

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

Friday 1st November is the last day to register for this event. If you haven't already done so and are interested in feeding into development of MRC policy – **Human Tissue and Biological Samples for use in research** and hearing from our speakers Professor Andy Hall and Dr Catherine Elliott then please get in touch ASAP 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
6 Nov 2013	Human Tissue blended learning	MBU, Cambridge
6 Nov 2013	GCP for non-trialists	Toxicology, Leicester

To book a place on any of these courses or to discuss the potential of holding training within your Unit or University in 2014, please contact us at info@rsc.mrc.ac.uk.

The changing regulatory landscape

In response to the [McCracken review](#) the HTA are progressing two of Justin McCracken's recommendations. To learn more please visit the following links:

- [Transfer of the regulation of cell based Advanced Therapy Medicinal Products \(ATMPs\)](#);
- [Joint working with the Clinical Pathology Accreditation UK \(CPA\)](#).

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

Consultations and Surveys:

HRA consultation on online Participant Information Sheet guidance

The Regulatory Support Centre has been working with the HRA to produce online guidance on consent and preparing consent documentation. A draft version is now available as consultation-in-use. We would very grateful if you could take the time to visit <http://www.hra-decisiontools.org.uk/consent/> and provide us with some feedback on this guidance.

ONS Consultation on Statistical Products 2013

The Office for National Statistics (ONS) has been consulting on reductions to its statistical outputs. Over the next two years they plan to make savings from streamlining business operations but are also considering cuts to statistical outputs such as:

- General Lifestyle Survey;
- Integrated Household Survey;
- Health statistics and analyses, life events;
- Health inequalities analysis etc.

For further details about this consultation, please see the [ONS website](#).

HTA consultation on the Code of Practice – Wales

The HTA is consulting on the Code of Practice that will provide advice and guidance on the Human Transplantation (Wales) Act. This Act will introduce deemed consent to organ and tissue donation after death in Wales from 1 December 2015. For further details on the scope of the consultation please see the [HTA website](#). Consultation responses are requested by **Monday 23rd December 2013**.

Other Regulatory news:

HRA Trial registration

From 30 September, all clinical trials are to be entered on a publicly accessible register as a condition of favourable approval from NHS Research Ethics Committees. Guidance on this has now been added to the HRA website which answers a number of questions which have emerged, such as:

- Which registers are acceptable?
- How should I register Phase 1 trials?
- Is it required retrospectively?
- Are there any exemptions?

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

HRA CAG new guidance on managing non-response to requests to share confidential patient data

The Confidentiality Advisory Group (CAG), in collaboration with the Information Commissioner's Office, have produced guidance in relation to the issue of processing confidential patient data from individuals who do not respond to invitations to participate in research. The "Managing non-response guidance" is available from the [HRA website](#).

Patient involvement in research boosts study success

Involving patients in the design and implementation of research programmes increases the likelihood of studies recruiting to target, according to a new study by King's College London. Delays in recruitment are a major reason why some studies fail, so better recruitment means studies are more likely to be successful and run on time and budget. The authors argue that researchers need to involve patients more comprehensively in research. For further details please see the [NIHR website](#).

Caldicott Guardian Application to use Multiple Boards or Scotland-Wide Personal Health Information for Health Research or Audit

Following a pilot of a single application process for multiple board Caldicott Guardian approval (for use of personal health information for health research or audit purposes) in Scotland, this process has now been accepted as business as usual activity. The "NHS Scotland Caldicott Guardian Application to use Personal Health Information" is available to download from the [Caldicott Guardian website](#).

WMA Publishes its Revised Declaration of Helsinki

The Seventh Revision of the Declaration of Helsinki has been released and provides increased protection for vulnerable groups involved in research, as well as a new provision for compensating people harmed as a result of participating in research. In addition there are expanded requirements for post-study arrangements to ensure that participants involved in research are informed of the results and have access to any beneficial treatments that emerge. For full details please see the [WMA website](#).

Science and Technology Committee demands action on clinical trial transparency

The Science and Technology Committee has described the current lack of transparency of many clinical trials as “unacceptable”, adding that it has not been impressed with Government efforts to tackle the problem to date. For details of the full report please see the [www.parliament.uk website](http://www.parliament.uk).

EMA Developing policy on publication and access to clinical trial data

In June 2013, EMA released the draft policy on publication and access to clinical-trial data. for a three-month public consultation: [Policy 70: Publication and access to clinical-trial data](#). EMA is now considering all of the comments submitted and expects this policy to come into force on 1 January 2014. It is also preparing an implementation plan.

HRA updated guidance on the template statement of insurance cover for Phase 1 studies involving healthy volunteers

There is no longer a requirement for sponsors to submit the Statement of Insurance Cover template with their application. Information required on insurance arrangements was incorporated into the REC application form as part of the most recent IRAS update (IRAS v3.5, March 2013).

HRA update on TOPS

The Over-Volunteering Prevention System (TOPS) transferred to the HRA in April 2013. The TOPS database aims to prevent healthy volunteers from taking part in clinical trials too frequently. For further information please visit the TOPS website www.tops.org.uk. If you have any feedback or queries about TOPS, please send these to Charlotte Allen, Operations Business Manager (charlotte.allen2@nhs.net).

Other courses:

CCB Ensuring Success in Sample Collection for Clinical Trials - Workshop

Date: 6 Nov 2013

Venue: Liverpool

Further details from the [NCRI 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](#)

Good Clinical Practice Symposium 2014

Date: 11 Feb 2014

Venue: Manchester

Further details from the [MHRA website](#)