The MRC Regulatory Support Centre www.mrc.ac.uk/regulatorysupportcentre **has compiled the following update:**

Please circulate this to any appropriate colleagues.

Regulatory Support Centre news:

Research Governance and Human Tissue Fora – save the date!

The Research Governance and Human Tissue fora will meet again on **16th May 2013** in Head Office, London. We plan a day of two halves with the morning session dedicated to the theme of working more closely with Universities and sharing experiences/learning from University Unit transfers; whilst the afternoon session is likely to focus on research data (sharing and protection). To register, please contact us on: info@rsc.mrc.ac.uk.

Regulatory Support Centre training courses

We are pleased to announce the following dates for training courses in 2013 and hope to confirm further dates in the coming months:

Date	Course	Location
19 Feb 2013	Good Clinical Practice for non-trialists	Epi, Cambridge
Mar 2013 (TBC)	Good Manufacturing Practice (GMP)	CTU, London
8 May 2012	Human Tissue blended learning	CSC, 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.

Launch of new HRA online tools

The Regulatory Support Centre is pleased to announce that the first outputs from our secondment with the HRA are about to launch: **Do I need NHS REC approval** and **Help with IRAS project filter question 2** are due for release in February/March. Watch this space for further details.

The changing regulatory landscape

Transfer of section 251 approvals from NIGB to the HRA is well underway. All functions advising on the use of confidential patient information without consent, under section 251 of the NHS Act 2006 will transfer from NIGB to the HRA on 31 March 2013. The HRA will convene a Confidentiality Advisory Group (CAG) to take on responsibilities which currently lie with the Ethics and Confidentiality Committee (ECC).

The Department of Health has published its response to the consultation on the HTA and HFEA. We can confirm that the decision is not to pursue a transfer of functions at this time but to retain both the HTA and HFEA with further efficiencies. To this end an independent review will investigate how both bodies carry out their functions and will seriously consider the feasibility of merging the HFEA and the HTA. The independent review will start immediately and report to ministers in April

The Department of Health has agreed to the HRA's proposal to test the potential benefits of a streamlined HRA assessment for all research in the NHS. The assessment would combine and replace aspects of the current review by NHS R&D and NHS RECs. For further details please see the HRA website.

The HRA reported its disappointment in not being able to deliver full electronic submissions for NHS RECs and the MHRA. However, they are developing a specification for the next generation of IRAS for delivery in early 2014. In the meantime, IRAS will be updated to version 3.5. For further information please see the HRA website.

The HRA is conducting a pilot to consider whether ethics officers can improve favourable opinion rates and reduce timelines/administrative burden on researchers and committees. Full details of the pilot are available from the HRA website.

The Ministry of Justice has published a response to the European Union Data Protection Regulation proposals. The full report is available from the Ministry of Justice website.

Government's annual update on Life Sciences Strategy is available from the BIS website.

We'll keep you informed of further developments on the RSC website.

Consultations:

Commons Select Committee Inquiry into Clinical Trials

Transparency and disclosure of clinical trial data is a topical issue and the Commons Select Committee are now seeking responses to an Inquiry into publication of clinical trials by **Friday 22 February 2013**. For full details please see Parliament UK website.

HEFCE launch consultation on the research integrity concordat

The Higher Education Funding Council for England (HEFCE) has invited comments on the Concordat to Support Research Integrity within higher education by **Friday 8 March 2013**. For full details of the consultation, please see the HEFCE website.

Other news:

News from the HTA

- The HTA has agreed licence fees for 2013/14 will reduce again for the third year running. For more details please see the HTA website.
- The HTA require notification of any changes to Designated Individual (DI) or Licence Holder (LH) at least 20 working days before the new DI/LH will be in place. To find out how to make these changes, please see the HTA website.
- The HTA has been invited to work with MRC UK Brain Bank Network Management Group to develop guidance for those involved in brain retrieval for research
- The HTA and the Sudden and Neonatal Death Society (SANDs) have released guidance, available on the HTA website.

MHRA – Release guidance

- The MHRA has released guidance on how to report serious breaches of GCP or the trial protocol. For further information, please see the MHRA website.
- Guidance Note 8: A guide to what is a medicinal product has been revised. For further details please see the MHRA website.

NIHR launches the revised Clinical Trials Toolkit for researchers

NIHR has launched the revised Clinical Trials (CT) Toolkit to help researchers navigate through the complex landscape of setting up and managing clinical trials. You can access the CT Toolkit from the Tool Kits logo on the MRC Regulatory Support Centre's website.

ABPI - Guidelines for Clinical Trials 2012

ABPI have produced the 2012 edition of 'Guidelines for Phase 1 Clinical Trials'. Although nominally restricted to Phase 1 trials, there is lots of valuable information relating to all phases for people new to clinical research. For full details, please see the ABPI website.

EMA – Major developments in Pharmacovigilance

New pharmacovigilance legislation will enable the European Medicines Agency (EMA) to charge fees for its new pharmacovigilance activities. A public consultation on this legislation took place from June-Sept 2012. For details of the comments received, please see the European Commission website.

Update Good Clinical Laboratory Practice (GCLP)

The Research Quality Association (RQA, previously BARQA) have updated their GCLP guidance. To download for free, please see the RQA website.

Open Research and Contributor ID (ORCiD) global registry launches

The ORCiD global registry launched at the end of October 2012. For further details, please see the ORCiD website.

NRES - New arrangements for the Gene Therapy Advisory Committee

From 30 November 2012 the Gene Therapy Advisory Committee (GTAC) will no longer operate. For more on these changes, please see the NRES website.

Public attitudes to Organ Donation (Wales) Bill – Soft opt-out

Almost 3,000 responses were received to the Welsh Government's consultation to introduce a soft opt-out for consent for deceased organ and tissue donation (49% in favour). The full report is available from the Welsh Government's website.

RCUK announces block grants for universities to aid drives to open access to research outputs

Research Councils UK is providing block grant funding to aid implementation of its policy on Open Access. The block grants, which will be provided by the Research Councils from April, are to fund article processing charges (APCs). Further information can be found on the RCUK website.

HRA - Year 1 Stakeholder Forum

Date: 6 and 7 February 2013
Venue: London
Further details from the HRA website

HRA Personal Data in Research

Date: 14 March 2013
Venue: Manchester
Further details from the HRA website

MHRA Pharmacovigilance Symposium 2013

Date: 26 March 2013
Venue: London
Further details from the MHRA website

World Conference on Research Integrity

Date: 5-8 May 2013
Venue: Montreal
Further details from the UKRIO website