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:

New decision tools for researchers

The Regulatory Support Centre is pleased to announce that the first outputs from our secondment with the HRA have been launched: the web-based tools answer the questions **Is it research** and **Do I need NHS REC approval** and are available from **RSC News** on the RSC website.

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
5 June 2013	Human Tissue blended learning	CTU, London
16 Oct 2013	Adverse Event reporting	HNR, 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

Section 251 approvals transferred from NIGB's Ethics and Confidentiality Committee (ECC) to the HRA Confidentiality Advisory Group (CAG) on 1st April 2013. Details of CAG can be found on the HRA website (the NIGB website will no longer be updated).

Other changes include the Government's NHS reforms coming into force with GP-led consortia now in charge of local health budgets and a new board, NHS England, to oversee the day-to-day running of services; the National Institute for Health and Clinical Excellence (NICE) being renamed the National Institute for Health and Care Excellence with an expanded remit to include the social care sector; National Institute for Biological Standards and Control (NIBSC) joining the MHRA and closure of NHS Connecting for Health (now part of the Health and Social Care Information Centre, previously NHS IC).

The MRC has signed a joint statement in response to the **Data Protection Regulation**. The joint statement highlights concerns that some amendments tabled by the rapporteur of the European Parliament's Committee on Civil Liberties, Justice and Home Affairs (LIBE) will prevent or severely impair scientific research studies using personal data.

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

Information Governance Review - recommendations

A review, led by Dame Fiona Caldicott, has recommended that dedicated centres should handle confidential patient information for the purposes of research. If created, these 'safe havens' would be able to receive data that have been de-identified for limited use. For full report please see the DH website.

Publication of the revised NHS Constitution

An updated NHS Constitution has been published. Of particular interest are pledges to inform people of research studies they may be able to take part in, and recognition of the value of collecting anonymised data to support research that improves healthcare. For more details please see the HRA website.

NHS Honorary Research Contracts

Any rights and liabilities held by PCTs prior to 1 April that have **not** been transferred to another holding body will transfer to the NHS Commissioning Board on that date. This gives some assurance to existing Honorary Research Contract holders that they can continue to carry on research under them. For more please see the NIHR website.

Transparency in clinical trials and their results

Dr Catherine Elliot, MRC Director of Clinical Research Interests, gave evidence at a House of Commons inquiry in April. The discussion addressed the regulatory framework for undertaking clinical trials in the UK, the visibility of clinical trials and their results, and issues around increasing access to findings and data from trials. The MRC supports increasing transparency in clinical trials (and has also signed the AllTrials petition).

Declaration of Helsinki Revision

A draft revision of the Declaration of Helsinki on medical research involving human subjects was approved for stakeholder consultation by the World Medical Association. For more please see the WMA website.

Research Councils UK updates its research integrity requirements

Research Councils UK has published the RCUK Policy and Guidelines on Governance of Good Research Conduct, replacing its existing guidance on research integrity.

Drug-data deceit

The MHRA has announced that a UK researcher has been found guilty of manipulating safety data in experiments that supported clinical trials. He will be sentenced in April for violating Good Laboratory Practice regulations. Full details are available in Nature.

MHRA: Serious breaches reporting and 'Innovation Office'

- The MHRA have issued updated guidance on reporting serious breaches of GCP or the trial protocol. For more please see the MHRA website.
- The 'Innovation Office' for novel medical products and devices will help organisations developing innovative medicines, medical devices or using novel manufacturing processes to navigate the regulatory processes to progress their products/technologies. For more please see the MHRA website.

IRAS updated to v3.5

For full details of what has been updated please see the HRA website.

HRA takes on responsibility for TOPS

The Over-volunteering Prevention System (TOPS) database transferred to the HRA on 1st April 2013. All Phase 1 studies are now required to register research participants onto TOPS as a part of ethical and MHRA approvals. For more see the TOPS website.

Tissue-specific news:

HTA: Joint seminars on consent and Adding removal of tissue from the deceased to research licences

- The HTA has held two joint seminars discussing issues of consent with respect to post-mortem examination and cord blood collection. Reports from the meetings will be made available on the HTA website, and will inform future advice and guidance.
- From 1 April 2013, any establishment applying for, or holding a research licence, can apply for a licence to additionally cover the removal of tissue from the deceased.
- For more details on either of the above, please see the HTA's April Newsletter.

Accreditation scheme for biobanks

The development of an accreditation scheme for biobanks is well underway. The scheme has been designed to apply to all biobanks, regardless of their focus. For more please see the CCB Newsletter.

Patients leading the way on consent: NHSB's groundbreaking initiative

Nottingham Health Science Biobank (NHSB) has taken a radically different approach to seeking/obtaining consent and now has 6 patient volunteers taking consent during clinics at the Breast Institute. For more please see the CCB Newsletter.

UK Brain Banks Network database

A new online database has been launched by the MRC which will give researchers access to samples from more than 7,000 donated human brains. The UK Brain Banks Network database will speed up access to donated brain samples held across 10 brain banks in the UK. For further details please see the MRC website.

Other courses:

EFGCP Workshop: A Practical Approach to Risk-Based Monitoring

Date: 24 June 2013
Venue: University College London
Further details from the EFGCP website

HRA Qualitative research and ethical review

Date: 8 July 2013
Venue: HRA Office, London
Further details from the HRA website

HRA Medical devices training day

Date: 19 September 2013
Venue: HRA Office, Manchester
Further details from the HRA website

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

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

HRA Researcher training days

Date: Various (June, October, November)
Venue: Various (Leeds, London, Manchester)
Further details from the HRA website