MRC Regulatory Support Centre

Highlights 2009–10
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Introducing the MRC Regulatory Support Centre

The MRC Regulatory Support Centre (RSC) is a small Head Office-funded initiative providing support and guidance for those conducting research with human participants, their tissues or data. Established in 2006, we support the UK research community to meet regulation, ethics and governance requirements. We do this through the development of online tools, provision of advice and training, building and supporting networks and representing the research community with regulators and policy-makers.

The initial focus for the RSC was to develop services and guidance; in 2009–10 the emphasis moved to promoting what we do, ensuring that the MRC community is able to find the right help when needed. As part of this we have brought all our services together on one website at www.mrc.ac.uk/ regulatorysupportcentre. This one-stop-shop aims to support the conduct of ethical and well-governed research, while keeping it simple.

During the year the RSC underwent a mid-funding review by MRC Head Office to ensure that we were meeting the objectives set, that our future work is evidence-based and strategically aligned, and to agree objectives until the end of our funding period. This publication highlights our achievements during 2009–10 and describes priorities for the coming year.
What do you need from us?

In 2009 we conducted a survey of MRC units and centres to identify RSC projects that have been well received and to find where unmet needs remain.

Results of MRC researcher survey

We currently offer training and guidance in many of the areas identified; during 2010–11 we will be addressing more of your needs by developing our training programme, expanding provision of Question and Answer sessions, building further e-learning modules and distributing email updates on changing regulatory requirements.

The major finding from the survey is that we need to ensure that the tools already developed contain the most up-to-date information and that you know where to find help when you need it: promotion and communication are a key theme for 2010–11.

Where to go for help

www.mrc.ac.uk/regulatorysupportcentre
Keeping up-to-date, while balancing the demands of your day job can be challenging; the following are ways to keep informed.

**Regulatory Support Centre website**

Late in 2008 we launched our website [www.mrc.ac.uk/regulatorysupportcentre](http://www.mrc.ac.uk/regulatorysupportcentre), which provides access to all of our services and guidance. Links are available to the *DI and Tissue Bank Managers* site, designed to support the Human Tissue Forum, our online tools and other sources of information. The number of visitors to the RSC website continues to grow and we will look to continue this trend in 2010–11.

**Promotional activities**

During the past year we have actively publicised our services, particularly within MRC units, promoting our website through gifts, signposting at events (including HR Business Partners and programme-leader track scientists) and articles in MRC publications.
Email updates

Every three months we produce an email update highlighting news and events, such as the revision of the Human Tissue Authority Codes of Practice; launch of the Integrated Research Application System (IRAS) e-learning and introduction of a minimum dataset on IRAS.

If you are interested in subscribing to our email updates, contact rscinfo@hrs.u.mrc.ac.uk.

“Many thanks for the very interesting update… I will be forwarding information to our staff and checking out some of the websites myself.”

Looking forward

Communication will continue to be a key part of our activities, in particular within the MRC community. The challenge for 2010-11 will be to reach out to MRC centres and develop a plan for communicating with MRC grantholders, while continuing to maintain and develop our online tools to ensure we deliver what you need, when you need it.
Developing guidance on regulation, ethics and governance

We aim to provide practical guidance that is easy to understand and where possible illustrated with real life examples. All our guidance is available from www.mrc.ac.uk/regulatorysupportcentre.

Management of established Tool Kits

The following online Tool Kits have been developed by the RSC to provide interactive guidance in areas that pose specific regulatory challenges.

• The Clinical Trials Tool Kit covering the conduct of Clinical Trials of Investigational Medicinal Products

• MRC Data and Tissues Tool Kit outlining the appropriate use of personal information and human tissue samples in research

• MRC Experimental Medicine Tool Kit supporting best practice in small scale, experimental medicine studies.

The Tool Kits continue to be a useful resource for researchers, with the combined number of visitors reaching almost 1.2 million in 2009–10.
Development of Stem Cell Tool Kit

Launched in December 2009, the Stem Cell Tool Kit was developed by the Department of Health, in collaboration with the RSC and other partners. It outlines the regulatory steps involved in developing new stem cell treatments from the laboratory to patient.

Revision of human tissue legislation summaries and flow charts

Produced in consultation with the Human Tissue Authority and Scottish Government these summarise the main aspects of human tissue legislation in bite-sized chunks. They are currently under review to ensure they reflect changes in published best practice.

Looking forward

In 2010-11 we will be reviewing the Data and Tissues Tool Kit and some of the MRC Ethics Series booklets to ensure they continue to support the needs of researchers and reflect current best practice.
Providing regulatory and governance advice

When you have a specific regulatory or governance question, you want to find an authoritative answer quickly. We provide two ways for you to obtain advice directly from a member of our team.

Question and Answer sessions

These sessions offer face-to-face advice to MRC researchers at local venues. Following a successful pilot, 2009 saw the first phase of a roll out to provide this service across the MRC. Researchers in MRC units were invited to ask any regulatory, ethics or governance questions. The vast majority of questions could be answered there and then, with the occasional question being escalated to an appropriate regulatory body.

“Really clear and reassuring.”

“Very clear information, very helpful. Would use this again.”
UKCRC Regulatory and Governance Advice Service

We have been a partner in the Advice Service since it was established in 2006. The Service, run collaboratively with NIHR Clinical Research Network Coordinating Centre and a network of regulators and experts, aims to support local advice givers (predominantly NHS or university R&D offices) as well as MRC staff. During 2009–10 the Service helped 200 people with nearly 300 queries.

The Service also provides a website which details best practice, provides answers to frequently asked questions and highlights forthcoming events.

Queries received by the Advice Service in 2009–10

Looking forward

The roll out of Question and Answer sessions will move into a second phase during 2010–11, to expand from MRC units and institutes to include MRC centres.

Following an independent review, the Advice Service is currently being restructured to best meet the needs of the research community.

MRC researchers can contact us directly for advice by email at RSCinfo@hrs.u.mrc.ac.uk.
Regulatory and governance training

We provide authoritative training to meet your needs. We understand that most researchers do not wish to become regulatory experts, but you do need to know a certain amount in order to pursue your research interests.

In 2009–10 we offered courses through the MRC core Learning and Development training programme as well as providing bespoke training to specific groups on request. The courses delivered to MRC staff during the year are shown on page 11.

A new development in our training strategy has been the introduction of e-learning for use by MRC staff and the wider research community. E-learning modules on IRAS, delivered on behalf of the UK Clinical Research Collaboration (UKCRC), and on the research use of human tissue are now available from www.mrc.ac.uk/regulatorysupportcentre.

We have also delivered training to external partners including NHS Research Ethics Committees and clinical trial managers.
Courses delivered to MRC staff in 2009–10

<table>
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<tr>
<th>Course</th>
<th>Attended</th>
<th>Number of courses run</th>
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<tr>
<td>Consent: Ethical, legal and practical aspects</td>
<td>22</td>
<td>1</td>
</tr>
<tr>
<td>Consent to use human tissue in research</td>
<td>86</td>
<td>4</td>
</tr>
<tr>
<td>Introduction to the Human Tissue Act (for investigators)</td>
<td>102</td>
<td>5</td>
</tr>
<tr>
<td>The Integrated Research Application System (IRAS)</td>
<td>43</td>
<td>3</td>
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Responses to evaluation question
‘How would you rate course quality overall?’

"First really clear explanation I’ve ever had of the Human Tissue Act. I now actually understand!"

Looking forward
In 2010–11 we will build on our current training programme to include; research data and confidentiality and Good Clinical Practice for non-trialists. Our e-learning portfolio will be developed further.
Working in partnership

We work in partnership across the MRC and beyond. We have been involved with a number of collaborative projects, especially through the UKCRC. This includes leading and coordinating the UKCRC Advice Service, chairing the UKCRC Regulatory Training Coordination Group and membership of the UKCRC Regulatory and Governance Project Group.

We have developed training materials and frequently asked questions in partnership with regulators, UK health departments and other experts.

The delivery of our services has been greatly facilitated by effective collaborations with other functions within the MRC, in particular Learning and Development and Corporate Affairs. MRC staff have helped us pilot new training courses, including e-learning.
Looking forward

We will continue to work in partnership, with both internal and external stakeholders, in particular in the development of online training and guidance, and in the organisation of a UK-wide conference for the users of human tissue to explore ways to realise the full potential of valuable tissue collections. The move to partner-led working within the UKCRC will increase our input into key UKCRC initiatives. We will continue to support our forums, in particular with implementing quality systems and appropriate sponsorship, and by developing a web-based resource to support the MRC Research Governance Forum.

Forums

The Human Tissue Forum and newly established Research Governance Forum have supported MRC staff and grant holders with specific governance responsibilities. Forums provide an opportunity to share best practice, to interact with regulators, to identify training needs and to commission specific support. The Human Tissue Forum is supported by the DI and Tissue Bank Managers web-based resource where documents can be shared.

Consultations

We have responded to a number of consultations and reports during the year: for example those from the Human Tissue Authority, National Cancer Research Institute and onCore UK, Medicines and Healthcare products Regulatory Agency, and National Research Ethics Service.

We are currently collating evidence to feed into the Academy of Medical Sciences review of the regulation and governance of medical research.

“Excellent opportunity for interaction between many MRC human tissue users.”
Support and guidance for those conducting research with human participants, their tissues or data

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