

A blurred photograph of several people walking in a modern, brightly lit hallway with large glass panels. The motion blur suggests a busy, active environment.

MRC

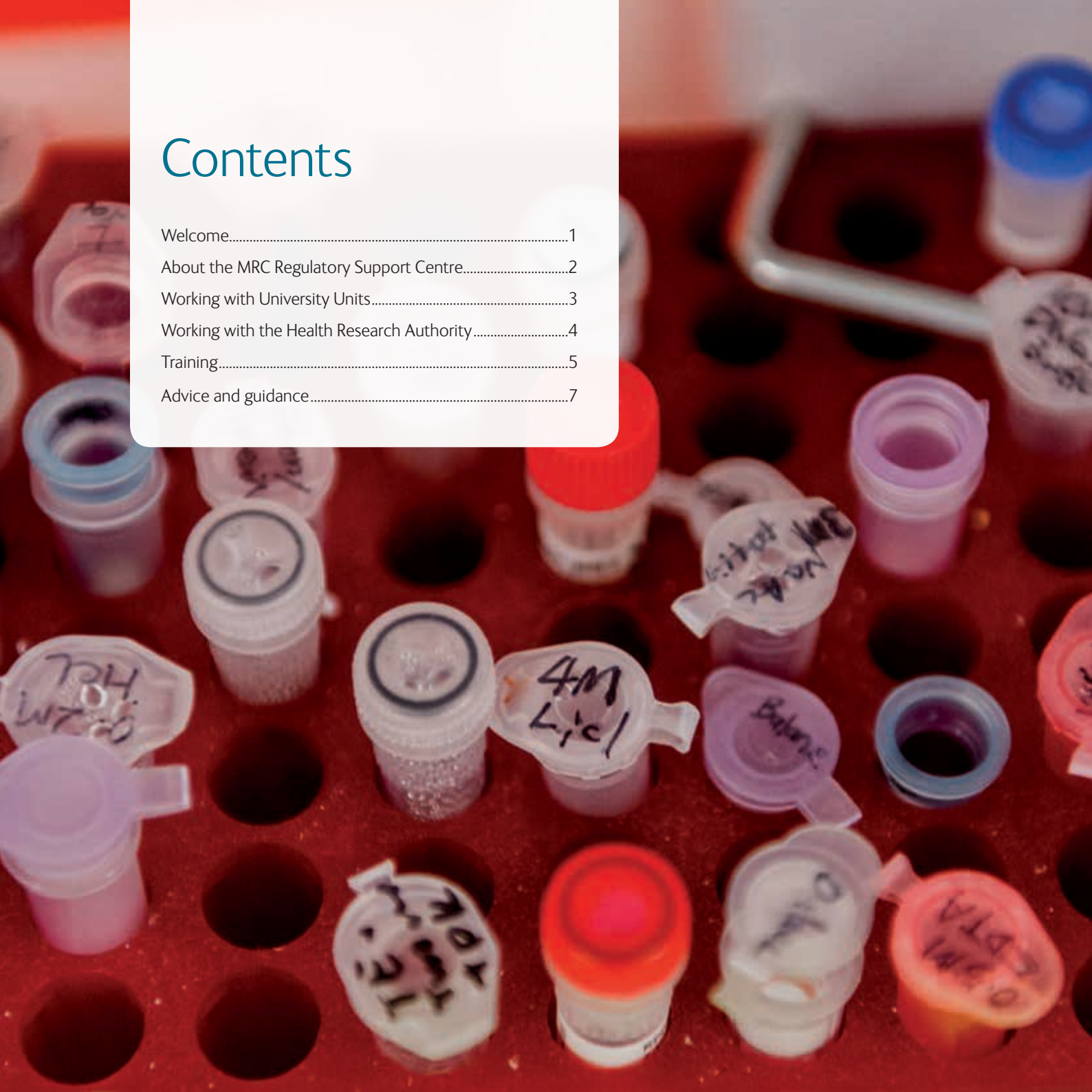
Medical  
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CENTENARY 1913-2013

# MRC Regulatory Support Centre Highlights 2012–13

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# Welcome

Whilst the regulation and governance of health research in the UK evolves (e.g. new EU Regulations on Clinical Trials of Investigational Medicinal Products and Data Protection, and the developing role of the Health Research Authority); the MRC Regulatory Support Centre continues to provide support and guidance for those conducting research with human participants, their tissues or data.

We have done this by developing online tools such as our e-learning and through the continued provision of advice and training all of which can be accessed from our one-stop shop [www.mrc.ac.uk/regulatorysupportcentre](http://www.mrc.ac.uk/regulatorysupportcentre). The MRC Regulatory Support Centre offers support to the “MRC family”: MRC grant holders; MRC Units; University Units and their new University partners.

This publication provides details of our activities in 2012–13 and outlines our plans for the year ahead.

# About the MRC Regulatory Support Centre

The Regulatory Support Centre provides support and guidance for those who are involved in research with human participants, their tissues or data. Established in 2006, we support the UK research community in meeting regulatory and governance requirements through the provision of on-line tools, advice and training. From our website [www.mrc.ac.uk/regulatorysupportcentre](http://www.mrc.ac.uk/regulatorysupportcentre) you can access all of our services including our two e-learning modules: Research and Human Tissue legislation and Research Data and Confidentiality.



# Working with University Units

## Sharing experiences and learning from University Unit transfer

The Research Governance and Human Tissue fora support those with specific governance responsibilities, by providing an opportunity to share best practice. Initially fora events were designed to support MRC staff and grant holders. Over the last year, as more MRC Units have transferred to University Units, the audience has widened to include our new University partners. We also ensure that the Fora are kept informed of other changes occurring outside of the MRC, for example the creation and development of the Health Research Authority (HRA).

## Supporting the University Unit transfer process

Over the past year the Regulatory Support Centre has assisted units transferring to their local university to help manage the research governance impact. We have devised a risk assessment tool to help units identify potential issues early. We have worked with units, Head Office and regulatory authorities to devise mechanisms to manage: the impact of transferring sponsorship to universities, the data protection implications of moving personal data to university systems and handling the regulatory approvals required for such changes.

### Looking forward

Within the next year the Regulatory Support Centre will ensure that experiences and learning from University Unit transfers are shared and inform future transfers; working with Head Office and the next wave of transferring units to ensure that lessons are learnt and that research governance risks are managed proportionately.

We will also provide networking opportunities for the MRC and our University partners, and ensure that the Fora are kept up-to-date with regulatory changes and developing MRC policy.

“Good opportunity to hear from different Units.”

“Thanks... it was really useful.”

# Working with the Health Research Authority

Staff from the Regulatory Support Centre have been seconded into the new Health Research Authority for a few days per week. We are helping the HRA build a consolidated advice service as well as developing these web-based tools:

- Do I need NHS REC approval?
- Is my study research?
- What type of study am I doing?  
(guidance on how to complete question 2 of the IRAS project filter)

The first of these tools have now been launched and are available from Policy and Guidance on [www.mrc.ac.uk/regulatorysupportcentre](http://www.mrc.ac.uk/regulatorysupportcentre). They have been built in consultation with the research community, ensuring that they offer brief but authoritative, practical advice.



“Excellent – I think this will be a really useful tool.”

“Well thought out, easy to use.”

We have also supported the HRA by providing training in data protection and confidentiality.

## Looking forward

Over the coming year we will continue to work with the HRA to develop web-based guidance on how to write a good Participant Information Sheet and help them implement a consolidated advice service, particularly important in light of the HRA's increasing regulatory function.

# Training



Tissue legislation e-learning module during a two hour face-to-face session. Initial feedback from the pilot has been very positive and we look forward to rolling the course out more widely in 2013–14.

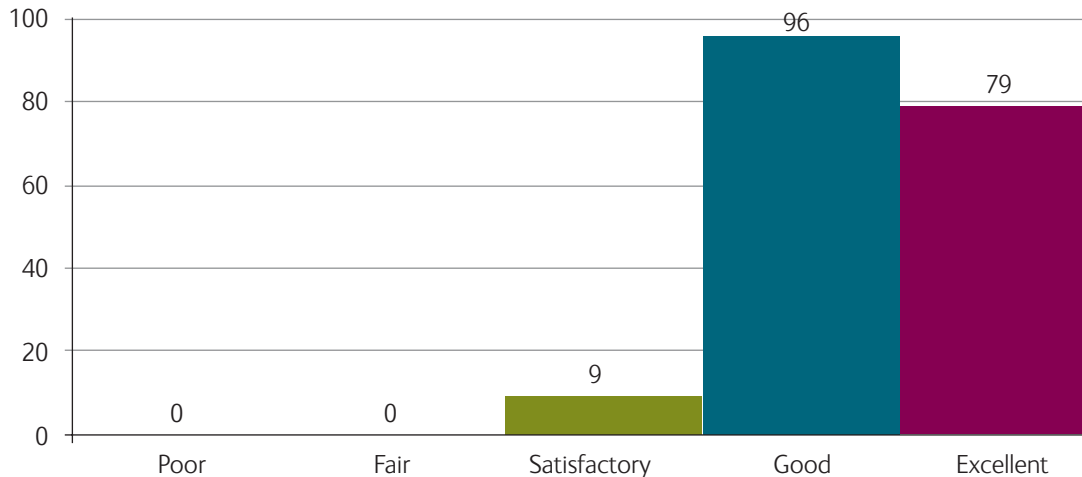
## Courses provided

For a full breakdown of the face-to-face training delivered in 2012–13, please see the table below.

Course	Attended	Number of courses run
GCP for non-clinical trialists	97	6
GCP for clinical trialists	23	1
Human Tissue Act blended learning	12	1
Research Data and Confidentiality (face-to-face)	32	3
Submitting a successful ethics application	17	2
The Integrated Research Application System (IRAS)	22	1

## Face-to-face training – How did we do?

Responses to evaluation question: 'How would you rate the course quality overall?'



## Tailored Good Clinical Practice training

Our tailored Good Clinical Practice courses have proved popular in 2012–13. These face-to-face courses take the principles of GCP and apply them to specific studies conducted within the unit. Our tailored GCP courses are ideal for those about to initiate a study; providing the opportunity to objectively consider potential risks and inform study management. For more, please see [www.mrc.ac.uk/regulatorysupportcentre](http://www.mrc.ac.uk/regulatorysupportcentre).

### Looking forward

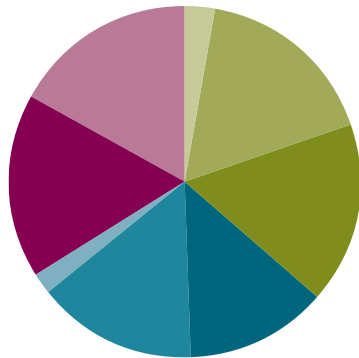
- We aim to provide a Research Data and Confidentiality blended learning course which will follow a similar format to our human tissue blended learning;
- We will continue to offer tailored Good Clinical Practice courses and provide these when we can; and
- We hope to commission specific regulatory training in 2013–14 through income generated by the Regulatory Support Centre.



# Advice and guidance

## Your questions answered

In 2012–13 we answered 136 advice queries ([info@rsc.mrc.ac.uk](mailto:info@rsc.mrc.ac.uk)). The number of queries relating to University Unit transfer increased 5 fold on the same time last year.



- Clinical Trials of IMPs
- Research Governance (incl NHS R&D permission)
- Human Tissue
- Consent (incl children and adults unable to consent themselves)
- Data (incl sharing, retention/destruction and NIGB)
- Experimental medicine
- Ethics/IRAS
- Other (University Unit; applying MRC policy & review of guidance)

“Many thanks for your very prompt and helpful advice”

“Thanks... you’ve made things much clearer!”

“Incredibly helpful!”

“I wish I’d thought of contacting you sooner!”

## Email updates

Every three months our email update provides a round-up of news and events relevant to those involved in research with humans, their tissues or data. In addition, it also provides the opportunity for our community to feed into relevant consultations (e.g. Information Commissioners Office; Human Tissue Authority / Human Fertilisation and Embryology Authority in 2012).

We currently have around 200 subscribers, if you would like to know more then please see Updates and Communications at [www.mrc.ac.uk/regulatorysupportcentre](http://www.mrc.ac.uk/regulatorysupportcentre).



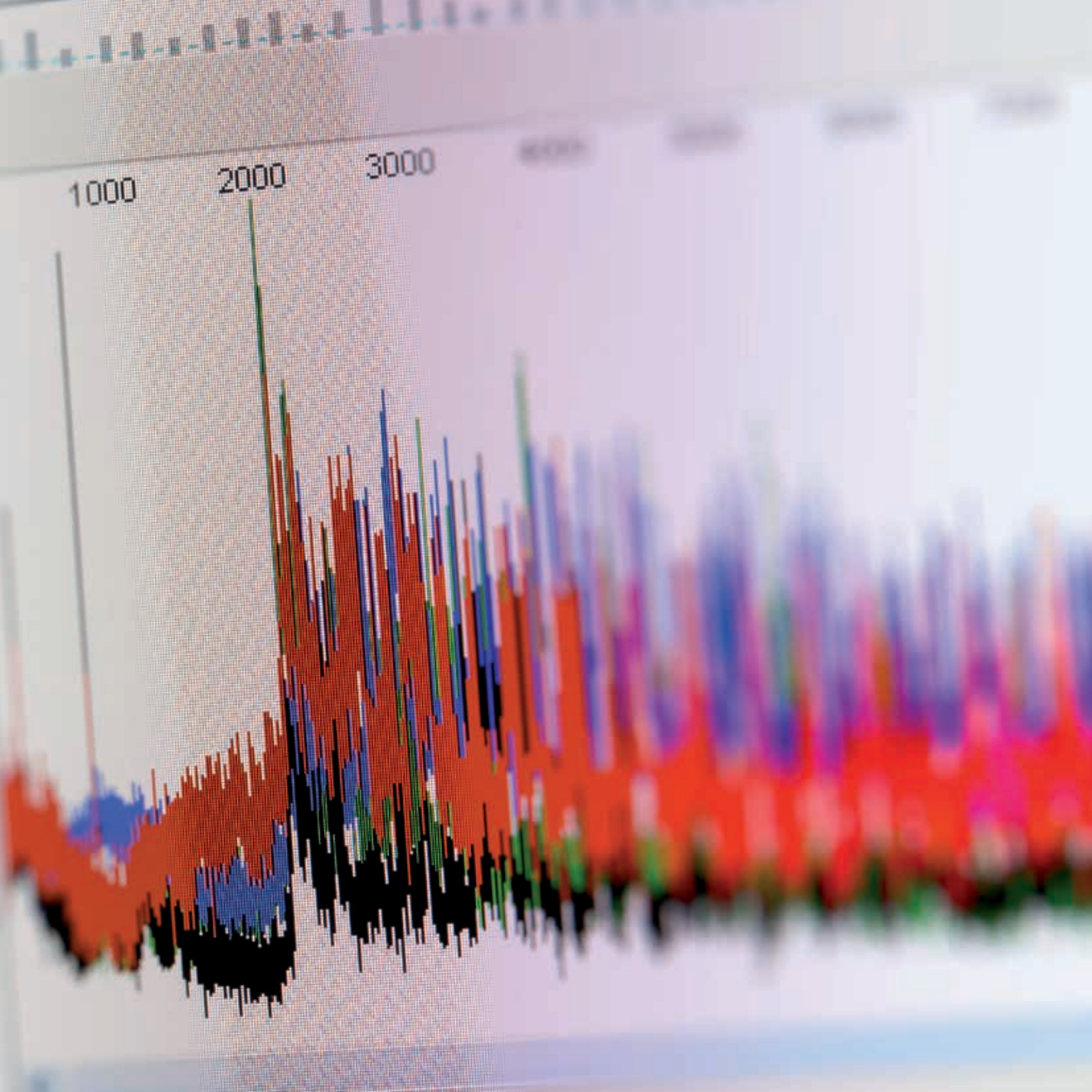
## Guidance

We continue to work in partnership to optimise use of human tissue in research across the UK by inputting to the STRATUM project and in providing practical expertise to the Scottish Research Tissue Bank Accreditation panel, responsible for accrediting Scottish Biobanks.

In 2012–13 we started a review of our human tissue legislation summaries. The licensing summary and the consent summary are currently being updated with input from the Human Tissue Authority.

## Looking forward

- In 2013–14 we will continue to invite you to participate in relevant consultations, allowing your voice to be heard;
- We will support the MRC community by answering queries from grant holders, as well as those based in MRC Units, University Units and University partners;
- We will continue to revise the human tissue summaries; and
- We will work with the MRC Ethics, Regulation and Public Involvement Committee (ERPIC) to amend the Human Tissue and Biological Samples for use in Research – Operational and Ethical guidelines. The aim is to release this new guidance in 2014.





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