

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:

Working with the Health Research Authority

Since our last update, the Regulatory Support Centre's secondment to the [Health Research Authority](#) (HRA) has been extended until the end of September 2014. We will continue to work in collaboration with the HRA to refine how best to provide advice and guidance to the research community. Our next project is with the HRA Confidentiality Advisory Group.

Regulatory Support Centre workshops

We are currently developing a Health Related Findings workshop which will introduce the [Medical Research Council / Wellcome Trust Health Related Findings Framework](#) and then apply the framework to real-life examples. The aim is to help researchers consider the issues involved when making decisions on the feedback of health-related findings. We currently have two dates booked (one in Edinburgh in September, and the other in London in November).

Date	Course	Location
16 Sept 2014	Health Related Findings Workshop	WTCRF, Edinburgh
6 Nov 2014	Health Related Findings Workshop	Wellcome Trust, London

To book a place on either of these workshops 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 - The EU Council has approved the draft Clinical Trials Regulation which means that the regulation is now adopted. It will enter into force 20 days following publication in the Official Journal of the European Union. 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 have developed a webpage where you can keep up-to-date with their progress against each of the recommendations. For more please see the [HTA website](#).

EU Data Protection Regulation – No further update, although a pan-European coalition of leading medical research organisations continue to voice their concerns around amendments to the regulation adopted by the European Parliament and lobby their respective governments. For more, please see the [MRC website](#).

Revision of the Medical Devices Directives - All legislation regulating medical devices is in the process of being revised at European level. This revision will replace the three existing European directives with two new European regulations. For further details please see the [MHRA website](#).

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

Consultations:

HRA seeks views on further advances in transparency

The HRA are consulting on ways to use the sponsor declaration in the NHS Research Ethics Committee application as a mechanism to check compliance with the requirement to register clinical trials (where applicable). If you would like to comment on these proposals, you will find full details on the [HRA website](#). Responses are requested by **30th June 2014**. [MRC is preparing a response, to contribute please contact corporate@headoffice.mrc.ac.uk.]

Other MRC news:

MRC / Wellcome Trust framework on feedback of health-related findings

The Medical Research Council and Wellcome Trust have launched a framework to help researchers make decisions on feedback of health-related findings. For full details please see the [MRC website](#).

Research funders outline steps to prevent re-identification of study participants

The MRC along with Cancer Research UK, Economic and Social Research Council, and the Wellcome Trust have issued a joint response to the Expert Advisory Group on Data Access (EAGDA) recommendations to reduce the risk of UK research subjects being re-identified from anonymised genomic, epidemiological and social science data. For more please see [MRC's website](#).

HRA news:

HRA single approval for research (HRA assessment and approval)

The HRA will provide a single approval for research in the NHS across all study types to incorporate assessments by NHS staff alongside NHS Research Ethics Committees. The process will be coordinated with other regulatory bodies to unify the approval process for research in the UK. The HRA plans full implementation of the single approval process by late 2015. It will also provide a UK platform for delivering the EU clinical trials regulations. For further details please see [HRA Latest](#).

NHS REC booking and submission changes, Spring 2014

The process for booking and submitting NHS research ethics applications is changing. These changes will affect both researchers and sponsors:

From April 28th 2014:

- Electronic authorisation will become mandatory for all ethics forms generated in IRAS for submission to RECs across the UK. Where the CTIMP Notice of Substantial Amendment form (EudraCT Annex 2 form) is generated outside IRAS the requirement for electronic authorisation is waived.

From May 19th 2014:

- All ethics applications will be booked in via a new Central Booking System (CBS). This will replace the existing Central Allocation System (CAS), Proportionate Review Allocation Systems (PRAS) and Local Allocation Systems (LAS). You can no longer book in via your local ethics (except for Phase 1 studies).
- All ethics applications have to be submitted electronically via IRAS i.e. IRAS will change to allow direct e-submission of all the ethics application paperwork (NHS REC forms, non-NHS Site Specific Information (SSI) forms and supporting documents). This will remove the need to submit hard copies.
- Electronic submissions must be submitted on the same day as a booking is made i.e. applications have to be ready to submit before phoning to book in your application.
- This includes all electronic authorisations being in place prior to submission. If anyone who authorises your research does not currently have an IRAS account; they will need to register for an account from the [IRAS website](#).
- Notice of substantial amendment forms will not be electronically submitted from IRAS. Submission of these forms will continue to be via email.
- For full details of these changes, please see the [HRA website](#).

New website for The Over-volunteering Prevention System (TOPS)

A new TOPS website will be launched at the end of May/early June 2014 following consultation with the Phase 1 research community. A summary of the changes and an updated user guide will be circulated once the launch date of the new site is confirmed.

HRA website – your feedback needed

The new HRA website has been live for almost six months, and the HRA would like to know what you think. If you would like to complete their survey, please visit the [HRA web survey](#).

Other news:

HSCIC - review of processes for the release of data

The Health and Social Care Information Centre (HSCIC) are currently reviewing processes for handling the release of data (e.g. Hospital Episode Statistics, data from the Office for National Statistics etc). It is anticipated that renewed policies, processes and governance will be implemented for new requests and renewals by July 2014. For further information on interim arrangements, please see the [HSCIC letter](#).

The NCRI Confederation of Cancer Biobanks (CCB) launch standards

NCRI CCB have launched two new standards (for quality management and data) to help biobanks and investigators in the UK. For more please see the [NCRI CCB website](#).

HTA regulatory alert - controlled rate freezers

The HTA has issued a regulatory alert (001/2014) for DIs in the human application and research sectors regarding controlled rate freezers manufactured by Planer plc. Further details are available from the [HTA website](#).

HTA's code of practice on Wales's soft opt-out system for organ donation

The HTA has produced a poster that explains the HTA's new Code of Practice on the Human Transplantation (Wales) Act. To download the poster please see the [HTA website](#).

HTA - Human application / tissue and cells for patient treatment sector

From March 2014 the HTA will only use the term 'human application' to refer to the human application / tissue and cells for patient treatment sector.

New chair of the HTA announced

Sharmila Nebhrajani has been appointed as the new Chair of the Human Tissue Authority. For further details please see the [HTA website](#).

MHRA – Critical definition updated and GCP inspection metrics for 2012-13

The MHRA GCP Inspectorate has updated their definition of critical to include requirements for Trial Master Files. For full details please see the [MHRA website](#).

A report covering GCP inspection metrics from 1 April 2012 to 31 March 2013 is now available from the [MHRA website](#).

Research Councils UK assurance on research integrity & ethics

As of 1 April 2014, Research Councils UK has updated the questions it uses in the RCUK Assurance Programme which aims to provide assurance on efforts made by organisations to strengthen research integrity. Further details are available from the [RCUK website](#).

New look Social Care Ethics Committee website

The new look website of the Social Care Research Ethics Committee is now live. For further details please visit the new [Social Care Research Ethics Committee website](#).

NIHR - Strategic review of public involvement

Over the next six months, NIHR will complete a strategic review of public involvement in health, social care and public health research entitled: 'Breaking Boundaries: thinking differently about public involvement in research.' For more see the [NIHR website](#).

NIHR – New model Clinical Investigation Agreements (mCIA and CRO mCIA)

NIHR has published updated model agreements designed for medical technology industry-funded trials. The key change in the 2014 versions is that sponsors should make clear when they intend to register these trials. The agreements are available from the [NIHR website](#).

New structure for NIHR clinical research network

The National Institute for Health Research (NIHR) Clinical Research Network, which supports clinical research studies in the NHS, has a new streamlined structure. Previously, the Network comprised 102 overlapping local networks, each supporting clinical research studies in different therapy areas or parts of the service. Since 1 April 2014, this has been rationalized into 15 local Clinical Research Networks across England, which will deliver studies across all therapy areas in the same geographical boundaries as the Academic Health Science Networks. Details of the newly restructured Networks are available from the [NIHR Clinical Research Network website](#).

Other workshops and training:

EFGCP - Workshop on quality risk management in clinical trials: Demonstrating how to implement Risk-Based Monitoring

Date: 16 & 17 June 2014

Venue: University College London

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

HRA – Researcher training day

Date: 17 June, 24 July and 6 November 2014

Venue: Manchester, Newcastle upon Tyne and Birmingham

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

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

Date: 19 June 2014

Venue: Glasgow

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

HRA – Medical Devices training day

Date: 9 October 2014

Venue: Manchester

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

HRA – Personal data in research

Date: 15 October 2014

Venue: London

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