

## Highlights 2011-12

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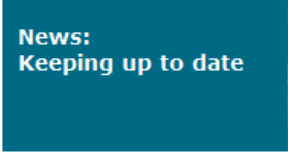




### Welcome

Last year's publication of the AMS report '[A new pathway for the regulation and governance of health research](#)' initiated a process of change within the regulation and governance of health research in the UK. To see how the MRC Regulatory Support Centre (RSC) is involved in this process visit [Partnerships: Strategic collaborations with others](#).

The shape of the MRC is also changing, with the move towards University Units. The MRC Regulatory Support Centre will continue to provide support to the "MRC family" in its widest sense: to MRC Units throughout these changes; and to the University Units and their new partners once established.

In times of change it's vital that we share and learn from the experiences of others, particularly those developing strategic partnerships with Universities; and that we keep up to date and know where to go for help. See how the MRC Regulatory Support Centre can help in the sections below.

You'll also see that it's been business as usual for the MRC Regulatory Support Centre with development of our new e-learning module on [Research Data and Confidentiality](#).

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**News:**  
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### News: Email updates

Our quarterly email updates remain popular; providing our subscribers with relevant news, consultations and events.

If you or your colleagues (e.g. Unit, NHS, University, etc) are interested in subscribing to our email updates, please contact [info@rsc.mrc.ac.uk](mailto:info@rsc.mrc.ac.uk).



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**News: The changing regulatory landscape**

The regular feature "The changing regulatory landscape" was introduced to our communications last year. It has followed the process of change in regulation and governance of health research in the UK.

Further details are provided in the timeline below.



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## News: Looking forward

Our website [www.mrc.ac.uk/regulatorysupportcentre](http://www.mrc.ac.uk/regulatorysupportcentre) will be revamped over the coming months. There will be a phased approach to these changes with the first phase supporting our training programme. Visit the e-learning and training icons on our home page to access the online modules or book a place on one of our face-to-face training courses.

Over time more functionality will be added allowing you to test your knowledge; or access our web-based fora resources.



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#### **Partnerships:** **Strategic collaborations with others**

**Working in partnership with the MRC family**  
**Working with the HRA to shape advice provision**  
**Improving tissue sharing across the UK**  
**Developing quality systems with BARQA**  
**UK Clinical Research Collaboration**  
**Looking forward**



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#### **Partnerships:** **Working in partnership with the MRC family**

The Research Governance and Human Tissue Fora continue to provide support for those with specific governance responsibilities within MRC and University Units. The fora are currently working with Head Office and regulatory bodies to smooth the path and reduce the bureaucracy involved in transferring to a University Unit.

*“Well prepared talks  
which were pertinent.  
Engaged audience”*

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### Partnerships: Working with the HRA to shape advice provision



Two members of the MRC Regulatory Support Centre have been seconded part time to the new Health Research Authority. Their role is to explore how best the HRA can support researchers.

This work has already begun: RSC provided Data and Confidentiality training with NRES in February 2012 and explored current guidance provided by HRA through two focus groups. Thanks to those who took part.

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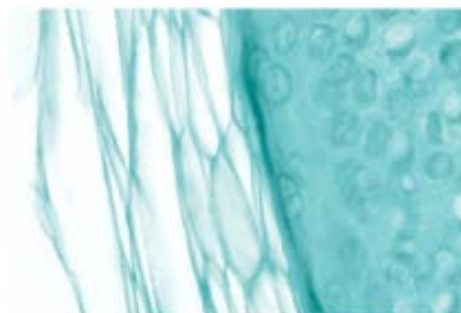
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### Partnerships: Improving tissue sharing across the UK

The MRC Regulatory Support Centre is working with Head Office and other UK funders to align tissue sharing policies in the UK. We are also working with wider partners in academia, industry and the UKCRC on the STRATUM project which aims to increase the efficiency of biobanking in the UK. More info on both initiatives can be obtained from the [UKCRC website](#).

In Scotland we have provided practical expertise on the Research Tissue Bank Accreditation scheme, collaborating with Scottish biobanks, Health Improvement Scotland and the Chief Scientist's Office.



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### Partnerships: Developing quality systems with BARQA

The MRC Regulatory Support Centre continues to work in partnership with the British Association of Research Quality Assurance (BARQA) to provide helpful products for the academic audience. The most recent output was the [BARQA Quality Systems Workbook](#) which aims to provide the tools to develop and implement a practical, risk proportionate Quality System that will work for the user.

“*This is one of the best manuals  
I have ever seen for establishing  
a quality system*”

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### Partnerships: UK Clinical Research Collaboration

We continue to work within the UK Clinical Research Collaboration, representing the research community on the UKCRC Regulatory and Governance Forum (for which we provide the secretariat) and by chairing the UKCRC Training Coordination Group.



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- Working in partnership with the MRC family – We will continue to work with forum members to ensure that we all learn from the experiences of others and share good practice;
- Working with the HRA – We will continue to represent the voice of investigators to influence development of the HRA;
- Improving tissue sharing across the UK – We will continue this work by organising a Scottish Tissue consensus meeting; and by working with the public and researchers to shape policy through STRATUM and the EM Funders Group.



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**Advice:**  
Ethics, regulation & governance support

Your questions answered

Guidance

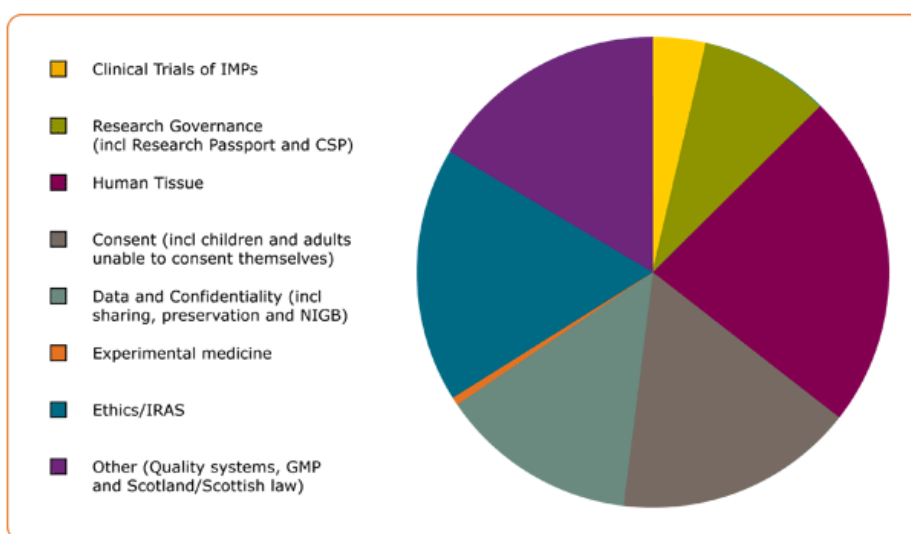
Looking forward



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In 2011-12 we answered 126 remote advice service queries ([info@rsc.mrc.ac.uk](mailto:info@rsc.mrc.ac.uk)). The RSC analyse the queries received and use this information to inform future training and guidance. This has included supporting a Framework 7 application from a University Unit; supporting a grant holder through a complex ethics application; advising the GPRF on retention of tissue samples / study data; and face-to-face meetings involving the MRC, University and NHS partners. In the future we will continue to support the MRC community, whether you're based in an MRC Unit or University Unit.



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Our aim to provide practical guidance continued in 2011-12 with the following changes and updates:

- The **MRC Data and Tissues Tool Kit** now incorporates a section for Pathologists and others using diagnostic archives / existing tissue collections in research.
- The **Clinical Trials Tool Kit** has transferred to NIHR who are currently reviewing its content.
- The **UK Stem Cell Tool Kit** has been reviewed by the Department of Health.

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“I’ll read RSC’s  
excellent documents”

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We look forward to the launch of Good Research Practice which was reviewed by Head Office in 2011-12 with our support. We also plan to collaborate on the Research Integrity section of the University Unit Tool Kit which is being developed by Head Office.

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**Training:**  
**Ethics, regulation & governance training**

**New e-learning in 2012**

**Courses provided**

**How did we do?**

**Looking forward**



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**Training: New e-learning in 2012**

Launched in May 2012, our new **Research Data and Confidentiality** e-learning module is the latest edition to RSC's suite of online learning (joining **Research and human tissue legislation** and **IRAS**). This new e-learning is based on our successful face-to-face course, and it explores the concepts of confidentiality and data protection. It aims to provide you with the framework and tools to interpret the requirements for research with confidence.



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In 2011-12, the Regulatory Support Centre trained over 2000 people: just over 10% at face-to-face training sessions; and almost 90% online. A full breakdown of the training delivered can be seen in the table below.

Course	Attended
GCP for non-clinical trialists	63
Good Manufacturing Practice (GMP)*	45
Human Tissue Act (face to face)	34
Research and Human Tissue Legislation (e-learning)	1964
Research Data and Confidentiality (face to face)	93
Submitting successful ethics	20

*“Really grateful to you for... delivering such high quality training”*

\* The Good Manufacturing Practice training course was commissioned by the Regulatory Support Centre to meet an identified need which we could not meet ourselves. Payment of this course was made possible through income generated by the RSC.

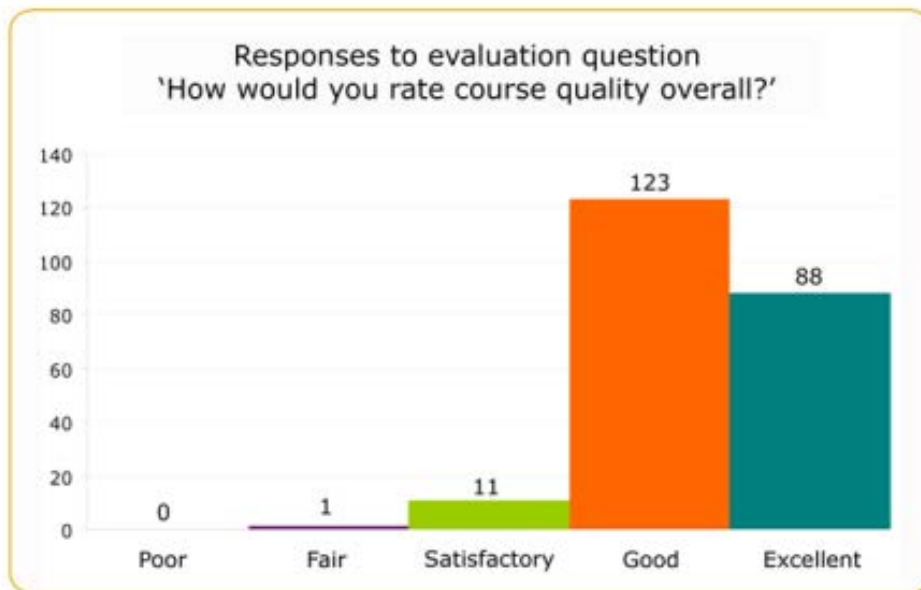
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Those who attended our face-to-face training rated our sessions as follows:



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### Training: Looking forward

In Autumn 2012 we plan to launch our new human tissue blended learning course. This course will consolidate the learning gained from completing our e-learning module Research and Human Tissue legislation, by providing a face-to-face workshop where knowledge will be applied to practical and relevant scenarios.

We will also continue to explore opportunities to collaboratively develop training with others.



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