get involved, please email: goodtrials@wellcome.ac.uk.

Drug Trials
EMA have provided a notice to sponsors on validation and qualification of computerised systems used in clinical trials.

Health Data Access
You can now access over 400 health datasets from HDRUK's Health Data Research Innovation Gateway. The second phase of the Gateway continues to develop in partnership with patients, the public, clinicians and researchers. To get involved, please contact enquiries@hdruk.ac.uk.

NHS Digital are working with Imperial College of London's Neonatal Data Analysis Unit (NDAU) to improve the UK National Neonatal Research Database (NNRD). In the meantime you can still access the current NNRD via the Data Access Request Service (DARS).

Global Health Research
WHO launched PHEPREN (Public Health Emergency Preparedness and Response Ethics Network) an epidemics ethics website, which includes resources on ethics and COVID-19.

UK Collaborative on Development Research - International development research funders publish guidance to anticipate, mitigate and address harm in research.

The Global Health Network publish new resources and tools to support global health research.

Conferences, Training and Consultations

NHS R&D Forum Annual Conference (RDF20)
Date: TBC, potentially Autumn 2020
Venue: Possible virtual event

RQA offer free data integrity e-learning.

NIHR develops interactive learning package to support embedding research in the NHS.

European Commission are consulting on a European approach to Artificial Intelligence. The consultation closes **14 June 2020**.