onCore UK

www.oncoreuk.org

The Effect of Regulation and Governance on Research Led by Pathologists or Involving Pathology in the UK

A Report of the Survey conducted by onCore UK, in collaboration with the Pathological Society, in response to the National Cancer Research Institute's Task Force on Pathology and Research

Dr BJ Clark
Chief Executive Officer, onCore UK and Consultant Pathologist

A Registered Company Limited by Guarantee in England and Wales No. 05370380.
A Registered Charity in England and Wales No. 1111606.

A charity funded by:

MRC Medical Research Council

DH Department of Health

CANCER RESEARCH UK

Table of Contents

Foreword

We are pleased to introduce this report, which was stimulated by the work of the National Cancer Research Institute's Task Force on Pathology and Research. This survey conducted by onCore UK, with the assistance of several other organisations, provides direct evidence that there are problems with the current provision of guidance relating to the regulation and governance of biomedical research. As a result, some healthcare workers and potential researchers are put off participating in or assisting with research. In the context of this report this particularly applies to pathologists, which as a consequence diminishes the effectiveness of the research conducted in many cases.

We believe this report leads to clear recommendations on how appropriate guidance on regulatory and governance matters can be obtained. Recommendations, however, are only effective if accompanied by appropriate actions to address existing problems. We are, therefore, particularly pleased to introduce the following announcement by the Medical Research Council (MRC) in response to the evidence and arguments contained in this report. In particular, onCore UK looks forward to assisting the MRC and its partners to revise and relaunch its Data and Tissues Toolkit in support of the research community using human tissues and especially pathologists working in academic and NHS departments.

Dr Brian J Clark
Chief Executive Officer
onCore UK

Professor Colin C Bird CBE
Chairman
onCore UK

Response from the Medical Research Council (MRC)

The Effect of Regulation and Governance on Research Led by Pathologists or Involving Pathology in the UK - A Report of the Survey conducted by onCore UK, in collaboration with the Pathological Society, in response to the National Cancer Research Institute's Task Force on Pathology and Research

The MRC supports the need for appropriate, risk-based regulation of research. At the MRC/Wellcome Trust workshop held in May 2008[1] , there was a consensus that research regulation is necessary, yet complex, with the need for clarity and simplification. The MRC has established a strong reputation in providing clarity and guidance in this field, and the MRC is committed to 'uphold and guide ethical research practice and the highest standards of research governance; to enhance the regulatory process by providing innovative approaches' [2].

In 2006, the MRC established the Regulatory Support Centre (RSC) to provide support and guidance for those conducting research with human participants, their tissues or data. The RSC does this by providing web-based Tool Kits and services such as Training, and by joint delivery of the UKCRC Regulatory & Governance Advice Service[3].

The MRC recognises the importance of pathology in medical research and was a participant in the Task Force that developed this survey; we support the recommendations made.
Below, the MRC sets out its previous work and actions for the future in response to these recommendations.

Recommendation 1 – Guidance should be consolidated into an accessible, authoritative and consistent multi-regulator endorsed resource. This will require relevant regulators to be willing and able to cooperate with the production of such a resource. The MRC Regulatory Support Centre has developed Tool Kits to consolidate available guidance and regulations. It is recognised that such Tool Kits have increased authority and confidence when developed with the endorsement or support of relevant regulators.

Recommendation 2 – A consolidated guidance resource should be made freely available to researchers from a restricted number of well-publicised points of access, principally via a single web portal, the use of which can be supported by the network of NHS Research and Development Offices. Direct and specific guidance should continue to be provided by the applicable regulators, many of whom have statutory requirements to provide guidance. Some provision should also be made for academics via a body such as a university research governance advisory service. These sources of the consolidated guidance resource can then be relied upon by researchers without the need to consider alternative sources.

Recommendation 3 – A consolidated guidance resource should clearly provide and distinguish minimum requirements for regulatory compliance and best practice standards and expectations where applicable.

The MRC is committed to the production of consolidated guidance as evidenced by the launch in 2007 of the Data and Tissues Tool Kit[4] , which was developed by the MRC Regulatory Support Centre. The Tool Kit is a freely available web site, which was developed in consultation with the relevant regulatory bodies, including the:

- Human Tissue Authority
- Scottish Government (then Scottish Executive)
- Department of Health, England
- NHS R&D Forum
- INVOLVE
- Information Commissioner's Office
- National Research Ethics Service
- MRC research units.

The Data and Tissues Tool Kit leads users through the regulatory and governance requirements of using human tissues or personal data in medical research in a step-wise fashion, through the life of a research project, via the use of route maps. 'Stations' are used along the routes to denote steps in the process, such as developing a protocol or obtaining NHS R&D permission, and once 'clicked' upon reveal explanatory text and a list of relevant resources, such as links to web-based application forms or authoritative guidance documents. In addition, individual stations and associated resources

are colour-coded to distinguish between legal requirements, good practice, or standard process.
Material disseminated via this Tool Kit was developed in consultation with the relevant regulatory bodies. For example, the 'MRC Human Tissue Research Summaries' summarise the research-relevant aspects of the UK Human Tissue legislation[5] , and were developed in consultation with the Human Tissue Authority and the Scottish Government (then Scottish Executive).

As such, the Data and Tissues Tool Kit is well placed to meet fully the recommendations of this Report. Future work between the MRC, relevant regulatory, governance and professional bodies, and onCore UK will serve to enhance the Tool Kit in line with the recommendations. The following work is planned by the MRC RSC and partners:

- Develop a user group with representation from communities such as researchers, pathologists, and relevant regulatory and governance bodies to identify and fill any gaps in the Tool Kit's guidance, in particular ensuring links are made to relevant guidance produced by authoritative sources, rather than through the development of new material.
- Work with the relevant regulators, governance, policy-making and professional bodies to publicly support and promote the Tool Kit and its contents as an authoritative resource.
- Explore opportunities to work with NHS R&D Forum and others to promote the Tool Kit as an expert source of advice for staff in NHS R&D Offices throughout the UK who have a key role in advising many researchers on relevant requirements.
- The MRC Regulatory Support Centre, via its joint delivery with NIHR Clinical Research Network Coordinating Centre of the UKCRC Regulatory and Governance Advice Service, will continue to support local advice providers in the NHS and in the university sector in handling tissues and data related queries. The Advice Service provides answers to specific queries and web-based resources using information from authoritative guidance and in conjunction with applicable regulators or governance/policy-making bodies, in order to enhance the quality and consistency of local advice that is given to researchers.

The MRC looks forward to working with its partners in enhancing, supporting and promoting the Data and Tissues Tool Kit as an authoritative form of guidance for use by all in the UK research community.

Sarah Dickson/Catherine Elliot
27 July 2009

[1] MRC/Wellcome Trust workshop: Regulation and biomedical research, May 2008 (www.mrc.ac.uk/Newspublications/News/MRC005615)
[2] Research Changes Lives, MRC Strategic Plan 2009-2014 (www.mrc.ac.uk/Newspublications/Publications/Strategicplan/index.htm)
[3] www.ukcrc-rgadvice.org
[4] www.dt-toolkit.ac.uk
[5] Human Tissue Act, 2004; and Human Tissue (Scotland) Act, 2006

1. Executive Summary

1.1 The National Cancer Research Institute (NCRI) formed a Task Force to examine and report on the role of pathology in cancer research.

1.2 The Task Force heard reports that the regulatory and governance environment is affecting the willingness and ability of pathologists to lead research or contribute to research.

1.3 onCore UK conducted a cross sectional survey specifically to: gauge the diversity, utility and availability of guidance that purports to assist researchers navigate the regulatory and governance environment; and gather direct evidence from pathologists and other cancer researchers such that an assessment of the overall opinion of the regulatory and governance environment could be made and the opinions of pathologists could be compared to other professional groups.

1.4 This survey was conducted as a participant-completed questionnaire study over a 2 week period in February 2009.

1.5 The questionnaire was distributed by email and posted on the website of several bodies, from where it could be downloaded. There were no inclusion or exclusion criteria for individuals wishing to participate.

1.6 The subgroups investigated included: those working in pathology laboratories (consultant pathologists, trainee pathologists, clinical scientists in pathology and biomedical scientists); those who are currently active in *human tissue or biological sample research*; those whose professional setting was a combined NHS and academic setting in comparison to those working wholly in the NHS or those working wholly in an academic role.

1.7 A total of 242 individuals participated in the survey. Of these 73% described themselves as active in research using human tissue or biological samples, 61% of respondents were involved with pathology and approximately equal numbers of respondents described themselves as being active in NHS service as being academics.

1.8 Current biomedical research extends across areas overseen by a wide variety of regulatory and governance bodies. Most researchers perceive several regulators as concurrently applicable to their work, with an average of 5 bodies being applicable to the work of each respondent (range 1 to 11 out of the 11 regulators offered).

1.9 Presumably because most of the respondents conduct some form of human subject based research, whether using human tissues / biological samples or not, most (93%) considered NHS Research Ethics Committees as regulators of their research.

1.10 Eighty three percent considered the governance role of NHS Research and Development approvals as being appropriate to their work.

1.11 Eighty six percent considered the Human Tissue Authority as applicable to their work. Notably, 79% of those described as not active in human tissue based research still considered the Human Tissue Authority applicable to their work. Only 46% considered the Health and Safety Executive as appropriate for their work and this view was consistent across all subgroups examined.

1.12 Only 23% thought that the National Information Governance Board, and 12% the Office of the Information Commissioner, applicable to their work and 10% admitted that they were not entirely clear which regulators were important to their work.

1.13 Seventy eight percent assessed the environment as either strict or very strict, with only 19% considering it about right. Respondents who were not pathologists had an overall assessment that was better than respondents as a whole, whereas pathologists had a worse overall impression.

1.14 Overall, 92% considered the complexity of the regulatory and governance environment for pathology research as either complex or very complex. More of those who were pathologists found it complex or very complex (96%). Complexity was also assessed higher by those with combined NHS and academic roles or purely NHS roles, whereas fewer of those with purely academic roles found the environment very complex.

1.15 More than half of the respondents (60%) find doing research difficult because of access to appropriate guidance. Thirteen percent don't do research as a consequence of this difficulty.

1.16 Pathologists are less likely to be happy to do research (15%) than non-pathologists (32%) and are also more frequently put off research by not knowing where to start or not bothering at all (19%) than non-pathologists (3%).

1.17 In terms of accessibility of guidance on regulation and governance of research, 76% of all respondents thought that it is "accessible but requires some work to find" it or is frankly "difficult to find". Those who are active in tissue based research reported that appropriate guidance either took some work to find or was difficult to find (81%) compared to those who are not active in human tissue based research (63%). Those with combined NHS and academic roles found accessibility more work or difficult to find (95%) in comparison to the other groups or the overall group of all respondents.

1.18 Seventy percent of respondents reported that the provision of guidance by different sources can be confusing and unhelpful (47%) or time wasting as they assess the guidance from more than one source (23%). This was increased to 89% of respondents with combined NHS and academic roles.

1.19 Most respondents reported using a number of sources for guidance on research regulation and governance with the average number of currently used sources being 3 (range 0-8), with all respondents and all subgroups of respondents consistently wishing to use fewer sources (average 1.6, range 0-7).

1.20 By far the most popular *current* sources of guidance are directly from the applicable regulators (20% of responses), from local NHS Research and Development Offices (22% of responses) and from trusted contacts and colleagues (24% of responses). This pattern changes very little for the *preferred* sources of guidance, except that fewer respondents would prefer to rely on trusted colleagues and contacts (15% of responses) and slightly more would prefer to use august professional bodies. The only notable differences from the overall trend is that respondents with solely NHS roles have a higher current (27% of responses) and future preference (31% of responses) for the use of NHS Research and Development Offices whereas those with purely academic roles have a preference (14% of responses) to reduce their use of such offices compared to the current situation (17% of responses).

1.21 Eighty three percent of respondents said that they would be more likely to be (more) research active if there was an easily accessible source of consolidated guidance endorsed by all regulators.

"Eighty three percent of respondents said that they would be more likely to be (more) research active if there was an easily accessible source of consolidated guidance endorsed by all regulators."

1.22 The nature of the guidance preferred was clear with 75% of respondents stating that they would like to see guidance that included, but distinguished between, best practice and minimum standards for regulatory compliance.

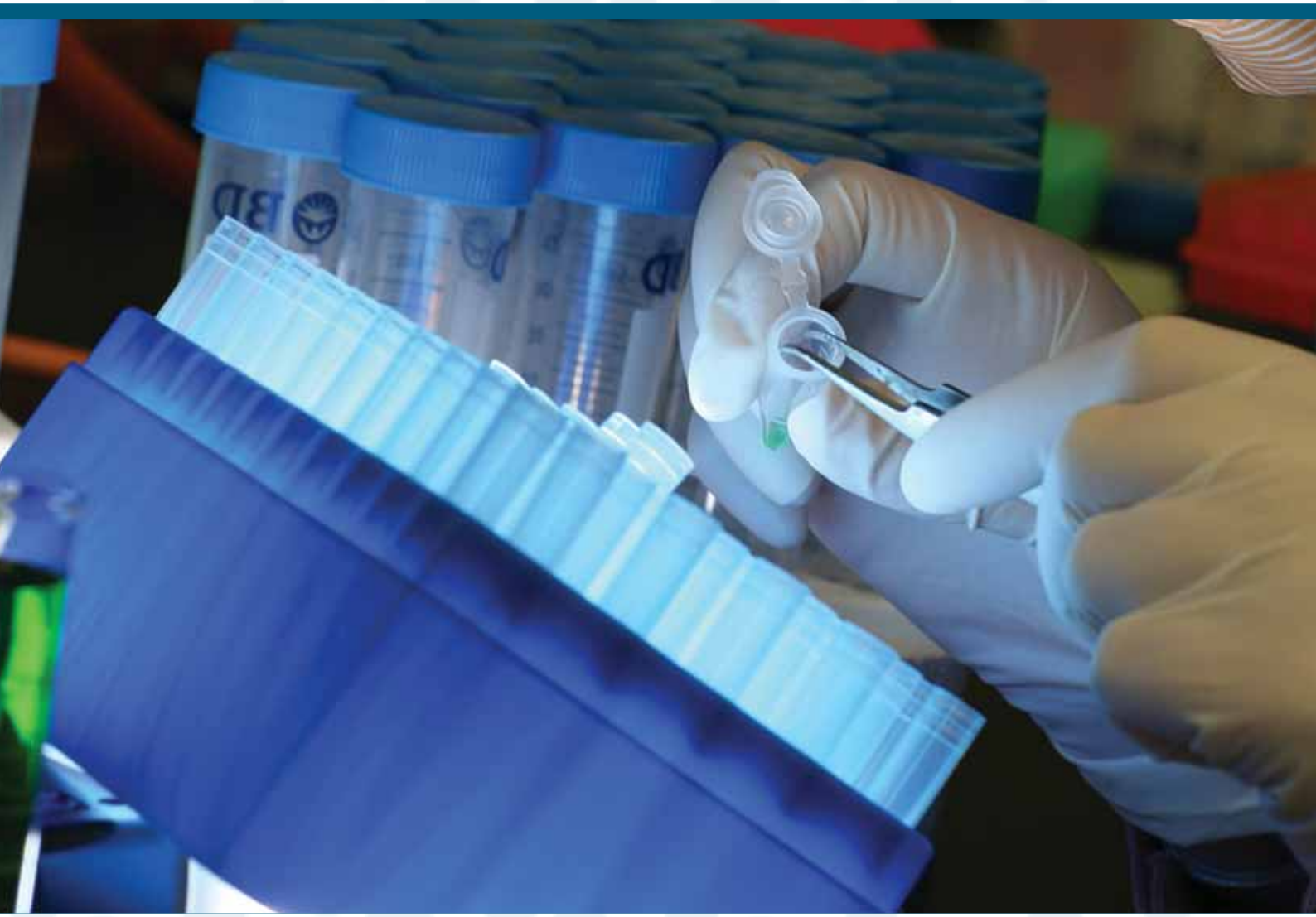
1.23 The provision of guidance is the best means of explaining the complex and strict regulatory and governance environment and enabling researchers to do their work in compliance with regulatory requirements. However, currently available guidance can be confusing, unhelpful and can lead researchers to waste time. Most respondents to this survey currently seek guidance from multiple distinct sources and would prefer to reduce this necessity. It is also perceived as being provided by enough or too many bodies.

1.24 Three recommendations extend from the observations made in this survey:

1.24.1 Recommendation 1 – Guidance should be consolidated into an accessible, authoritative and consistent multi-regulator endorsed resource. This will require relevant regulators to be willing and free to cooperate on the production of such a resource. The MRC Regulatory Support Centre has developed Tool Kits to consolidate available guidance and regulations. It is recognised that such Tool Kits have increased authority and confidence when developed with the endorsement or support of relevant regulators.

1.24.2 Recommendation 2 – A consolidated guidance resource should be made freely available to researchers from a restricted number of well publicised points of access, principally via a single web portal, the use of which can be supported by the network of NHS Research and Development Offices. Direct and specific guidance should continue to be provided by the applicable regulators, many of whom have statutory requirements to provide guidance. Some provision should also be made for academics via a body such as a university research governance advisory service. These sources of the consolidated guidance resource can then be relied upon by researchers without the need to check alternative sources.

1.24.3 Recommendation 3 – A consolidated guidance resource should clearly provide and distinguish minimum requirements for regulatory compliance and best practice standards and expectations where applicable.



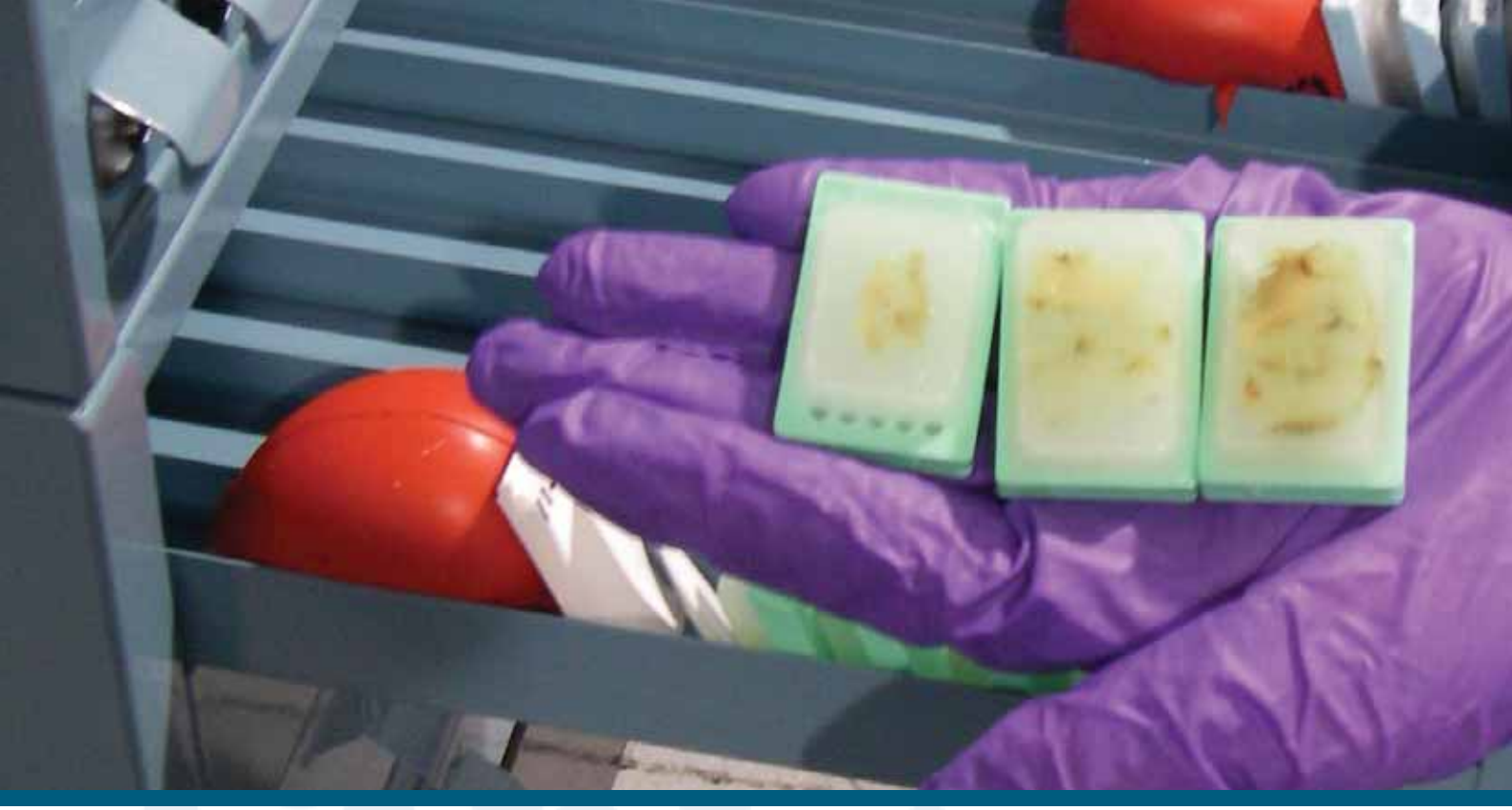
2. Introduction

The National Cancer Research Institute (NCRI)[1], in response to concerns raised from the cancer research community in the UK, formed a time limited and scope restricted Task Force to examine and report on the role of pathology in cancer research. Whilst the remit of this Task Force was predominately focused on cancer research, it was realised that the issues identified and recommendations or actions made were likely to be relevant to wider areas of biomedical research in the UK.

During the course of its work, the Task Force heard reports that the regulatory and governance environment relating to:

- the involvement of NHS patients in research;
- the use of human biological samples in research;
- the use of personal and health information in research; and,
- the need to gain NHS Research & Development office and Research Ethics Committee approvals

are affecting the willingness and ability of pathologists to lead research or contribute to research.
These reports were frequent but anecdotal and there was no firm evidence base on which the Task Force could rely to substantiate its conclusions and recommendations. To gain quantitative evidence, onCore UK[2], working in conjunction with the Pathological Society[3], conducted a survey that was stimulated by the work of the NCRI Task Force. This survey aimed specifically to gauge the diversity, utility and availability of guidance that purports to assist researchers navigate the regulatory and governance environment. It was also designed to gather direct evidence from pathologists and other cancer researchers such that an assessment of the overall opinion of the regulatory and governance environment could be made and the opinions of pathologists could be compared to other professional groups.



3. Methodology

This cross sectional survey was conducted as a participant-completed questionnaire study. The questionnaire consisted of 9 groups of questions totalling 16 questions. Most questions required categorical answers to be selected from predefined lists, although in many places the options of selecting "other" and providing a free text entry or providing free text comments were also offered. A copy of the questionnaire is included in Appendix 1.

Responses were welcomed over a 2 week period in February 2009. The survey was announced as open to responses and widely disseminated via a variety of routes using various UK bodies. These included the Royal College of Pathologists[5], the National Cancer Research Institute[1], the Pathological Society[3], the National Cancer Research Network[6], the Experimental Cancer Medicine Centre Network[7] and onCore UK[2]. In some cases, these bodies distributed the call for participation to further subgroups who, in turn, then forwarded the information on to other bodies for onward dissemination. The survey questionnaire was distributed by email and was also posted on the website of several bodies, from where it could be downloaded. There were no inclusion or exclusion criteria for individuals wishing to participate.

Responses were returned as paper copies of completed questionnaires or, more commonly, as electronic responses emailed to a central address.

Results were analysed by manual transfer of responses into a custom designed Microsoft Excel workbook for further data handling. Responses are reported as absolute number of responses, as percentages of the overall number of respondents or as percentages of subgroups of respondents. Two questions, related to the current and preferred use of sources of regulatory and governance guidance, generated multiple responses from most participants. For ease of comparison, these responses are reported as percentages of responses rather than percentages of respondents.

The subgroups investigated included:

- those working in pathology laboratories (consultant pathologists, trainee pathologists, clinical scientists in pathology and biomedical scientists), referred to in this report as "Pathologists" in comparison to all other respondents, referred to as "Non-pathologists";
- those who are currently active in *human tissue or biological sample research* ("tissue research active") in comparison to those who are not ("not active in tissue research");
- those whose professional setting was a combined NHS and academic setting ("NHS and academic") in comparison to those working wholly in the NHS ("NHS") or those working wholly in an academic role ("Academics"). Some respondents did not identify their work environment as either of these and this subgroup is compared with the others under the title of "Not stated".

The results in this report are presented as descriptions of observations and summaries (frequencies of responses, relative proportions, etc). No attempt has been made in this report to test any hypotheses or assess statistical significance of differences observed between any groups.

4. Results

4.1 Overview of the Respondents

A total of 242 individuals participated in the survey. Of these 177 (73%) described themselves as active in research using human tissue or biological samples.

Table 1 shows the professional groupings and predominant work settings of the individuals who responded.

Table 1 – Professional Groupings and Work Settings of Respondents

Consultant Pathologist	Trainee Pathologist	Clinical Scientist in Pathology	Biomedical Scientist	Scientific Researcher	Research Nurse	Tissue / Biobanker	Data Manager	Clinical Trialist	Other	NHS Service	Academic
112 (46%)	11 (5%)	16 (7%)	9 (4%)	59 (24%)	4 (2%)	44 (18%)	5 (2%)	58 (24%)	30 (12%)	98 (41%)	103 (43%)

[a]The percentages relate to the percentage of all respondents and the total exceeds 100% as many respondents categorised themselves in more than one group.

In the context of this report, it is noteworthy that 61% of respondents were involved with pathology, as consultants, clinical scientists, biomedical scientists or in-training. Research nurses and data managers were relatively under represented. Thirty individuals (12%) described themselves as "other".

Approximately equal numbers of respondents described themselves as being active in NHS service as being academics. Expressed as a percentage of all respondents, 18% (n=44) described themselves as having both NHS and academic roles, 23% (n=55) as wholly NHS, and 24% (n=59) as wholly academic. Eighty four (35%) respondents did not specify either working environment.

4.2 The Regulators Applicable to the Work of the Respondents

A wide variety of regulatory bodies or other governance related organisations were reported as applicable to the work of the respondents. These are shown in detail in Table A in Appendix 2.

Presumably because most of the respondents conduct some form of human subject based research, whether using human tissues / biological samples or not, most (n=224, 93%) considered NHS Research Ethics Committees[8] as important. Perhaps related to the fact that 24% (n=59) of respondents classified themselves as entirely academic, a smaller number (n=202, 83%) considered the governance role of NHS Research and Development approvals[9] as being appropriate to their work.

Whilst only 73% described themselves as active in research using human tissue or human biological samples, such research seemed to be more widely important to the respondents of this survey, perhaps reflecting in part the large number who were pathologists, as 86% (n=207) considered the Human Tissue Authority[10] as applicable to their work. Notably, 79% (n=50) of those described as not active in human tissue based research still considered the Human Tissue Authority applicable to their work. Again surprisingly given the prominence of the Human Tissue Authority, and hence the potential bio-hazardous work with human biological samples, only 46% (n=111) considered the Health and Safety Executive[11] as appropriate for their work and this view was consistent across all subgroups examined.

Only 23% (n=56) thought that the National Information Governance Board[12], and 12% (n=29) the Office of the Information Commissioner[13], applicable to their work. Non-Pathologists (31%, n=30) and those with a combined NHS and Academic role (34%, n=15) considered the National Information Governance Board more applicable to their work whereas pathologists (18%, n=26) and those with purely NHS roles (16%, n=9) considered it less so. Both pathologists (51%, n= 74) and those with combined NHS and academic roles (59%, n=26) considered the General Medical Council[14] applicable, perhaps reflecting the likelihood that both groups had more medically qualified respondents.

The respondents frequently considered more than one regulator as important, with an average of more than 5 bodies being applicable to the work of each respondent (range 1 to 11 out of the 11 regulators offered). Table 2 summarises the average number of regulators applicable to each group of respondents analysed.

Table 2 – Average Number of Regulators Considered Applicable to the Work of Respondents

Group of Respondents	All	Tissue Research Active	Tissue Research Inactive	Pathologist	Non Pathologist	Both NHS and Academic	NHS	Academic	Not stated
Average Number of Applicable Regulators	5	5	4	4	5	5	4	5	4

Ten percent of respondents (n=24) admitted that they were not entirely clear which regulators were important to their work – these did not clearl represent any particular subgroup of respondents.

4.3 The Overall Regulatory and Governance Environment

In this section, respondents were asked for their assessment of the overall regulatory and governance environment for pathology research. Figures 1 and 2 show the responses in graphical form.

Seventy eight percent (n= 188) assessed the environment as either strict (43%, n=103) or very strict (35%, n=85), with only 19% (n= 45) considerin it about right. As illustrated in Figure 1, respondents who were not pathologists had an overall assessment that was better than respondents as a whole whereas pathologists had a worse overall impression.

Those who had a combined NHS and Academic role also considered the environment more strict (n=20, 45%), or very strict (n=21, 48%) with fewe considering it about right (n=3, 7%). Those with purely academic roles considered the environment similarly to the whole group, whereas those wit purely NHS roles were more similar to those with combined roles. There were no real differences in assessment by the groups that were active i human tissue based research and those that were not. (Data not shown)

Only 7% (n=16) considered the regulatory and governance environment for pathology research as straight forward, with most considering it either

complex (51%, n=124) or very complex (41%, n=100). Fewer of those who were not tissue research active (n=22, 35%) or were not pathologists (n=25, 26%) found the environment very complex whereas more of those who were pathologists found it very complex (n=75, 51%). Complexity was also assessed higher by those with combined NHS and academic roles (n=26, 59% as very complex), a pattern repeated for those with purely NHS roles (n=29, 53% as very complex) whereas fewer of those with purely academic roles found the environment very complex (n=21, 36%).

Figure 1 – Respondents' assessment of the overall regulatory and governance environment for pathology research

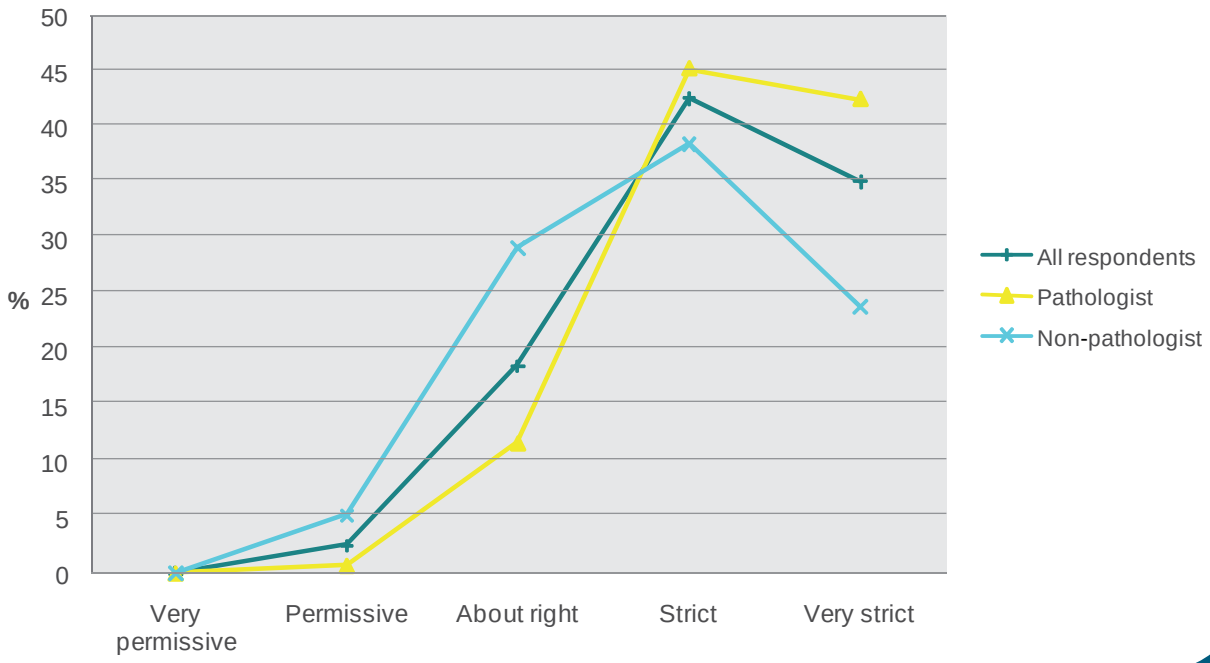
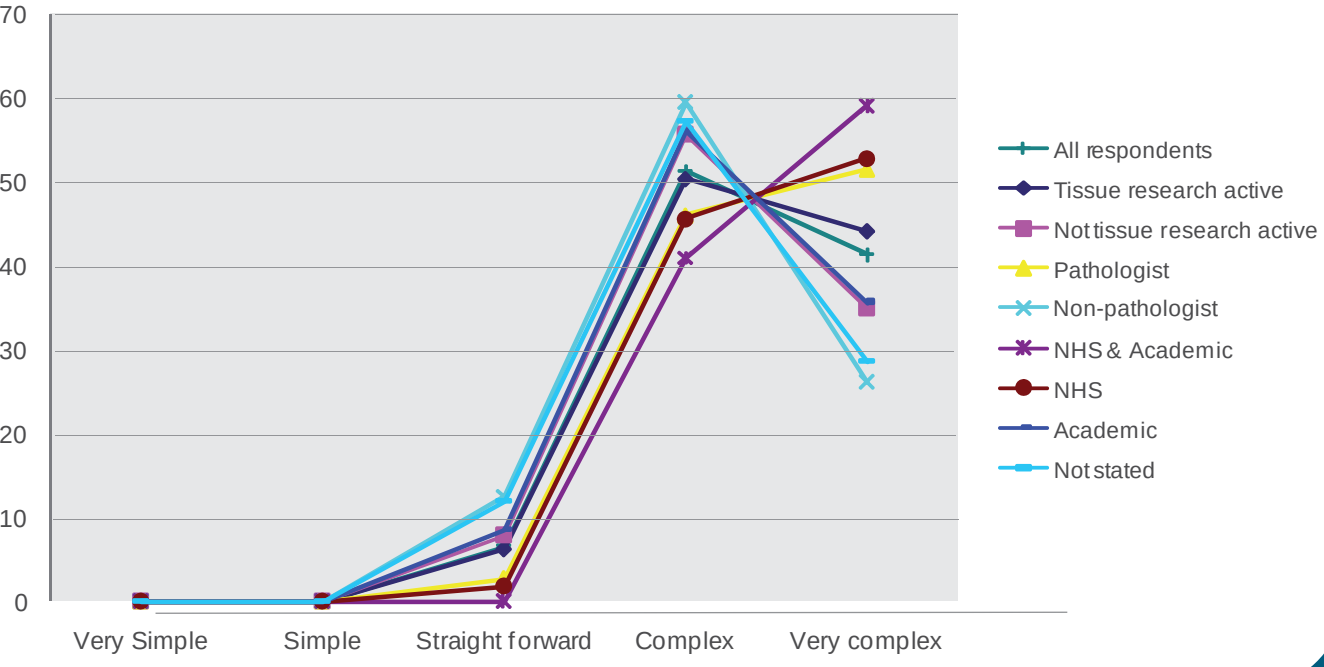


Figure 2 – Respondents' assessment of the complexity of the regulatory and governance environment for pathology research



4.4 The Available Guidance, Sources and Accessibility

> "More than half the respondents (60%) find doing research difficult because of access to appropriate guidance. Thirteen percent don't do research as a consequence."

In response to a question on whether respondents know where to access guidance on the regulatory and governance aspects of research, only 40 (17%) were certain that they did. Table B in Appendix 2 shows the other responses in detail. Less than 17% (n=39) said that they did not know where to access guidance (not usually or not ever), but 41% (n=99) said that they did know, but needed assistance.

Those with combined NHS and academic roles were less certain where to find guidance (n=2, 5%) and more in need of assistance (n=24, 55%) than the overall group of respondents (n=40, 17% and n=99, 41% respectively) or those with purely academic roles (n=13, 22% and n=24, 41% respectively).

Those with purely NHS roles more frequently identified themselves as "not usually" knowing where to find guidance (n=12, 22%) as opposed to the overall group (n=38, 16%), those with combined NHS and academic roles (n=6, 14%) or those with purely academic roles (n=9, 15%).

The effect of the ability to access guidance on the research activity of the respondents is summarised in Figures 3, 4 and 5. Further detail is available in Table C in Appendix 2.

More than half of the respondents (n= 144, 60%) find doing research difficult because of access to appropriate guidance. Thirteen percent (n=31) don't do research as a consequence, although 7% (n=16) would do so if they were appropriately guided.

Those respondents active in tissue based research more frequently find it difficult to do research (n=118, 67%), in comparison to those who aren't (n= 26, 41%). Those who are not active in tissue based research (n=19, 30%, c.f. n=12, 7%) are more likely not to know where to start or not to undertake research at all.

Figure 3 – Tissue research active respondents' assessment of the effect of guidance on the ability to do research

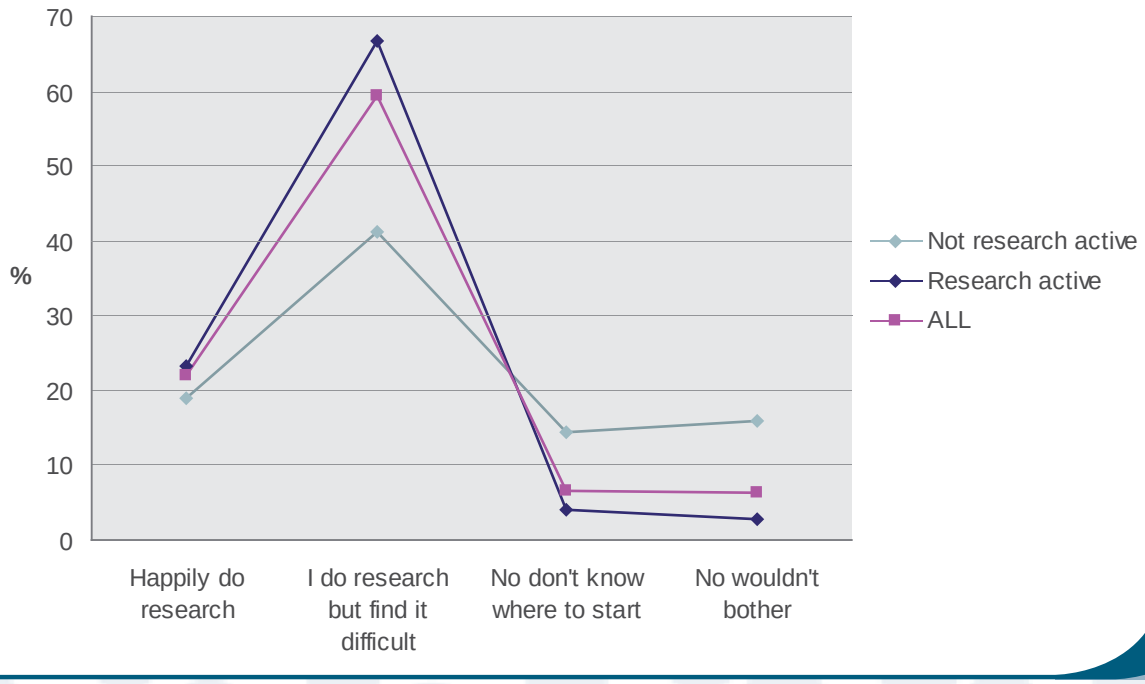
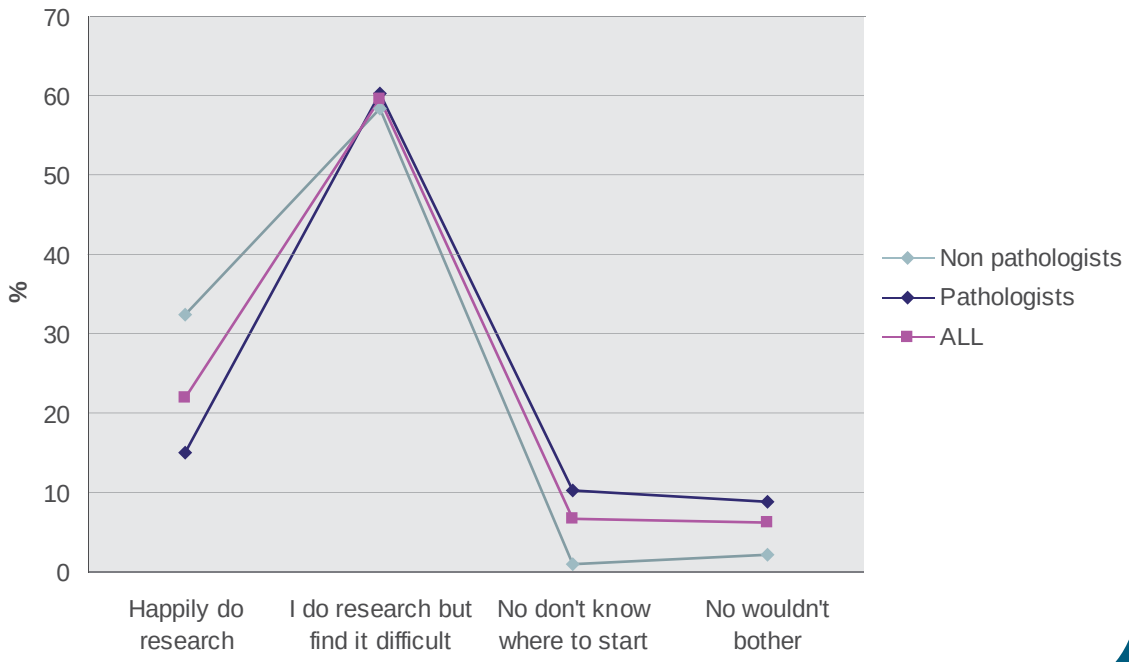


Figure 4 – Pathologist respondents' assessment of the effect of guidance on the ability to do research



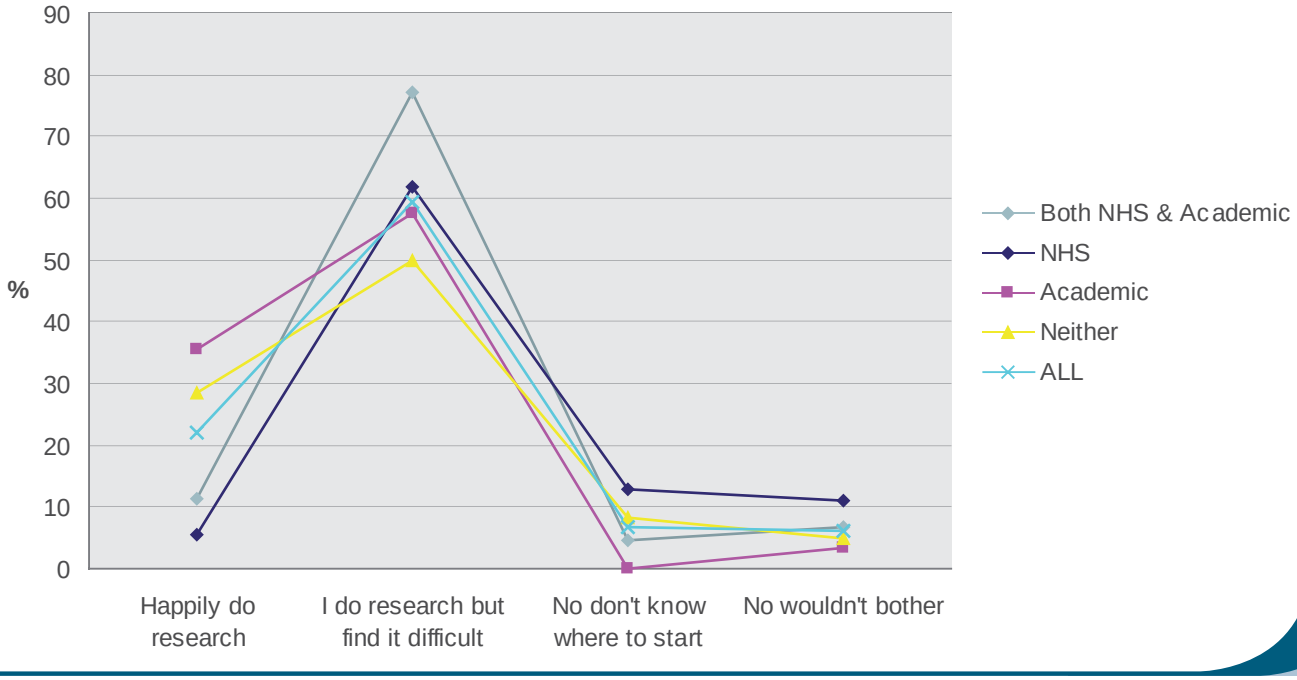


Figure 5 – Opinions of respondents from different work settings of the effect of guidance on the ability to do research

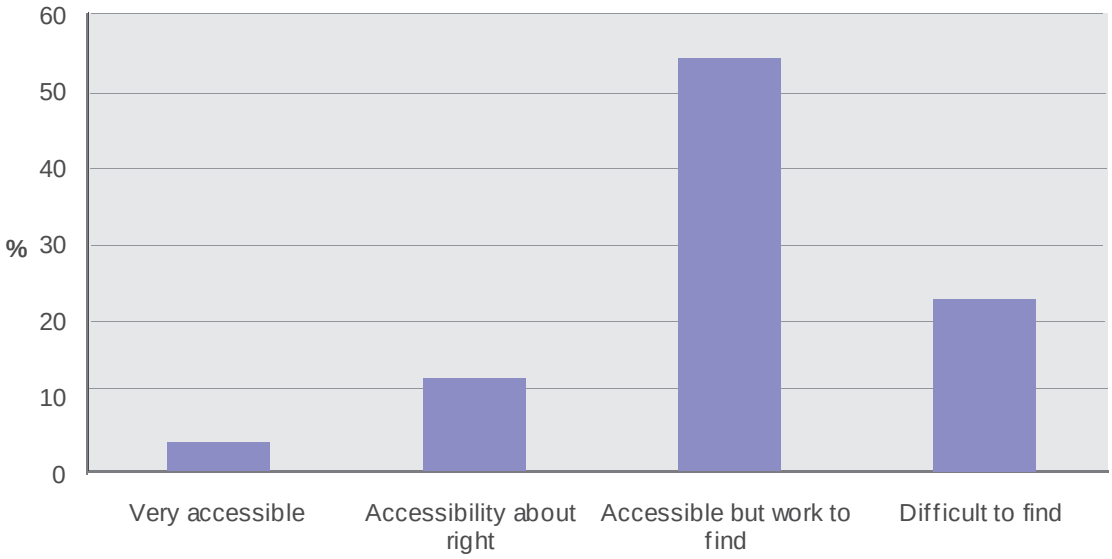
Pathologists are less frequently happy to do research (n=22, 15%) than non-pathologists (n=31, 32%). Pathologists are also more frequently put off research by not knowing where to start (n=15, 10%) or not bothering at all (n=13, 9%) than non-pathologists (n=3, 3% combining both categories of responses).

Academics are most frequently happy to do research (n=21, 36%) than either those with combined NHS and academic roles (n=5, 11%) or those with purely NHS roles (n=3, 5%).Those with combined roles more frequently do research whilst finding it difficult (n=34, 77%) in comparison to the overall group and the other subgroups. Respondents with purely NHS roles less frequently know where to start and more frequently don't bother to do research (combined n=13, 24%) when compared to the overall group (n=31, 13%) or to the other role related subgroups.

Figures 6, 7 and 8 summarise the views of those respondents who knew where to access appropriate guidance on their experiences of using such guidance.

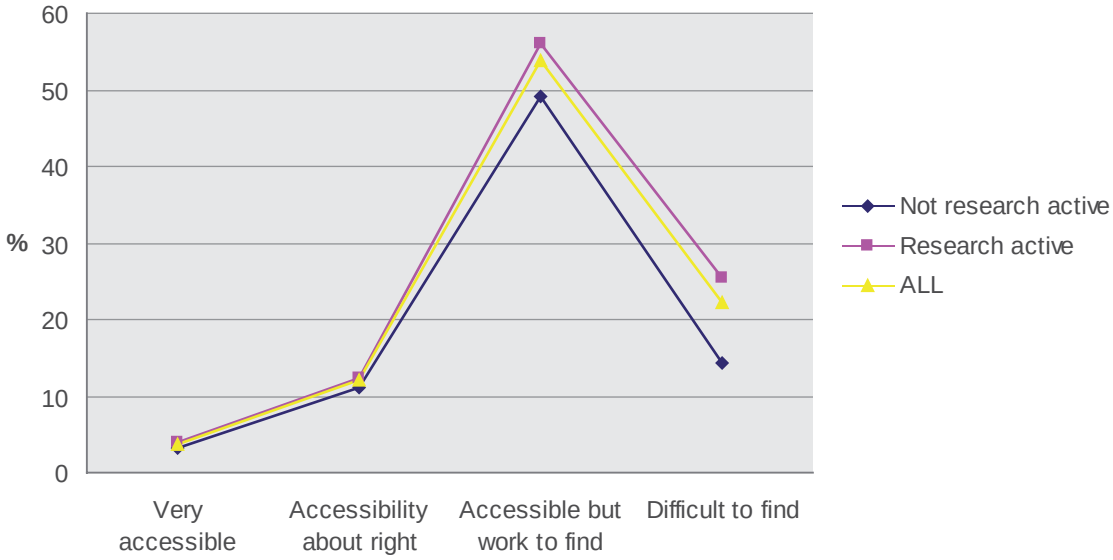
In terms of accessibility (Figure 6), 76% (n=184) of all respondents thought that it is either accessible but requires some work to find it (n=130, 54%) or is difficult to find (n=54, 22%). Only 4% (n=9) of all respondents thought that guidance was very accessible.

Figure 6 – The views of respondents on the accessibility of appropriate guidance



Those who are active in tissue based research (Figure 7) reported that appropriate guidance either took some work to find or was difficult to find (n=144, 81%) compared to those who are not active in human tissue based research (n=40, 63%)

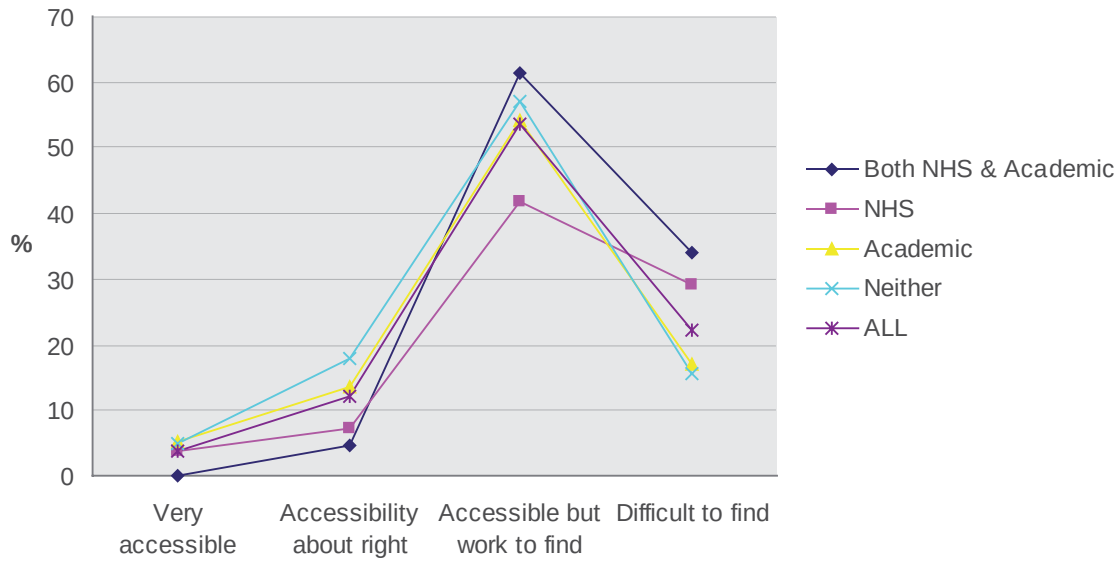
Figure 7 – The views of tissue research active respondents on the accessibility of appropriate guidance



Pathologists generally reflected the group overall, with the only notable difference of opinion being that fewer pathologists (n=13, 9%) compared to non-pathologists (n=16, 17%), thought that accessibility of appropriate guidance was "about right".

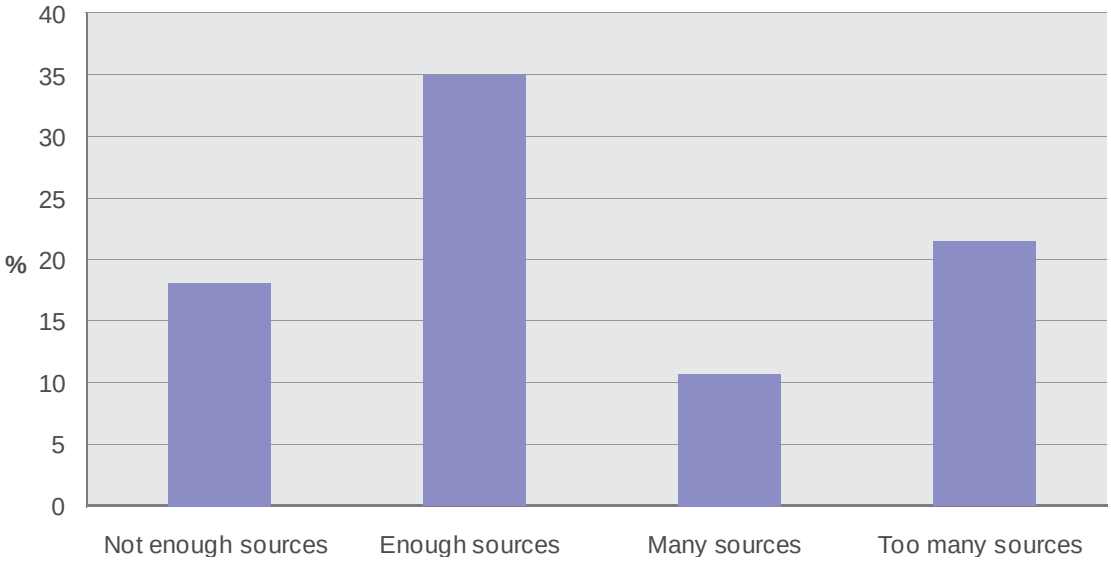
The greatest differences of opinion were revealed when respondents were considered by work setting and roles (Figure 8).Those with combined NHS and academic roles found guidance more work or difficult to find (n=42, 95%) in comparison to the other groups or the overall group of all respondents. Those with purely NHS roles found guidance more difficult to find (n=16, 29%) than those with purely academic roles (n=10, 17%).

Figure 8 – The views of respondents working in different roles on the accessibility of appropriate guidance



The views on the number of available sources of guidance (Figure 9) showed that respondents thought that guidance was available from many or enough sources (46%, n=111) with only 18% (n=44) thinking that there were not enough sources. In contrast, 21% (n=52) reported that in their view there were too many sources.

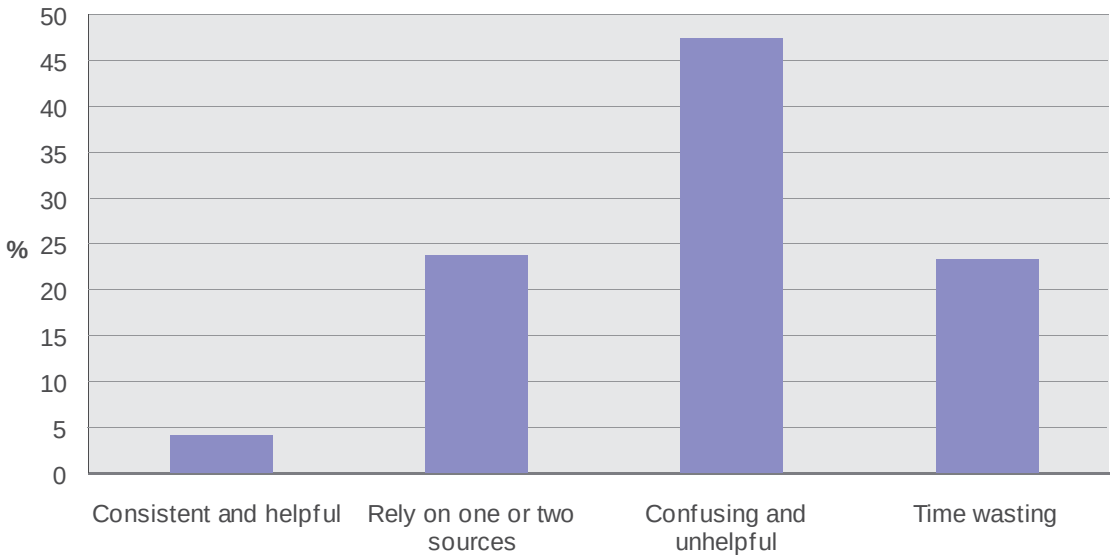
Figure 9 – The views of respondents on the available sources of appropriate guidance



Fewer who were not active in human tissue based research thought that there were too many sources of guidance (n=7, 11%) as compared to those who were active in research using human tissue (n=45, 25%).There was otherwise little difference between the various subgroups of respondents or from the group of all respondents.

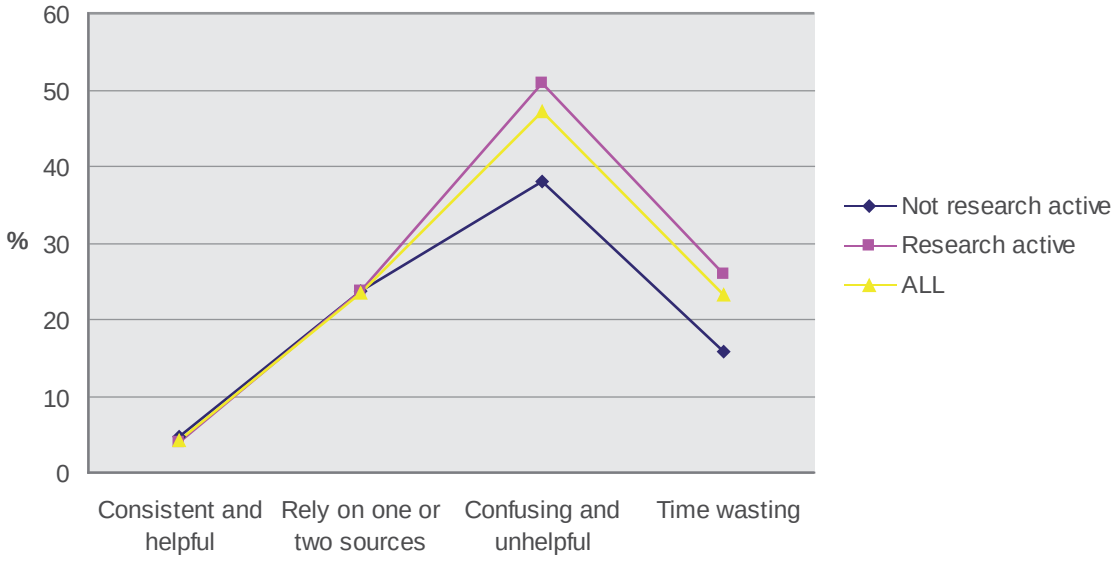
The net effect of ease of accessibility and availability of sources of guidance in terms of usefulness of current guidance is demonstrated in Figure 10. Only 10 respondents (4%) thought that the guidance available from different sources is consistent and helpful. Twenty four percent (n=57) find that they can rely on one or two sources to guide them on particular subjects. However, 70% of respondents reported that the provision of guidance by different sources can be confusing and unhelpful (n=114, 47%) or time wasting as they assess the guidance from more than one source (n=56, 23%).

Figure 10 – The views of respondents on the overall usefulness of existing guidance



The majority of those who are active in human tissue based research (Figure 11) reported the available guidance from one or more sources as confusing and unhelpful or time wasting (n=136, 77%).

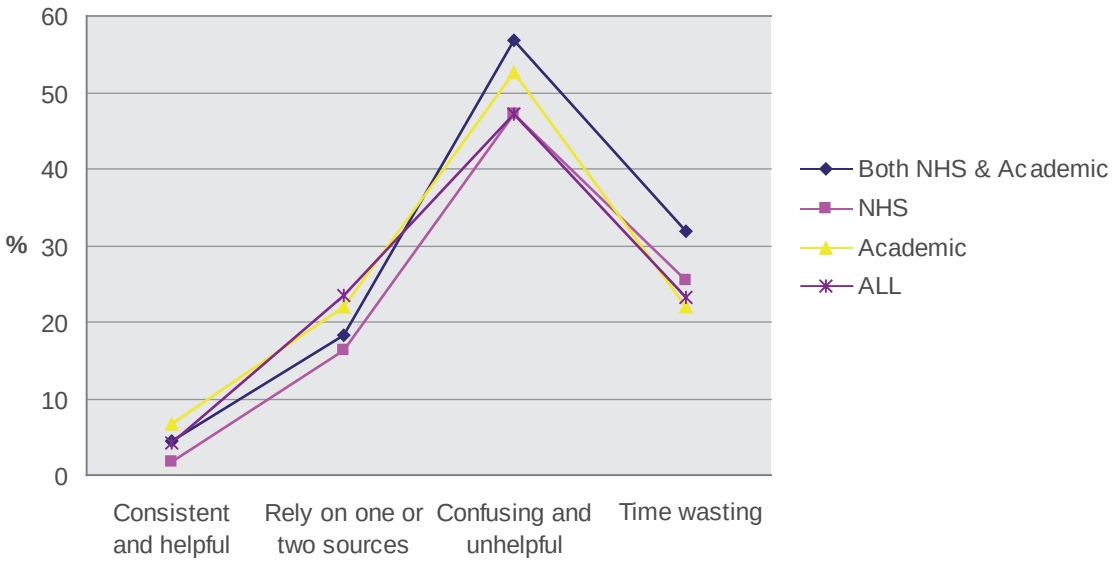
Figure 11 – The views of respondents active in human tissue research on the overall usefulness of existing guidance



Pathologists less frequently rely on one or two sources (n=30, 21%) than non pathologists (n=27, 28%), but more frequently reported guidance from more than one sources as time wasting (n=39, 27%) when compared to non pathologists (n=17, 18%).

Eighty nine percent (n=39) of respondents with combined NHS and academic roles consider the current guidance provided by more than one source as confusing and unhelpful or time wasting (Figure 12) in comparison to those with purely NHS roles (n=40, 73%) and those with purely academic roles (n=44, 75%).

Figure 12 – The views of respondents working in different roles on the overall usefulness of existing guidance.



4.5 Current and Preferred Sources of Guidance

Respondents were asked to indicate the sources they currently tend to use when seeking guidance and also to indicate where they would prefer to seek such guidance.

Most respondents reported using a number of sources for guidance on research regulation and governance. Figure 13 shows that the average number of currently used sources is 3 (range 0-8) with all respondents and all subgroups of respondents consistently wishing to use fewer sources (average 1.6, range 0-7). Thirteen respondents (32%) did not have an opinion on their preferred sources.

Figure 13 – Average number of currently used and preferred sources of regulatory and governance guidance

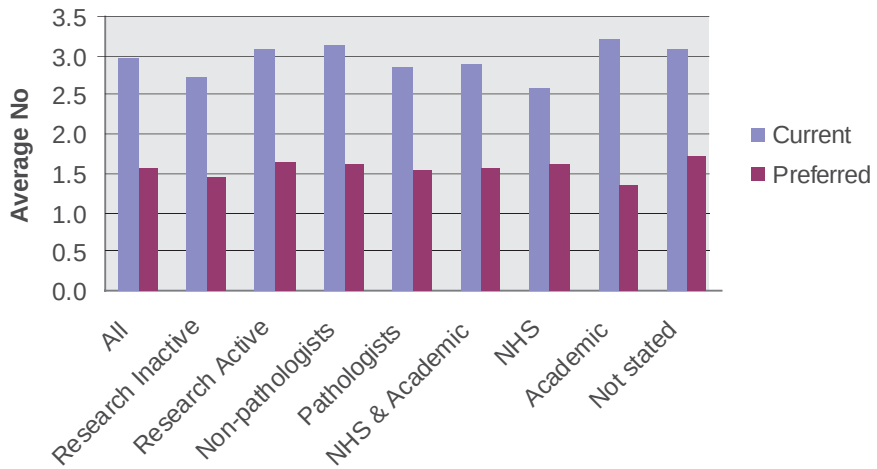
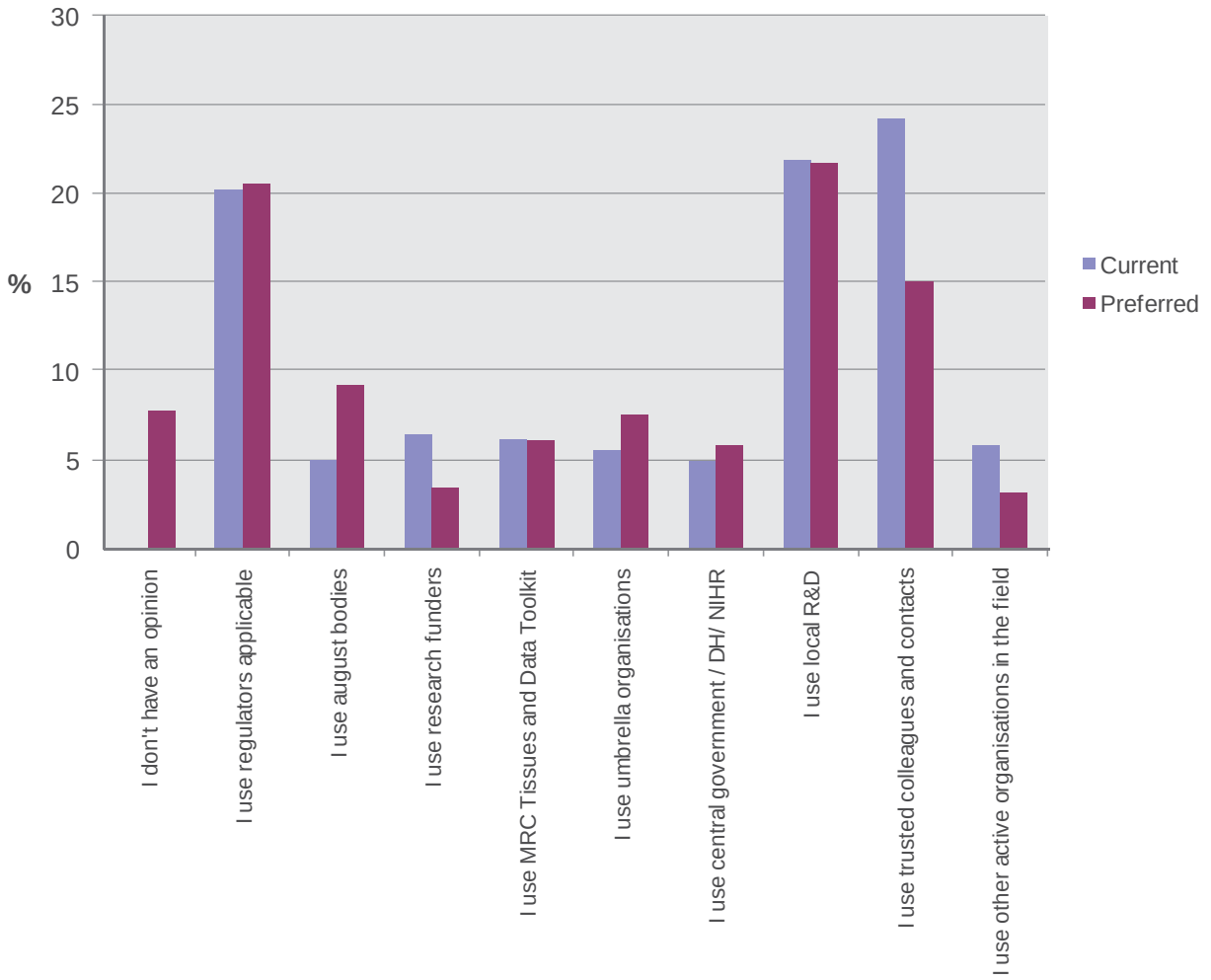


Figure 14 illustrates the detailed responses to both questions in terms of the actual current and the preferred sources of guidance. By far the most popular current sources of guidance are directly from the applicable regulators (20% of responses), from local NHS Research and Development Offices (22% of responses) and from trusted contacts and colleagues (24% of responses). All other sources, without exception, were currently much less used and much less preferred for future use. This pattern changes very little for the preferred sources of guidance, except that fewer respondents would prefer to rely on trusted colleagues and contacts (15% of responses) and slightly more would prefer to use august professional bodies. Fewer would prefer to rely on other active organisations in the field. The only notable differences from the overall trend is that respondents with solely NHS roles have a higher current (27% of responses) and future preference (31% of responses) for the use of NHS Research and Development Offices whereas those with purely academic roles have a preference (14% of responses) to reduce their use of such offices compared to the current situation (17% of responses).

Figure 14 – Currently used and preferred sources of regulatory and governance guidance



Relatively few respondents currently choose to or would prefer to rely on a resource specifically created to assist them with guidance - the MRC Data and Tissues Toolkit[15].

4.6 Predicted Effect of a Consolidated Source of Guidance on Likelihood of Being Research Active

Respondents were asked "if there was an easily accessible source of consolidated guidance endorsed by all regulators, would that make you more likely to be (more) research active?" The response to this was clear with 83% (202) of all participants saying yes and 13% (31) saying no. This pattern was repeated amongst all subgroups of respondents examined.

Comments offered by those replying YES to this question included:

- "Emphatically yes, but it would need to be clear, up to date and easily accessible"
- "Yes, Yes, Yes and for goodness sake write it in simple language, and or provide human beings on the end of a phone who can talk one through it."
- "This sounds like an excellent idea. Researchers require one place to go to be certain they are not contravening any regulations and that it should be a simple to follow system that is not too time consuming. Although it must be rigorous so that peers and the public have confidence in the system."
- "Its not guidance that's the problem it's the sheer amount of regulation. I used to do large amounts of research in breast disease - now I don't because it takes too long to put all the forms together."
- "I think a single national source of guidance and a single national place to refer queries would be a major step forward in helping researcher to cope with regulation."
- "YES PLEASE! The original "Red Book" [Nuffield Council on Bioethics 1995 book on Human Tissue: Ethical and legal issues] was a godsend until everything went haywire in 2000 and is a good example of what we need."

The comments from those who answered NO to the proposal included the following:

- "Only say no, because I do research and have the luxury of someone else to sort out tissue issues."
- "But it would make the job a lot easier"
- "Most of the research I am involved with is part of the …. national portfolio. Rightly or wrongly, I am assuming that these protocols meet with all requirements relating to collections, storage and transfer of blood and tissue and consequently, I do not overly worry about it."
- "My role is that of a facilitator rather than active researcher so it would not have any direct impact on me doing research although it would make my day to job much simpler"
- "The problem is not the guidance but the sheer time taken to check it out and identify compliances and non compliances."
- "Only because I already spend all my time doing clinical research!"

"Researchers require one place to go to be certain they are not contravening any regulations and ..... it should be [a] simple to follow system that is not too time consuming. Although it must be rigorous so that peers and the public have confidence in the system."

4.7 Nature of Regulatory and Governance Guidance in the Future

The respondents were asked to indicate which type of guidance should be available to them – guidance that outlines minimum standards for compliance, guidance that describes "best practice" or guidance that sets out both minimum standards and best practices and distinguishes between them. The combined approach was of interest to most respondents (75%, n=181) with relatively few preferring to see only minimum standards for compliance (12%, n=29) or only best practice (14%, n=33). This pattern was repeated amongst all subgroups of respondents examined.

One respondent summed up the prevailing opinion in a comment as follows: "We should strive for best practice but it should be clear what the minimum standard benchmarks [are]."

4.8 Other Comments

Many respondents contributed free text additional comments, too numerous to include here. They are available as a compilation in Appendix 3.

5. Discussion

This survey is the only one of its kind in the UK in recent years to assess the complexity and impact of the overall research regulation and governance environment on the work of a variety of researchers and other research associated professionals. However, at the time of writing the Human Tissue Authority is also conducting a survey of its stakeholders and it will be interesting to see how much agreement or disagreement these two surveys report. Additionally, the Medical Research Council and Wellcome Trust recently published a joint summary of a workshop on "Regulation and biomedical research", held in May 2008, and many of the conclusions in that summary are in agreement with the responses to this survey[16].

In particular, this survey gauges the opinions of pathologists in comparison to other respondents, distinguishes between those workers active in human tissue or biological sample based research and those who are not, and also describes the views of respondents working in different settings – NHS, academic and combined settings. The guidance available to support researchers, its availability, sources and overall impact are also particularly assessed.

It is striking that most respondents identified a wide range of regulatory and governance bodies as applicable to the oversight of their work, the average being 5 separate bodies. This is particularly interesting because it would appear that some respondents have under reported the number of regulators, such as those governing personal information management or health and safety, perhaps unaware of their obligations and liabilities in these areas. However, it does illustrate that any individual conducting biomedical research in the UK at the current time needs to be aware of and conversant with a wide range of legislation and regulations related to diverse topics. It is interesting to note that 10% of all respondents stated that they were not clear which regulators were applicable to their work.

The number and diversity of applicable regulators is also of interest because much attention in recent years, particularly for those active in research using human tissue or biological samples, has centred on the Human Tissue Act 2004[17] and the work of the applicable regulator – the Human Tissue Authority. Objections to the provisions of the Act and complaints about the work of the Authority are still regularly aired although the available published information, mostly emanating from the Human Tissue Authority itself[18,19], suggests that this is increasingly a minority view. This survey demonstrates, however, that the regulation of human tissue research is only one component of a complex environment, albeit one of the most recently added and prominent components. Equally prominent in the responses to this survey, however, are the roles of NHS Research and Development Offices[9] and Research Ethics Committees[8].

Perhaps in keeping with the intentions for a regulatory and governance environment, few consider it permissive and most respondents consider it strict or very strict, with pathologists particularly prone to these opinions. However, less welcome is the perception of complexity that prevails amongst the participants in this survey. This seems to be a particular problem for those with multi-setting roles, such as those with combined NHS and academic roles and for those working in the NHS, including pathologists. It is interesting to speculate that this is a product of these groups having less time to become conversant with the appropriate legislation and regulations and to keep up with developments. It is also attractive to extrapolate this to being a contributor to the observation that most respondents find it difficult to do research and pathologists and those working in the NHS find this less conducive to being involved in research, perhaps accounting for the well documented decline in research activity and output from pathology departments in the UK[20]. This survey was not specifically designed to and is not capable of assessing the impact of the regulation of human tissue based research in comparison to other forms of regulation. However, there are suggestions from this survey that the addition of this Act and regulator to an already complex environment may have compounded the landscape as evidenced by the free text comments (see Appendix 3), even if not necessarily problematic in itself.

If a strict regulatory and governance environment is desirable and complexity of regulation and governance oversight inevitable as a result, the antidote to assist researchers should be provided through effective guidance. Ideally such guidance is readily accessible, from easily identified sources, is authoritative, can be trusted, is consistent and should ease

the path for research and not impede it. Unfortunately, the responses to this survey suggest that the current provision of guidance is anything but ideal. The participants too frequently reported that finding appropriate guidance is difficult or requires excessive effort. This seems to be more of a problem for those who are active in human tissue based research and for those with combined NHS and academic or purely NHS roles. The problem seems to be compounded by the impression that there are (too) many sources. Investigators become confused and waste time whilst using multiple sources of guidance. These problems could be overcome by reducing the number of sources, ensuring that sources are consistent and demonstrating such sources to be authoritative. The latter is important to reassure users that the guidance can be relied upon without recourse to checking additional guidance elsewhere.

Currently, the respondents to this survey report using an average of 3 separate types of sources of guidance – a number that can undoubtedly be viewed as conservative as "applicable regulators" have been counted as a single group whereas in practice it could amount to several discrete organisations. The most popular current sources by far are applicable regulators, local NHS Research and Development Offices and trusted colleagues and contacts. Surprisingly, other expected sources such as august bodies, central government departments or bodies, research funders, and umbrella organisations (many of whom provide some forms of guidance for their own communities) are not particularly popular current sources nor are they preferred future sources by the respondents to this survey, with none of these types of sources being supported by more than 10% of the responses.

A specific resource created in recent years to support researchers and assist with "governance busting" (at least in a helpful sense rather than in a subversive sense), the Data and Tissue Toolkit available via the internet from the Medical Research Council[15], is neither currently used much by the respondents to this survey nor would it be preferred to currently used sources. It is not clear from the data in this survey whether this toolkit does not fulfil its purpose or whether the apparent unpopularity of this resource may reflect that the cohort of participants in this study may be simply unaware of its existence or may feel that it is not directed at them. Those responsible for this resource might like to review its use patterns in terms of volume and types of individuals using it to assess whether a review supports or refutes the observations made in this report. If it is to be effective, it may need wider publicity or tailoring to suit the needs of the types of researchers represented in this survey.

For future provision of guidance, it is overwhelmingly clear that the participants in this survey would welcome the existence of an accessible source of consolidated guidance, endorsed by the relevant regulators, and would be likely to be (more) research active as a result of using such a resource. Where such a resource should be provided is also overwhelmingly clear – from NHS Research and Development Offices and mirrored by the applicable regulators as the future preferred sources of choice. However, it should not be forgotten that academics may not feel able or wish to use NHS Research and Development Offices, so some parallel arrangement that caters for them may also be required. It is clear that the nature of the guidance needs to make it apparent to users what the minimum regulatory requirements are as well as distinguishing these from prevailing or expected best practice standards.

Whether the provision of an authoritative source of consolidated guidance is attainable any time soon remains to be seen and is largely dependent on the will and freedom of the various regulatory bodies to work together to produce such a resource. However, it would be desirable from a "principles of better regulation" perspective[21] and there is a clear indication from this survey that this would be welcomed by researchers and may make research easier to conduct. It is surely the first step to ease the path for researchers and is preferable to the alternative of relaxing the regulatory burden itself, a burden that has developed piecemeal but for good reasons to reassure and protect the public and patients, as well as researchers in many circumstances. As technology advances and opportunities for research increase as a result, it is likely that regulation and governance will become more, not less, important. If the opportunities for research and the consequential patient benefits are to be realised, practical steps to assist and encourage research need to be used whilst preserving appropriately strict regulation and governance where necessary.

6. Conclusions and Recommendations

1. Current biomedical research extends across areas overseen by a wide variety of regulatory and governance bodies. Most researchers perceive several regulators as concurrently applicable to their work.
2. The overall regulatory and governance environment is perceived as strict and complex, with a tendency to being seen as over strict and over complex. This is a particular problem for pathologists and those working in the NHS or in combined NHS and academic roles. It is also more of an issue for those actively working in human tissue or biological sample based research.
3. The willingness and ability of researchers to do their research is impaired as many find it difficult and some do not do research as a result.
4. The provision of guidance is the best means of explaining the complex and strict regulatory and governance environment and enabling researchers to do their work in compliance with regulatory requirements. However, currently available guidance can be confusing, unhelpful and can lead researchers to waste time. Most respondents to this survey currently seek guidance from multiple distinct sources and would prefer to reduce this necessity. It is also perceived as being provided by enough or too many bodies.
5. Recommendation 1 – Guidance should be consolidated into an accessible, authoritative and consistent multi-regulator endorsed resource. This will require relevant regulators to be willing and able to cooperate with the production of such a resource. The MRC Regulatory Support Centre has developed Tool Kits to consolidate available guidance and regulations. It is recognised that such Tool Kits have increased authority and confidence when developed with the endorsement or support of relevant regulators.
6. Recommendation 2 – A consolidated guidance resource should be made freely available to researchers from a restricted number of well-publicised points of access, principally via a single web portal, the use of which can be supported the network of NHS Research and Development Offices. Direct and specific guidance should continue to be provided by the applicable regulators, many of whom have statutory requirements to provide guidance. Some provision should also be made for academics via a body such as a university research governance advisory service. These sources of the consolidated guidance resource can then be relied upon by researchers without the need to consider alternative sources.
7. Recommendation 3 – A consolidated guidance resource should clearly provide and distinguish minimum requirements for regulatory compliance and best practice standards and expectations where applicable.

7. Acknowledgements

I am indebted to the following for their various contributions to this survey and report:

Professor David Levison in his roles as Chair of the NCRI Task Force on Pathology and Research and as President of the Pathological Society; Dr Jane Cope, Administrative Director of the NCRI; Dr Rebecca Stratford, Senior Programme Manager at NCRI with special responsibility for the Pathology Task Force; Julieann Cambridge, Executive Assistant, onCore UK; Michele Lizio and Anne Carter, onCore UK; Dr Catherine Elliott, Head of Clinical Research Support and Ethics, Medical Research Council; Dr Sarah Dickson, Head of MRC Regulatory Support Centre; Professor Peter Furness, President of the Royal College of Pathologists; Dr Louise Jones, Interim Senior Research Manager Experimental Cancer Medicine Centre (ECMC) Network, Cancer Research UK; Elliann Fairbairn, National Cancer Research Network; Elize Roelofse, Creative and Communications Officer, NCRI; Agneta Hedvall, Administrator, NCRI; Ros Pitts, Pathological Society.

I am particularly grateful to the 242 individuals who participated in this survey by offering their completed questionnaires for analysis.

8. References

1. http://www.ncri.org.uk/
2. http://www.oncoreuk.org/
3. http://www.pathsoc.org/
4. Kelly K, Clark B, Brown V, Sitzia J. (2003) Good practice in the conduct and reporting of survey research. Int J Quality in Health Care 15;261-266
5. http://www.rcpath.org/
6. http://ncrn.org.uk/
7. http://www.ecmcnetwork.org.uk/
8. http://www.nres.npsa.nhs.uk/
9. http://www.rdforum.nhs.uk/rdform.htm
10. http://www.hta.gov.uk/
11. http://www.hse.gov.uk/
12. http://www.nigb.nhs.uk/
13. http://www.ico.gov.uk/
14. http://www.gmc-uk.org/
15. http://www.dt-toolkit.ac.uk/home.cfm
16. MRC/Wellcome Trust workshop: Regulation and biomedical research. 13 -14 May 2008. Full report. http://www.wellcome.ac.uk/About-us/Publications/Reports/Biomedical-science/WTX053465.htm
17. Human Tissue Act 2004. http://www.opsi.gov.uk/ACTS/acts2004/ukpga_20040030_en_1
18. http://www.hta.gov.uk/newsroom/quotes_and_endorsements.cfm
19. Human Tissue Authority Annual Review 2007/2008. Building Confidence. July 2008. http://www.hta.gov.uk/about_hta/publications.cfm
20. Fostering the role of pathology in research. Report of the NCRI Task Force on Pathology and Research.
21. http://www.betterregulation.gov.uk/

Survey on the Effect of Regulation and Research Governance

The NCRI Taskforce has heard reports that the regulatory and governance environment relating to: the involvement of NHS patients in research; the use of human biological samples; the use of personal and health information; and, the need to gain NHS R&D and Research Ethics Committee approvals are affecting the willingness and ability of pathologists to lead research or contribute to research.

To gain quantitative evidence, onCore UK and the Pathological Society are conducting this survey on behalf of the NCRI Taskforce. This survey is aimed at gauging the **quality, diversity and availability of guidance on regulatory and governance matters**. We would be interested in hearing the views and experiences of those whose primary role is in pathology as well as those who handle biological samples for research but are not doing so from a pathology base (for example, those who do so for clinical trials).

We would be very grateful if you could spare some time to complete and return this questionnaire and give us the benefit of your opinion and experience, whether positive or negative. This will take you less than 5 minutes to complete.

Many thanks,

Dr Jane Cope, NCRI
Dr Brian Clark, onCore UK
Prof David Levison, Pathological Society President and NCRI Taskforce Chair

Please complete and return this questionnaire by start of business on **Monday 23rd February 2009**. All responses will be treated in confidence and only summary information or unattributed comments will be used in any subsequent reports of this work. **This form can be:**
1) completed on screen, saved and then emailed back as an attachment or
2) completed on screen, printed and the hardcopy returned by post to the freepost address at the end of the questionnaire.

Questionnaire

1. About you					
1.1. What is your name (optional to allow us to follow-up on any points raised if necessary)	Enter text in the box above		**1.2 Email address (optional)**	Enter text in the box above	
			1.3 Telephone No (optional)	Enter number in the box above	
1.4 Are you currently actively involved in research using human tissue or other biological samples? (Select from the drop down choices of Yes or No)					
1.5 In what role are you responding? (select as many as are relevant to you)	Consultant Pathologist ☐	Pathologist in training ☐	Clinical Scientist in Pathology ☐	Biomedical Scientist ☐	Scientific Researcher ☐
	NHS Service ☐	Academic ☐	Research Nurse ☐	Biobanker / Tissue banker ☐	Data / Information Manager ☐
	Clinical Trialist / trial support ☐	Other (Please specify)	Enter text in the box above		

2. The "Regulators" applicable to your work			
2.1 Which of the following do you believe are applicable to your involvement in pathology research? (please tick as many as are relevant to you)	NHS R&D Offices		☐
	NHS Research Ethics Committees		☐
	Health and Safety Executive		☐
	National Information Governance Board (including the functions previously fulfilled by PIAG)		☐
	Office of the Information Commissioner		☐
	MHRA		☐
	Human Tissue Authority		☐
	National Radiological Protection Board / Health Protection Agency		☐
	Home Office Animals (Scientific Procedures) Inspectorate		☐
	Human Fertilisation and Embryology Authority		☐
	General Medical Council		☐
	Not very clear to me		☐
	Others (please specify):	Enter text in the box above	

3. About the overall regulatory and governance environment	
3.1 How do you assess the overall regulatory and governance environment for pathology research? (please select once choice)	Select from the drop down choices of Very permissive, Permissive, About right, Strict or Very strict
3.2 How do you assess the complexity of the regulatory and governance environment for pathology research? (please select once choice)	Select from the drop down choices of Very simple, Simple, Straight forward, Complex or Very complex

4. The available Regulatory and Governance Guidance			
4.1 Do you know where to access appropriate guidance on regulatory and governance aspects of research?		Select from the drop down choices of: Yes - certainly, Yes - probably, Yes - with assistance, No - not usually, No - not ever	
4.2 What effect does your ability to access guidance have on your research?		Select from the drop down choices of: I am happy to do research, I do research but find it difficult, I would do research but don't know where to start, I don't bother to do research as a result	
4.3 If you answered Yes to 4.1 please indicate your experience of using guidance in terms of accessibility, availability and usefulness (please tick those statements you most agree with):	**Ease of accessibility**	Guidance is very accessible	☐
		The accessibility of guidance is about right	☐
		Guidance is accessible but requires some work to find	☐
		Guidance can be difficult to find	☐
	Available sources	Guidance is available from many of sources	☐
		Guidance is available from enough sources	☐
		Guidance is *not* available from enough sources	☐
		Guidance is available from *too* many sources	☐
	Usefulness of existing guidance	Guidance on the same subject provided by different sources is consistent and helpful	☐
		When Guidance on the same subject is available from many sources I find I can adequately rely on one or two sources	☐
		Guidance on the same subject provided by different sources can be confusing and unhelpful	☐
		Guidance on the same subject provided by many sources leads me to waste time checking more than one	☐
Comments (optional):	Enter text in the box above		

5. Where do you currently to seek Regulatory and Governance Guidance?		
5.1 When seeking guidance, which of the following sources do you tend to CURRENTLY rely on? (please tick those statements that are most applicable to you):	I seek guidance from those "regulators" I believe are applicable to my research	☐
	I seek guidance from august professional bodies such as the medical Royal Colleges, British Medical Association and the General Medical Council	☐
	I seek guidance from research funders	☐
	I use the MRC Tissues and Data Toolkit	☐
	I seek guidance from "umbrella organisations" such as UKCRN, etc	☐
	I seek guidance from central government such as the Department of Health / NIHR	☐
	I seek guidance from my local NHS R&D office	☐
	I seek guidance from trusted colleagues and contacts	☐
	I seek guidance from other organisations active in the field	☐
	Other - please specify in the box below	☐
Comments (optional):	Enter text in the box above	

6. Where would you PREFER to seek Regulatory and Governance Guidance?		
6.1 If seeking guidance, which of the following sources would you PREFER to rely upon? (please tick those statements that are most applicable to you):	I don't have an opinion	☐
	I prefer guidance from those "regulators" I believe are applicable to my research	☐
	I prefer guidance from august professional bodies such as the medical Royal Colleges, British Medical Association and the General Medical Council	☐
	I prefer guidance from research funders	☐
	I prefer to use guidance resources such as the MRC Tissue and Data Toolkit	☐
	I prefer guidance from "umbrella organisations" such as UKCRN, etc	☐
	I prefer guidance from central government such as the Department of Health / NIHR	☐
	I prefer guidance from my local NHS R&D office	☐
	I prefer guidance from trusted colleagues and contacts	☐
	I prefer guidance from other organisations active in the field	☐
	Other - please specify in the box below	☐
Comments (optional):	Enter text in the box above	

7. Source of Regulatory and Governance Guidance in the Future:	
7.1 If there was an easily accessible source of consolidated guidance endorsed by all "regulators", would that make you more likely to be (more) research active? (***For example, for consent for research using human tissues and supporting clinical information, a single piece of guidance could be co-authored and endorsed by the GMC, Departments of Health, Human Tissue Authority, National Research Ethics Service and National Information Governance Board.***)	Select from the drop down choices of Yes or No
Comments (optional):	Enter text in the box above

8. Nature of Regulatory and Governance Guidance in the Future:		
8.1 Which of the following types of guidance would be of interest to you? (please tick ONE statement that is most applicable to your opinion):	Guidance that tells me what the minimum standards for compliance are	☐
	Guidance that tells me what the minimum standards for compliance are and also what is considered "best practice"	☐
	Guidance that describes "best practice", such that I can try to achieve this	☐
Comments (optional):	Enter text in the box above	

9. Any other comments?
9.1 Please feel free to provide other comments here (for example, can you describe a situation where guidance relating to regulation, and governance was either very helpful to your research or a hindrance to your research?)
Enter text in the box above

THANK YOU FOR TAKING PART

Completed forms should be returned to:

By post:

Regulation & Research Governance Survey,
FREEPOST

or By Email:

Please **save the file** and then **attach** it to an email to:

Appendix 2

Tabulated responses to selected questions

Table A - Regulators Considered Applicable to the Work of Respondents[b]

	NHS R&D Offices	NHS Research Ethics Committees	Health & Safety Executive	National Information Governance Board	Office of the Information Commissioner	Medicines and Healthcare Regulatory Authority	Human Tissue Authority	National Radiological Protection Board / Health Protection Agency	Home Office Animal Inspectorate	Human Fertilisation and Embryology Authority	General Medical Council	Not clear to me
All	202	224	111	56	29	88	207	28	40	13	103	24
	83%	93%	46%	23%	12%	36%	86%	12%	17%	5%	43%	10%
Tissue research active	154	167	80	41	23	69	157	25	30	10	78	17
	87%	94%	45%	23%	13%	39%	89%	14%	17%	6%	44%	10%
Not tissue research active	48	57	31	15	6	19	50	3	10	3	25	7
	76%	90%	49%	24%	10%	30%	79%	5%	16%	5%	40%	11%
Pathologists	121	137	67	26	18	39	122	16	20	8	74	16
	83%	94%	46%	18%	12%	27%	84%	11%	14%	5%	51%	11%
Non Pathologists	81	87	44	30	11	49	85	12	20	5	29	8
	84%	91%	46%	31%	11%	51%	89%	13%	21%	5%	30%	8%
Both NHS & Academic	38	43	23	15	8	15	38	5	8	5	26	5
	86%	98%	52%	34%	18%	34%	86%	11%	18%	11%	59%	11%
NHS	46	50	23	9	7	16	47	7	1	2	24	5
	84%	91%	42%	16%	13%	29%	85%	13%	2%	4%	44%	9%
Academic	50	56	29	13	1	23	53	8	20	1	26	2
	85%	95%	49%	22%	2%	39%	90%	14%	34%	2%	44%	3%
Not stated	68	75	36	19	13	34	69	8	11	5	27	12
	81%	89%	43%	23%	15%	40%	82%	10%	13%	6%	32%	14%

[b]The percentage total exceeds 100% as many respondents selected more than one regulator. The percentages for each group other than All is expressed as a percentage of the number of respondents in that group, e.g. "tissue research active".

Table B - Responses to the question "Do you know where to access appropriate guidance on regulatory and governance aspects of research?"

	Yes certainly	Yes probably	Yes with assistance	No - not usually	No - not ever
All	40	63	99	38	1
	17%	26%	41%	16%	<0.5%
Tissue research active	28	49	79	21	1
	16%	28%	45%	12%	1%
Not tissue research active	12	14	20	17	0
	19%	22%	32%	27%	0%
Pathologists	23	34	61	26	1
	16%	23%	42%	18%	1%
Non Pathologists	17	29	38	12	0
	18%	30%	40%	13%	0%
Both NHS & Academic	2	12	24	6	0
	5%	27%	55%	14%	0%
NHS	7	12	23	12	1
	13%	22%	42%	22%	2%
Academic	13	13	24	9	0
	22%	22%	41%	15%	0%
Not stated	18	26	28	11	0
	21%	31%	33%	13%	0%

The percentages for each group other than "All" is expressed as a percentage of the number of respondents in that group, e.g. "tissue research active".

Table C - The effect that access to appropriate guidance has on the ability to do research[c]

	Happy to do research	I do research but find it difficult	I would do research, but don't know where to start	I don't bother to do research as a result
All	53	144	16	15
	22%	60%	7%	6%
Tissue research active	41	118	7	5
	23%	67%	4%	3%
Not tissue research active	12	26	9	10
	19%	41%	14%	16%
Pathologists	22	88	15	13
	15%	60%	10%	9%
Non Pathologists	31	56	1	2
	32%	58%	1%	2%
Both NHS & Academic	5	34	2	3
	11%	77%	5%	7%
NHS	3	34	7	6
	5%	62%	13%	11%
Academic	21	34	0	2
	36%	58%	0%	3%
Not stated	24	42	7	4
	29%	50%	8%	5%

[c]The percentage total is less than 100% as some respondents did not answer this question. The percentages for each group other than "All" is expressed as a percentage of the number of respondents in that group, e.g. "tissue research active".

Appendix 3

Compendium of Free Text Comments

In the following each new individual quotation appears as a new bullet point. All quotations are unattributed. Some content that could be used to identify individuals have been removed to protect the confidentiality of respondents. Text is otherwise unaltered from its original submission.

In response to question 1.5, the following were specified for those 30 respondents who selected "other":

- Head of academic department with overall responsibility
- Pharmaceutical Industry Scientist
- Professor and Hon. Consultant Immunologist.
- Regulatory Advisor
- I am a member of the …….. sitting on the …….. I have worked in a pharmaceutical industry. I am also studying for an MSc and trying to set up a study collecting saliva samples for analysis.
- Consultant in microbiology and infectious diseases
- Project Manager, ……. Cancer BioResource
- Pharmaceutical Industry
- Research lead and grant holder for research projects
- Also member of local tissue governance committee.
- NCRI …….. cancer subgroup chair, …….. trial management group
- Investigations of genes linked to Sids
- Clinical operations manager
- Consultant obstetrician & gynaecologist
- Microbiologist, ex Ethics Chair
- Microbiologist
- Director of Private diagnostic company and virologist.
- Pharmaceutical medicine - preclinical
- Also as Research Governance Lead for Laboratories and member of hospital trust research committee
- Consultant haematologist and academic in haematology
- Supervising BMS MSc projects
- Surgeon
- Research tissue coordinator for histopathology and ethics committee member
- Tissue Governance Lead for …… NHS Trust.
- Research support, epidemiology, not a trial.
- As regulatory affairs manager at an academic cancer trials unit (CTU) which coordinates clinical trials, some of which have translational elements however we do not collect, handle, analyse specimens
- Cancer research network manager
- Consultant Haematologist
- Statistician
- We are collecting samples of a sub-study of a surveillance clinical trial

In response to question 2, the following were specified for those respondents who selected "other":

- BMA, MRC, RCPath, DH, Clinical Governance of Trust, NHS Management of the Department, University, Charitable Funders including CRUK, YCR, NIHR etc.
- University Research Ethics committee
- COREC
- I have had very limited need to look into this area.
- MREC
- Being an …….. tissue bank our principal regulator is the National Health & Medical Research Council (NHMRC) of ……..
- Local organisation rules/guidance
- Trust and regional ethics and trust boards
- Local information governance department. Clinical Audit department (what used to be simple clinical audit and/or service evaluation is now classified as research [requiring NRES] and therefore monitoring outcomes in our services is not done because of the large amount of paperwork).

- Home office (Storage of dangerous pathogens), MHRA (Test kit failures)
- Company policies and procedures relating to human samples.
- Health professions council, clinical pathology accreditation.
- Collaborating NHS Colleagues and also my own medical ethics
- Various institutional ethical review bodies
- Trust Research Department
- Trust Research committee
- Institutions cancer tissue bank
- Customs
- Top of department, local research committee, chief executive
- Trust Governance Board
- Local R&D research ethics, health protection agency research ethics. Regional NHS research ethics, local university health and safety and research ethics, genetic manipulations regulation.
- MRC Stem Cell steering committee
- Some will depend on nature of research
- I don't get directly involved at this level.
- Trial centres, CLRN, CRN, Local Ethics and R&D…
- Local NHS trust R&D office

In response to question 4.3, the following were specified for respondents as comments:

- Even with assistance there is immense confusion for example the DI research for the …… trust in ……. and the Head of Department told me that I could not do molecular mutation work on paraffin without explicit consent from patients in spite of having ethics approval and the material being from before 2006. Confusion is rife and leads to refusal to submit material for central analysis. Setting up a cadaveric bank has been severely delayed due to bureaucracy and lack of understanding.
- Within higher education institutes and NHS trusts work with human biosamples should be and is generally regulated internally, with all researchers registering their work with the appropriate committee/department. As such, these departments may have information packs/ websites for the researchers detailing where this type of information can be found. Help is generally available if you ask.
- There remain many unanswered questions regarding consent particularly in situations where the results obtained from the tissue must be linked to clinical data to develop biomarkers and prognostic scores, and many of the patients are now lost to follow-up or have died. Even more problems with respect to movement of data and or samples to other research departments in the UK or overseas.
- There may be published guidance, but it is so difficult to follow, and is so poorly joined up in its thinking that it ends up being very difficult to access: it is akin to being guidance but written in a foreign language. Allied to the draconian threats now enshrined in law, eg. HTA, this is a real disincentive to participate in research. It is all written along the lines what you cant do, rather than how do I do something, at least, that is how it feels. It is debatably unethical for such obstructions now to be placed in the way of research.
- Part of the problems is the procedures for sorting out the paperwork associated with research are constantly changing - supposedly for the better but it is hard to keep up.
- As an academic researcher, I received no administrative help in dealing with ethical issues related to tissue acquisition, handling and storage. Overall, I regard the environment as unsympathetic if not downright obstructive.
- One set of guidance would be most helpful.
- I rely on others to sort out the tissue issues
- Generally I rely on my head of department for guidance and advice on this. However in 5 years time he will be retiring so I will need to be the guiding light for the department in a few years time.
- The answers above relate to research with patient samples and the setting up of investigator-led clinical trials.
- The most difficulty I found to have consent from the coroner on issues like photography of the organs without deceased identification, never got the consent so never use photographic technology for research and training.
- On some issues, e.g. Whether or not 4um paraffin sections of human tissue can be said to include [intact? complete?] cells and are therefore converted, relevant material as specified by the 2004 HT Act, it is almost impossible to obtain clear, definitive guidance.
- No guidance is provided by ……. on tissue banking.
- Continual change in the regulatory environment is a huge hindrance also. I have been put off several projects by the initial effort/time involved in starting a project.
- The amount of time spent to get guidance and fill all the paperwork is underestimated and is difficult to account for in job plans.
- The whole system in the UK was designed to be punitive and discourage research except in large centres. Doing proper research in the UK now is a pain because the governance and consent rules are complex and with the problems round funding I tell trainees that you must be mad (or very committed) if you want to pursue an academic career pathology.
- I am involved in clinico pathology studies that sometimes require performing immunohistochemistry and or FISH and or PCR. These

are simple projects that most of the times aim to draw attention of other histopathologists to pitfalls in the diagnosis of certain tumours. Whenever I ask, I am told that complex ethical forms need to be completed and many times i am told that consent is also required for theses simple studies. This makes pursuing these projects very difficult. In fact some journals have requested written patient consent to publish such studies and we have to give up publishing

- Can be a danger of missing guidance on esoteric points if not available from major source.
- Even authorities can give differenct guidance depending who you talk to!
- Guidance is often ambiguous and difficult to apply to my own setting. Different parts of regulation (HTA) can be conflicting and open to different interpretations.
- Confusing and unnecessary strict rules will hamper research. We need a clear and realistic approach especially if prior ethical approval and patients consents are in place.
- Basically, the morass of regulation and oversight has stifled the type of research that can be carried out in a DGH such as mine to the point of extinction.
- Since the Liverpool thing its becoming increasingly difficult to conduct research ultimately one spends a whole lot of time moving bits of paper - I think college should not have run scared as a result of Liverpool
- For e.g. is ethics approval required for imported tissue or not if it has been cleared at the site of tissue collection? This is actually very hard to find and conflicting.
- We have a limited amount of time to spend on research and so more of our time is spent on governance issues than actually doing research. Excessive bureaucracy dampens one's enthusiasm for research and enthusiasm is without doubt the most important ingredient for research. I suspect that the regulatory authorities are blissfully unaware of this.
- Whilst ethics committees become more professional the regulation in R&D is less fixed more fickle and highly dependant on quality of staff. In my trust senior management of R&D has been poor and severely hampering work and has led to repeated loss of high quality individuals. I believe like ethics all R&D should be regionally led by parallel system working as one stop shop. Poor quality research is unethical also supervision is of variable quality.
- The temptation is to get on with it and await the brick bats as the regulatory hoops are so all consuming and delaying.
- Lots of guidance but their application is inconsistent and confusing - even home office inspectors variably interpret their own guidelines and the bureaucracy is over the top.
- I help with the research of others but would no longer dream of starting anything of my own. It has taken 6 months just to get permission to send tissue blocks away for ….., and that is only retrieval of tissue already taken for treatment and all permissions and ethics approved elsewhere !!!!!
- It would be helpful if the RCPath or PathSoc could summarise all the relevant regulations into a single, user-friendly, brief document with hyperlinks to the relevant documentation. While there is a lot of bureaucracy, I would feel very vulnerable without it, given the repercussions of Alderhey etc. I think it is also important that researchers understand the full legal and ethical implications of what they are doing. If one goes back a decade or more, I'm not sure this was always the case.
- I rely on my Trust R&D Manager to tell me what I need to do, and she will do most of the paperwork for me.
- Only tend to access dept of health, NRES or HTA type websites as not actively doing my own research just guiding others where needed.
- The HTA web site is overly complex and difficult to navigate. The search function is useless. NRES has improved but the site is still very slow. Advice is difficult to get.
- Streamlining of documentation and guidance from the various sources into a single easily accessible, well-publicised source would be most welcome, to avoid wasting time and energy checking them all out. It is difficult to envisage clarity, however, when the legal framework is so restrictive, especially in regard to definition of "relevant material" as not being confined to material from the deceased [as the Scots cannily did], setting the default to "discard" rather than "retain" when we don't know families' and patients' wishes in respect of tissue storage for future research, and insisting on a burdensome ethical approval seeking process no matter how simple the research project, especially projects using archived material. I welcomed hearing at the recent Bioethics meeting that the ethical approval process is being tackled imaginatively on the last issue. And rendering samples totally anonymous is self-destroying except if the material is to be used as controls or to validate a method. I know the Act says "anonymised to the end user" - but even that is burdensome enough.
- I think the main point is that many of us with strong research backgrounds have simply either given up trying to do human tissue-based research at all, or else just piggyback on projects run by others with the requisite administrative backup. Either way our skills and expertise are not at all, or are not fully utilised, to the detriment of the remaining work that is taking place. (Incidentally, as I know from my work on the Physiology Society Council, the animal-based research environment isn't much better).
- I quit the NHS consultant post basically because it had become so difficult to carry out research that was desired by patients, staff, administration, etc. but so difficult to organise through officialdom that it had become virtually stopped. Some of the impediments were ridiculous (and one has been withdrawn). Research was so slow to get permission to carry out that it was being done by my overseas competitors before me. Even if things were not costing any money and were potentially of advantage to large numbers of people, yet were not even vaguely likely to be of risk to anyone they were being stopped by officials. I was finding that junior docs simply could not get any permission in time to carry out research projects and hence were not learning how to look on research in the future. Appalling. The system is a mess and I would be willing to stand up in court if required and give good explanations of why major good research is being stopped. And you can see I am very angry about this.

- Regarding 4.2 It would be more complete to say "I do research at the moment, but the difficulties I encounter put me off doing it in the future".
- guidance seems to change between projects, particularly HTA
- It is not so much the quality of help and guidance but more the amount of work required. This trust has now introduced a MTA that has to be signed by all stakeholders for transfer of tissue from trust to University.
- The overall quality of available advice is poor and the continuous changes in forms and regulations e.g. ethics, is extremely frustrating and has led many in my environment to abandon any semblance of an effort to conduct research.
- I have experience directly opposing guidance/responses from different ethical authorities, including LRECs, HFEA, R&D and University. The biggest problem is that each approval organisation wants to be last in the queue. The 'sponsor' usually university or NHS R&D wants funding to be organised in advance, and ethics approval. Ethics committee wants sponsorship and funder wants ethics approval in advance (particularly when the topic is ethically challenging, such as embryology). HFEA approval needs prior ethics approval. No work can be done in advance of ethics and HFEA approval, so it is often difficult to initiate pilot work necessary to gain more substantial research funding. When one organisation requires changes, they have to be fed back to each of the other organisations to get approval and this is often an iterative process. All of the above also require annual reports on progress, which is time consuming. My last approval of project via LREC took 2 years to achieve. Owing to changes in legislation, the topic now will need additional HFEA approval and this will add top the regulatory burden and cost money.
- There is a lack of clear comprehensive guidance. Correct guidance can be hard to find. The variety of bodies involved and the nature of available guidance mean that it can be conflicted.
- My role is to facilitate research to happen in the …….. Cancer Research Network. I do not get directly involved, but offer assistance and advice to liaise, coordinate or unblock blocks.
- Just when I think I understand the rules, I read/hear conflicting advice and then am not sure I have applied the rules correctly.
- I would like to see a less hostile and more focused and cohesive approach to the governance of biomedical research so that definitive answers can be found in just one or a few places to essentially all the key questions, this would help the preparation of submissions a great deal. I would prefer if the rules were simpler and covered only essential needs. In particular I would like the approval committees (e.g. RECs) to be more sensitive to the needs of research and to provide responses in a more timely manner as it can take a very long time (many months) to get ethical approval for even a simple investigation.

In response to question 5.1, the following were specified for respondents as comments:

- Depending on the type or aspect of guidance I need depends on who or where I ask. It sometimes helps to try and get a concensus of opinion from verious sources.
- The colleagues to ask for guidance are very few. It is my though them most NHS pathologists are overwhelmed by the high numbers of regulations and regulatory bodies to decide to give up research.
- The Royal colleges are simply their members, so they don't really know any better than the rest of us, hence why I tend to go to colleagues who may understand the complexities, and have, in effect, already translated the rigmarole into understandable language. I certainly dont waste the time of my local NHS R&D office as they are so swamped dealing with all the other beaurocracy impeding research.
- It would be useful to have a single unified source of information based on a simplified flow diagram.There seem to be too many authorities involved in this exercise. At the same time, academia is very limited in its ability to provide guidance.
- Not sure where to go for which type of sample. Eg stored clinical material, setting up reference serum bank, is it permissible to retain any fixed tissue, setting up prospective study with patient samples.
- I have sometimes had to correct misunderstandings through referring LREC or other local regulatory staff to the wording of specific legislation or to FAQs listed on the HTA website. A recent example concerned a disagreement as to whether or not additional/extended LREC approval was needed for a 'pure' research lab (not part of an HTA-licenced facility) to retain histological sections after completion of an LREC-approved research project if the sections were to be retained solely to ensure that funders/other interested parties would have the option of auditing the research data, should they query the findings, but not for any further research using those sections
- Internet makes most of these useful. Most guidelines produced Royal Colleges etc are of marginal use
- For anything that is 'out of box' I had to tease out information from various sources with great difficulty and had a feeling that the information was rather arbitrary without clear arguments to support it, especially at the REC level.
- Most of my work is clinical trials for therapies but some involves tissue work transferred to a colleague.
- I am utterly confused as to the purpose of CLRN and NIHR in this role, as indeed they seem to be themselves.
- Local NHS R&D office difficult to contact, some members of staff seem incompetent
- I let others deal with all the admin, and am happy to contribute provided I don't have to have much to do with it all. It's all just too much to deal with - hammers to crack nuts, or pointless, or unthought through, etc etc etc
- But all of them admit that the system has become so difficult that simple research has dried up
- Speakers and attendees at workshops
- They seek it here they seek it there …. And only rarely find it…..

- I seek advice from the local REC coordinators as they are very useful!
- There is a plethora of guidance. What is needed is some joined up procedures among the different organisations.

In response to question 6.1, the following were specified for respondents as comments:

- At the University of ……., The Research Governance Implementation Group is centralising a coherent flow-chart of assistance and instructions together with hot-links to appropriate documentation so that researchers will be directed to the documents and regulatory guidance appropriate for their individual type of research. This guidance will be accessible on the University Intranet, prominently displayed and linked through the University Home Page. There should be an equivalent set of guidance documents, agreed nationally by all interested bodies, as a single source from which all researchers obtain their information.
- Depending on the guidance needed tends to influence who I approach.
- One source is needed with a help desk
- A one-stop shop would be helpful but they would need to understand the nature of the research being done and the levels of consent and regulation required. Very few individuals would want to block the use of their tissue for genuine research if the details were appropriately explained to them but current regulations seem to assume that the default position would be refusal. I think that there should be an assumption of consent and efforts should be made to develop an opt out policy.
- I would prefer to see less number of regulations and regulatory bodies.
- Should be available on college website (or some such) as to which one body for the research you wish to carry out.
- I would prefer guidance from the local NHS R&D office, but they are hopelessly disorganised (due it seems to constant use of locum staff).
- I don't care where it comes from so long as it is easily accessible and consistent.
- I appreciate it is difficult to make one organisation the one and only reliable source, but it certainly would make things easier.
- The problem is that even the regulators are sometimes unclear about how to regulate clinical trials using biologicals.
- I don't have a firm view as to who should be the source of the guidance but feel that it should be accessible through a single portal
- I don't think it matters; as long as a single agency took control and simplified the process
- I don't mind where it comes from, but knowing one place where authoritative, comprehensive guidance could be obtained would be extremely useful.
- I would prefer all the guidance to be in one place e.g. local R&D and them to have the time and expertise to help me access the right guidance.
- University research and governance office
- Does not matter as long as accessible, understandable, consistent
- I prefer the guidance of the University Research Governance Office
- Would be nice to fill out one set of forms - guidance from one source, preferably NHS R&D would sort this out.
- Trusted colleagues offer security (i.e. expert witness) in a professional environment in case of challenge by other sources.
- I find my local R&D office too preoccupied with being the "regulator" to offer informal advice about the procedure but this seems the obvious place to be the advisor
- I am happy to follow guidance from "regulators I believe applicable to my research". However, frequently I am unsure which is the appropriate regulator (particularly since trials involving blood sampling but not requiring administration of a trial drug have been included in the Clinical Trials Directives) since the HTA and MHRA overlap. I do not believe that the full weight of GCP compliance (sponsorship, CTA etc etc) should be applied to clinical studies in which some extra blood samples for laboratory analysis where there is no patient safety issue. This is not something which the MHRA appears to be interested in regulating and I fail to understand what increases in quality are achieved by MHRA regulation in this setting.
- Common sense and a moderate approach still has much to recommend
- Anywhere as long as it gives the advice without shunting you on to somewhere else, and is not then contradicted by local "committees" or the other way round. Also does not change forms etc when part way through as happened to Ethical approval applications recently
- One organisation to oversee all guidance and to do it very well, and with complete authority. Not concerned as to which organisation takes it on
- A single source of regulatory and governance guidance would be best (see last comment)
- I prefer a properly unified regulatory environment where I don't have to "seek" guidance, but where the rules are straightforward and proportionate, and everyone knows what is going on. Currently many of the quangos charged with these issues (e.g. HTA) are staffed by inexperienced and unqualified staff, and issue "guidance" which is both internally and externally inconsistent, and not even necessarily specified by or even related to the statutory requirements.
- A single source, with ability to advise how to obtain (rapidly) permission to carry out research. You must never forget that we are dealing with disease and must never linger simply to await 3 months for the ethics committee.
- No preferred source for advice on multicentre collection of histopathology data and tissue
- I don't have an opinion, providing it is clear, comprehensive, concise and correct. By "correct" I mean that if I follow it, my employer, funder, local REC, PIAG, etc etc all then agree that the work can proceed.
- In general support is poor and not freely available. In pathology most senior staff who conduct research, write applications etc. In non-standard hours - they have to devote working hours to their day job - when they need the help its not available

because its 'out of hours'.

- I would like definitive, consistent guidance that reflects what I am told by the clinicians seeing the patients. Is what the vast majority of patients want i.e. their anonymised data to be used to further our diagnosis and understanding of their disease.
- It doesn't matter where the guidance comes from, as long as it is straightforward, accessible and not duplicated.
- I would prefer one authoritative source of guidance that avoids repetition and discrepancy.
- Would value comprehensive guidance from any one appropriate source
- I believe there are areas that are grey in the rules! And hence global communication can clarify if the specific situation is addressing the right rules and accounted for the reasons its not addressing others.
- I believe that all regulations and rules on human research should be administered from one authority and guidance should come only from that authority, this would allow users to be clear on what is required.
- To do good research, effective networking is essential. NCRI has been and remains a highly successful model of how this is best achieved.

In response to question 8, the following were specified for respondents as comments:

- Best practice guidance needs to be tailored to specific situations.
- Guidance that helps one to do something, rather than issue dyer threats of retribution if one doesn't comply.
- We should strive for best practice but it should be clear what the minimum standard benchmarks.
- Again simple straightforward guidelines, not something like the current Home Office ones for example.
- What is the role of best practice in this context? Proposals are either compliant in terms of regulatory or ethical framework or not. They cannot be better compliant or extremely compliant. Scientific validity will be judged in the time honoured way by peer review.
- Guidance should deal with the legal requirements. "Best practice" (if that can be clearly defined) is something else and should be dealt with elsewhere, e.g. by Colleges etc. But if it's not legally required, then it's actually discretionary, unless "best practice" is virtually unanimously agreed.

In response to question 9, the following were specified for respondents as comments:

- The inconsistencies between RECs is difficult to cope with. Clear guidance on when tissue used in research has to be consented would be helpful, but only if it were not too defensive.
- Please can we all work towards clarity, coherence and consensus with respect to the regulatory framework within which we are all trying to work. There is no place for internecine rivalry between individual groups with petty invested interests. This is the current situation that is only becoming increasingly detrimental to the performance of world-class biomedical research in the United Kingdom.
- Lack of continuity of information and contradicting information makes some areas a minefield and makes some researchers very wary. It is very difficult to give good advice when there can be so much inconsistency of information available.
- Inadequate knowledge of DI's for research, inadequate knowledge in REC's but this has got much better.
- Time is the main constraint for clinical researchers the process should not be over burdensome in terms of bureaucracy
- We wish to send data and the results of basic tests (nothing particularly novel) to a central registry in Europe so that larger numbers are available for more accurate analysis. No-one seems to know if the patients have to be consented. Also in association with the NCIN we wish to develop a national registry of patients with a certain disease associated with basic test results and a biobank of diagnostic material. We cannot get help regarding how to go about consent and ethics without assuming an enormously laborious approach to many individual ethics committees.
- It would be helpful if consultant pathologists like me, were responsible for the quality of their research rather than for the regulatory and governance guidance issues. In order to promote more research in my department I had to become involved in local discussion to include the use of tissue for research in the patients consent form. I am now exploring how to obtain research licenses from the HTA. However I find very difficult to be involved in patients consent and HTA issues on top of my heavy NHS workload.
- I do not find the guidance the problem. The problem is all the red tape and hoops that we have to jump to do simple research. I rely on R&D committee for guidance, but they are too busy to be efficient. My last project (which in my opinion did not require ethics or R&D approval) took one year to get started.
- As a geneticist, myself and many colleagues are constantly beset with the problem of collecting rare cases, necessarily from across the UK, and such that there may only be one case per hospital or even NHS region. Getting ethical approval on a national basis, without the necessity to get approval from each and every contributing centre, would be so much more ethical in terms of avoiding unnecessary hindrance and time wasting. Also, the drag on the whole research system of having to have so many disparate and unconnected regulations means that, for example, doctors in training who wish to do projects can spend the whole of the time allocated to them in simply filling in forms and getting ethical approval, such that the research is put at risk, or even never gets carried out. This has to be considered unethical. The whole ethos of the law and regulations is designed around trying to catch the occasional wrongdoer by imposing draconian rules on the law-abiding majority, to the detriment of all, which feels like being considered guilty before you've even started.

The balance has to be re-addressed. Many years ago I was involved in medical research under a related, though separate, jurisdiction to the UK. Discussing a project with the local CMO over the phone, 8,000 miles away, I mentioned that we would need ethical approval, which elicited the response "I am the local ethics committee, we can just get on with it." This highlights that the positive disincentive now to carrying out research in the UK encourages collaborations in other countries where it is easier to carry out such work

- I feel that anonymised research on archival tissue is grouped together - in governance etc terms - with many different types of research including therapeutic trials and other studies of living patients. As a histopathologist I believe that the current system severely stifles research as, to me, a lot of what research is about is developing an idea or clinical observation into a hypothesis, maybe with some pilot experiments, prior to engaging on a larger scale study. However, nowadays one feels as though one cannot undertake even the smallest study without mountains of paperwork. Would it not be possible to explore a new direction, in which departments could be given ethics approval etc for archival tissue studies - ensuring that the studies fit certain guidelines such as being unlinked - without having to go through all of the paperwork for every small study undertaken? I recently supervised a BSc student with an intercalated BSc project and she spent more time sorting out paperwork than actually doing the study! Also, as a full-time NHS consultant, even working in a teaching hospital, I don't have the time to go through a new set of paperwork for every idea that I have for a study. I am personally committed to research activity but I can imagine that the paperwork must be putting many of our bright trainees off following an academic career path. I'd be very happy to discuss this further with anyone if that would be useful.
- I consider that the current regulatory environment is slowly strangling translational research in this country. I think our performance in this area is poor. Increasingly I am seeking clinical material from overseas colleagues. A move toward establishing disease-related biobanks seems a positive development, but both local and national efforts in this area have yet to provide material for the research I wish to carry out. If biobanks are properly funded, and cover all of the regulatory issues, such that all I have to do is to apply for access to material, this would be a positive development. Whilst there has been some progress by the NHS in this area, I am not convinced that academia, the potential source of much high impact research, has yet signed up to this task
- Opportunistic research of the traditional kind in histopathology - try a technique on a series of tumours of cases to test a hypothesis - used to be easily done and was essentially free. This is now impossible without individual patient consent, funding and ethical approval. Without these done many months in advance, no journal will publish the results. Trainee pathologists cannot now do research projects and must instead do 'audit' projects. It is now my conviction that i cannot do any research in an NHS laboratory setting without a burden of administrative effort which cannot realistically be achieved in the time and resources available. Research is now a closed field. Interesting work which could be started in DGH laboratories must now be subsumed in larger institutions who maintain an industrial approach to administration, governance and funding for research. Perhaps this is a good thing for quality and ethics; it cuts me out completely and ones efforts will be elsewhere than research. I am completely inhibited in attempting any scientific research at all apart from, i suppose, managerial surveys or epidemiological studies. I do contribute material to other people's research on request.
- FAQ section would be useful to deal with specific cases.
- Several interesting small projects looking at diagnostics but unable to be carried out as keen and interested medical staff finished rotation by time permission came through.
- It is time needed to complete all the paperwork and satisfy all the regulatory requirements which is inhibiting clinical research to a marked degree.
- I provide HIV+ brain material for researchers, from my personal autopsy cases. There is confusion over what constitutes consent between the local NHS REC and the HTA. Ultimately the HTA were wrong and had to back off their restrictive position. But is reinforced to me the silly position we are in when dealing with tissues from the dead. Everyone is scared and moves to a position of no-blame-can-happen, it do nothing, so making productive research endeavour difficult. If HIV happened now, we would not be as fast in working out what is going on, using human tissues, as we were back in the 1980s - thankfully.
- We have abandoned some projects after finding the process too complicated and time consuming.
- Virtually impossible as an individual to fulfil all the regulatory obligations for research that means only larger groups can function. This stifles individuality from where much ground breaking research has originated in the past.
- The R&D offices need to have more knowledge about this process. They usually employ lay people who do not have a clue of a) research, b) governance frame or c) biology. I believe the R&D offices should be ahead of us, researchers, in regulatory framework.
- Research activity for the 'interested' as opposed to the professional worker has been seriously undervalued and compromised by the overabundance of regulations.
- I feel that its going to become impossible to conduct research in the future one key component of any committee has to be representation of individuals active in research.
- Jargon and language used in regulatory documents is often difficult to understand. Simple text will make it easier to read and understand. Flow charts are useful.
- Lets make it easier rather than harder for NHS staff to set up research. If we don't, people will vote with their feet and justify their existence by doing more clinics.
- As chair of ethics biggest problem Path research was getting an elusive "no need for direct consent" for research more annonymised tissue/organisms etc was only need if clinical data or epidemiological data only. I spend a great deal of time trying to XX projects to service review/audit format to avoid ethics submissions if this would suffice learners' needs. Academic quality of many submissions was poor. The fragmentation of

ethics review from R&D is stupid as most of the reasons for flaking ethics submissions was quality of research not ethics. Understanding of regulations by researchers/supervisors was poor as was understanding of research methodology/stats etc. If I were creating it I would have a 1 stop research shop in each region/high quality supervision and 1 stop info shop. All HCW require formalised training (could be email based) in R&D/ethics req beyond certain grade all med/dental students compulsory sessions at F1/F2 level. Org could be private or DOH attached either would work. Add hoc local arrangements / absense of quality R&D staff. Ignorance in new R&D staff at ED level hampers local research more than regulators.

- I find the whole system very complex and labyrinthine. Despite going through this process on a number of occasions, I still struggle with the jargon, the acronyms, the questions that I cannot understand (not being a medic) and most particularly, that the huge number of different forms seem to be designed for people doing clinical trials rather that collecting tissue or accessing pathology specimens for biological research. Things have improved and people are very helpful, but the whole system is designed to put someone off ever trying to do research on human material.
- A recent study on fine needle aspiration material which was superfluous to requirement was said to require patient consent and the means of getting this involved so many people the whole study fell apart before it could begin even though it had taken 12 months to set up. Very frustrating and totally over the top!
- My local R&D and Ethics committees have in the past insisted on individual patient consent for retrospective histopathology review type studies for material taken prior to enactment of the HTA. This makes such "bread and butter" pathology research almost impossible. Clearer central guidance needs to be given to R&D committees regarding interpretation of the law.
- I am fairly new to research. I have submitted just two research protocols for approval in the last 18 months and have to say that the process was (and still is) tortured, frustrating, long winded, demoralising, and bureaucratic. The system seems to be set up to discourage research. Some individuals involved in the approval process appear to be more concerned with 'covering their backsides' than with facilitating the procedure. This is clearly not in the best interests of the NHS or of patients.
- Collaborative research NHS/academia and industry can reveal interpretation differences between sectors. Where research across international boundaries is planned, it can be difficult to get researchers and tissue suppliers in other countries to understand and accept the consent requirements of HTAct
- Too many organisations involved all of which gold-plate their requirements, are incapable of delivering quick decisions and generally obstruct through an inability to make decisions.
- I have always found the language of this guidance very difficult. Many times one can interpret these statements in more than one way. Therefore, I would like to have guidance in a simple English which could be understood by students (with no experience) and scientists alike.
- I have found at times the distinction between service development and research is blurred. Understandably you need consent for extra samples or procedures, but where investigations done on stored samples as part of service development generates publishable work the process is unclear with contradictory advice from NRES and local NHS R&D.
- On the basis that when patients are asked a simple question "do you consent to left over tissue or giving a blood sample to be used in medical research" almost all patients are in agreement to their tissue being used and all researchers are in agreement to respect the wishes of those who do not consent. Despite this self evident fact the current regulations are complex, massively time consuming, extremely bureaucratic and strongly discourage commitment to research. If such complex regulations are required then there should be either an acceptance that research will be discouraged or that charitable funding by society to support research will be taken up to employ individuals to fill out forms for submission to the various regulatory bodies.
- Many, many colleagues have dropped out of research because it is not worth the candle. Importantly, colleagues tend to strongly advise trainees that research is best avoided. IT IS TERRIBLY bureaucratic AT PRESENT. HELP!!!!!
- Guidance relating to regulation and governance was helpful to write our Tissue Bank ethics IRAS form.
- Much of microbiology research involves use of bacteria cultured from patients yet our R&D dept require patient consent, ethical approval when studies are epidemiological (no change in patient management as a consequence), but outcomes are recorded. E.g. I required patient consent to find out from patients' GPs if patients with pneumococcal bacteraemia had been vaccinated prior to infection in a retrospective study.
- The whole area of regulation of human tissue is very confusing and has caused a vast amount of waste of resources for something which should essentially be simple. There is a huge amount of confusion about what needs to be registered under the Human Tissue Act - many researchers believe it is any human tissue being used in research rather than just tissue banks and are consequently wasting a large amount of time trying to comply with something that they don't need to comply with. I see many researchers moving away from studies with human tissues towards cell lines because it is so much easier to carry out that work and I myself am moving towards mathematical modelling of disease which does require any ethics or R&D approval if it is away from the clinical environment. The major blocking point in this university/NHS trust is not the ethics committee or compliance with the Human Tissue Act but the Trust's R&D office. They insist on sending applications for internal scientific review which is usually from people who are not actively engaged in clinical research but are worried about compliance with regulatory authorities and usually propose unnecessary and draconian conditions upon any research. The office is also swamped with applications and can take 3-4 months to process an application before ethics committee application can be made. It is also interesting to note that there has been a collapse of the ethics committee infrastructure in this area under pressure of applications, with committees unable to fill vacant membership slots and those committees have

had to be disbanded causing extra pressure on the remaining committees. I recently received external funding for a project (and the conditions had been changed so ethics application was made after successfully obtaining the grant) and it took 10 months to gain the NHS R&D and ethics approval for a straightforward pathology project of immunohistochemical staining of archival paraffin-embedded material with patient anonymisation.

- The following greyer areas would be good to get guidance on: what to do with archived samples; how to get permission so that your research nose can lead you down different paths without having to keep on going back to ethics.
- The system needs to be simplified. Application forms need to be fit for purpose. The whole process needs to be streamlined as it is slow and cumbersome. The labrynthine complexity does not appear to me to offer any added value in terms of protection of patients.
- As soon as a bureaucratic process is undertaken, many of those attracted to the administration will be mentally adjusted to stop activity as this is their source of power. Therefore the temptation is to rely on my own judgement and that of colleagues to save time and the huge effort to satisfy these regulators
- It is quite clear that a number of my colleagues simply do not bother to do pathology research with laboratory animals because of the sheer complexity and confusion of it all. It can be made even more difficult by additional procedures being applied locally.
- I conducted a very simple piece of research using archived slides only. I had to complete numerous forms for the NHS R & D and seek ethics committee approval which seemed rather a lot for such a simple project. If I had said that the project was 'audit' I probably wouldn't have had to jump through these hoops. I feel that regulation is obviously important but it is somewhat excessive and unclear at the moment and this certainly puts me off conducting 'micro research' let alone bigger projects.
- The whole process is now too complicated and bureaucratic. This dissuades student-type projects and therefore research exposure to potential future academics. Non-academic Consultants who used to like to undertake small projects, case reviews, ICC etc. to enhance the day job, now fall at the first hurdle. Moreover, the guidance and guidance sources undergo such rapid changes and shifts in direction that it is difficult to maintain currency unless one is in full time research. The perception at the front line is one of positive discouragement to undertake research - particularly small projects. This is reinforced by funding changes and the requirement to compete with large, established centre-of-excellence for funding. Between the HTA, NRES and Trust R&D committees, the cost in time, effort and money is now compellingly dissuasive. Bravo HMG !
- As a co-ordinator of clinical trials it is notable the difficulty that pathologists have in taking part in studies and providing specimens. The issues appear to be 1. They do not feel that the research is relevant to their practice. 2. They have neither the staff not the funds to participate 3. They are often not asked directly whether they wish to participate 4. They are worried about the legal/ethical implications particularly in light of recent pathology issues in the UK. 5. I suspect they often do not receive feedback on the results of the work they have participated in. Additionally I would add that having previously tried to get advice about a particular project from PIAG, it was very difficult to get someone to give a definitive answer as to whether a particular approach was acceptable or not, therefore one body would be a good idea.
- It's the implementation of the guidance that seems to be the problem. By the time the paperwork has been done, one has to start again with literature searches and revise the topic. Much of the time that was available to do the research has been lost.
- Proliferation of regulations is undoubtedly discouraging many researchers, in particular reducing the number of 'investigator lead' projects in health related topics, and causing undue delay in commencement of such research. Furthermore, Clinical Trials in UK are being held up by an over regulatory approach, with consequent detrimental affects for patients. For example, commercial Clinical Trials are increasingly being directed towards former 'Eastern Block' countries with consequent non availability in the UK of novel , but as yet unlicensed, drugs which may offer some hope to, for example, advanced stage cancer patients. The problem appears to be twofold: the proliferation of regulations, often promoted by those with little or no understanding of the nuances of the issues involved, in a regulation obsessed State (UK), and over interpretation of the content of these regulations with implementation of processes which are overly bureaucratic. The regulation of the activity has become more important that the activity itself, consuming considerable resources which, as a result, become unavailable for the research. Collaborators in Continental Europe appear to have far fewer hurdles to overcome than UK based researchers. What is the evidence that any of the regulations introduced during the past decade has had anything but a negative effect on research, and what is the evidence that any has had any positive benefit for the wider public?
- We do a lot of research where all we need is a blood sample at diagnosis. The patients are very willing and eager to do this. However, it is now almost impossible. We have to get R and D approval for each project which consists of filling in a large number of forms (We can no longer no local investigator with a single form and letter but have to fill in all the forms, thus making sending samples to other projects very difficult). It is obviously of interest to those in the R and D offices to do this as they have to justify their new jobs The university who is one of my employers have no understanding of the human tissue act and have decided that they must have all samples logged and forms filled in regardless of the fact that ethically approved research does not come within the remit of the human tissue act. Those holding the licences are non medical and just do not understand the human tissue act. We have been threatened that if we do not comply we will be disciplined. However this has just another set of forms to the detriment of any research project.
- I'm not sure that the regulatory frameworks are a major barrier to research in pathology. The difficulties encountered in trying to get funding are, in my view, a much bigger problem. This

appears to relate to scientists' and funding bodies' perception of pathology as an irrelevant and descriptive specialty that has not embraced scientific developments, which is not a universally fair criticism. As we all know, the RAE has not helped the universities' and funding bodies' perception of pathology. My personal view is that the reinvigoration of pathology relies upon close collaboration with clinical medical or scientific research, including joint applications for grants. However, it may just be that I have been very lucky in …….. to have colleagues who have kept abreast of regulatory changes and implemented relatively user-friendly mechanisms to comply with them and so my experiences may not be entirely representative.

- Interpretation of HTA varies and in order not to accidently contravene (which carries unusually harsh personal penalties) most this DGH and the BMS have opted not to attempt the minefield to do a lan based project. These were very good training for them and an audit is not a good replacement but does not risk refusal or unanswerable questions at late stages. Even local ethics committees do not seem to know how to deal with these things when relating to tissue in labs as opposed to patient/drug trials
- One of the biggest hindrances to carrying out research is the very low status that research has in the job planning process. It seems that most Trusts regard time carried out on research as a waste of time that could be invested into a greater level of clinical activity. It is not unheard of that this Trust attitude has pushed medical staff to pointedly disengage with all research activity in order to avoid possible future cuts in their number of paid sessions. To some degree I can understand Trusts holding this view for "basic" research, but activity in applied research can only enhance the quality of clinical care. I appreciate that this is not directly relevant to your questionnaire, but unless Trusts permit time to be spent jumping through regulatory hoops, no matter how the regulatory systems are overhauled, research will continue to be hindered in the NHS.
- I think you need to be careful about making too many assumptions - i.e. don't assume that everyone has research infrastructure that works, trials practitioners, R&D depts - a lot of work is done by , essentially "committed amateurs"
- More practical guidelines, not just regulations would be useful. From experience, the main hindrance to research has been the lack of pathology support staff to obtain material not simply the regulatory issues. Also, pathology departments also expect payment (sometimes quite substantial) for their work in relation to clinical trials and this is not always possible, especially in the case of charity funded studies.
- There is considerable variation in research regulation internationally. The UK is so tightly regulated it clearly puts UK researchers at a disadvantage. We should revert back to internationally agreed standards of ethics in order to be competitive in output. Recent legislation has made everyone suspicious of researchers and their activities. This is wearing and does little for moral. Many clinical colleagues refuse to get involved on a matter of principle, or because they are genuinely afraid of conviction. This damage this has done to UK research is incalculable.
- The problem is not one of guidance but the sheer weight of regulation such that more time, effort and energy is spent on complying with regulatory matters than on the scientific research. For clinicians and scientists, the prime motivation for doing research is to answer scientifically interesting questions. Regulation is becoming a huge obstacle to addressing such questions and putting off all except full time academics from undertaking research. This may be seen as a good thing by regulators but will inevitably have an impact on "translational" research which involves clinicians sitting in clinics rather than at their desks. I have been chief investigator of childhood leukaemia trials for 10 years in a full time NHS position but the time and effort involved with regulation means this will no longer be possible.
- I spent 6 months getting approval for a grant application that was turned down. It was really time consuming and a bureaucratic nightmare. I have not done any research since for fear of having to repeat the process or of being caught out by missing some new piece of legislation.
- The approval form for the ethics committee is so long that it takes longer to fill in than to do the research project. The questions often repeat themselves in different words. It is so tedious that I no longer do research.
- In organ transplantation taking and using tissue and other samples is a minefield as it depends on what it is taken for and hence whether it comes under an HTA Licence or not. A recent example at …….. illustrates the tortuous reasoning required. Our immunologist wanted to ask the harvesting surgeon to take an extra 50ccs of blood from cadaveric heart and lung donors so she could run a new test for anti-endothelial antibody cross-matching alongside the standard diagnostic anti-HLA antibody cross-match. This was to test if a positive anti-endothelial cross-match increased the risk of subsequent rejection in the recipient. She presented this as a research project for ethical review and it was sent to an outside REC because it involved taking blood from patients who cannot consent for themselves. The project was approved, but the REC said that she needed only generic consent and could use left-over blood rather than upsetting the family by approaching them for specific consent to take extra blood. Unfortunately with the 20 - 30ccs of blood currently taken for tissue typing, there would have been insufficient left over for this work - hence the need for the extra 50ccs. She approached the HTA for advice and they immediately said that the donor centres must have an HTA Pathology Licence as the primary purpose for taking the extra 50ccs of blood from the cadaveric donor was research. While this was going on, our immunologist obtained access to a paper from researchers in the US and Sweden, THEN in press in THE JOURNAL Transplantation, doing exactly this in both cadaveric and live related renal transplants [and outside UK jurisdiction boundaries!], and confirming a significant risk of rejection in the presence of a positive anti-endothelial cross-match. So she was able to convert her "research" project into a "Service development" project based on the evidence gleaned in renal transplantation. The HTA agreed this and our surgeons now take the extra 50ccs of blood for her as the primary aim for the sample, now, is diagnosis relating to transplantation. While this episode ended well for us, as someone else did

the research (but got the glory!) and we just put it into clinical practice, it illustrates the great difficulty we have in teasing out the regulatory aspects of our research in these "gray areas". If the renal work hadn't come to publication via my colleague's desk she would not have been able to get the extra sample for the research that would have been needed to justify its use in clinical practice. She tells me that several groups in the UK doing transplant-related research using donor tissue now feel unable to do so because of this issue of the donor site having to have a pathology licence, and suggests that when a transplant is in the offing, the sites should be exempt from the Pathology Licence requirement as the research using donor tissue that is envisaged is done with the aim of improving recipient survival. She has taken it up with the British Transplant Society - but not taken further, as far as I know.

- Successful research is essentially a bottom up activity. The current environment is relentlessly top down. The two don't really mix. If the UK is to have a healthy research environment the balance must be redressed properly with a rationalisation of all the legislation. I don't think rationalisation of "guidance" by itself will do the trick. This will really just be window dressing. We need to lobby for a proper legislative overhaul.
- R&D offices guidance and processes have been of least use and are too variable and complex. - difficulty with finalising NHS Trust approvals has negative impact on research. Some Trusts are unable to begin processing our application for requesting follow-up material due to work overload. Seeking multiple approvals and collaboration for epidemiological research involving pathology is seriously challenging Some pathologists have been alarmed by and been unfamiliar with the R&D approval process required for helping with research e.g. signing the Declaration on the SSI form.
- The frustration for me is the diversity of organisations that must "approve" my research. I came into research 6 years ago determined not to end up like my jaded senior colleagues who gave up research when the paperwork got mildly challenging in the early 2000's. I made the effort to familiarise myself with REC forms, and managed to get projects approved and get on with some work done. But even in my short career the paperwork burden has mushroomed. I now can't put a spreadsheet together without registering it with the Trust. I can't get follow-up data from our cancer registry, despite having ethical approval to do so, because I now need the additional approval of PIAG. The NRES site is good and deserves credit for unifying the Trust R&D and Ethics side of things, but there are still too many approvals required from separate organisations. The result is that I've become as jaded as the aforementioned senior colleagues, and am increasingly unlikely to pursue a research career in this country. It quite genuinely takes longer to do the paperwork than it does to do the science, and that's just not a satisfying way to spend one's professional life. (3) Back on track, "Guidance, what guidance?" I see a multiplicity of sources, none convincingly authoritative, none offering model answers, and on the day it all comes down to the whims of my LREC and local R&D office. And now PIAG (or whoever they are now).
- I have never been able to make the quantum leap to obtaining high level funding for my research interests over the years and have therefore focused on service and development in my field of molecular haematology - setting up a specialist diagnostics service in a hospital setting. The amount of regulation means that it has become impossible to perform any research on a small scale and I am limited to contributing to the academic work of others for example by contributing to biobanks. One negative spin off is that I am unable to provide laboratory projects for BSc and MSc students which is frustrating. It has become very noticeable at international meetings that the UK lags behind in research - quite commonly I see EU colleagues presenting data from studies that I know my UK colleagues are still trying to get through regulatory hoops. To me, research is about curiosity, impulsiveness and enthusiasm. This dissipates rapidly as one grinds through the 6 - 12 months of paperwork and I suspect that this process is having a massive negative effect on young researchers.
- The main problem is that simple research based on surplus tissue and minimal demographic data is treated almost as if it were a clinical drug trial despite the fact that there is no potential harm to the patient. It has become almost impossible for junior staff to gain a research grounding by doing such small projects. The proportionality has been lost.
- I rely on my pathology colleagues quite a bit and this can be time consuming for them. Since I do not carry out clinical trials most of the ethical issues and governance for my tissue based work are relatively simple, yet I have to fill out the same expansive forms as if i carrying out such trials.
- I have found the majority of guidance confused and subject to continuous change. Some stability and consolidation might be useful.
- The problem is not just the regulations and guidance available but the differing interpretations put on the regulations by the various bodies involved. This is a serious problem with the simplest research that is not only self evidently ethical and has no real risk to patients and has few resource implication e.g. a simple project looking at the impact of an immunohistochemical stain of archival tissue on patient outcome will require approval from Trust R&D, Caldecott guardian, and an Ethics committee. Time to approval is at best 3 months making such projects difficult to use as student project; more often each committee will find some additional question (jobs worth) and require clarification on some point or add an unreasonable restriction that will have to be appealed. (there is particularly poor understanding of the HTA and due to the criminal sanctions committees take an unnecessarily restrictive view) more realistic time to approval is 4 to 6 months. Several of my colleagues have given up this type of research due to these problems. This is particularly to the detriment of student and trainee project in histopathology. I have calculated that for one simple project taking 50 man hours to complete and having no prospect of harm to patients there may be 100+man hours of regulatory and approval work (including admin) How efficient is that - Proof of Parkinsons Law. WHAT IS NEEDED IS MASSIVE SIMPLIFICATION OF APPROVAL FOR SIMPLE (AND HARMLESS) RESEARCH
- The most difficult issue is the use of data that has been generated from routine diagnostic processes from patients all over the UK

and potentially world wide.The definition of service evaluation, audit and research and how it applies to a body of data and to what level you can manipulate or add to that data is too open to interpretation and the subject of endless argument. The subject of databases, contributing to them and their use is so fraught that it is almost beyond discussion.

- The experience of myself and other part time researchers, who are not obliged to do research, but would like to, is that the whole regulatory environment is burdensome and excessive, and serves to deter us from doing clinical research at all. The system has evolved in response to the need to govern clinical trials and interventions, and in response to the Alder Hey scandal, but the response has been disproportionate, and includes non-interventional research with no potential for patient harm. In my experience, Ethics Committees are increasingly risk-averse and seem to regard researchers as potential threats to patient welfare who need to be controlled and curtailed, rather than seeing their role as facilitating good and useful research. My last encounter with an ethics committee involved a study into MRSA carriage - when the committee realise that some MRSA carriers who may be approached to be asked to participate might in fact be unaware of their status, they were appalled and refused to let the study go ahead before the matter was referred to the Trust clinical governance team, who debated it for a year or two, by which time the idea for the project, and the enthusiasm of various collaborators, had run out of steam.The Human Tissue Act in particular is a piece of bad law, which has the effect of criminalising research which is actually ethical: surplus diagnostic tissue was previously accepted to belong to nobody and could be studied by researchers acting in good faith, in order to increase medical knowledge, but now patient consent must be sought for most tissue types; working in Pathology, this is seldom practicable, and this puts a brake on this type of research by Pathologists. Full-time academics and researchers have no choice but to try to work through the system to get their research done, no matter how unhelpful the system is. Many NHS consultants like myself, however, tend to find it all too much, and either do no research, or limit themselves to non-clinical areas where we do not have to interact with the bureaucrats. Central to the problem, I think, is confusion over what research actually is. Research is part of the spectrum of learning, and learning from your patients and your experience is a core part of medicine, and should not need a separate bureaucracy to govern it, distinct from the rest of medical practice.This is the reason it can be so hard in practice to distinguish research from surveillance, evaluations of diagnosis, audit, etc - they are really aspects of learning, and clear lines cannot be drawn. Clinical trials involving therapeutic or other interventions do need some degree of governance because of the risk to patients, but the same criteria do not (or should not) necessarily apply to all the other activities that can be called research.
- I would be happy to discuss examples by phone. Thank you for taking this topic on - it does need addressing.
- I think the HTA has a very efficient system to solve queries based on questions sent to a specific email address the answer is always helpful and never takes more than a week to be resolved
- The complexity of the regulations is close to the edge of making research impossible in some topics. That researchers persist is a tribute to their tenacity.
- The complexity of regulation surrounding Research applications is, a priori, the main reason why I think once, twice and many times before seriously embarking on a research project application. The MRC and other Research Councils have also introduced several layers of accountability which makes the whole process time consuming leaving little time for thinking about the science behind what one is trying to achieve.
- I find that the major confusion arising with researchers locally is whether to apply for NHS R&D approval when the research is using none/very minimal NHS facilities (e.g. accessing a few samples from the NHS Pathology Archive). I haven't personally explored this for a while but it seems that there isn't enough clear guidance available about this (or maybe they're just not looking in the right place). The MRC Data and Tissue Toolkit is useful and I cannot fault the advice I receive from the local REC coordinators. I think that there needs to be more input sought from pathologists and their staff to ensure that the guidance available fits with the Clinical Pathology Accreditation framework i.e. approaches the issues from the perspective of the researcher but also from the person issuing samples for research, specifically does the pathologist/their staff know what ethics/R&D boxes must be ticked? This lack of clear guidance slows down research locally and the systems in place are possibly over- bureaucratic because of this.
- Don't forget the cost of regulation. E.g. HTA licences - pure extortion.
- Membership of the NCRI CSG for my site specific cancer and the networking amongst all groups of health professionals has revolutionised our R&D clinical trials portfolio. Sadly we still struggle badly in terms of infrastructure at local level and funding, at least so far, is not folling accrual to portfolio studies, at least in my discipline.

onCore UK
Devonshire House
Manor Way
Borehamwood
Hertfordshire
WD6 1QQ
Tel: +44 (0)20 8731 4588
Email: info@oncoreuk.org

National Cancer Research Institute
PO Box 123
61 Lincoln's Inn Fields
London WC2A 3PX
Tel: +44 (0)20 7061 8460
Email: info@ncri.org.uk