

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:

Human Tissue Forum

The Human Tissue forum will meet again on **Tuesday 27th Sept 2016** in MRC Head Office, London. The Agenda will include sessions on the new HTA Codes of Practice and an update on UKCRC initiatives. To register your interest, please email: info@rsc.mrc.ac.uk

Non-commercial sponsor workshop – adapting to HRA Approval

We are running a large workshop for those who manage sponsorship decisions and processes in HEIs, the NHS and MRC units. Attendees will discuss processes and identify any changes that are needed to align well with HRA Approval. The workshop will take place in The Light, Friends Meeting House, London on **Wednesday 9th November**. Invites will be circulated next week, if you're interested please get in touch at info@rsc.mrc.ac.uk

NEW – Guidance on Type 2 patient opt-outs

In this guidance, developed in conjunction with the HSCIC, we provide clarity on opt-outs, when they apply and what to expect from the HSCIC, including how to handle communications as the HSCIC retrospectively implement them.

UPDATED - Guidance on obtaining data from the HSCIC for health research

This guidance was updated in early June, please see the [RSC website](#).

The Health and Social Care Information Centre (HSCIC) will change its name to NHS Digital. Plans are underway to implement the new name later in the summer.

Updated IRAS online guidance

We have worked with the HRA to provide updated guidance on making applications through the Integrated Research Application System (IRAS). You can access this from the e-learning tab on the [IRAS website](#).

Programme Manager - Regulatory Impact Analysis post (closing date 31st August)

We are currently recruiting a new team member to lead a programme evaluating the impact of regulation and governance on research, focussing initially on informatics research. For more information see the details on [jobs.ac.uk website](http://jobs.ac.uk).

Regulatory Support Centre training courses

To book a place on any of the following courses or to discuss the potential of holding training within your Unit or University, please contact us on info@rsc.mrc.ac.uk.

Date	Course	Location
14 Sept 2016	Health Related Findings	HRA room, Bristol
28 Sept 2016	Human Tissue workshop	CSC, London
26 Oct 2016	Human Tissue workshop	University of Cambridge
6 Dec 2016	Human Tissue workshop	WTCRF, Edinburgh

The changing regulatory landscape and consultations

National Data Guardian for Health and Care Review of Data Security, Consent and Opt-Outs (Caldicott 3) – [Dame Fiona Caldicott's report](#) makes recommendations to the Secretary of State for Health which are aimed at strengthening the safeguards for keeping health and care information secure, and ensuring the public can make informed choices about how their personal confidential data is used. For full details on the consultation please see the [DH website](#). Responses are invited by **7 September 2016**.

The MRC will be responding to this consultation, please contact us at info@rsc.mrc.ac.uk if you would like to feed in.

EU Regulations

The Human Tissue Authority, in their most recent [newsletter](#) (26 July), comment that until EU exit negotiations are concluded the Government will continue to negotiate, implement and apply EU legislation.

The Information Commissioner's Office have released the blog [General Data Protection Regulation still relevant for the UK](#) and a [Data Protection Reform website](#) to help organisations understand the new legal framework. This includes 12 steps to take now in preparation for the change in the new legal framework, which is anticipated to apply by May 2018.

EU regulations on medical devices and in vitro diagnostic medical devices – On 15 June the EU Council Committee endorsed the agreement reached with the European Parliament. Next steps are for Council to approve the agreement at ministerial level, this is planned for September.

Clinical Trials – It's expected that the Clinical Trials Regulation will take effect at the end of 2018. The timetable for the new law to take effect is dependent on the European Medicines Agency's development of requisite information systems. This timetable has already been substantially revised.

The European Commission are seeking comments on 3 separate consultations:

- "Risk proportionate approaches in clinical trials";
- "Summary of Clinical Trial Results for Laypersons" and
- The revision of the "Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)" (previously called "Guidance on Investigational Medicinal Products (IMPS) and Non-Investigational Medicinal Products (NIMPs)).

For further details please see the [EC website](#). Responses are invited by **31 August 2016**.

We'll keep you informed of further developments on the [RSC website](#).

RCUK Publish Open Data Concordat

Released on 28 July, you can find full details of the Concordat on the [RCUK website](#). RCUK are developing related FAQs and the need for a separate MRC Data sharing policy will be reviewed.

UK Anonymisation Network (UKAN) publish decision-making framework

UKAN have developed a practical guide to anonymisation to provide more operational advice and complement the ICO's Anonymisation Code of Practice. For more please see the [UKAN website](#).

Updated ICO encryption guidance

Scenarios have been added to help you consider when and how to use encryption. For full details please see the [ICO website](#).

DH release guidance on the Psychoactive Substances Act 2016

For full details please see the [DH website](#).

HRA News

HRA Approval

In [a recent update](#) the HRA describe how they had received a higher than anticipated volume of applications and amendments for existing studies, which have now reduced to near expected levels. They have issued a [performance update](#) which outlines how they are working to clear the backlog. Their most recent newsletter [HRA Latest](#) volume 20 contains top tips for applicants and for amendments. If submitting an application or amendment, we encourage you to read these so you know how best to navigate the system.

Public consultation on the UK Policy Framework for Health and Social Care Research

You will find details of the responses to the consultation on the revised UK Policy Framework for Health and Social Care Research on the [HRA website](#).

New Health Research Authority (HRA) and INVOLVE briefing and guidance on public involvement and ethical review – Can be found on the [HRA website](#) and [Involve website](#).

News from the Human Tissue Authority

- **HTA Fees Consultation** – The HTA seek your views on the proposed changes to the fee structure, which are due to be implemented from April 2017. The consultation will run until 30 September 2016. For full details please see the [HTA website](#).
- **Codes of Practice and Standards update** - The new Codes of Practice and Standards are available in draft form on the [HTA website](#). They are due to come into force in April 2017. Later this year, the HTA will put in place a training package to ensure all are up-to-speed by the time the new Codes apply. Keep an eye on [HTA News](#) for further details.
- **HTA 2015/16 annual review launched** and available from the [HTA website](#).
- **Research Sector reviews** – The HTA has found a high level of compliance and good practice amongst licensed establishments in their Compliance Review (last December) and throughout their inspections. Reports on both will be available shortly on the HTA website.
- **Human Application Sector: Coding and Import update** – Following the EU referendum, the HTA *have been advised that the Government will continue to negotiate, implement and apply EU legislation*. Therefore the HTA will continue to work towards implementation by April 2017.

EMA Improving safety of first-in-human clinical trials

The European Medicines Agency (EMA) has started a review of the guidelines that describe first-in-human clinical trials and the data needed to enable their appropriate design and allow initiation. This is being done in cooperation with the European Commission and the Member States of the European Union (EU). For full details please see the [EMA website](#).

MHRA borderline products guidance updated

The following MHRA guidance has been updated:

- [A guide to what is a medicinal product](#) (updated March 2016)
- [Borderlines between medical devices and medicinal products](#) (updated May 2016)
- [Borderlines between medical devices and other products \(such as personal protective equipment, cosmetics and biocides\)](#) (updated May 2016)

Other training and conferences:

UKCRC Tissue Directory and Coordination Centre: Annual Biobanking Showcase

Date: 16 November 2016

Venue: The Oval, London

For further details please see the [Eventbrite website](#).

HRA Quantitative Research Methods and Statistics Workshop

Date: 20 October 2016

Venue: Newcastle Upon Tyne – Life Conference and Banqueting

For further details please see the [HRA website](#).