

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

The Research Governance forum will meet again on Tuesday the 10th November 2015 in **MRC Head Office, London**. The Agenda will include sessions on University Unit Transfer, the new HRA approval and research data / records management. To register your interest, please contact us on: info@rsc.mrc.ac.uk.

NEW Translational Project Managers Forum

The new Translational Project Managers forum will meet for the first time on Friday the 6th November 2015 in **MRC Head Office, London**. This event is now full, however to add your name to our waiting list, please contact us on: info@rsc.mrc.ac.uk.

Regulatory Support Centre training courses

We are pleased to announce the following training courses. To book a place or to discuss the potential of holding training within your Unit or University, please contact us on info@rsc.mrc.ac.uk.

Date	Course	Location
6 Oct 2015	Research Data and Confidentiality Blended learning	WTCRF, Edinburgh
22 Oct 2015	Research Data and Confidentiality Blended learning	Addenbrookes, Cambridge
3 Dec 2015	Human Tissue workshop (Scotland)	WTCRF, Edinburgh

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.

The changing regulatory landscape

EU Clinical Trials Regulation – Nothing new to report. Efforts are now focussed on preparing for implementation.

EU Data Protection Regulation – The Regulation continues its progress through the European Parliament. The next meeting is the Justice and Home Affairs Council meeting in October. Further details can be found at: <http://www.datasaveslives.eu/>

Psychoactive Substances Bill - The MRC is working with the Department of Health and the Home Office to ensure that this new bill does not unintentionally impede medical research. The MRC Regulatory Support Centre has provided regulatory expertise to underpin these discussions.

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

Consultations

RCUK Draft Concordat on Open Research Data

The Research Councils UK is seeking views and comments on the concordat. For further details please see the [RCUK website](#). Responses are invited by **28 September 2015**.

The HTA's Codes of Practice and Standards consultation

The Human Tissue Authority are consulting on changes to its Codes of Practice and Standards. For further details please see the [HTA website](#). Responses are invited by **30 October 2015**.

Public consultations on Good Manufacturing Practice for Investigational Medicinal Products for human use and inspection procedures

The European Commission currently have two consultations on Good Manufacturing Practice. Further details are available on the [EC website](#). Responses are invited by **24 November 2015**.

Other News

UKCRC Tissue Directory and Coordination Centre – Informatics and Directory Survey

The Centre is currently conducting a survey on their Informatics work and forthcoming tissue directory to ensure their work is relevant to stakeholder needs. If you are biobank, researcher, funder, regulatory or governance body or member of the public, they would like to know your thoughts and opinions. For full details please see the [UKCRC Informatics Survey](#).

HRA News

Implementation of HRA approval

From 10 August the new HRA approval system was rolled out to include studies taking place in primary care settings (e.g. NHS GP practices, dental practices and community pharmacies). In addition a new form was rolled out in IRAS to allow applications for HRA approval to be submitted electronically to the HRA. The new single IRAS form replaces both the R&D and REC Forms only for studies which are currently eligible for HRA Approval. For more please see the [HRA Approval webpage](#).

Research Ethics Committee Application Review and Advice service

The HRA has been developing and testing an extended Research Ethics Committee (REC) Application Review and Advice service. This new service aligns with HRA Approval as HRA staff help applicants during the ethical review process. The HRA aim to provide this service to all studies submitted to England RECs by the end of the year. For more information please contact the HRA Improvement and Liaison Manager [Catherine Blewett](#).

HRA to develop EU guidance for lay summaries of clinical trial results

The HRA has volunteered to lead on the development of EU guidelines for summaries of clinical trials results for lay persons. The summaries will sit on the future EU portal as part of the new Clinical Trials Regulations. A first draft of the guidance is expected in November.

News from the Human Tissue Authority

- **HTA: triennial review** - The government has completed a triennial review of the Human Tissue Authority. The MRC was involved in the review and the MRC Regulatory Support Centre fed into the MRC's response.
- **HTA: Compliance updates** - All licensed establishments will be asked to complete a compliance update. Establishments will need to submit their compliance updates via the HTA portal between November and December.
- **Revised information for research tissue banks** - The HTA have updated their policy on research tissue banks. This can be accessed from the [HTA website](#).
- **EU Import and Coding Directives** - The Directives for Import and Coding of tissues and cells for human application were published earlier this year, and are due to come into force throughout the EU by 30 April 2017. The HTA is helping the Department of Health to transpose these directives into UK law. For further details please see the [HTA website](#).
- **Revision to the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment** - The HTA have recently updated this Guide, which was revised primarily to bring the wording for HTLV testing requirements as well as other minor amendments detailed on page 2. To access the guide please see the [HTA website](#).
- **HTA and MHRA policy on the regulation of blood as a starting material for ATMP manufacture** - The HTA and MHRA have agreed to extend their existing policy relating to dendritic cells. This extended policy will allow collection of blood as a starting material for an ATMP to be performed under either a Tissues and Cells or Blood Establishment Licence. This policy has been adopted as an interim position and may be subject to revision pending legal opinion from the European Commission. For full details please see the [HTA website](#).

- **Supporting brain and spinal cord donation** – The HTA has Frequently Asked Questions on brain and spinal cord donation for staff working in hospitals and mortuaries. Full details are available from the [HTA website](#).
- **'Your Guide to Consent and Organ Donation' published** – The HTA developed this guide in collaboration with NHS Blood and Transplant. For more please see the [HTA website](#).

Research integrity and ethics

A feature article in *Times Higher Education* examines the difficulty in reproducing scientific research results and what is being done to address the issue. The article cites a recent study of 100 psychology research papers which was unable to reproduce more than half of the papers' results. For full article please see the [Times Higher Education website](#).

HSCIC launch Information and technology for better care: Strategy for 2015-2020

For full details please see the [HSCIC website](#).

Other training and conferences:

UKRIO 'Research integrity: training and development'

Date: 16 September 2015

Venue: London

Fee: £150

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

The Role of the UKCRC Tissue Directory and Coordination Centre

Date: 29 September 2015

Venue: Olympia Conference Centre, London

Fee: €85 to register for this event only

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

HRA: The Ethical Issues of Research Involving Children

Date: 19 October 2015

Venue: London

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

HRA: Research Training Day

Date: 12 November 2015

Venue: Oxford

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

HRA: Personal Data in Research – A Workshop

Date: 19 November 2015

Venue: London

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

e-learning: An Introduction to Good Clinical Laboratory Practice

Date: e-learning

Venue: e-learning

Fee: £119

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