**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:***

**Translational Project Managers Forum**
The Translational Project Managers forum will meet again on **Thursday 19th May 2016** in Head Office, London. The Agenda will include sessions on developing a study start-up timeline, describing risk in studies to ethics committees and submitting a successful ethics application. To register your interest, please email: info@rsc.mrc.ac.uk

**Guidance on obtaining data from the HSCIC for health research**
The process for obtaining data from the HSCIC has recently changed and as a result we are in the process of updating our guidance (this is currently with HSCIC and HRA CAG for sign off). Once agreed the new edition will be available from the RSC website (to replace the 04-11-15 release).

*From July 2016, the Health and Social Care Information Centre (HSCIC) will change its name to NHS Digital.*

**Human Tissue Forum – save the date!**
The Human Tissue forum will meet again on **Tuesday 27th September 2016** in the Academy of Medical Sciences, 41 Portland Place, London. To register your interest, please email: info@rsc.mrc.ac.uk

**Regulatory Support Centre training courses**
We are pleased to announce the following training courses for 2016. To book a place 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 |
|---|---|---|
| 28 Apr 2016 | Research Data and Confidentiality: What you really need to know | CTSU, Oxford |
| 10 May 2016 | Health Related Findings | WTCRF, Edinburgh |
| 17 May 2016 | Research Data and Confidentiality: What you really need to know | WTCRF, Edinburgh |
| 8 Jun 2016 | Consent: how can we do it better? | AMS, London |
| 9 Jun 2016 | NEW - Consent, payments and voluntariness | Homerton College, Cambridge |
| 29 Jun 2016 | Health Related Findings | HRA room, Manchester |
| 14 Sept 2016 | Health Related Findings | HRA room, Bristol |
| 20 Sept 2016 | Consent: how can we do it better? | WTCRF, Edinburgh |
| 28 Sept 2016 | Human Tissue workshop | CSC, London |

***The changing regulatory landscape***

**EU Clinical Trials Regulation** – Nothing new to report. It's anticipated that the Regulation will apply by the end of 2017 if the EU clinical trial portal and database are deemed fully functional. For full details please see the EMA website.

**EU Data Protection Regulation** – is moving ever closer and looking much more positive for research. Broad forms of consent may be acceptable in research; researchers can use health related data without specific consent; and several provisions that would otherwise apply will not apply to research (e.g. data storage limitations). For further detail please see the Lancet.

**Proposal for the public to opt out of research use of NHS data (Type 1 & Type 2 Objections)**
A proposed recommendation in the Caldicott 3 report could have implications for research that uses NHS patient data from HSCIC. Type 1 & Type 2 objections would allow the public to opt out of flows of their identifiable data. Type 1: To opt out of identifiable data leaving their GP practice (i.e. not provided to HSCIC and therefore not available to pass on to researchers); Type 2: To opt out of identifiable data flowing to secondary users (i.e. identifiable data provided to HSCIC but cannot be passed on to researchers or others). HSCIC has been instructed to implement type 2 objections from 29th April 2016.

We'll keep you informed of further developments on the RSC website.

## *HRA News*

Consultation on UK policy framework for health and social care research has now closed.

**HRA Approval**
HRA Approval was fully rolled out on the 31 March 2016 and is now the process for applying for approvals for all project-based research in the NHS led from England. (HRA Approval does not apply to Research Tissue Banks and Research Databases). Closure of NIHR CSP was timed in line with the final roll out. The MRC Regulatory Support Centre's tool to help guide researchers through the process of applying for HRA Approval can be accessed from **News** on the MRC RSC website.

**HRA Approval: new NHS sites in England for all studies**
From 31 March, all studies with existing approvals but that want to set up new NHS sites in England will need to complete the set-up through HRA Approval systems.

**HRA Approval: amendments for the NHS in England for all studies**
From 31 March, amendments for all English-led studies taking place in the NHS will be categorised on behalf of the NHS by the HRA in line with the UK Process for Handling UK Study Amendments. Amendments should no longer be submitted to NIHR CSP.

**Cross-border arrangements for provision of NHS R&D local site-specific information for cross-border studies**
As part of the roll out of HRA Approval in England, operational and policy leads from the 4 Nations have worked closely to ensure compatibility of NHS research approval systems across the UK.

As part of this, over the next 6 months, the 4 Nations have committed to review the information required for study approval/confirmation of capacity and capability at the local NHS site level. This is with the aspiration of coming to a common UK position, that supports the timely set-up of studies and that meets the needs of sponsors, research sites, NHS patients and service users.
This review will be facilitated through a series of workshops involving operational and policy leads from across the UK. Until further UK-wide guidance on local information can be agreed and issued, the interim position for management of local NHS site information is as follows:

- Site Specific Information (SSI) forms will continue to be used for setting up studies in the devolved administrations (DAs).

- The above includes research studies that are sponsored/led from England with research sites in a DA, where the DA will continue to use SSI forms.
- Where research studies are sponsored/led from a DA with sites in England, the HRA will accept SSI forms.
- For DA-led studies, the HRA Approval team will facilitate the completion of any additional information requirements in England in order to review the study and will confirm with the sponsor that the information is correct.
- Sponsors from a DA (or authorised delegates) are advised to contact the HRA at the earliest opportunity so that the HRA Approval team can facilitate the review of the research study for English sites.

The above arrangements will be reflected in updates to operational guidance documents, including the HRA Approval Q&A.

**Pilot of revised Proportionate Review process**
A project is being undertaken to review whether there is benefit to allowing up to 21 calendar days for Proportionate Review. (The current process requires an opinion within 14 calendar days).

**UKCRC Tissue Directory and Coordination Centre announce launch of the Tissue Directory**
The Tissue Directory is now open to allow custodians of samples to register their collections. The Directory will go live to researchers in the coming weeks. For more information please see the UKCRC Tissue Directory website.

Running in parallel is a survey designed to gather feedback on whether assumptions about the potential users of the Tissue Directory are correct. The 'User Personas' are fictional characters that are meant to identify users' needs, behaviour and the challenges they face. Please visit the following link to take the survey.

***News from the HTA***
- **Codes of Practice and Standards update** - The Codes and Standards are now with the Department of Health for legal review, after which they will need approval from Parliament. The HTA expect this to happen later in 2016 and aim to bring the Codes into force in 2017.
- **Fees for 2016/17** - There will be no increase in the 2016/17 annual licence fee for the post mortem, research, public display, organ donation and transplantation and anatomy sectors. There will be around a 4% increase for human application. For more see the HTA website.
- **Cord blood banking: a guide for parents** – Is available from the HTA website.
- **Donating your body** – A new information pack has been developed which includes a body donation card. For more details please see the HTA website.

**MHRA: CTA submission via the Common European Submission Platform (CESP)**
From 1 February 2016 the MHRA will no longer accept submissions on physical media (CD/DVD/Letters); only submissions using the Common European Submission Platform (CESP) will be accepted. This applies for any new CTA submissions along with substantial amendments, and DSURs etc. Further information can be found on the MHRA website.

**Home Office guidelines for human-animal hybrids research released**
The Home Office has published advice on the regulation of scientific research involving the use of human material in animals. The guidance was produced in collaboration with the Human Tissue Authority, the Human Fertilisation and Embryology Authority and the Academy of Medical Sciences. It is available from the gov.uk website.

**Public need to know how patient records are used, including by commercial organisations**
An IPSOS Mori survey, commissioned by the Wellcome Trust, reveals that 53% of people support the idea of patient data being used by commercial organisations for research. In general, participants used four key tests in order to judge the acceptability of a company accessing data:
- WHY Is it for a particular public benefit and not just private profit?
- WHO Can the people using my data be trusted to produce a public benefit?
- WHAT Am I giving sensitive data? Could it be linked back to me?

- HOW Are there safeguards in place to keep my data private and secure?

Full details of the survey can be found on the Wellcome Trust website.

**HSCIC revised pricing structure**
Pricing for DARS services has been revised, for more detail please see the HSCIC website

**NIHR Enrich – A Toolkit for care home research**
NIHR have released a toolkit for care home research, please see the ENRICH website

***Other training and conferences:***

**2016 Annual NHS R&D Forum in association with the HRA**
**Date:** 23-24 May 2016
**Venue:** Stratford upon Avon
For further details please see the NHS R&D Forum website.

**UKRIO Conference**
**Date:** 5 May 2016
**Venue:** London
For further details please see the UKRIO website.

**HTA annual conference 2016**
**Date:** 12 July 2016
**Venue:** Central London
For further details please see the HTA website.

**The Health Services Research UK (HSRUK) Symposium 2016**
**Date:** 13-14 July 2016
**Venue:** Nottingham
For further details please see the HSRUK website.

**Personal Data in Research – A Workshop**
**Date:** 14 July 2016
**Venue:** London HRA Office
For further details please see the HRA website.