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Executive Summary

Background
Most of the queries the Medical Research Council Regulatory Support Centre (MRC RSC) receive relate to difficulties around the governance of health research. We define research governance as the regulatory, ethics, policy and local health research requirements that apply to health research. To gain a comprehensive insight into the reasons that underly these issues we conducted an anonymous online survey between July and October 2019. The primary aim was to understand more about research governance issues with a view to sharing this with research approvers and other stakeholders. A secondary aim was to inform our work by highlighting what support we should be providing to the research community.

Audience
We received 365 responses with an approximate even split between researchers and research managers. Most respondents had over 5 years’ experience in health research and were involved with 1-5 applications in the year preceding the survey. Just about all respondents were involved in UK research, with 20% also involved in non-UK research. Half of respondents had previously heard of the MRC RSC, the majority of whom were research managers.

Main Themes
With a few exceptions there were no appreciable differences between the responses of researchers and research managers. Overall, dissatisfaction with research governance was rated as 6.5/10 and the acceptability of this rated at 6.6/10. The main areas where governance issues arose, alongside our activities to help address these, were:

- **Data protection and confidentiality** - we have published extensively on this topic, we continue to work with ICO on anonymisation guidance and clarify international transfer requirements
- **Health data access** - we have developed a **Health Data Access Tool Kit** and continue to work with HDR UK and data providers on streamlining
- **How to collaborate with the NHS** - not typically within MRC RSC capabilities
• **Governing international research** - we held a conference on Global Health Oversight in May 2020 and how to provide support with the specific topics highlighted will be explored further

• **Research with human tissue samples** - we have launched new [Human Tissue e-learning](#) and continue to work with banks and regulators

• **Development of Medical Devices** - we held a conference in April 2020 sharing expertise across academia and participate in the NHSX AI-lab regulatory workstream. We are developing links with the MHRA on post-EU Exit and collaborate with the [Oxford Global Guidance](#)

**Planning research**

Although no issues were raised about understanding local processes, arranging local support emerged as the predominant problem, mainly due to lack of resource and lack of local enthusiasm for research. However, most respondents chose to provide more detail about understanding governance requirements, where the main problems related to unclear and inconsistent guidance. Researchers’ own organisations were the primary place where advice was sought when planning research, whilst research managers were more likely to approach other organisations.

**Applying for approvals**

The major issue reported with applying for approvals was poor communication and interactions with approval bodies, particularly lack of clarity about what paperwork to submit and when. Overall feedback about the organisations involved in research governance was generally positive, although this varied considerably between organisations. There was a clear positive correlation between the clarity of approval assessment criteria and satisfaction with approval processes.

**Running research**

The principal problem raised with running research was ensuring that all approvals are in place and knowing when to start a project. Further analysis revealed that this mainly related to problems in organising local agreements and approvals, rather than national approvals.
Finishing research
A wide range of issues were reported for finishing research. The main problem encountered was sharing data and / or tissue. Underlying reasons related to confusion over what consent allowed, obtaining data / tissue sharing agreements and the logistics of sharing.

When asked to relay positive experiences several themes emerged. Research governance was described as easier if the following were in place:

- Good and / or established relationships with clear communication
- Clearly defined protocols / roles
- Local support (sponsor, R&D, Clinical Trial Units)

Key Messages and Recommendations
- Dissatisfaction with research governance was lower than expected, although a number of issues were reported consistently. Some of these issues have been temporarily addressed during the COVID-19 pandemic, but there is a clear need to sustain the recent improvements in system agility and efficiency, with adequate resource provided to do so.
- To address problems with gaining approvals, better coordination between approvals bodies and a reduction in duplication of assessment, is required. Approvers could do more to take account of other approval bodies where requirements are similar e.g. central data providers.
- More effective communications are required from:
  - HRA & MHRA to promote greater visibility of GCP training policy, and for new GCP training to be more targeted to specific audiences
  - Decision-making bodies across the sector to be more transparent in their assessment criteria
  - Sites and sponsors in communicating their requirements and decisions
  - Funders for availability of funding for archiving and data / tissue sharing costs
• Increased resourcing of university service departments - the need for legal agreements and research governance assurances are not likely to go away.

• This survey deliberately didn’t ask about EU Exit. It is now emerging that Great Britain will diverge from EU regulation on medical devices and diagnostics (and medicines and advanced therapies). This obviously means there is considerable need to influence and understand the new landscape. This will be a focus of MRC RSC for the next few years.
Introduction

The Medical Research Council Regulatory Support Centre (MRC RSC) works with the research community to help increase understanding of research governance to facilitate health research. We define research governance as the regulatory, ethics, policy and local health research requirements that apply to health research. Various stakeholders discuss the problems that they have encountered when involved in research or research governance. Frequently these discussions reveal that the actual issues(s) differ from perceived issue(s). We also receive anecdotal reports about various aspects of governance that appear sub-optimal, but it is not always possible to ascertain exactly where the real problem lies. To gain empirical evidence about the interplay between research governance and difficulties encountered in research we designed an online survey. The primary aim of the survey was to gain a granular understanding about research governance issues to share with health research approvers and other stakeholders. A secondary aim was to inform our work by highlighting what support should be provided to facilitate health research.

The survey contained some initial demographic questions to aid analysis but focussed on four different stages of the research governance process:

- Planning research
- Applying for approvals
- Running research
- Finishing research

Questions were initially developed by analysing our database of queries, questions that we were asked at our training events and from discussions with data providers (e.g. NHS Digital, Public Health England, CPRD, ISD) and research approvers (e.g. HRA, CAG, PBPP). Some survey questions were mandatory, but respondents were given a choice about which questions (if any) from the planning, applying, running, finishing sections, they wished to answer. It was also possible to answer questions from more than one sub-section. Respondents were asked to restrict their answers to activities that took place in the year preceding the survey. Most answers involved selecting responses, but free text answers were also available for each section. All averages are means and replies were anonymous.
Following a period of user testing the survey was made available online between July 1st, 2019 - October 1st, 2019. The survey was distributed through our email distribution lists with a request to cascade further. The survey was also publicised at several research events over Summer 2019, as well as being posted on the MRC’s Twitter feed.

**Results**

**Audience**

We received 365 responses from the research community. Just over half of respondents (54%) had previously heard of MRC RSC, the majority of whom were research managers. The remainder of respondents had not previously heard of us. Analysis of response over time revealed that direct emailing to distribution lists was the most successful method for eliciting responses.

In terms of roles, the survey responses split almost equally between research managers and researchers. Some answers placed under ‘other’ are more customarily considered as either research manager or researcher and were added to the appropriate group. There were very few respondents that remained in the ‘other’ category. There were few notable differences in the responses between research team leaders and research team members, so we have split respondents into two groups:

1) research managers: (governance roles (e.g. sponsors offices) or research services (e.g. CTU trial managers, statisticians, agreements / contracts managers))

2) researchers (research team leaders and members)

We thought it important to compare results between these two groups in order to capture different perspectives, e.g. researcher issues with local governance or local service provision; research manager issues with national approvals from a portfolio of studies. We acknowledge that this is an imperfect split, for example a trial manager may be part of a specific research team rather than just a CTU service provider.
Respondents were primarily academic (79%), with some NHS representation (18%) and 3% of people identifying as ‘other’. Most (82%) respondents had over 5 years’ experience in health research, with only 2% having less than a year’s experience. Research managers were much more likely to have been involved in 10 or more research applications in the preceding year (54%), than researchers (20%). Just about all (96%) respondents were involved in UK research, with 20% also involved in non-UK research.

**General Themes**

All respondents were asked to gauge the difficulties (10 being maximum difficulties) that they had encountered with research governance over the previous year. Both research managers and researchers reported this as 6.3. Similarly, when asked if these difficulties caused delays, both groups reported 6.5 and the acceptability of these delays as 6.6.

Delays in research governance were not the only issues reported. Respondents also stated that research governance increased their workload and meant less time was available for other research activities. Several replies detailed difficulties with research governance threatening their ability to undertake research. Difficulties with research governance had also resulted in loss of funding, loss of research sites and research being unnecessarily scaled back.

Some respondents thought that excessive research governance contributed to rendering participant-facing paperwork less understandable to participants. Research governance was also seen as a contributor to antagonism between the various stakeholders involved in research.

*Quote:* Delays in study set-up and start of recruitment. Delay in transfer agreements which led to delay in transferring samples with potential loss of collaborators

**Good Clinical Practice (GCP)**

As GCP and its interpretation has been consistently reported to us as a major issue in research governance, specific questions about GCP were added to the survey. Figure 1 shows how often organisations require GCP training to be undertaken. Most organisations require GCP training to be undertaken every two years, although this varies considerably.
Respondents were asked which aspects of GCP they felt were most relevant to their role.

Although there was general agreement about the most relevant aspects, research managers placed more emphasis on the principles of GCP (86%), than researchers (73%). Team leaders were less inclined to consider maintaining trial documentation as a priority (47%) as either team members (63%) or research managers (62%). Respondents also felt that GCP training could be better matched to particular roles, and that once completed, GCP training *per se* becomes less relevant.

Quotes from respondents

“GCP training is relevant but not sufficiently tailored to different roles.”

“Updates to relevant regulations is more relevant to me than just rehearsing simple exercises about GCP principles.”
MRC Regulatory Support Centre

Approximately half of respondents (53%) had heard of MRC RSC. Most (87%) research managers had heard of us, compared to about a third of researchers.

People that have heard of MRC RSC

Two-thirds of people that had heard of the MRC RSC had asked for our help over the previous year. They were slightly more likely to ask for our help (65%), than ask the HRA (57%), but also relied heavily on their own organisation (74%). The majority of respondents found our services easy to find (82%), timely (84%), and good quality (87%). When asked about what further training was required 85% of people in this group highlighted data protection and confidentiality, followed by health data access (76%). This group preferred to get help and advice from websites (85%), although only two-thirds of researchers preferred this method.

People that have not heard of MRC RSC

This group’s main source of advice was also their own organisation (80%), with 42% consulting the HRA. When asked about what further training was required, access to health data was the main response (62%), followed by data protection and confidentiality (57%). Although this group access help and guidance from websites (58%), their preferred channel is directly via phone or email.
Figure 2: Which topics would you like to see more help with (all respondents)?

- Data protection and confidentiality: 70%
- How to collaborate with the NHS: 60%
- Running international research: 50%
- Research with tissue samples: 40%
- Medical Devices: 30%
- Involving the public in research: 20%
- Artificial Intelligence: 10%
- Social Media research: 5%
- Other (please specify): 3%
- Gene and cellular therapy research: 2%
- Good Manufacturing Practice: 2%
- In vitro diagnostics: 1%
- Xenotransplantation: 1%
- Embryology research: 1%
Planning Research
This section was optional and was completed by 291 people. No issues were reported for understanding local processes or when to start research projects. Arranging help from local support departments and services was rated as severe or moderate by 37% of the 291 respondents, followed by understanding governance requirements (34%). Difficulties in formalising research collaborations were reported as severe or moderate issues by 23% of people, particularly for researchers. When it came to providing further details, half the respondents chose to expand on understanding governance requirements.

Understanding requirements
116 people chose to tell us more about this. People sought help from a variety of organisations when trying to understand regulatory requirements as shown in Table 1. For researchers their local organisation was the primary place to seek advice, followed by the HRA. Research managers were more likely to seek advice from a range of organisations, with a preference to approach the HRA over their own organisations.
Table 1: In the last year which organisations did you get help from (answers with less than five responses excluded: N/A)

<table>
<thead>
<tr>
<th></th>
<th>Research Managers (n=46)</th>
<th>Researchers (n=70)</th>
</tr>
</thead>
<tbody>
<tr>
<td>My organisation</td>
<td>68%</td>
<td>80%</td>
</tr>
<tr>
<td>Health Research Authority</td>
<td>77%</td>
<td>25%</td>
</tr>
<tr>
<td>MRC RSC</td>
<td>61%</td>
<td>19%</td>
</tr>
<tr>
<td>NIHR</td>
<td>25%</td>
<td>20%</td>
</tr>
<tr>
<td>Human Tissue Authority</td>
<td>20%</td>
<td>N/A</td>
</tr>
<tr>
<td>MHRA (Medicines)</td>
<td>32%</td>
<td>13%</td>
</tr>
<tr>
<td>NHS R&amp;D Forum</td>
<td>20%</td>
<td>10%</td>
</tr>
<tr>
<td>eDRIS</td>
<td>N/A</td>
<td>12%</td>
</tr>
<tr>
<td>Medical Research Council</td>
<td>32%</td>
<td>5%</td>
</tr>
<tr>
<td>MHRA (Devices and IVDs)</td>
<td>15%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Only a minority of people reported serious issues with finding help. However, there was a lack of overall satisfaction with the length of time taken to obtain advice, but the quality of the advice received was generally good. Analysis of the free-text answers showed that when advice was perceived as sub-optimal the main issues were a lack of clarity, followed by guidance that was hard to understand. However, there are considerable differences between organisations as shown in Figures 3 - 6.
Figure 3: In the last year how easy was it to find help from?
(Answers with fewer than five responses excluded)

Blue: Easy or very easy
Orange: Neither
Purple: Difficult or very difficult

Figure 4: Over the last year, how satisfied were you with the length of time it took to get help?
(Answers with fewer than five responses excluded)

Blue: Satisfied or very Satisfied
Orange: Neither
Purple: Dissatisfied or Very dissatisfied
Figure 5: How satisfied were you with the quality of the help you received from?
(Answers with fewer than five responses excluded)

Within this group the predominant way people preferred to receive guidance was via the web or via phone / email. Attending face-to-face training was favoured by less than half. Overall, research managers wanted to get more advice than researchers.

Blue: Satisifed or very Satisifed
Orange: Neither
Purple: Dissatisfied or Very dissatisfied
Figure 6: How do you prefer to get help with understanding these requirements?

When asked about any other issues that adversely impacted understanding requirements the predominant responses focussed on guidance and approval / application systems continuously changing.

Quote from respondent
“Preparing REC submissions when systems seem to be frequently changing and R&D departments also changing procedures which are usually for the best, but help, support and guidance from them would save a lot of time frustration and delay”
Arranging help from local support departments and services

70 people chose to tell us more about this, with the biggest problem cited as lack of resource (46 / 70), reported as: people, time and money. Within this group there was little difference between the dissatisfaction reported by research managers and research team members. Additionally, over half of people reported a lack of enthusiasm from other departments and services; a similar figure to that reported for a lack of organisational support (33 / 70).

Formalising research collaborations

46 people chose to tell us more about this and the major concern was setting out arrangements for sharing / access to data (32 / 46). This was followed by determining legal responsibilities (23 / 46).

When asked to relay positives about planning for research there were several themes. Research governance was generally thought to be easier if the following were in place or could be arranged:

- Good relationships with clear communication
- Clearly defined protocols / roles that are followed
- Local support (sponsor R&D, CTUs)
- Use of templates (contracts, information sheets etc.)
Applying for Approvals

This section was optional and was completed by 231 people. In 2019, the top three approvals that respondents were involved in were:

- NHS REC
- Sponsorship
- NHS site approvals

When asked if there were any approval bodies whose approval was not anticipated, the Confidentiality Advisory Group and The Public Benefit and Privacy Panel featured most.
Figure 7: In the last year what approval processes were you involved with?
Half of respondents reported no real difficulties with applying for approvals, although there were more complaints from research managers. The two major issues reported by about a third of people as severe or moderate were:

1) Communicating with approval bodies and notification of approvals
2) Interactions between different approval bodies

Preparation and submission of paperwork was seen as less of an issue, although most people wanted to provide further information about this. Apart from these topics no other issues were raised.

**Preparation and submission of paperwork**

94 people chose to tell us more about this. When asked about assessment criteria most people thought that these were generally clear. Data access committees were seen as the opaquest in terms of assessment criteria, as well as NHS site approvals. There was a moderate to strong (0.73) correlation between how clear assessment criteria were (Figure 8) and satisfaction with the approval times (Figure 9).
Figure 8: Was it clear what assessment criteria the approval body based their decision on?

Blue: Clear or Very Clear
Orange: Not Clear or Not Clear at all
Figure 9: How satisfied were you with the length of time that it took to get approvals from?

Blue: Satisfied or very Satisfied
Orange: Neither
Purple: Dissatisfied or Very dissatisfied
Figure 10: How satisfied were you with your communications with the approval organisations?

Blue: Satisfied or very Satisfied
Orange: Neither
Purple: Dissatisfied or Very dissatisfied

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Satisfied/Very Satisfied</th>
<th>Neither</th>
<th>Dissatisfied/Very Dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsorship</td>
<td>29</td>
<td>24</td>
<td>21</td>
</tr>
<tr>
<td>MHRA (Medicines)</td>
<td>17</td>
<td>11</td>
<td>41</td>
</tr>
<tr>
<td>Other Research Ethics Committee</td>
<td>8</td>
<td>28</td>
<td>8</td>
</tr>
<tr>
<td>National Research Scotland</td>
<td>17</td>
<td>11</td>
<td>28</td>
</tr>
<tr>
<td>NHS Research Ethics Committee</td>
<td>25</td>
<td>21</td>
<td>41</td>
</tr>
<tr>
<td>HTA (Licence for Research Storage)</td>
<td>17</td>
<td>11</td>
<td>28</td>
</tr>
<tr>
<td>NHS Site approvals</td>
<td>25</td>
<td>21</td>
<td>41</td>
</tr>
<tr>
<td>HSC R&amp;D permission (Northern Ireland)</td>
<td>17</td>
<td>11</td>
<td>28</td>
</tr>
<tr>
<td>NHS Digital</td>
<td>25</td>
<td>21</td>
<td>41</td>
</tr>
<tr>
<td>HRA and Health Care Research Wales</td>
<td>17</td>
<td>11</td>
<td>28</td>
</tr>
</tbody>
</table>
For specific issues around the preparation and submission of paperwork about 50% of people had been asked to make repeated changes to submitted paperwork as shown in the table below.

Table 2: Did you encounter any of the following difficulties? (Always or sometimes)

<table>
<thead>
<tr>
<th>Difficulty</th>
<th>n=89</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asked to make repeated changes to submitted paperwork</td>
<td>49%</td>
</tr>
<tr>
<td>The application processes weren't clear</td>
<td>45%</td>
</tr>
<tr>
<td>Wasn't clear what paperwork to submit</td>
<td>44%</td>
</tr>
<tr>
<td>Not sure what approvals were required</td>
<td>40%</td>
</tr>
<tr>
<td>Asked to make contradictory changes by different approvers</td>
<td>40%</td>
</tr>
<tr>
<td>Difficulties in getting the right signatures / authorisations</td>
<td>30%</td>
</tr>
</tbody>
</table>

Quotes from respondents

“I find that the same information is being repeatedly requested in additional forms, schedules, organisational documents etc. It feels like each reviewing body is not reading the information in the main paperwork and is asking for the information they are interested in to be input into their specific form.”

“There are severe delays with NRS/NHS Site approvals.”

Communicating with approval bodies and notification of approvals

51 people chose to tell us more about this. Overall, the rate of dissatisfaction (not satisfied / not at all satisfied) was 12 / 51. Although this ranged from 0 - 30 / 51 between organisations. Issues reported under ‘other’ included sponsors reporting that they are not always copied into correspondence and multiple issues with site approvals, particularly when Scottish sites were involved.
Interactions between different approval bodies

49 people chose to tell us more about this. The three main problems reported were:

- Being asked to submit the same paperwork to several organisations (24 / 49)
- Differences between UK nations (19 / 49)
- Differences in approval times between organisations (17 / 49)

When asked to relate positives about applying for approvals there were several themes. Research governance was generally thought to be easier if the following were in place or could be achieved.

- Templates and checklists were developed and used.
- Experienced people were involved in the process.
- IRAS was mandatory for all application processes.
**Running Research**

This section was optional and was completed by 201 people. A wide range of issues were reported in this category. This report focuses on those issues reported by more than 10% of people. Most people wanted to provide more details about making sure all approvals were in place and knowing when to start research.

Figure 11: When running research projects did you have severe / moderate difficulties with the following?

![Bar chart showing difficulties in running research projects]

- Making sure all approvals were in place and knowing when to start: 58 people (100%)
- Recruiting participants: 52 people (90.7%)
- Making changes to the project paperwork: 43 people (76.6%)
- Bringing new collaborators/sites on board: 40 people (69.0%)
- Obtaining data/tissue: 34 people (59.3%)
- Getting appropriate training: 21 people (36.2%)
- Overseeing the research: 18 people (30.9%)
- Submitting reports: 17 people (29.3%)

*Quote from respondent*

“The majority of my time as a researcher is spent wrangling reports and approvals for regulatory bodies. This is immensely frustrating, and had I known, I would have tried to employ a full-time person to do it; however, this is often frowned on.”
Making sure all approvals were in place and knowing when to start
51 people chose to tell us more about this. Managing local approvals and local arrangements were the biggest problems here (31 / 51), followed by confusion about knowing what approvals were required to start research projects (27 / 51).

Recruiting participants
34 people chose to tell us more about this. The primary issue with recruitment was unwillingness of potential participants (13 / 34) and a lack of staff dedicated to participant recruitment (13 / 34).

Sharing data / tissue
27 people chose to tell us more about this. The vast majority of people (22 / 27) reported delays in negotiating agreements / contracts, followed by difficulties in determining what legal frameworks applied (16 / 27).

Making changes to the project paperwork
20 people chose to tell us more about this. Three-quarters of people in this group reported that the process took longer than expected. There were also difficulties in clarity, both in terms of whether amendments required approval (9 / 20) and what the process was for approval (7 / 20).

Bringing new collaborators / sites on board
20 people chose to tell us more about this. Nearly everyone in this group reported delays in negotiating contracts / agreements (17/20) and there was a general feeling (14/20) that the process took longer than anticipated.
When asked to relate positives about running research there were several themes. Research governance was generally thought to be easier if the following were in place or could be arranged.

- Support and experienced colleagues are available.
- SOPs were consistently used.
- Clarity around the different roles of people and organisations.
Finishing Research

This section was optional and was completed by 195 people. A wide range of issues were reported in this category. This report focuses on those issues reported by more than 10% of people. Most people wanted to provide further details about sharing data / tissue (26%). For all categories there was a general higher level of dissatisfaction from research managers.

Figure 12: Finishing research issues

<table>
<thead>
<tr>
<th>Issue</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharing data / tissue</td>
<td>23</td>
</tr>
<tr>
<td>Archiving data / tissue</td>
<td>23</td>
</tr>
<tr>
<td>Long term follow-up</td>
<td>22</td>
</tr>
<tr>
<td>Knowing what constitutes the end of the study</td>
<td>18</td>
</tr>
<tr>
<td>NTS / ASC adoption</td>
<td>17</td>
</tr>
<tr>
<td>Closing the database</td>
<td>9</td>
</tr>
<tr>
<td>Disseminating findings</td>
<td>8</td>
</tr>
<tr>
<td>Commercialisation</td>
<td></td>
</tr>
</tbody>
</table>

Quotes from respondents

“Different understanding depending on what is involved. e.g. statistician doesn’t want everything archived until report is published, sites want to close much earlier.”

“Once a study has completed recruitment and analysed data, there are no resources left to close sites, archive, submit final reports etc as usually no funding left and new recruiting studies take precedence for allocation of resources.”
Knowing what constitutes the end of the study

54 people chose to tell us more about this. Although the largest response here was ‘other’, the two main themes can be summarised as inadequate definition of end of study (16 / 54) or different definitions from different regulators (12 / 54).

Sharing data / tissue

38 people chose to tell us more about this. Approximately half of respondents in this group said that sharing data or tissue was an issue as they were not sure whether the consent allowed sharing. Difficulties were also reported with obtaining data / tissue sharing agreements (14 / 38) and with the logistics of sharing (10 / 38).

Archiving data / tissue

23 people chose to tell us more about this. Archiving was deemed difficult due to lack of adequate funding (13 / 23) and because of difficulties in determining what should be archived (9 / 23).

Long-term follow-up

18 people chose to tell us more about this. Long-term follow-up was seen as problematic due to a lack of resource for around half of respondents. Other issues related to lack of clarity about the approvals required (7 / 18), what the protocol allowed and whether consent was in place for long-term follow-up (7 / 18).
When asked to relate positives about finishing research there were several themes. Research governance was generally thought to be easier if the following were in place or could be achieved.

- The end of study was clearly defined in the protocol.
- Working with experienced people.
- SOPs were consistently used.
Discussion

The survey generated a healthy number of responses from an audience that were primarily academic. An approximate even split between research managers and researchers (and a general homogeneity of responses of team members and team leaders) allowed useful comparisons to be made. MRC RSC’s audience is primarily research managers, so it is encouraging to see that we reached a considerable number of researchers who had not previously heard of us, indicating that the survey had reached audiences that we do not normally communicate with. It is also encouraging to see that the overall assessment of research governance difficulties was placed at 6.5 / 10, with little deviation from this for individual responses. Some of the individual comments highlight the implications of these issues beyond individual research projects e.g. loss of funding, reduced inclination to undertake research.

The results from the GCP training questions show how differently organisations interpret GCP requirements, with most organisations insisting on training every two years. However, the MHRA and HRA are clear that there is no legal obligation for non-CTIMPs to follow full ICH-GCP and that CTIMPs have to follow the high-level ‘conditions and principles’ of GCP. Both regulators advocate a proportionate approach to GCP training and don’t specify a training schedule but are clear that training must be appropriate to each individual’s tasks. The survey responses suggest that GCP training is not necessarily tailored to individual roles, nor is it necessarily being applied appropriately once it has been undertaken.

These results suggest the balance needs to shift to more nuanced application of GCP training. An important step here is to engage with research organisations to understand why this hasn’t already happened and see whether these findings can be taken forward in the Wellcome GCP Collaborative and key organisations that provide GCP training e.g. NIHR.

MRC RSC received a largely favourable response in the survey. This is perhaps to be expected as our primary audience is research managers, sponsors in particular, and we are a unit dedicated to research governance. However, it is notable that even though we have recently focused on producing guidance about data protection / confidentiality, and access to health data, even people that use our service, list those as two topics that they would like to see more of. Determining whether this pertains to clearer guidance or new guidance on areas not already covered is an immediate aim for us.
Applying for research approvals

Arranging local support was cited as the biggest issue faced when applying for research approvals, yet most people chose to provide more detail about understanding governance requirements. Analysing this revealed that only 20% of research managers think understanding requirements is an issue, but 63% of them preferred to provide more details about this. For researchers this was a closer to parity at 35% versus 48%.

It appears that although everyone understands their local processes, they find it difficult to obtain the support they need. Local support services cover a range of potential interactions e.g. sponsorship office, legal, contracts/agreements, statisticians, pharmacy, etc. A common theme seems to be lack of organisational resource put into these support functions, reported from both within the service itself and its researcher ‘customers’. A lack of service staff enthusiasm reported by some, may be a symptom of inadequate resource.

When trying to understand governance requirements there was a clear difference between researchers (approaching their own organisation) and research managers (more likely to approach the HRA than their own organisation). This perhaps reflects their different roles (service user versus service support) and highlights the need to tailor advice to appropriate audiences.

Satisfaction (ease of finding, speed, quality) with advice provided varied considerably between organisations. Dissatisfaction centred on a lack of clear and easy to understand guidance. Generally, people preferred to receive guidance directly from the web or via phone/email. Attending face-to-face training was favoured by less than half. There is clearly a need for clear, understandable, readily accessible guidance about requirements.

Although preparation and submission of paperwork was seen as the least pressing issue when applying for approvals, most people wanted to talk about it and particularly about the lack of clarity around assessment criteria from national data access committees. Additionally, CAG and PBPP were the only approvals that were not anticipated, which perhaps ties in with more need to understand data/information law (in particular common law of confidentiality). Since people were more satisfied with approval bodies that were transparent about how they assess applications, some approval bodies may wish to look at how they describe how assessments are made, if they describe this at all. This may link into the need for repeated changes to submission of paperwork. How can researchers compile ‘good’ applications if they don’t know what good looks like?
Lack of clarity around what paperwork to submit, lack of sponsor notifications, submitting the same paperwork to multiple bodies, repeated changes which are sometimes contradictory and differences between the 4 UK nations all seem to stem from poor communication and coordination. This echoes what we’ve found about lack of transparency of decision making and suggests that there are gains to be made if bodies communicate better with all parts of the system.

Joined-up decision making would also help. Approvals bodies could take better account of other’s approvals and reduce duplication. For health data access, this may well be addressed by the development of the HDRUK Research Innovation Gateway. Issues with site approvals can be explained by delays to assessing capacity to deliver research in an already stretched care environment.

**Running research**

The findings about governance issues when running research back up what we’ve already found about local approvals and service provision being under resourced, and the need for an improvement in communications. We also see contract / legal departments being identified as an issue.

Over the last 20 years the need for research agreements and contracts have increased drastically, and lack in resource in these departments can significantly delay research. HRA has worked with stakeholders to develop model trial agreements for sponsors and sites, among other partnerships. The utility of these was not specifically unpicked in this survey.

Looking at research use of tissue samples and data, legal frameworks have meant an increased need for sharing agreements. Tissue licensing standards require traceability of samples which is often aided by Material Transfer Agreements, which dictate what recipients can use samples for, conveying consent and REC approval terms. Data sharing agreements are a common way to manage liabilities around individual level data, stipulating conditions on storage, access, use, etc. They can also help render pseudonymised data as functionally anonymised. Universities need well-resourced contract services with a clear understanding of the practicalities of health research to deliver collaborative research efficiently. A broad risk proportionate view is also helpful, balancing the reputational risks related to universities not doing research in a timely fashion, with any corporate risks of non-compliance.
Another potential solution is increased use of Trusted Research Environments (TREs) whereby data is not disseminated to researchers, but researchers are provided with access to data within a controlled environment. Whilst not negating the need for contracts / agreements, the nature of TREs means that relatively simple, standardised contracts can be utilised. As with all these things there may be trade-offs (need for advanced planning, potential loss of researcher spontaneity and creativity), although ensuring research utility is high on the TRE agenda. The TRE benefits of a more coordinated system with reduced bureaucracy and maintained patient privacy will be huge.

**Completing research**

The results from the completing research section of the survey, around not knowing whether consent allows sharing, backs up what we have found about greater need for guidance and training on tissue and data laws (in particular how consent exemptions can be used and / or when laws no longer apply). Confusion in this area could be greatly reduced with regulator guidance about anonymisation, so we have a clear picture when data protection no longer applies. The subtleties about how this dovetails with the anonymisation of confidential information needs to be discussed and agreed by others (National Data Guardian, CAG, etc.)

Increased communications about the funding of data preservation and sharing appears to be needed so universities know that funders will contribute to these costs. Researchers also need appropriate local support to plan for archiving costs up front, to cost these into their funding applications and promote the importance of the data management plan. More information is available on the [MRC website](https://www.mrc.ac.uk).