

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 **Wednesday 2nd April 2014** in Head Office, London. We are currently approaching potential speakers and hope to be able to release a draft Agenda soon. To register your interest, please email: info@rsc.mrc.ac.uk.

Regulatory Support Centre training courses

We are currently scheduling the Regulatory Support Centre's training programme for the year ahead. We hope to be in a position to announce dates for our 2014 training calendar over the coming months.

RSC collaboration with Health Research Authority

We are pleased to announce that new on-line guidance on consent and developing participant information sheets will launch in March. This guidance has been produced by the Regulatory Support Centre, working in collaboration with the HRA and can be accessed from the [HRA decision tools website](#).

Collaborative HRA, NIHR and MRC Workshop – Improving Informed Consent & Participant Information Sheets

Dr Rachel Smith will facilitate at one of the collaborative training events in March. Two workshops are planned and both are fully booked. We will keep you updated of any plans to run this workshop again in our quarterly updates.

The changing regulatory landscape

EU Clinical Trials Regulation - Informal agreement has been reached on the text of the European Clinical Trials Regulation. Text was endorsed by Member States in Dec 2013 in the meeting of Coreper (Committee of permanent representatives of Member States). The text will go through linguistic and legal checks and then it will need to be formally adopted by both the Council of Ministers and the European Parliament before it can be published in the Official Journal of the European Union. Once approved, it's anticipated that it will apply from mid-2016. Consolidated text of the draft regulation is available to [download in PDF](#).

In response to the McCracken review the HTA continue progress towards Justin McCracken's recommendations (including transfer to the MHRA of all aspects of regulating Advanced Therapy Medicinal Product (ATMP) development, and joint HTA/CPA inspections which will be in place from April 2014). For more please see the [HTA e-newsletter \(no. 42\)](#).

Amendments to European Data Protection Regulation will damage medical research, warn science organisations - Health and scientific research will be severely threatened if proposed amendments to the Data Protection Regulation are taken forward by the European Parliament, a pan-European coalition of leading medical research organisations has warned. Full article is available from the [Wellcome Trust website](#).

NHS database put on hold as officials accept privacy fears Officials from NHS England have agreed to delay the care.data initiative which will aim to share patients' medical data, following criticism from patients groups, privacy campaigners, doctors and the Information Commissioner that the right to opt out has not been properly publicised. Officials will now launch a publicity campaign to explain plans to the public. *The MRC is part of a campaign (which includes the Wellcome Trust, Cancer Research UK, and many medical research charities) to raise awareness among the public of the benefits of patient data to research.*

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

Consultations:

European Commission (EC) - Revision of Guidelines on Good Manufacturing Practice for Medicinal Products

The EC has launched a Public Consultation on the revision of Annex 15: Qualification and Validation. Stakeholders are invited to comment on this draft by **31st May 2014**. Full details are available from the [EC website](#).

HRA Consultation on Sponsorship Responsibilities

The HRA has launched a consultation on a mechanism for sponsors to declare and promote their capacity to sponsor different types of research. Responses by **28th February 2014** are welcome from across England. For full details please see the [HRA website](#).

Other regulatory news:

News from the Health Research Authority

The HRA have announced a number of new initiatives in the last quarter:

REC-R&D Interactions Project

The HRA has published some of the outputs from their REC - R&D interactions project (part of the HRA Collaboration & Development Programme). Links to the outputs are grouped together at the bottom of section 3 of the "Improvements to the research process" page on the [HRA website](#).

HRA Assessment

The HRA aims to align the Research Ethics Committee approvals process with NHS R&D approvals. The HRA have presented a business case and options appraisal to the Department of Health. DH supports the options in principle.

Research Governance Framework

The HRA will take responsibility for and review the NHS Research Governance Framework later in the year. Ahead of this, the HRA have initiated some projects to help define issues with the current document. These projects will come together to form a revised framework, which will then be available for consultation. For more please see the [HRA website](#).

Patient involvement increases public confidence in health research studies

An Ipsos MORI survey of 1,295 British adults has shown that public confidence in health research studies can be increased by knowing that patients have advised on the design of the study. Full details of the study are available from the [HRA website](#).

New national booking service and electronic submission

The HRA's National Research Ethics Service is launching a new national (UK-wide) booking service in Spring (meaning all bookings for applications to RECs will be made through a single phone number). For phase I trials, researchers may continue to book directly with the REC or use the new system. Researchers are still encouraged to discuss application pre-booking with their local REC manager. When the service is launched, all REC applications will also be submitted electronically from IRAS.

Pilot of application management and coordination for complex applications

The HRA will recruit new staff to support researchers submitting applications that require review by a number of regulatory and review bodies. The staff will liaise between these bodies and help applicants negotiate the approvals process. The new service of application management and coordination will be regionally piloted from Spring-Summer 2014.

Further details on the HRA's plans and projects to improve the research process can be found on the [HRA website](#).

MHRA Guidance

The MHRA have updated the following pieces of guidance:

- [Guidance for the Notification of Serious Breaches of GCP or the Trial Protocol](#). This includes a recommendation that sponsors notify the chief / principal investigator of breaches (so corrective and preventative actions can be implemented).
- [A Guide to Defective Medicinal Products](#) (applies to licensed and unlicensed products)
- [Guidance on legislation: Clinical investigations of medical devices – guidance for investigators](#)
- [Guidance on legislation: Borderlines with medical devices](#)
- [Guidance on legislation: Requirements for UK notified bodies](#)
- [Guidance on legislation: Clinical investigations of medical devices – biological safety assessment](#)
- [Guidance on legislation: Clinical investigations of medical devices – guidance for pre-clinical assessors](#)

European Medicines Agency launches a new version of EudraCT

The European Medicines Agency has launched a new version of the European Clinical Trials Database (EudraCT V9). This version marks the initial step towards summary clinical trial results being made publicly available through the EU Clinical Trials Register (EU CTR). For further details please see the [EMA website](#).

European Commission – Update to Good Distribution Practice (GDP) Guidelines

The updated version of the Good Distribution Practice (GDP) guidelines corrects factual mistakes identified in subchapters 5.5 and 6.3 of the revised guidelines, and gives more explanations on the rationale for the revision as well as a date of coming into operation. The updated guidance is available to [download in PDF](#).

New and revised Draft Guidances CDER is planning to publish during 2014

The FDA has published details of the guidances CDER is planning to revise during calendar year 2014. These details are available to download from the [FDA website](#).

Ensuring smooth brain and spinal cord donation

In collaboration with the MRC UK Brain Bank Network, the Human Tissue Authority (HTA) has published guidance on brain and spinal cord donation. For more see the [HTA website](#).

Vigilance and Surveillance of Substances of Human Origin (SOHO V&S) guidance

SOHO V&S is an EU funded project which has developed guidance on reporting and investigating serious adverse events and reactions relating to donation and human application of tissues and cells. You can find this guidance on the [HTA website](#).

RCUK publishes annual narrative statement on research integrity

Research Councils UK has published its first annual narrative statement on research integrity. The statement is available from the [RCUK website](#).

Training and workshops:

HRA – Personal data in research

Date: 1 May 2014

Venue: Manchester HRA Office

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

HRA – Quantitative Research Methods and Statistics

Date: 8 May 2014

Venue: London - HRA Office

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

HRA – Assessing the consequences (benefits and harms) of research

Date: 14 May 2014

Venue: Manchester HRA Office

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

HRA – Research Training Day

Date: 17 June and 24 July 2014

Venue: Manchester and Newcastle Upon Tyne respectively

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

HRA – Qualitative research and Ethical review

Date: 25 June 2014

Venue: London - HRA Office

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

NHS R&D Annual Conference in association with the HRA

Date: 9-10 June 2014

Venue: Birmingham

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