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) – Preparations for implementation
The MRC Regulatory Support Centre are working with the HRA Research Guidance Group to help the research community prepare for the implementation of GDPR. The first in a series of guidance notes was released on the 7 August and updated on the 24 August. For more please see **'News'** at: http://www.mrc.ac.uk/regulatorysupportcentre.

Save the date! We are planning an event on GDPR as it applies to research in the **Friends Meeting House, London** on **Thursday 8th March 2018**. This is likely to be applicable to research governance managers and Data Protection Officers. More details to follow.

Using information about people in health research
This practical guidance is on the MRC Regulatory Support Centre's Supporting research using health data page. It reflects the current relevant legal framework when using information about people in health research, and will be revised when GDPR comes into force. This guide is part of the MRC Ethics Series, it replaces Personal Information in Medical Research.

Translational Project Managers Forum - Wednesday 8th November 2017
A draft Agenda has been circulated to members of the Translational Project Managers Forum. Places at this event are limited, to register your interest please email: info@rsc.mrc.ac.uk.

The changing regulatory landscape and consultations

DH have accepted all recommendations in the National Data Guardian review.

EU Regulations

General Data Protection Regulation - The new regulation will come into force in the UK on 25 May 2018. Following a consultation in April/May, the Department for Culture, Media and Sport released a statement of intent: New Data Protection Bill: Our planned reforms (p19 has a section on research). The Data Protection Bill was presented to the House of Lords on 14 September. It will be debated their first, before it goes to the House of Commons.

The ICO have also added a new section about the Data Protection Bill to their website and released a series of blogs to bust the myths about GDPR such as Consent is not the 'silver bullet' for GDPR compliance.

EU regulations on medical devices and in vitro diagnostic medical devices – In April the new regulations were adopted by the EU. Since then the MHRA has confirmed that their 'preparations to implement proposed new Regulations for Medical Devices and IVDs continue'.

Clinical Trials – The EU Clinical Trial Regulation will now *not* come into application until 2019 (instead of October 2018). It is not clear whether the CT Regulations will come into application before or after the UK leaves the EU. For further details, please see the EMA website.

Evaluation of the EU blood and tissues and cells legislation – This EU consultation closed on the 14 September. The final evaluation report is expected to be published by the end of 2018. The EC website has 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
12 Oct 2017	Research data and confidentiality	WIMM, University of Oxford
17 Oct 2017	Consent and transparency	Epidemiology, Cambridge
18 Oct 2017	Human Tissue workshop	University of Cambridge
9 Nov 2017	Research data and confidentiality	University of Cambridge
15 Nov 2017	Human Tissue workshop	University of Oxford

HRA News

- Janet Wisely has announced that she is to step down as Chief Executive
- **UK Policy Framework for Health and Social Care** – The HRA hope to achieve UK ministerial sign off for the framework in September. (The UK Policy Framework will replace the current four nation's Research Governance Frameworks).
- HRA Technical Assurances update – developing an integrated, UK-wide approach to the technical reviews for research involving pharmacy and/or ionising radiation.
- From 18 October 2017, IRAS will officially support specific internet browsers and browser versions. Please refer to the IRAS 'Supported Browsers' for more information.
- HRA website redevelopment update – The new site is due for launch in September
- HRA provide clarification on the use of electronic vs ink signatures in applications for research approvals.
- New eLearning modules released.

Other News

ICO News:

- ICO publishes International Strategy 2017-2021 to help protect UK public's personal information in a global environment.
- Four lessons NHS Trusts can learn from the Royal Free case
- ICO update Subject access code of practice, CCTV code of practice and Guide to data protection after court rulings on disproportionate effort.
- Children and Young People Information Sharing (Scotland) Bill and Code of Practice Consultation response – The ICO raises a number of concerns about the Code of Practice under the current laws and under the new GDPR.
- Webinar for SMEs in the health sector – Access the ICO's webinar (originally delivered in August). The focus is on data protection and information security, both under the current DPA and the future GDPR, for SMEs within the healthcare sector.
- ICO publishes an updated version of its guidance on section 43 – commercial interests under the Freedom of Information Act.
- ICO fee and registration changes next year

NHS Digital News:

- **Data Access Request Service (DARS) webinars** – you can sign up to use DARS online to make an application and/or make a good DARS application.
- GP Data Hub – includes details of Type 2 patient opt-outs (in Care information choices).
- **New publications management system** – NHS Digital have launched a new online system for use by statisticians and researchers to access their statistical publications.
- NHS Digital produces a bi-monthly **Research Bulletin**, you can register here to subscribe to the bulletin. If you have any news for the bulletin, or feedback on content please email enquiries@nhsdigital.nhs.uk stating 'Research Bulletin' in the subject field.

Exceeding expectations – The National Data Guardian's Panel is carrying out some public engagement to explore what people would reasonably expect in terms of how information about them is used and shared.

HTA News:

- Compliance updates 2017: DIs were asked to submit compliance updates by 2 October 2017. If you have any queries about this please contact licensing.enquiries@hta.gov.uk
- New section for DIs and named contacts published on HTA website.
- Licence application process, forms and guidance have been updated.
- How to challenge an HTA licensing decision

Human Application sector

- **Coding and Import update:** The regulations are not yet legally binding in the UK. Directives are however in force in other EU countries. If you distribute tissues and cells for human application to other EU countries, this may affect you. Please contact the HTA if you would like further advice on how to comply.
- Chikungunya Virus: Guidance for HTA organisations: If you work in human application, you should review your donor selection procedures. Updated donor selection guidelines will also be available on the JPAC website from 2 October 2017.
- The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) publish their Donor Selection Criteria Report.
- Third Edition of EDQM's Tissues and Cells Guide published. Download from EDQM.

Biobank Sustainability Survey – Please take the time to complete the survey so the needs of UK Biobanks are better understood.

ISO Biobank Standard – The ISO recently asked for comments on the Biobank Standard ISO/DIS 20387 which is set to be published next year.

EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products - The guidance has been revised to address first-in-human (FIH) and early phase clinical trials (CTs) with integrated protocols. It is intended to help researchers transition from non-clinical to early clinical development and in identifying factors influencing risk for new investigational medicinal products (IMPs).

The Department of Health has updated the Use of Master Indemnity Agreement (MIA). The MIA can be used by those supplying equipment free of charge to the NHS for use in research. It should not be used where the equipment is the subject of a clinical investigation.

Life sciences: industrial strategy – a report to government from the life sciences sector.

Wellcome release new policy on sharing research data.

HFEA update their Code of Practice.

The Health & Care Professions Council have published Guidance on social media.

The Royal College of Physicians publish Research for all: Sharing good practice in research management.

Other training and conferences

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

Caldicott Guardian Leadership Summit 2017
Date: 18 October 2017
Venue: The Studio Conference Centre, Birmingham

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