

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:

Updated Research and Human Tissue legislation summaries

In collaboration with the Human Tissue Authority (HTA), the Regulatory Support Centre has updated our Research and Human Tissue legislation summaries on Consent and Licensing. These are available from **News** on www.mrc.ac.uk/regulatorysupportcentre.

Updated Human Tissue e-learning

Our human tissue e-learning has also been updated. The updated module and separate assessments (for England, Wales and Northern Ireland and for Scotland) can now be accessed from the RSC website (available from the “**e-learning**” link under **Training & e-learning** on www.mrc.ac.uk/regulatorysupportcentre). The previous version of the module will be removed at the end of November 2014.

Human Tissue and Biological Samples for use in research guidance

The Human Tissue and Biological Samples guidance has been reviewed and approved by MRC Management Board. We are now organising electronic publication with the MRC Communications team and hope that the final version will be available from **News** on www.mrc.ac.uk/regulatorysupportcentre early in 2015.

New Fora webpages

New webpages to support the Research Governance and Human Tissue fora have been developed. These are available from www.mrc.ac.uk/regulatorysupportcentre (**Training & e-learning, Regulatory Support Centre** button, then green **Fora** button). For access please contact info@rsc.mrc.ac.uk.

Regulatory Support Centre training courses

We are pleased to announce the following training course. To book a place or to discuss the potential of holding training within your Unit or University, please contact us at info@rsc.mrc.ac.uk.

Date	Course	Location
11 Feb 2015	Good Clinical Practice for non-trialists	WIMM, Oxford

The changing regulatory landscape

EU Clinical Trials Regulation – The NHS European Office have published a [briefing](#) on the new EU Clinical Trials Regulation. The Regulation is expected to apply from 2016.

EU Data Protection Regulation – No further update on progress of the Regulation, details to date are available on the [MRC website](#).

Human Tissue Authority – Last July the [McCracken review](#) suggested changes for the HFEA and HTA. Since then the HTA have met all 7 recommendations it was set. For more details please see the [HTA website](#).

Health Research Authority - Following implementation of the Care Act 2014, the Health Research Authority will take on legal responsibilities for providing guidance on the principles of good practice for health and social care research. This includes replacement of the current Research Governance Frameworks and is due to take place early in 2015.

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

Consultations:

HRA – Seeking informed consent for simple and efficient trials in the NHS

The Health Research Authority (HRA) would like comments on proposed guidance on seeking consent in a proportionate manner from patients to take part in large-scale simple and efficient research trials within the NHS. For further details please see the [HRA website](#). Responses are requested by 5pm on **28th November 2014**.

HRA news:

HRA Approval

HRA Approval will provide a single approval for research in the NHS. HRA are taking a phased approach to development which is planned for completion by the end of 2015. Further details are available from the [HRA website](#).

Research Governance Framework update

A UK wide steering group is overseeing a number of projects to inform the development of a new UK wide policy framework to replace the existing Research Governance Frameworks. A detailed update on these key areas is available on the [HRA website](#).

HRA updates requirements for sponsor registration of clinical trials

From 30 September 2014, the HRA require all sponsors to declare that all clinical trials approved by an NHS REC since 30 September 2013 have been registered (or the HRA has granted a deferral that is still valid) in order to comply with the condition of their favourable ethical opinion. For further details please see the [HRA website](#).

HRA Application Managers

The HRA have employed a team of application managers who can provide support for researchers encountering difficulties with any aspect of the current NHS approvals process. If you are currently experiencing difficulties please contact the HRA queries line: hra.queries@nhs.net and request assistance from an application manager.

New IRAS helpline number

From 14 September, the new IRAS helpline contact details are tel: 0207 043 0734 and email: helpdesk@myresearchproject.org.uk.

Other news:

'One stop shop' regulatory advice service for regenerative medicine

A new 'one stop shop' that will provide regulatory advice for those working on regenerative medicines was launched in October. The service will provide a single point of access to regulatory advice from the four regulatory bodies that work in the sector. For further details please see the [MHRA website](#).

HSCIC Data Access Request Service (DARS)

The process for requesting access to health and social care information has changed. For further information please see the Health and Social Care Information Centre [\(HSCIC\) website](#).

HTA E-learning update

The HTA have withdrawn the now outdated e-learning package for Designated Individuals (DIs) responsible for licences under the Human Tissue Act. They planned to discuss other options for supporting DIs, including sector-specific events, at their Stakeholder group meeting in October.

HTA advice for Research tissue banks regarding cost recovery

Research tissue banks may charge for providing human tissue samples to researchers, including those working for private companies, so that their running costs are recovered. For further details please see the [HTA website](#).

HTA Guidance on disclosing patient data during inspection

On occasion, HTA regulation staff are challenged when they ask to see documentation that includes patient-identifiable information during inspection. Working with lawyers, the HTA have produced guidance that explains the basis on which this information can be requested and why establishments should grant it. The guidance has been reviewed by the Information Commissioner's Office and is available on the [HTA website](#).

AMRC - 10 tips for writing a lay summary

Sally Thompson, Communications Officer at AMRC, gives her best tips for effective writing. For full details please see the [AMS website](#).

Other workshops and training:

Involve 2014 – Changing landscapes

Date: 26-27 November 2014

Venue: National Exhibition Centre, Birmingham

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

HRA Personal Data in Research – A Workshop

Date: 3 December 2014

Venue: Manchester HRA Office

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

HRA Research in Vulnerable Groups

Date: 11 December 2014

Venue: London – (Venue to be confirmed)

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

HRA Workshop: Quantitative Research Methods and Statistics

Date: 15 December 2014

Venue: Birmingham – Thistle Hotel – Birmingham City Centre

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

Research in the NHS – the basics

Date: 4-5 February 2015

Venue: Bristol

For further details please see the [NHS R&D Forum website](#)

HRA Researcher Training Day

Date: 24 February 2015

Venue: London – (Venue to be confirmed)

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

MHRA Good Clinical Practice Symposium 2015

Date: 3 March 2015

Venue: The Novotel, London West

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