

MRC

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MRC Regulatory Support Centre

Highlights 2010-11

Welcome >

January 2011 saw the publication of the Academy of Medical Sciences report '**A new pathway for the regulation and governance of health research**'. The report recommends change to the regulation and governance of health research in the UK. Over the coming year we will see how these recommendations will be taken forward, (See the Government's '**The Plan for Growth**').

During periods of change, it's vital that investigators are kept up to date, can access help and have their voices heard by decision-makers. With this in mind the MRC Regulatory Support Centre (RSC) was awarded a further four years funding to build on our achievements:

- **Information** - Avenues that provide timely, accurate information and manage expectations during this uncertain period
- **Influence** - Partnerships that exploit opportunities to influence future change
- **Impact** - Intelligence gathering to measure impact of change, so those in the MRC can adapt process as required
- **Training** - Equipping MRC investigators with the relevant skills and competencies

Contact the **MRC Regulatory Support Centre**.

www.mrc.ac.uk/regulatorysupportcentre

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RSC Highlights 2010-11

Information and managing expectations

[> Welcome](#)[One-stop-shop >](#)

www.mrc.ac.uk/regulatorysupportcentre

The Regulatory Support Centre (RSC) website continues to be the one-stop-shop for access to all our tools and guidance - the [MRC Tool Kits](#), [e-learning](#) packages and [Advice](#). The last 12 months has seen the number of visitors to our website almost double.

Over the coming year we will investigate new technologies (such as Twitter and podcasts) to deliver regulatory and governance information to you.

[Email updates >](#)[Advice >](#)[Guidance >](#)

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[Email updates >](#)

Readership of our [quarterly email updates](#) has steadily grown (up 75% from readership in 2009-10). These updates pick out relevant news, consultations and events to keep you up to date.

If you are interested in subscribing to our email updates, please contact info@rsc.mrc.ac.uk

*“Many thanks for your latest update,
I found it incredibly useful”*

[Advice >](#)

[Guidance >](#)

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April 2010 saw the launch of our remote advice service (info@rsc.mrc.ac.uk). We have now addressed more than 150 queries from the MRC community and other investigators / research managers, over a quarter of whom regularly return.

Advice



“ Thank you ever so much for your prompt and thorough support ”

[Guidance >](#)www.mrc.ac.uk/regulatorysupportcentre

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We are committed to ensuring that MRC policy outlined in the Ethics series reflects current expectations and to this end we have been involved in reviewing Good Research Practice, Human Tissue and Biological Samples for Use in Research and Good Clinical Practice.

We have updated the Data and Tissues and Experimental Medicine Tool Kits in response to feedback and will continue to review our guidance in light of future changes to the regulatory environment.



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Exploiting opportunities to influence change

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Influence through consultation responses >

Over the past 12 months the Regulatory Support Centre (RSC) has provided input into a number of consultations:

- AMS two-phase consultation reviewing the regulation and governance of health research
- Department of Health consultation workshop on development of the Research Support Services in NHS R&D
- Review of EU Clinical Trials Directive
- Ministry of Justice consultation on changes to data protection legislation

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Copies of responses are accessible from the MRC website [Public evidence](#) page. During the coming year we will continue to participate in relevant consultations, seeking your input to ensure that the voices of researchers are heard.

To keep up to date please see RSC News at www.mrc.ac.uk/regulatorysupportcentre.

Working in partnership >

Working within the MRC >

Bringing people together >

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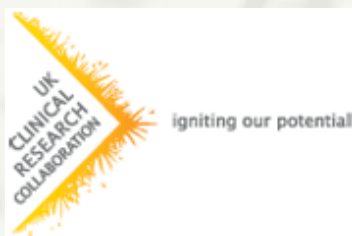
Exploiting opportunities to influence change

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Influence through consultation responses >**Working in partnership >**

We have continued to work within the UK Clinical Research Collaboration, as members of the Regulatory and Governance Forum and by chairing the UKCRC Training Coordination Group, including:

- Delivering regional workshops on the use of human tissue samples with onCore UK, NCRI and NRES
- Initiating a training needs assessment for those conducting medicinal trials for the MHRA
- Developing a partnership with the British Association of Research Quality Assurance
- Providing input into the Scottish Human Tissue Governance Accreditation Scheme
- Development of a harmonised human tissue policy across UK funders

**Working within the MRC >****Bringing people together >**www.mrc.ac.uk/regulatorysupportcentre

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We have spent the greatest amount of time building partnerships with MRC units and centres through the services we provide and fora we support. We are also supporting units currently moving to work under University governance structures.

We continue to work with MRC Head Office including the Research Programmes Group, Corporate Affairs Group (in particular supporting implementation of internal audit findings), Information Security and MRC contracts managers.

Bringing people together >

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300 delegates attended Birmingham's Motorcycle Museum for our ***Sharing Human Tissue: New Opportunities, New Horizons*** conference on 15th September 2010. Together they examined the regulatory, ethical and practical aspects of sharing human tissue in order to realise its full potential.

“***Excellent and informative, thank you***”

Organised by the MRC Regulatory Support Centre in collaboration with onCore UK and the Experimental Cancer Medicine Centre Network we brought together an audience of investigators, tissue managers, funders, regulators and patient representatives. The day was rated as either good or excellent by 83% of evaluation respondents.

“***Kept me up to speed with what's going on***”

Discussions highlighted the need for patient and public engagement; and a variety of approaches to generic consent. Investment from funders was described as key for effective sharing to work. Take home messages from the day included support for fair access; the need for quality to underpin good science; and the promotion of well-managed generic consent to meet donor expectations. This successful event will help to steer future development of policy in this area.

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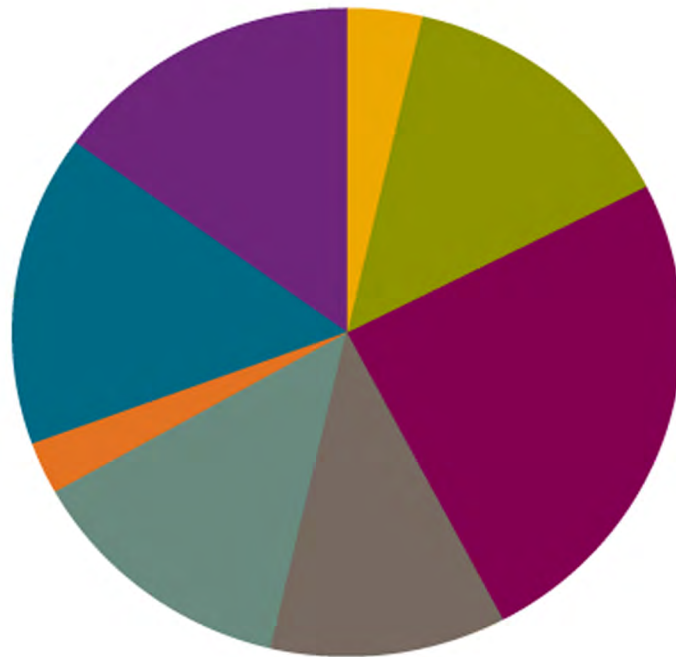
Assessing impact

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Identifying issues >

From our remote advice service (info@rsc.mrc.ac.uk) we can identify areas of confusion and difficulty. Many questions relate to the processes involved in obtaining approvals; an area that is likely to change in the near future. This data has informed development of our Research Data and Confidentiality training in 2010 (see [Training to build relevant skills and competencies](#))

- Clinical Trials of IMPs
- Research Governance (incl Research Passport and CSP)
- Human Tissue
- Consent (incl children and adults unable to consent themselves)
- Data and Confidentiality (incl sharing, preservation and NIGB)
- Experimental medicine
- Ethics/IRAS
- Other (Q&S regulations and research in other countries)



Supporting staff to share good practice >

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Our Research Governance and Human Tissue fora provide opportunities for those with governance responsibilities to network and share good practice when managing sponsorship responsibilities and human tissue collections, and provide opportunities to meet with regulators. Through these fora we hear about the day-to-day challenges you face directly in your units. The fora are supported by the *MRC DI and Tissue Bank Managers* and *Research Governance* portal sites to promote document sharing.

“**Great to meet people, I will be in email/telephone contact with**”

“**Relaxed, focused & relevant**”

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Training to build relevant skills and competencies

[> Welcome](#)[Courses provided >](#)

The Regulatory Support Centre (RSC) provides MRC researchers and managers with **Training** in a number of regulatory and governance areas. During 2010-11 we have provided face-to-face training and e-learning in the following areas:

Course	Attended
Human Tissue Act (face to face)	35
Human Tissue Act (e-learning)	1863
Good Clinical Practice	64
*Research Data and Confidentiality	39
Consent to use tissue in research	9
*developed in collaboration with MRC Information Security	

[How did we do >](#)[Future plans and development >](#)

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To meet demand, Research Data and Confidentiality will be developed into an e-learning module to be launched in 2012 and a face-to-face module on how to apply for NHS approvals using IRAS will also be developed. To support our e-learning portfolio, we plan to develop a user-friendly Learning Management System which will help you manage your training.

Training



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