

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:

Regulatory Support Centre funding

We are pleased to announce that the Regulatory Support Centre has been successful in securing full funding for 2015 – 2020. Many thanks for all of your support; we look forward to working with you over the next 5 years.

Regulatory Support Centre training and workshops

Our Health Related Findings workshops have proved popular with the Edinburgh date now fully booked. The workshops will introduce the [Medical Research Council / Wellcome Trust Health Related Findings Framework](#) and then allow participants to practically apply the framework to real-life examples. Places are still available in London in November where Dr Beth Thompson will provide some background to the framework.

Date	Course	Location
1 Oct 2014	Human Tissue blended learning	CSC, London
15 Oct 2014	Human Tissue blended learning	HNR, Cambridge
16 Oct 2014	Good Clinical Practice for non-trialists	HNR, Cambridge
6 Nov 2014	Health Related Findings Workshop	Wellcome Trust, London

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

Research Governance Forum – [save the date!](#)

The Research Governance forum will meet again on the 5th November 2014 in the **Academy of Medical Sciences, London**. The day will focus on research data / records management and we hope to have input from Head Office. To register, please contact us on: info@rsc.mrc.ac.uk.

The changing regulatory landscape

EU Clinical Trials Regulation – The EU Clinical Trials Regulation was published in the Official Journal of the European Union on 27 May 2014. For details of resulting changes to process, please see HRA news below.

You can follow the HTA's progress towards each of the recommendations within the [McCracken review](#) on the [HTA website](#).

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

Revision of the Medical Devices Directives – No further update on progress of the medical device regulation. For further details to date please see the [MHRA website](#).

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

Consultations:

HSCIC - Feedback sought on Code of Practice for confidential information

The Health and Social Care Information Centre (HSCIC) is inviting feedback on its draft Code of Practice on Confidential Information. Further details are available from the [HSCIC website](#). Responses are requested by **18th August 2014**.

RCUK launches call for evidence in Open Access Review

Research Councils UK (RCUK) has launched a call for evidence for the 2014 review of their policy on Open Access. This is an open call with comments invited from individuals, institutions and organisations. Further details on the call can be found on the [RCUK Website](#). The deadline for submissions is **12th September 2014**.

Scottish Government Health Research Strategy

The Chief Scientist Office invites comments on its draft Health Research Strategy. For full details see the [CSO website](#); responses are requested by **30 September 2014**.

HRA news:

EU Clinical Trials Regulation – single approval process

One requirement of the new EU Clinical Trials Regulation is that a single decision on clinical trials will be made by each member state involved. In the UK, this will mean a single approval for clinical trials will replace the current separate approvals given by the MHRA and NHS REC. It is hoped that these changes will apply from 28 May 2016. For more please see the [HRA website](#).

Replacing the Research Governance Framework

This year the HRA will take responsibility from the Department of Health for issuing guidance relating to research in England. The aim is to replace the current Research Governance Frameworks of the four devolved nations with a single UK framework for health and social/community care research. Work is ongoing to ensure that a set of high level principles will be ready for consultation in late 2014. For more please see the [HRA website](#).

Other news:

HSCIC - review of data releases made by the NHS Information Centre

HSCIC has completed its review of data releases (e.g. Hospital Episode Statistics, data from the Office for National Statistics etc). Four steps were announced as a result, and the following will be of interest to those currently receiving data from HSCIC:

- All data agreements will be re-issued, to ensure activity is centrally logged, monitored and audited, for a more transparent process. Decisions will be documented and published.
- A new, strengthened audit function will monitor adherence to data sharing agreements and halt the flow of data if there are any concerns exposed.

There are no details on when these steps will be implemented on the [HSCIC website](#), but we'll keep you posted of any developments in future updates.

NIHR - Make it clear campaign

The National Institute for Health Research (NIHR) made good quality plain English summaries, a requirement of funding submissions from 14 May 2014. [Guidance](#) has been developed for researchers and for board and panel members.

UKRIO's Self-Assessment Tool for the Concordat to Support Research Integrity

For details on how to access UKRIO's Self-Assessment tool, please visit the [UKRIO website](#).

Incentives needed to further improve sharing of research data, says new report

A report by the Expert Advisory Group on Data Access (EAGDA) highlights the need to develop new incentives within the biomedical research community to improve data sharing. For further details please see the [Wellcome Trust website](#).

Other workshops and training:

EFGCP Multi-Stakeholder Workshop & Discussion - How to Ensure Optimal Ethical Review within the New Clinical Trials Regulation?

Date: 11 September 2014

Venue: Square Congress Centre, Brussels, Belgium

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

EFGCP Annual Conference 2015 - How do we improve health without betraying confidentiality within current and upcoming EU Regulations?

Date: 28 & 29 January 2015

Venue: Square Congress Centre, Brussels, Belgium

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

HRA Researcher Training Day

Date: 6 November 2014 @ 09:45am

Venue: Concept Conference Centre, Birmingham

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

HRA Qualitative Research and Ethical Review

Date: 10 November @ 10:45am

Venue: London – HRA Office

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

ABHI Regulatory Conference on Medical Device Regulation (MDR)

Date: Tuesday 25 November 2014

Venue: Simmons & Simmons LLP

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