

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:

Research Governance Forum – save the date!

The Research Governance forum will meet again on Tuesday the 10th November 2015 in **MRC Head Office, London**. The Agenda is still being developed but is likely to focus on research data / records management. To register your interest, please contact us on: info@rsc.mrc.ac.uk.

NEW Translational Project Managers Forum – save the date!

The new Translational Project Managers forum will meet for the first time on Friday the 6th November 2015 in **MRC Head Office, London**. To register your interest, please contact us on: info@rsc.mrc.ac.uk.

Regulatory Support Centre training courses

We are pleased to announce the following training courses. 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
30 Jun 2015	Research Data and Confidentiality Blended learning	CBU, Cambridge
1 Jul 2015	Research Data and Confidentiality Blended learning	BSU, Cambridge

To book a place on either 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.

The changing regulatory landscape

EU Clinical Trials Regulation – Nothing new to report. Efforts are now focussed on preparing for implementation.

EU Data Protection Regulation – In March 2015, the Justice and Home Affairs Council (EU) rejected amendments to the Data Protection Regulation which had threatened health research. The Council recognised the importance of a Regulation that can facilitate research and this move represents a much more positive outlook in terms of research. This decision was in no small part influenced by lobbying activities which are still ongoing: <http://www.datasaveslives.eu/>

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

Consultation

The 2021 Census - Initial view on content for England and Wales

The Office for National Statistics are consulting on the next Census to ensure that content stays relevant and credible. For further details please see the [ONS website](#). Responses are invited by **27 August 2015**.

HRA News

Implementation of HRA approval

The HRA is currently developing the new HRA approval system, which will ultimately replace NHS R&D permission and CSP. They have already started a phased development process, and will continue to roll-out across defined study types. There will be a period of learning and development as the HRA make adjustments to the approval system to ensure it is both efficient and effective for all studies. Keep a watchful eye on developments, and if you are unsure, please ask the HRA for help. For more please see the [HRA Approval webpage](#).

Feedback on revised model Non-Commercial Agreement (mNCA)

The HRA are collating feedback from this consultation with a view to updating the template. They will work with a range of NHS and university stakeholders on the revised version to ensure it can be used from summer this year.

Transparency: Requirements for sponsor registration of clinical trials

From 1 April 2015 the HRA required sponsors to register all clinical trials on a publicly accessible register or have HRA agreement for deferral of registration. (This applies to clinical trials approved by a Research Ethics Committee (REC) in the UK from 30 September 2013, and those approved prior to this date which are actively recruiting in the UK).

HRA guidance on information at the end of study

The HRA have released guidance on the information that should be provided to participants at the end of a research study. For more please see the [HRA website](#).

Other News

Children and clinical research: ethical issues

The Nuffield Council on Bioethics have released a report calling for children's views to be taken into account in shaping how health care research is conducted. For full report please see the [Nuffield Council on Bioethics website](#).

New Public benefit and privacy panel in Scotland

A new Public benefit and privacy (PBP) panel has been formed to help facilitate the release of health data from NHS Boards in Scotland. The following summarises how the PBP panel will work together with Caldicott Guardians' in Scotland:

- Release of data from one / two NHS Boards - you should apply to the local Caldicott Guardian for approval
- Release of data from a number of NHS Boards - you should apply to the PBP panel for approval. The panel will include the relevant Caldicott Guardian(s) in the decision making process (i.e. you will not need local Caldicott Guardian approvals from each NHS Board once the PBP panel have approved access to data).
- Release of data from the Information Services Division (ISD) Scotland - you should apply to the PBP panel. If they approve access to ISD data, you will not need ISD Caldicott Guardian approval (as this person sits on the PBP panel and are part of the group decision making process).
- If an individual Caldicott Guardian is not sure what to do - they can ask the PBP panel for help at any time, even if a request is only for release of data from that single Board.

This application system will become the only way to access data from multiple NHS Boards in Scotland from mid-June.

HTA Codes of practice

The Human Tissue Authority Codes of Practice are currently being significantly reviewed. The HTA are planning to launch a formal consultation on the Codes in the autumn. We'll announce details of the full consultation when these become available.

HTA publishes guidance on the sensitive handling of pregnancy remains

The Human Tissue Authority has published guidance for professionals who work with women who have experienced a pregnancy loss or termination. The full guidance is available from the [HTA website](#).

Research misconduct

An editorial in Nature reports on the results of a survey finding just a fraction of Universities have made public their investigations into research misconduct. For full article please see [Nature](#).

Other training and conferences:

HRA Researcher Training Day

Date: 29 June 2015

Venue: London

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

ABHI Regulatory Conference 2015: Countdown to the Medical Device Regulation

Date: 30 September 2015

Venue: London

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

HRA Introduction to Phase 1 Research – Trials & Regulation

Date: 7 October 2015

Venue: London

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