Support and guidance for those conducting research with human participants, their tissues or data.

Regulatory Support Centre
Highlights 2013-14
Welcome

In an ever evolving environment it’s important to keep up to date, to access practical help and to feed into relevant consultations. The Regulatory Support Centre is here to help you interpret requirements, empower you to find your way, and to influence decision makers. In 2013-14, the regulatory environment for research involving human participants their tissues or data continued to change. The impact of these changes will affect the research community not only in the year ahead but for many years to come. These changes include:

- The Health Research Authority Assessment and Approval which will bring together NHS R&D and NHS Research Ethics Committee approvals.

- Amendments to the new Data Protection Regulation which could severely restrict the use of personal data for research. The MRC are working in partnership to ensure a pragmatic solution.

- The McCracken review which suggested legislative change for human tissue.

This publication provides details of the Regulatory Support Centre’s activities in 2013-14 and outlines our plans for the year ahead.
About the MRC Regulatory Support Centre

The Regulatory Support Centre is a small MRC Head Office function providing support and guidance for those involved in research with human participants, their tissues or data. Established in 2006, we support the UK research community, helping you meet regulatory, governance and ethics requirements with our online tools, practical advice and training.

We are continually assessing need, identifying how best to empower researchers and research managers to apply governance and regulation proportionately. Our aim is to ensure that research is delivered efficiently and effectively.

All of our services are available from: www.mrc.ac.uk/regulatorysupportcentre including access to our free e-learning modules.

The Regulatory Support Centre is currently working in collaboration with the Health Research Authority to provide authoritative guidance. We are working together to increase efficiency, promote risk proportionality, influence policy and shape regulation; ensuring your views are heard.

“Good mix of people including those from Universities so getting fuller perspective”
Working across the MRC and beyond

We have strong working relationships with MRC Head Office, Units and University Units, and have strengthened links with our University partners. Our practical help, training and networking opportunities serve the MRC and our University partners alike.

Our Research Governance and Human Tissue fora provide support and networking opportunities to those with specific governance responsibilities. Through the fora we promote risk proportionate approaches to ensure research is delivered effectively and in a timely manner.

Supporting the University Unit transfer process

We are keen that experiences and learning from previous University Unit transfers inform future transfers. To this end, the research governance forum has been invited to provide input to the University Unit Tool Kit, recently revised by Head Office.

“Great opportunity for university staff to keep up to date and talk to others"
Working across the MRC and beyond

Working with the MRC Corporate Affairs Group
During 2013-14 we have led the revision of MRC’s guidance: Human Tissue and Biological Samples for Use in Research with a group of experts. This will be launched later in the year.

We have shared our expertise in e-learning development, reviewing the Corporate Affairs Group’s Good Research Practice module. This module will be hosted on a dedicated section of the Regulatory Support Centre’s learning management system.

Looking forward
- We will develop a practical framework on research record retention; empowering the community to decide what to retain, for how long and in what format.

- We will build further links to increase networking across the University sector assessing how best to support this group.

- We will build new partnerships (e.g. with the Farr Institute of Health Informatics Research, to facilitate the exploitation of existing data sets for research).

- We will develop a workshop to support the MRC / Wellcome Trust Health Related Findings Framework, using examples to help apply this in practice.
Working in partnership with the HRA

2013-14 has seen the Regulatory Support Centre’s secondment to the Health Research Authority (HRA) go from strength to strength with the launch of Consent and Participant Information Sheet Preparation Guidance in March 2014.

This online guidance has been designed for researchers and ethics committees to cover the principles of consent and how to prepare documents that support the consent process. Consent and Participant Information Sheet Preparation Guidance joins the two decision tools ‘Do I need NHS REC approval’ and ‘Is my study research’ to form a suite of online tools designed to inform and empower the user. These tools were developed by the Regulatory Support Centre on behalf of the Health Research Authority and are available from www.mrc.ac.uk/regulatorysupportcentre.

We have also provided training to research ethics committee members in data and confidentiality.

Looking forward

- We will work with the HRA Confidentiality Advisory Group to develop online guidance exploring practicable alternatives to accessing confidential NHS information without consent, balancing research need with privacy.

- We are also scoping how best to support the replacement of the Research Governance Frameworks; and communicate changes to the UK approvals processes.

“It will help Ethics Committee members, staff and researchers find accurate answers quickly and efficiently.”
Training

New Blended learning in 2014
A big thank you to those who provided feedback on our first blended learning course on the Human Tissue Act, which was rolled out in 2013-14. We are reviewing course content to fully meet your needs, and will re-launch later this year.

Courses provided
The aim of our training programme is to help researchers interpret regulatory and policy requirements and to increase confidence when navigating the approvals processes. In 2013-14, the Regulatory Support Centre provided training to 3053 people: almost 10% at face-to-face training sessions; and over 90% online. The table below provides a full breakdown of all training delivered.

<table>
<thead>
<tr>
<th>Course</th>
<th>Attended</th>
<th>Number of courses run</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse events</td>
<td>31</td>
<td>1</td>
</tr>
<tr>
<td>GCP for non-clinical trialists</td>
<td>76</td>
<td>3</td>
</tr>
<tr>
<td>Good Manufacturing Practice</td>
<td>21</td>
<td>1</td>
</tr>
<tr>
<td>Human Tissue Act blended learning</td>
<td>62</td>
<td>4</td>
</tr>
<tr>
<td>Research and Human Tissue legislation (e-learning)</td>
<td>2113</td>
<td>-</td>
</tr>
<tr>
<td>Research Data and Confidentiality (e-learning)</td>
<td>720</td>
<td>-</td>
</tr>
<tr>
<td>Submitting a successful ethics application</td>
<td>19</td>
<td>2</td>
</tr>
<tr>
<td>Tissue, research and the HFEA</td>
<td>11</td>
<td>1</td>
</tr>
</tbody>
</table>

“The e-learning was very helpful and was consolidated by the teaching”
Looking forward

- We are working with the Plain English Campaign to develop training to help researchers make sure that the language used in the consent process is as clear as possible.

- We hope to develop a new Research Data and Confidentiality blended learning course to complement our existing e-learning, whilst combining the benefits of a face-to-face session.

- We will develop a Good Clinical Practice module to supplement the Corporate Affairs Group’s Good Research Practice e-learning.
Practical help and updates

Providing practical help
2013-14 saw 136 requests for practical help to info@rsc.mrc.ac.uk. The Regulatory Support Centre provides clarity on process and interprets requirements specific to your project, enabling you to drive your research forward.

“Excellent pragmatic examples”
Practical help and updates

Human Tissue Summaries
Last year we reviewed our legislative summaries, new versions will be released this year.

Keeping you up to date
Our quarterly emails provide regulatory news, details of events and consultations.

You can subscribe to these email updates by contacting info@rsc.mrc.ac.uk

Looking forward
- We will keep you abreast of new developments e.g. “HRA Assessment and Approval”.
- We are investigating the use of Apps to provide guidance in more accessible formats.

During 2014 we will seek future funding. Thanks for your words of support, it’s great to hear that we are making a real difference.

“REC approval received! Very much appreciated.”

“Thanks... I don’t know where we would be without the RSC!”