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:

Human Tissue Forum – Tuesday 12 Nov 2013 - save the date

The next fora event will focus on developments with respect to human tissue. We have invited speakers to discuss the NCRI biobanking standards, Wellcome Trust and MRC work on health related findings and the MRC's plans for future investment in tissue initiatives as well as progress on the MRC Human Tissues and Biological Samples guidance. If you would like to attend, then please email us at info@rsc.mrc.ac.uk.

Regulatory Support Centre training courses

We are pleased to announce the following dates for training courses in 2013:

Date	Course	Location
5 Sept 2013	Submitting a successful ethics application	CBU, Cambridge
15 Oct 2013	GCP for non-trialists	HNR, Cambridge
16 Oct 2013	Adverse Event reporting	HNR, Cambridge
6 Nov 2013	Human Tissue blended learning	MBU, Cambridge

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.

MRC RSC Highlights 2012-13

We are pleased to announce the launch of MRC RSC Highlights 2012-13 on the web. "Highlights" showcases the work of the Regulatory Support Centre over the last year and our plans for the year to come - we hope you'll enjoy our publication.

The changing regulatory landscape

The Public Health Committee endorsed a draft of the new Clinical Trials Regulation at the end of May. The regulation is designed to encourage research whilst protecting patients' rights and will replace the existing Directive. New text makes specific provision for low-risk trials, clarifies the duties of ethics committees and details how to obtain informed consent from patients. For more please see the European Parliament's website.

The HRA has published an article detailing how it is streamlining health research (MRC RSC are currently working with the HRA on Participant Information Sheet guidance). HRA have also outlined plans for their role in promoting transparent research.

The Department of Health has announced that both the HTA and HFEA will be retained as independent regulators. However, legislative changes may still be coming. Full details are available from the DH website.

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

Consultations and Surveys:

NCRI Consultation on Biobanking Standards

The National Cancer Research Institute's Confederation of Cancer Biobanks (CCB) is seeking comments on draft biobanking standards designed to improve the quality of

samples and data for research. The MRC are planning a response, if you would like to contribute, please forward any comments to info@rsc.mrc.ac.uk by **30 August 2013**.

EMA Consultation on the publication and access to clinical trial data

The European Medicines Agency has released a draft policy on the publication of and access to clinical trial data. The closing date for comments is **30 September 2013**; consultation available from the EMA website.

World's health researchers join together to build data sharing future

More than 60 leading health care, research and disease advocacy organisations from across the world are joining together to form an international alliance dedicated to enabling secure sharing of genomic and clinical data. For more see the Sanger website.

Wellcome Trust Survey on data access and sharing

The Expert Advisory Group on Data Access (EAGDA) has been set up by Cancer Research UK, Economic and Social Research Council, Medical Research Council and the Wellcome Trust to explore issues in data access. EAGDA are currently seeking views of research data users on how they discover, access and use existing research datasets through the following link: http://survey.euro.confirmit.com/wix5/p1468821575.aspx.

HEFCE Consultation on open access

The four UK higher education funding bodies aim to promote open-access by introducing it as a requirement in the next Research Excellence Framework. HEFCE has invited comments on this proposed policy by **30 October 2013** from the HEFCE website.

ICO Consultation on privacy impact assessments code of practice

The Information Commissioners Office invites comments on its new draft code of practice. It aims to produce a practical guide, which will help organisations conduct assessments of new projects that involve the use of personal information. Deadline for comments is **5 November 2013**, consultation available from the ICO website.

Other Regulatory news:

WMA Declaration of Helsinki

The Declaration of Helsinki has been redrafted and is out for public consultation. For details of the proposed changes please see the WMA website.

WHO - Ethical issues in Patient Safety Research

The World Health Organisation has produced guidance for patient safety researchers and research ethics committees to help interpret existing research ethics guidance. More details are available from the WHO website.

HTA: Submitting a change to a licence; and Compliance updates for those licensed under the Human Tissue Act 2004

- The HTA reminds DIs and Licence Holders that they should be informed of any changes to licences as soon as possible. For more please see the HTA website.
- All licensed establishments, including those in the research sector, will shortly be asked to complete a compliance questionnaire. Directions will be emailed to DIs and Licence Holders in September (starting with the post mortem sector).
- For more details on either of the above, please see the HTA's June Newsletter.

HFEA – Draft regulation on use of mitochondria replacement techniques

The government has announced its decision to proceed with draft regulations to enable the use of mitochondria replacement techniques for patient treatment. The decision follows the HFEA's public consultation and expert scientific review into the efficacy and safety of these techniques. Further details are available from HFEA's website.

Human Transplantation (Wales) Bill – Soft opt-out

The Welsh Government has passed a Bill introducing a soft opt-out for consent for deceased organ and tissue donation. Wales will now become the first UK nation to introduce such a system. The law is due to come into effect in 2015. For more please see the Welsh Government website.

EMA - Draft guidelines on good pharmacovigilance practices

The European Medicines Agency has released guidelines to prevent or reduce the occurrence of adverse reactions as well as manage and report those that do:

- Module XVI– Risk minimisation measures: selection of tools and effectiveness.
- Module VI – Management and reporting of adverse reactions to medicinal products.

MHRA guidance on legislation – Borderlines with medical devices

The MHRA has developed guidance to help determine whether or not a product would be considered a medical device within the terms of the Medical Devices Directive 93/42/EEC. For more please see the MHRA website.

MHRA - New requirements for active substances imported into the European Economic Area

From 2 July 2013 active substances (ASs) imported into the European Economic Area (EEA) for use in the manufacture of medicinal products can only be imported upon written confirmations, from competent authorities in non-EEA countries, that standards of manufacture are equivalent to EU Good Manufacturing Practice. For more please see the MHRA website.

NRES – No Material Ethical Issues Tool has been updated

The No Material Ethical Issues Tool, designed to help researchers determine whether they can apply for proportionate review, has been updated. Please see the NRES website for more.

Science and Technology Committee – Regenerative Medicine Report

The report investigates translation and commercialisation of regenerative research and discusses current barriers highlighting regulation "as a source of great frustration." http://www.publications.parliament.uk/pa/ld201314/ldselect/ldsctech/23/2302.htm.

HEFCE to require compliance with research integrity Concordat

The Higher Education Funding Council for England (HEFCE) will make compliance with the Concordat to Support Research Integrity a condition of its grants to higher education institutions from the 2013-14 academic year onwards. See the HEFCE website for more.

RCUK publishes assurance questions on research integrity

A set of 6 assurance questions have been developed and agreed across funders signed up to Research Council UK's Concordat to support research integrity. These questions will be rolled out from summer 2013 to all Higher Education Institutions as part of the overall RCUK assurance programme. For more please see the RCUK website.

Evolving the NIHR Clinical Research Network

- From April 2014 the NIHR Clinical Research Network will comprise 15 NIHR Local Clinical Research Networks; boundaries will be based on the Academic Health Science Networks.
- Each NIHR Local Clinical Research Network will provide support for **all** therapy areas or clinical "themes" and will cover both commercial and non-commercial research.
- There will be a single host organisation for each NIHR Local Clinical Research Network. More details can be found on the NIHR website.
- Scottish government have also launched a consultation seeking views on its vision to adopt the new NIHR themes in Scotland. For more please see the CSO website.

NIHR Journals Library

The NIHR Journals Library officially launched in June; providing full publication and open access to an extensive body of health research: http://www.journalslibrary.nihr.ac.uk.

Other courses:

HRA Personal Data in Research – a workshop (Scottish law)

Date: 22 Oct 2013
Venue: NHS Lothian, Edinburgh
Further details from the HRA website

HRA Qualitative Research and Ethical Review

Date: 31 Oct 2013
Venue: Manchester
Further details from the HRA website

HRA Researcher training days

Date: 12 Nov 2013 and 5 Feb 2014
Venue: Manchester and London
Further details from the HRA website

Quantitative Research Methods and Statistics: An HRA Workshop

Date: 10 Dec 2013
Venue: Manchester
Further details from the HRA website