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Making research work better

Findings from a consultation on ethics and governance in health services research

Helen Snooks | Ashrafunnesa Khanom | Rokia Ballo | Kieran Walshe
On behalf of HSR UK and research permissions working group

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Executive summary

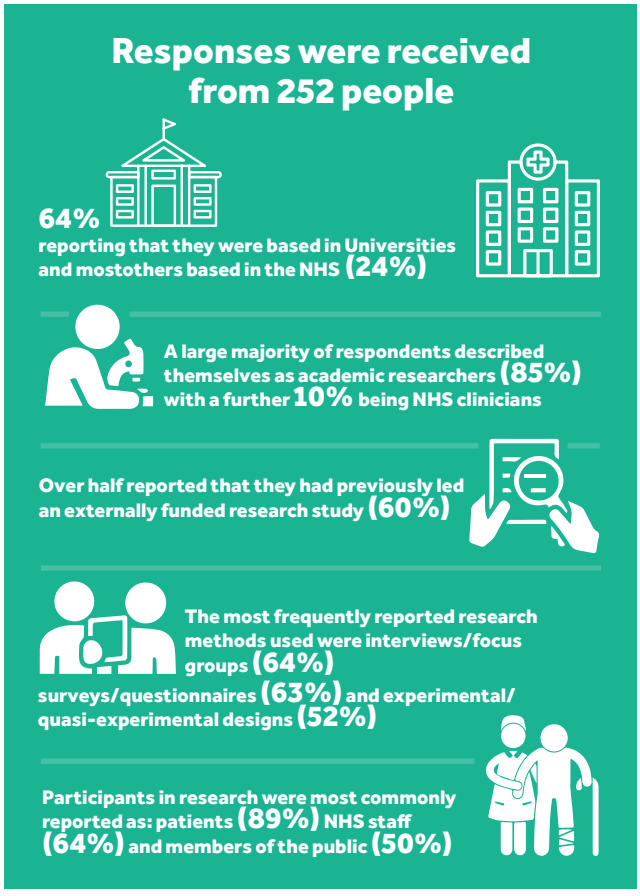
This report presents findings from a consultation, undertaken in May-June 2021, on how the arrangements for research ethics, research governance and information governance in the NHS in the UK work for Health Services Research (HSR) and how they could be improved. We think the findings are relevant to those who fund, do, and use health services research and will be of interest to the wider health and care research community.

Background

Before undertaking research in NHS settings, researchers need to be awarded ethical approval, largely from the Health Research Authority (HRA) in England and Wales or its equivalents in the other devolved nations. They must then also get local research governance approval from each NHS site where research fieldwork will take place. In addition, if they want to use existing NHS data sets they must also get information governance approval from the data controller – often though not always NHS Digital in England and its equivalents in the devolved nations. The use of non-anonymised data is subject to further oversight by the Health Research Authority and its Confidentiality Advisory Group.

These arrangements for research ethics, research governance and information governance have been in place for at least three decades and have been the subject of multiple revisions and reforms over the years. Despite efforts to streamline them and a number of past reviews, there have been widespread concerns that the arrangements are unwieldy, duplicative, and bureaucratic and that they result in delays and increased costs for research and may even deter or prevent research taking place. We undertook this work at a time of wider initiatives on 'busting bureaucracy' to carry out research responsibly.

We undertook an online survey which was widely distributed to our member organisations and contacts and through the HRA and other networks, and for each of the three areas (research ethics, research governance and information governance) we asked open questions about what works well; what problems people had encountered; what impact current arrangements had on the delivery of research; whether and how things had changed during the COVID-19 pandemic; and what improvements they would suggest. We also collected information about respondents and their roles and organisations.



Research ethics

Overall, people felt that the current Integrated Research Application System (IRAS) online ethical approval process operated by HRA was rigorous and robust, and they liked the fact there was a single, coordinated national process for ethical approval. They reported positively on the staff who manage it and deal with queries. They did however complain that it was very bureaucratic, with unnecessary duplication of information and sometimes conflicting and apparently arbitrary detailed requirements for changes to study protocols (which had been approved by funders and through peer-review) being introduced by ethics committees.

The commonest concern was that the system was not proportionate to risk, and was not well suited to many HSR studies, particularly non-intervention studies, studies using routine data only and qualitative research. They felt it was designed for clinical (randomised) trials and was not suited to qualitative, participatory or other mixed methods studies where research fieldwork may be planned iteratively during the conduct of the research. The requirement for all study materials to be developed and submitted before any research can begin was reported to be detrimental to collaborative working, particularly with patients or the public, and resulted in the need for frequent amendments to be submitted and approved – a further time consuming process that could again cause delays to study timelines. Requirements imposed by ethics committees for lengthy Patient Information Sheets and inflexibility sometimes had the effect of exclusion of vulnerable or marginalised groups. Respondents reported high levels of stress related to slipping timescales during ethical approval processes.

During the COVID-19 pandemic, respondents observed that it had proven possible to speed up the ethics approvals processes dramatically - for studies which had the COVID "urgent public health" designation. However, it was noted that for other research, approvals had slowed dramatically and even stopped completely in some cases.

Respondents made many suggestions for improvements to the current research ethics arrangements, focused on radically simplifying them especially for low-risk research; making them much less risk-averse and much more proportionate to actual risk of harm to research participants; not requiring committee review or even ethics approval for low-risk research (in the way that service evaluations and improvement studies are already excluded from the ethics approval process).

Research governance

Again, respondents praised the centralised and coordinated online system for applying for and registering research governance approvals from the NHS organisations where fieldwork for their research was to take place. But in practice, they reported a great deal of fragmentation, duplication and inconsistency in the response from NHS research and development (R&D) departments, and felt that they often went beyond assessing the capacity and capability of their organisation to participate in the research and revisited issues of research design and methods which had already received HRA ethical approval.

They reported that NHS R&D departments were highly risk averse, defensive, and took little account of the impact of their decisions on research costs or delivery. Different NHS R&D departments imposed seemingly arbitrary and inconsistent requirements for governance approval, and the system seemed more designed to deal with clinical intervention studies than with non-intervention HSR studies. Any amendment to the research protocol (as noted above, HSR studies often have iterative research designs) would trigger a whole round of new governance approval processes. It was noted that the system was also ill suited to research that crossed boundaries into non-NHS provider settings (such as private healthcare providers, national healthcare organisations/agencies, and the social care system).

Researchers reported many delays and increased costs as a result of the research governance approval process, and some said that securing approvals took longer than the actual research fieldwork, and that they had adjusted research protocols (for example, to use fewer sites, or avoid NHS organisations as sites, or reduce the volume of fieldwork) as a result. Respondents again reported feeling stressed and demoralised by confusing processes, inconsistent decisions and non-integrated systems. Processes during the COVID-19 pandemic were reported to be very variable in their effects on timelines, with many R&D departments "grinding to a halt" and others making "heroic" efforts to facilitate research.

Many suggestions for improvement were put forward – most of which echo those for research ethics approvals, such as triaging research studies and having a much lighter touch approach to low-risk studies with few or no associated NHS research costs, or even excluding them from the governance approvals process. It was often suggested that where a study covers multiple NHS sites, research governance could be dealt with by one lead site on behalf of all others.

Information governance

The importance of effective information governance arrangements to protect the privacy of patients and service users was widely recognised, and respondents felt that in general, guidance and support on information governance had improved over time. Concerns about information governance related to national organisations which manage access to routine data sets (NHS Digital in England and its equivalents in other UK nations) tended to focus on the costs, delays and bureaucracy involved in securing access to data sets. In contrast, concerns about information governance in local NHS organisations were often more about the lack of understanding of research in information governance teams and the variations in data sharing requirements/agreements between and across different organisations. It was noted that information governance processes were often not well integrated into those for either research ethics or governance approvals, and the sequencing of approvals was not clear. Sometimes, information governance approvals imposed conditions which had not been required either through ethics or governance approval, and this could adversely affect research costs and timescales. Indeed, some respondents reported extensive delays to research (many months or more) resulting from information governance requirements and some suggested that, as a result, they had avoided using routine data sets in their research.

It was noted that during the COVID-19 pandemic, changes to regulations had allowed some data sharing and linkage to progress much more rapidly (respondents cited the ONS public health data asset and the OpenSAFELY initiative as examples) but that those benefits had not been widely shared or experienced. There was a view that improved access to routine data for research could be a consequence of the experiences during the pandemic.

Conclusions and next steps

It is important to recognise that existing processes and requirements for research ethics, research governance and information governance approvals were reported to cause stress and demoralisation for those involved in trying to do research, particularly as most research is contracted for fixed time periods, and many researchers are employed on fixed term contracts. The impact on research delivery was reported to be high, in terms of timescales for completing studies, deterrence of research - particularly for clinicians and students, quality of outputs and costs. The hidden costs of the approvals processes were repeatedly highlighted – not just in terms of increased costs and delays for research teams and funders, but also in terms of the reduced scope and scale of research fieldwork, the deterrence of research activity, and the costs to patients and NHS organisations of not having the evidence base that results from that research.

Suggestions for improvement across all three areas focused on reducing duplication and unnecessary paperwork/form filling and making approvals processes much more proportionate to actual risk of harm to participants, while also considering the risks and harms associated with research delays and increased research costs. We recommend that Health Services Research UK now seeks to work in partnership with the Health Research Authority, research funders and others involved in 'busting bureaucracy' initiatives to seek practical ways to implement improvements.

1 Introduction

Despite wide acceptance of the desirability of basing practice and policy in healthcare on rigorous evidence of safety, and cost-effectiveness, it has long been noted that the chain from identification of need (research gap) to impact in the real world is both long and tortuous. Initiatives have tried to address hold ups at each stage so that research funding is well spent to deliver research findings that are relevant, timely and implemented to achieve real improvements in care delivered and health outcomes for patients or across populations.

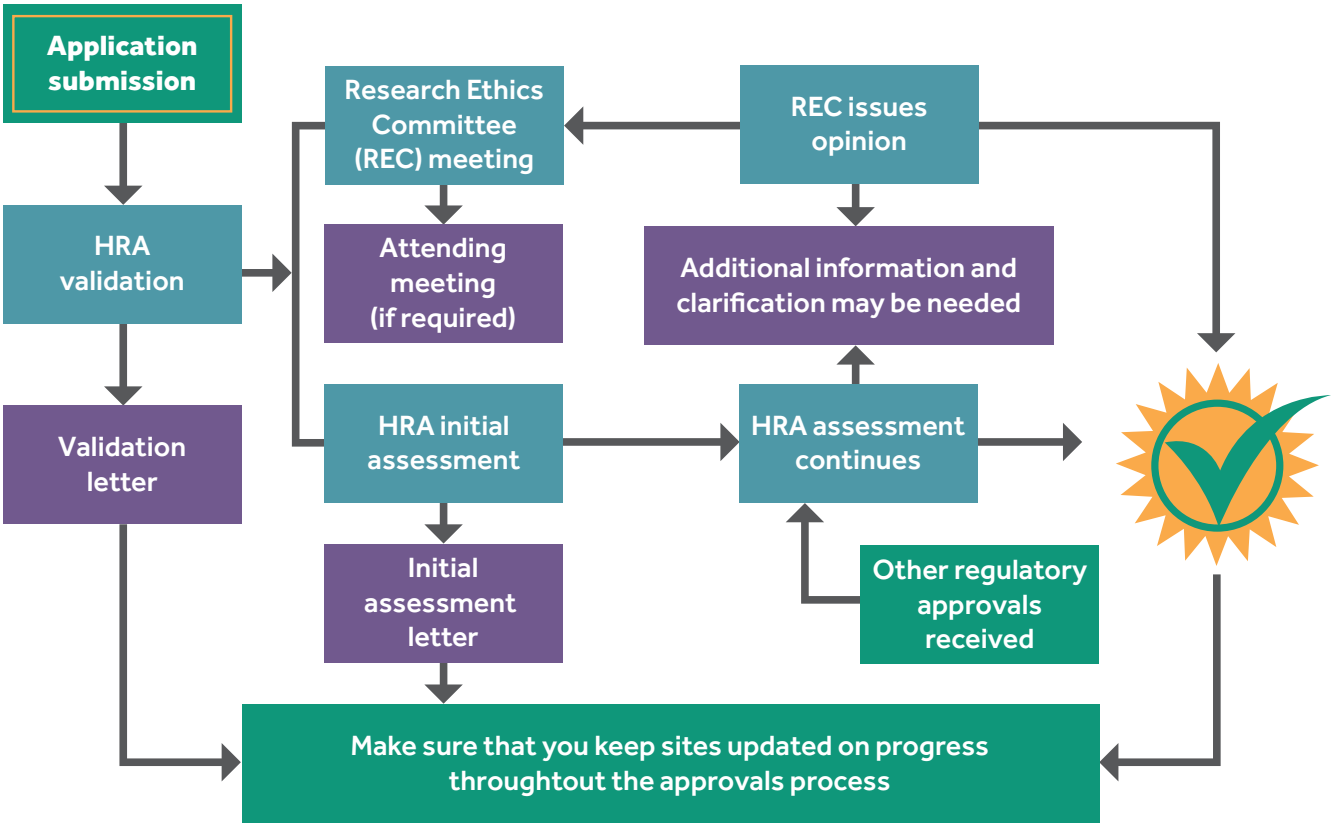
Although rapid evaluation and evidence dissemination centres have been commissioned in several countries (1, 2), researchers remain susceptible to criticism for producing high quality evidence too slowly for decision makers to include that evidence in policy or practice guidance.

Health services research (HSR) is a multidisciplinary field that investigates access, quality and cost of healthcare in order to improve health and well-being (3) of patients and populations. Health care innovations are of particular interest. Healthcare policies and practices continue to be implemented widely without evidence of effectiveness (4, 5).

In this report we focus on the links in the chain of research production and implementation which relate to the permissions required to carry out research in NHS settings in the UK. Health services researchers need to gain permissions in order to set up and undertake research with patients, the public or members of staff based in NHS settings – these permissions cover ethical approval; capability and capacity of sites to participate; data protection compliance and information governance.

Structures and processes to gain permissions to undertake research in NHS settings have been developed over the last thirty years. Despite many efforts to streamline these structures and processes (6, 7), there have been concerns that the regulatory journey for HSR studies has resulted in over complex, duplicative pathways that can cause delay to initiation and completion of studies and are costly to follow (8 – 16).

The legal framework for research governance varies between nations of the UK, although efforts have been made to try to ensure compatibility (17). Since 2016 in England, and 2018 in England and Wales there has been a unified system for applying for approvals for all project-based research in the NHS. Figure 1, below, summarises the processes to be followed before research can start (18)



"HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee so that you only need to submit one application. It applies where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers."
www.hra.nhs.uk/approvals-amendments

During the COVID-19 pandemic the need for research to underpin healthcare provision was even more urgent than usual due to the unprecedented volume of demand by patients who were extremely sick and lack of previous evidence or experience of this virus – risk factors; epidemiology; effective treatments; means of prevention (vaccinations) and optimal health care organisation. Changes were made to health research permissions processes in order to expedite COVID-19 related research, including fast tracking or prioritisation of studies with "urgent public health badging" (19, 20) and the implementation of COPI notices (19, 20) which provide a temporary legal basis for processing confidential patient information without consent for research in response to the COVID-19 emergency.

This report presents findings from a consultation, undertaken in May-June 2021, on how the arrangements for research ethics, research governance and information governance in the NHS in the UK work for health services research (HSR) and how they could be improved. We think the findings are relevant to those who fund, do, and use health services research and will be of interest to the wider health and care research community. Chapter 2 of the report sets out the aims and methods of our consultation, and then chapter 3 presents the findings in four main sections. It first explores who responded to our consultation, and then details findings on research ethics, research governance and information governance in turn. Chapter 4 discusses our findings, sets out some study limitations and considers their policy implications. Finally, chapter 5 sets out our conclusions and suggested next steps.

2 Aims and methods

HSR UK collaborated with the Health Research Authority, the National Institute for Health Research and with other partners to undertake this consultation. We set up a small working group drawing mainly on some researchers from member organisations to scope out the consultation and design our online survey. We chose to focus on asking about three main areas – research ethics, research governance, and information governance. In each of these three areas we asked five main questions – what works well; what problems exist; what impacts on research delivery; what (if anything) has changed or been different since March 2020 and the start of the COVID pandemic; and what improvements they would suggest could be made.

Our online consultation survey was widely distributed on 20th May 2021 to HSR UK member organisations (n = 41 organisations who were asked to cascade the survey to people within their organisation) and to contacts registered on the HSR UK contacts list (n = 4212 individuals who are generally people who have in the past attended our conference or other events or registered their interest in HSR UK). The invitation to participate asked people to forward the survey link to others, using a snowball sampling approach. We also publicised the survey through the HSR UK Twitter account (n = 4609 followers, who were encouraged to retweet it). The survey closed on 18th June 2021.

The questionnaire was designed by HSRUK board members and partners (authors HS, KW, RB, AK) to included closed questions related to demographics and role; and open questions related to our study objectives: what works well; problems (if any); impact on delivery (if any); differences during the COVID-19 pandemic; suggestions for improvement in the three domains of research ethics, research governance and information governance.

Closed (categorical) questionnaire responses such as place of work and job role were analysed descriptively and are presented without further manipulation. Open (narrative) questionnaire responses were coded thematically within each question and domain. Responses were split by theme so that if one respondent reported several aspects within one response e.g. delays; stress; costs this one response would be assigned to three codes. Results are presented by coded comments rather than by respondent so that there may be more coded responses than total respondents in any one question/domain. Quotations are provided to illustrate comments made – and where these varied widely, more quotations are provided to demonstrate the range of responses. Tables in the results section include categories with 5 comments or more.

3 Findings

3.1 Characteristics of respondents

Completed responses were received from 252 people, although not everyone answered all questions.

Over two thirds were based in universities (68%, n = 172) with a further quarter based in the NHS (24%, n = 61). Other respondents reported that they were based in the Academic Health Science Network (0.8% n = 2), charities (1.6% n = 4), pharmaceutical companies (0.4% n = 1) or non-NHS healthcare providers (0.8% n = 2).

Out of 250 responses, two thirds described themselves as academic/researchers (66%, n = 164); a further 10% as NHS clinicians (n = 24); 7% as research administrators (n = 17), 3.6% as students (n = 9) and others as trial managers/directors (2% n = 5), Advanced Clinical Lecturers (0.8% n = 2), evaluators (0.8% n = 2) or managers (0.8% n = 2).

Over half of respondents reported that they had been named as lead (principal/lead) investigator for externally funded research (59%, n = 148).

Methods used included (respondents could tick more than one box): interviews/focus groups (64% n = 160); surveys/questionnaires (63% n = 159); experimental/quasi-experimental (58% n = 146); secondary data analysis (42%, n = 107); observation/ethnography (39%, n = 97); with small numbers reporting involvement in mixed methods studies (1.6% n = 4); evidence review (0.8% n = 2); participatory research/co-production (0.4% n = 2); health economics (0.4% n = 1) and biomedical research (0.4% n = 1).

Most respondents carried out research with patients as participants (91%, n = 229); with 64% reporting that they carried out research with NHS staff (n = 162) and 50% reporting their research involved members of the public (n = 126). Small numbers reported carrying out research with other (non-NHS) professionals including social care staff (5.2% n = 13); social care users (2% n = 5); policy makers (1.6% n = 2); commissioners (0.8% n = 2); carers (0.4% n = 1) and other researchers (0.4% n = 1).

Table 1: Results to demographic questions

1. Where do you mainly work? (252 responses)	n	%
Universities	172	68.3
NHS	61	24.2
University and NHS	6	2.4
Charity	4	1.6
Academic Health Science Network	2	0.8
Non-NHS healthcare providers	2	0.8
Healthcare Regulator	2	0.8
Industry	1	0.4
Local Authority	1	0.4
Pharmaceutical companies	1	0.4
2. What is your main role? (250 responses)	**n**	**%**
Academic/Researcher	164	65.6
NHS clinician	24	9.6
Research administrator	17	6.8
Research manager	15	6.0
Clinical academic	14	5.6
Student	9	3.6
Advanced Clinical Lecturer	2	0.8
Evaluator	2	0.8
Patient and Public Involvement and Engagement	1	0.4
Commissioner	1	0.4
Chief Medical Officer	1	0.4
3. Have you been the lead named investigator for externally funded research (chief/principal investigator) (250 responses)	**n**	**%**
Yes	148	40.8
No	102	59.2

4. What type of research do you mainly carry out? (please tick all that apply) (251 responses)	n	%[1]
Interviews or focus groups	160	63.8
Surveys or questionnaires	159	63.4
Experimental or Quasi-experimental studies	146	58.2
Secondary data analysis	107	42.6
Observation/ethnography	97	38.7
Mixed method studies	4	1.6
Other	4	1.6
Co-production/Participatory research	2	0.8
Evidence review	2	0.8
Health economics	1	0.4
Biomedical	1	0.4

5. Who are the participants in your research? (please tick all that apply) (252 responses)	n	%[1]
Patients	229	90.9
NHS Staff	162	64.3
Public	126	50.0
Other professionals (non-NHS)	13	5.2
Social care users	5	2.0
Policymakers	4	1.6
Commissioners	2	0.8
Carers	1	0.4
Other researchers	1	0.4

[1]*Respondents were able to select multiple responses to questions 4 and 5*

3.2 Research Ethics

3.2.1 Research ethics: what works well?

A large majority of respondents (n = 231) provided narrative text about what they perceived to work well about current systems for gaining a favourable ethical opinion.

Although the question sought positive experiences and views related to research ethics structures and processes, a range of responses were provided, including some negative views and some which related directly or indirectly to other parts of the system for gaining approvals before starting a health services research study.

Table 1 provides a summary of responses, categorised by theme. Areas and features that were reported to work well included the availability of a national online system, with timelines for response. Some respondents noted that this part of the overall approvals process had improved recently. Overall, the process was felt by a substantial proportion of respondents to be rigorous and well respected, gave confidence to researchers that they were following acceptable ethical standards, particularly when research included vulnerable participants, and sometimes provided feedback which helped to strengthen their research. There was some support for processes for clarifying whether ethical approval was needed, and for proportionate review when appropriate. HRA and other staff were reported to be helpful in supporting development and submission of applications. A minority of respondents reported that systems were well designed and transparent, and applications could be shared between investigators.

However, even in this first question which specifically asked about positive experiences and views, several respondents provided comments which were wholly or partially negative, including comments about the process being overly bureaucratic.

Table 2: What works well about the current systems for gaining favourable ethical opinion?

Theme	Count	Key quotation(s)
One national co-ordinated system	43	One system to access information on all approval forms and submit applications like IRAS is good.
Robust/thorough/rigorous	24	Ethics approval is well-regarded and has input from a panel of contributors with a wide range of skills.
Improved speed/timelines for response	22	There is a timely response once the application is submitted.
Online/virtual process	22	Thorough online systems accessible from home/by different project members.
Clarity about approvals required	20	The quick HRA check about whether ethical approvals are required.
Proportionate review/exceptions for students/staff	15	Having a fast-track system for low risk research is helpful, except that the bar is far too high.
Helpful staff	14	REC administrators are very helpful.
Helpful feedback/strengthening study	14	Feedback from ethics committees can be very helpful in shaping/refining/ improving projects.
Well-designed/ streamlined/transparent	13	Some progress towards unifying systems and de-duplicating.
Availability/choice of RECs	10	Online booking systems; seeing REC meeting dates online.
Gives confidence that ethical standards are met	9	It acts as a safeguard for vulnerable people.
Consistency	8	It applies a 'yardstick' across all studies, ensuring uniformity and consistency which is important and good.
Provision of templates/guidance	7	Provision of templates and guidance.
Improved	6	Speed of panels/committees much quicker than before.
Simple and quick process for amendments	5	Simple amendment system to add additional sites etc.

3.2.2 Research ethics: problems

Of all the sections of the questionnaire this question received the most comments (n = 239).

The area most frequently commented on was the complex and bureacratic nature of the approvals process, with unnecessary duplication of information and sometimes pernickety approach of ethics committees to completion or correction of details provided. Respondents noted that the system is not easy to use, clarity about permissions required is difficult to find – and sometimes seems arbitrary. Support was not always available, changes to processes were frequent and delays were reported to be extensive.

In particular, many respondents reported that the process is disproportionate to risk for many studies, particulalry non-intervention studies, studies using routine data only and qualitative research. Several respondents here described the poor fit between a system designed for clinical (randomised) trials and qualitative, participatory or other mixed methods studies which evolve during the conduct of the research. The requirement for all study materials to be developed and submitted before any research can begin was reported to be detrimental to collaborative working, particularly with patients or the public, and resulted in the need for frequent amendments to be submitted and approved – a further time consuming process that could again cause delays to study timelines.

Respondents reported inconsistent practice between ethics committees, resulting in wasted time, frustration and the potential for selection of preferred committees, where they had previously had a good experience. Related to this was the noted lack of understanding or expertise in clinical, population or methodological areas e.g. palliative care; people with mental health problems; vulnerable groups; and observational/routine data/qualitative approaches.

Several respondents reported that some areas of feedback that have become standard practice e.g. lengthy Patient Information Sheets exclude participants, particularly 'hard to reach' groups – becoming an ethical risk in itself.

Several respondents referred to the behaviour of ethics committees as unreasonable, unfair or aggressive – leaving researchers in tears. Ethics committees were reported to provide comments on study design and other aspects of the research that were felt to be out of remit

Table 3: What problems, if any, have you encountered?

Theme	Count	Key quotation(s)
Disproportionate for low risk studies	71	Its very time consuming. So many forms and boxes to complete for ethics for a simple qualitative interview study. So much required in PIS and consent form that is very off putting for people, especially people who struggle with literacy so works against inclusivity in research. The whole system started with RCTs and has never really moved beyond them, just added in separate options for qualitative research.
Overly bureaucratic/repetitive	53	The amount of repetition across the questions on the forms, and the supporting documentation, especially with regard to data management and confidentiality, is absolutely exhausting and would strongly benefit from being streamlined into one or two clear questions The IRAS form is far too long and is really onerous to complete. So much of the detail requested is available in the protocol and patient information materials so it is just repetition. Why submit your protocol and repeat it all in a form. There should just be a series of tick boxes to confirm that your protocol includes x, y, z information and maybe there could be a brief free text submission to signpost the page number. All of this unnecessary admin just delays submission.
Delays/lengthy process	49	Excruciatingly long timescales to get research approved.
Lack of integration of systems	49	Marrying the ethics and R&D system. There is still duplication of effort and a lack of congruence in what ethics and R&D need.

continued

Table 3: What problems, if any, have you encountered?

Theme	Count	Key quotation(s)
Inconsistent	23	Different ethics committees give different feedback about the same topic. It feels like pot-luck sometimes.
Out of touch/unethical practice	22	Requiring patient-level consent for randomisation of established treatment or service configuration alternatives that, in practice, are allocated haphazardly and without an evidence base; random allocation is inherently more ethical, especially where it will generate data and no additional information beyond routinely collected outcomes are 100%required. A requirement for individual level consent just keeps us in the dark age. Procedures often exclude vulnerable people due to definitions of capacity whereas participatory research takes consent as a process throughout the research. Research within and for primary care e.g. breast-feeding mothers needs a completely different approach to direct medical research but there are no tiered procedures that enable100% applicability to the research at hand. One size doesn't and can't fit all.
Lack of clarity about permissions required	21	Uncertainty about what approval s are needed and from whom, and uncertainty about what labels to use, especially for qualitative work involving health professionals. Significant confusion about the difference between research and evaluation.

continued

Table 3: What problems, if any, have you encountered?

Theme	Count	Key quotation(s)
Lack of specialist understanding/expertise	17	Lack of knowledge from RECs about research on sensitive topics e.g. palliative care. As a mental health researcher, I know there are some committees I submit to, and some not, because unless they have experience with mental health research the responses and recommendations can be quite odd e.g. assuming patients with certain types of mental health problems are necessarily likely to interpret the study aims bizarrely or in catastrophising ways; assuming patients are incredibly fragile and any discussion of their mental health problems is likely to be harmful. These are common stereotypes that I've encountered on some ethics committees
Availability of help/support	8	Challenges in finding the right person to speak with queries or indeed finding anyone.
System changes frequently	7	A constantly changing landscape. Every time I come to another project the process and the forms have changed yet again so you can't even used what you learned last time to help you.
Not sticking to remit	6	Ethics committees requesting changes to format and designs, which has nothing to do with ethical considerations.
Poorly designed system	6	The IRAS forms are not easy to complete as you can only see two lines at a time!
Different processes for service improvement/evaluation and research	6	The definition of the distinction between [service evaluation or research].does not make sense and is not consistent between University and NHS documentation, leading to the risk of game-playing.
Pedantic	5	Minor changes being requested to documentation which are not really needed.
Unfair/aggressive committees	5	They are intimidating and often hostile, and some quite frankly abuse their powers ... several of my students have come out in tears.

3.2.3 Research ethics: impact on research delivery?

There were 229 comments provided on impact on delivery – more than half of these comments related to delays (n = 121).

Many respondents reported that processes for gaining ethical approval changed or deterred research, innovation and collaboration. This was reported to be a shame, inhibiting the production of research evidence to inform policy and practice. Several respondents specifically noted that ethics requirements affected adversely the quality of research e.g. by discouraging changes to methods or patient facing materials to improve recruitment or community representation.

Many respondents (n = 26) reported high workloads related to the bureaucracy of ethics approval processes, which for some (n = 15) became stressful and affected their morale. The challenge of gaining approvals in order to start and complete research was described in the context of external funding and short-term contracts for many researchers.

Respondents cited examples of how delays in gaining ethical approval had directly impacted on research delivery – and the challenges of planning and managing research delivery when timelines can be uncertain.

Some respondents felt that research delivery was not affected by ethics approvals processes (n = 19) – especially if time was allowed and the process was managed efficiently, with one respondent commenting that the research could be improved through this process.

Table 4: What impact, if any, has there been on research delivery?

Theme	Count	Key quotation(s)
Delays	121	There are delays to research even though there is no flexibility on funding. There have been delays in starting critical projects, including several COVID ... as well as other ... studies.
Deters or changes research, innovation/collaboration	46	Sometimes we don't do research that needs [to be] done because of the time consuming and bureaucratic nature of the rules. Inhibits clinicians from doing research. I have completely avoided doing any studies that involve NHS staff or patients, which is missing huge areas that could be researched which is a huge shame for patients.
Workload/difficulty/waste	26	Drains resources in terms of manpower to produce documents with unnecessary and sometimes unhelpful additions. Waste of researcher time on endless formfilling.
None/Minimal/improved research delivery	19	None usually if well planned within the study timetable. Improved research as the REC/research governance review often spot things that the research team haven't.

continued

Table 4: What impact, if any, has there been on research delivery? *continued*

Theme	Count	Key quotation(s)
Reduced quality of research	18	[the more time on approvals] the less time there is for thorough recruitment to ensure there is diverse and representative samples, to put in place agreements with NHS sites ... of actually going "live" with data collection, and therefore knock on impact in either 1) lengthening the time needed for analysis/write up or 2) being forced to deliver these outputs on a much shorter timeframe, therefore impacting on quality. Rushed analysis because data arrives too late. Perhaps the most pernicious impact is the fact that every time you want to change a sentence on a leaflet you have to go through an amendment, which is more paperwork and more delays. It basically means that you don't bother changing things even if it would improve the study/recruitment/participant experience and the research is of lower quality as a result.
Research delivery/performance	17	Unable to complete project because funding/contract agreements ran out of time
Staff stress/morale	15	Massive, catastrophic: it now takes up more time than the research itself sapping the will to live let alone motivation to undertake research. It drains the energy of staff before we ever collect data. My wellbeing is affected by stress, higher workload leading to delays – lack of support to work through the PROCESS rather than the actual application.
Increased costs	12	It makes research much more expensive. The main impact is to raise the cost of the work, as researcher time is invested in negotiating a byzantine process of form-filling with significant invisible costs which are, inevitably, borne by the research funders.
Planning burden/uncertainty	8	Timelines unknown so can't progress things and indicate to sites when amendments will be rolled out as unknown when approvals will be received.
Systems problems	8	Complications when submitting initial application and any subsequent amendments as comments from more than one committee can be baffling.

3.2.4 Research ethics: differences during the COVID-19 pandemic?

Many respondents stated that they had not experienced differences over the previous 12 months (n = 56), with some stating that they had not submitted approvals, or carried out research during the pandemic.

There were conflicting views regarding whether processes were quicker (n = 23), or slower (n = 16), especially for non-COVID research (n = 17).

Others noted the move to virtual working, in research or approvals, with some concerns about ethical issues raised, but with appreciation for the speed of response by ethics committees at the outset of the pandemic and also for the efficiency of remote meetings.

Table 5: In the last 12 months has your experience of these systems been different due to the COVID-19 pandemic?

Theme	Count	Key quotation(s)
None	56	Some expediting due to COVID status of the study but because not badged as "Urgent Public Health" ...and despite being commissioned by a COVID specific NIHR call was not pushed through the system any quicker.
Variable/miscellaneous	39	At the beginning of the pandemic, processes were very quick to change ... to remote. This was a pragmatic response which worked well. Coming out of the pandemic and going back to face to face work has been (m)ore challenging and slower – which has been particularly a problem for trial recruitment. Some reviews have been faster, others much slower.
Fast(er)	23	Generally approval has been quicker and more light touch which is good. Amendments to existing ethics have been processed quickly.
Not applicable	37	Not attempted to secure approvals during pandemic.

continued

Table 5: In the last 12 months has your experience of these systems been different due to the COVID-19 pandemic?

Theme	Count	Key quotation(s)
Quicker if COVID research	18	Yes COVID studies have received effective rapid review.
Unable to carry out research	17	Had to put externally funded project on hold due to restrictions and change of policy by Trust. Mostly came to a standstill.
Delays for non-COVID research	17	Non-COVID studies have been deprioritised by some departments, this has led to further delays.
Delays	16	Things have been slower and more complicated. We needed to adapt our research methods, but using remote methods seems to have a whole new range of challenges. Often these are also different across the NHS Boards and approval organisations as local rules influence what is allowed.
Virtual working	13	The move to virtual working and data collection has raised many questions about ethics and governance and some general guidance regarding how to be compliant for virtual qualitative research would be welcome. Virtual ethics reviews - these are welcome – due to convenience.

3.2.5 Research ethics: suggestions for improvement

Many respondents provided comments in this section (n = 231). There were many suggestions for areas to improve, and some suggestions about how this could be achieved.

We have provided more direct quotations in this section as they are so important for considering how to improve processes.

In line with challenges described in previous questions, most suggestions related to streamlining or simplifying processes (n = 82), in particular for low-risk research (n = 52). Suggestions about how to do this included the elimination of duplication e.g. between documentation such as study protocol and various sections of the online form; avoidance of complex arrangements; development of triage and potentially different pathways for different types of research; and a flexible approach for study designs which evolve over the period of the research.

Some respondents made suggestions about changing attitudes or overall approach – committees being less confrontational, a shift in assumptions about the behaviour of researchers; consideration of the balance of risks – of harms to research participants and also those outside the research process who may lose the benefit of the findings, should the research not go ahead or be delayed.

Several respondents asked for more provision of support, clarifications, improvements to online systems and changes to timelines to improve speed of processes.

Respondents suggested that lessons of the past - and in particular, from the last year - be taken on board in any further changes to systems.

Respondents suggested ensuring that committee membership represented the populations served, through e.g. Equality Assessment processes. Virtual processes and meetings were appreciated by some, others wanted to see a return to face to face meetings.

There was general agreement that inconsistencies need to be addressed e.g. through provision of standardised templates and guidance.

Table 6: Looking forward, do you think these systems should change and if so, how?

Theme	Count	Key quotation(s)
Streamline/simplify	82	Yes streamline. Only require processes where necessary to protect the subject and researcher. Avoid multiple levels and systems. Yes I think it should be reconsidered, and have potentially different pathways depending on the type of research. Systems should be built in collaboration with frontline R&D, ethics and research governance staff, alongside researchers from different fields. This might create a better system for all those involved. Reduce information in forms, use documents submitted and protocol for key info rather than repeating in form. Cut out duplication so things get approved once. If universities are going to ethicsreview, give them delegated authority for HRA approval, otherwise just do it in HRA. When ethics committees look at studies they should NOT start reviewing methodology in the study protocol which has been previously reviewed and signed off in an NIHR funding panel.
Make more proportionate/ better fit for non-RCTs	52	Better understanding of the spectrum of research being carried out, better provisions for collaborative research and a more proportionate time investment to gain ethical approval for small projects. More recognition that some very good qualitative studies can't predict exactly what is needed to be done in advance. A way of triaging studies that require less scrutiny from a patient safety perspective for rapid approval. They have to change if they are not going to kill everything except big clinical trials. I understand that ethics committees face huge workloads and do need to catch possible problems, but treating all studies as of equal high importance is ridiculous. There si a difference between invasive research on sick people and asking conscious and coping patients about their experience of care. Risk stratification would make far better sense.

continued

Table 6: Looking forward, do you think these systems should change and if so, how?

Theme	Count	Key quotation(s)
Change of attitude/approach	26	Our PPI asked us to reduce the length of our consent form in one study – the committee refused – this sent a very bad message back about role of PPI. Quicker and kinder panels, better chairing to prevent unnecessarily aggressive committees. It should totally change ... get rid of 90% of ethics approval paper permissions etc ... no evidence that the system safeguards or protects. Researchers should sign up to code of ethics and that's it apart from CRB checks. A relentless focus on actual risk of harm to participants and a proportionate approach which balances risk of harm against risk of harm to others from research not being undertaken or being delayed (which in the current system is not considered).
Support/guidance	18	A helpline/dedicated email address specifically to support researchers to determine whether their work is research or service evaluation without having to prepare and submit a full IRAS application first. More worked examples to help you complete applications.
Faster turnaround	15	A faster turnaround for ethical amendments Low risk studies should be fast tracked. Speedier review for urgent studies without detriment to non-urgent studies.
Clarify	11	Clarity around service evaluation and audit. Clarity around approvals for independent units that interact with the NHS such as charities, nursing homes, hospices etc.

continued

Table 6: Looking forward, do you think these systems should change and if so, how?

Theme	Count	Key quotation(s)
Improve form/online system	9	… create a word version of the IRAS answers … for research teams to work on off line … because sharing access on IRAS is a nightmare. IRAS form should be updated so it is easier to enter details and navigate.
Learn from experience	8	It would be good if the pragmatic approach that has been used during the pandemic is continued after things start to return to normal.
Meeting format	7	Routine virtual ethical reviews. More public meeting soon.
Panel membership	6	A list of panels with specialist knowledge and the ability to nominate them would be helpful. The road to greater inclusivity has many components and the ethics committees can ha a more prominent role in this. It is also important to take steps that ethic committees are truly representative of the community – with representation at senior levels from a broad range of minority ethnic groups.
Standardise	5	Greater consistency through more explicit operating procedures. There should be a more transparent set of criteria that are consistently applied.

3.3 Research governance

3.3.1 Research governance: what works well?

There were 105 positive comments about research governance although there were comments that related to other parts of the research permissions process (n = 5), and many negative comments even in response to the question (n = 61).

Many reported that they found the system to be streamlined and appreciated the online, centralised, standardised application (n = 46). Staff were generally reported to be helpful and supportive (n = 30). Some respondents noted that the system provides robust governance and protects research participants (n = 22). Some reported that processes were clear, especially if researchers had experience and local contacts. Respondents appreciated working at local site level and developing relationships.

Some negative comments were made; and there was some confusion over which part of the approvals process this section referred to, with several comments related to ethical approvals rather than research governance checks.

Table 7: What works well in research governance?

Theme	Count	Key quotation(s)
Streamlined standardised online application	46	It makes sense to cut out the multiple local reviews and centralise. There is one system for both ethics and research governance.
Staff (including CRN, HRA) helpful, friendly, supportive	30	Early engagement with R&D depts. in the NHS always helps in enabling research activity, especially when it comes to understanding responses to capacity and capability issues. Having a named person at the HRA to contact to resolve any issues has certainly made things easier. individuals handing the applications tend to be helpful and supportive.
Robust scrutiny and checks	22	It is good that there are checks in place to keep people safe.
Clear process	19	That the researcher is guided to carefully plan and think through different eventualities when preparing their research (e.g. the protocol for if a participant drops out early).

continued

Table 7: What works well in research governance?

Theme	Count	Key quotation(s)
Working with local lead, good relationships	12	I know the people I need to work with. Always made simpler by existing relationships with NHS organisations, but if you're not a known entity things are slow and difficult.
Reduce burden on Trusts, good co-ordination amendments are easier to notify	8	Lower administrative burden for Trusts. HRA approval letter provides clear instruction for Trust. Everything is overseen by one NHS trust/body, which makes it easier when coordinating between different trusts.
Sponsor support (University, CCG) – good systems in place and contacts provided	7	We have a great research department who are all well versed in research - academic, healthcare, government and commercial. I have been well supported by our lead sponsor (CCG) with some useful tips and advice and putting in touch with people who can help.
Timely response, particularly for some (low-risk) studies	6	Timely response/feedback, comprehensive information made available.
HRA – responsive and good process	5	HRA are generally quick to respond and approve low risk studies.

3.3.2 Research governance: problems

Comments related to problems encountered were made by most respondents and themes drawn out from narrative responses totalled 284.

There was a great deal of frustration apparent in comments made in response to this question, mostly related to the fragmented system which resulted in delays and duplication of work, as well as errors.

Respondents also felt that staff in R&D departments had defensive and risk averse attitudes which could impede research timescales. The lack of clarity around definitions of research and service evaluation, and processes of ethics and governance - what is required, who provides what, and where to seek help - was highlighted by many.

Table 8: What problems, if any, have you encountered?

Theme	Count	Key quotation(s)
Delays	66	Another experience meant that I had completely finished my data collection (at other hospital sites) by the time one NHS trust granted approval. Lack of transparency, very little input, often having to wait weeks, months to be told that we have not submitted the right document. A tracking tool/checklist rolled into ethics would help aid this. Having some accountability in terms of timelines for research governance to respond.
R&D approvals daunting. Inflexible process especially when multisite approvals are sought	42	Endless stream of middle managers in different organisations requiring the same information from me, not trusting information given elsewhere and not being in a position to make decisions - it's endless.
Laborious process requirement to contact multiple people	13	We have to keep track of so many different names and contacts. Also if you try to find details online e.g. email address for R&D admin at a specific site, it wasn't always up to date, or it was the wrong person and you were passed on to someone else. It's almost impossible to keep track of individual people within R&D.
A challenge to find the right advice on required approvals in particular cross nation approvals, approvals for research in primary care, or outside the NHS	21	Over engineered conditions to have different sites approved. e.g. within same hospital; situation even worse if service research involves different GP practices.

continued

Table 8: What problems, if any, have you encountered?

Theme	Count	Key quotation(s)
Fragmented system	22	The research governance process is abysmal. Each site has different requirements, different forms. It doesn't really work as a joined up system. We have to upload hundreds of documents to IRAS but HRA does not send them to the included Trusts despite requiring a name and contact for each Trust. So everything has to be sent separately.
Unrealistic demands on researchers	12	I've been asked to do training about consent of adults with dementia despite not taking consent from this type of person. It was very much geared towards someone working on a hospital ward. I think the process does not consider the face that we are researchers often outside the NHS. Very frustrating. I don't really want to do another project because of this.
R&D staff attitude, risk averse, lack of understanding of the research process	16	The defensive attitude and slowness of many R&D departments, and their ability to make you feel like you're a dangerous threat.
Not fit (proportionate) for non-clinical studies	18	OIDs, SoEs and SoECATs and other onerous forms...are simply not designed for qualitative research. The phrase 'sledgehammer to a walnut' comes to mind - lots of irrelevant paperwork for studies that are not likely to be harmful or use resources. Often, it seems as though these studies are at the end of the queue. Overly bureaucratic processes for low risk qualitative research because they are tailored to clinical trials/interventions.
Student research require more guidance	7	Student research applications not meeting NHS HRA standards. Lot of resource invested in explaining the system and referring students back to their HE to refine their applications.
Financial review additional burden	6	SoECAT not being accepted despite hours of work creating and getting approval. Pharamcy delays, additional local documents being requested, individual departments asking for funding despite SoECAT and saying that they don't see any research funding.
Amendments cause additional delays	7	The fact that you have to get C&C again with every amendment is a complete nightmare.

3.3.3 Research governance: impact on research delivery

Many respondents (n = 110) cited delays caused by R&D governance processes as threatening research in terms of research completed and also the quality of research delivered. Bureaucracy, complex processes and duplication were reported, causing significant additional workload, frustration and stress for research staff (n = 45). A further 21 respondents reported that researchers avoid initiating research in the NHS due to the burden of permissions.

Table 9: What impact, if any, has there been on research delivery?

Theme	Count	Key quotation(s)
Delays threaten volume and quality of research	110	Delays, delays, delays; weeks of work, tearing your hair out trying to answer questions which have no meaning for your kind of study; and it frankly makes me want to avoid putting in funding applications for studies which require R&D approvals. Huge amounts of time spent on this instead of on the research, serious delays to starting research. Research is biased – as only certain people included due to difficulties in obtaining RG – choose the safe route. Delays in data collection/study commencement, site set up can "threaten integrity of results" as it introduces bias into the project, to mitigate effects research activity is reduced or study design changed.
Bureaucracy, duplication, complex processes, researchers exhausted, staff morale, frustration.	34	Research takes longer, more time is spent on getting approval than doing the work. researchers have to be expert in … research methods, but also in ethics, governance and administrative systems.

continued

Table 9: What impact, if any, has there been on research delivery?

Theme	Count	Key quotation(s)
Discouraged research	21	Disastrous in terms of training the next generation of applied clinical researchers. If they do try to grapple with this it puts them off for life. We have avoided setting up studies, compromised on our sampling strategies and generally been discouraged. The general feeling is that HRA should be avoided if possible. Serious disincentive to conduct research involving patients which is a terrible indictment of the system.
Affected researcher morale and caused stress	11	More stress/time wasted = less time to design and deliver good quality research. And also the human element which makes an already overburdened work life more stressful. If frustration is an impact – a lot! The system is not intuitive, the different sites lack cohesiveness and all need/want different things at different times.

3.3.4 Research governance: differences during COVID-19 pandemic

There were 93 comments in response to this question, with 84 respondents reporting no change or no experience during this period.

Those who responded reported varying experiences – some positive, some negative, and some depending on whether the study was COVID-19 related or not. The additional burden of stopping and restarting studies was noted by several respondents (n = 14).

Table 10: In the last 12 months has your experience of these systems been different due to the COVID-19 pandemic?

Theme	Count	Key quotation(s)
Extra delays worse than before	41	We couldn't get hold of most R&D departments as staff had been redeployed but it just went into a black hole. I understand that COVID was a unique situation, but we still had a large project to try and deliver. A lot of things have just ground to halt. Little difference for COVID studies (whereas ethics felt a bit swifter). It took us around 4 months to get approval for a COVID-related study with 1 year of funding *in one site*. Teeth grindingly awful. Just as difficult, even with study designated 'Urgent Public Health'.
Positive impact/approvals faster	25	Responses do seem to have been quicker, within days instead of weeks but overall I think the goodwill and effort by most has been over and above to ensure things happened, this level of effort cannot be realistically maintained within the system. Some R&D departments have made heroic efforts. HRA has worked quite well and efficiently especially for Urgent Public Health studies.
Non-covid studies take longer or on hold.	8	Yes. If managing a COVID study everything has been quicker than before but if doing a non-COVID study it has been almost impossible to progress studies. Non-COVID studies have been de-prioritised.

3.3.5 Research governance: suggestions for improvement

There were fewer suggestions about how to improve research governance than in the previous section (ethics), however 161 suggestions were made. The largest category of responses was related to streamlining and centralising systems (n = 69). Again, proportionate processes for low-risk studies were advocated by many respondents (n = 27). Some respondents stressed the need to standardise processes and documents with the use of more templates, guidance and support for applications, particularly the SoECAT and OID documents/processes (n = 19). Enabling easier access to the right people was a priority for 12 respondents. Setting and monitoring of time-based targets was suggested by 5 respondents.

Table 11: Looking forward, do you think these systems should change and if so, how?

Theme	Count	Key quotation(s)
Single centralised system	69	A single central team that oversees arrangements in multiple sites. Where multiple sites are involved (or multiple sponsors) there should be a better system for a single site taking the lead and paperwork not being duplicated (e.g. acceptance of the main site's paperwork). A more centralised specialised approach to research governance fully integrated with ethics approval - so that approval happens at a high level first and at the same time. Local governance/PI would then consider any particular local issues that could impact and feed these back for central consideration and a decision. Suggest a move away from "Setting based governance" and towards "UK Citizen first governance" which covers everyone including frontline staff. This is particularly necessary for complex research designs that cut across NHS/Public sectors, mixed methods, and where citizen first approaches to recruitment and participation are offered (i.e recruit across primary, secondary, social care and social media (citizen first approach). Obviously surgical/some drug trials etc would still take place in secondary care. So many priorities (social care, mental health, prevention, co-morbidities, disability, infection) require a whole system approach. The silo mentality is not working!

continued

Table 11: Looking forward, do you think these systems should change and if so, how?

Theme	Count	Key quotation(s)
- *continued* Single centralised system	69	Why can't the system generate an automatic approach when we know they get the IRAS forms and generate the letters of approval etc. they're all pretty standard. The Trust could just approve what is already there rather than us having to email 20 different departments and send them all our documents and then spend the next three months chasing them up.
Urgently require simplification for low-risk studies – qualitative, audit, quality improvement, stored samples, computer based studies	27	R&D approval should simply not be required for low risk qualitative or survey-based studies, evaluation studies etc, with very low time/cost implications for the NHS... It should be proportionate to the research being conducted. Dedicated 'approvers' would help. Remove need for so many R&D approvals for low risk studies especially at boundary of research and audit or research and quality improvement.
Simplification, clarification and guidance for: • Primary care and non-NHS studies • Remote/virtual data collection, flexibility • Organisation Information Document (OIDs) / Schedule of Events Cost Attribution Template (SoECAT) • Research passport/letters of access	19	Please create guidance specifically for setting and managing a research study (especially a Clinical Trial of Investigational Medicinal Product (CTIMP)) in primary care, community care (e.g. district nurses visiting patients at home) and non-NHS organisations. SoECAT is a waste of time. I understand need for such a system to assess costs but this is far too resource heavy and still open to local interpretation.
Enable access to R&D departments and CRN	12	Guidance on how to make these connections would be very useful, certainly better than just an R&D directory that for me did not contain the relevant information.
R&D should have time targets	5	Perhaps a system you could log in to and see your applications progress? Time should start from first approach not when sites decide the time should start.

3.4 Results: Information governance

3.4.1 Information governance: what works well?

There were generally fewer responses in this section as many people said that this was not applicable to their research (n = 45), and others left this question blank.

There were 76 comments made about what works well, covering the need for a robust system in place which ensures safety of individuals (n = 28). Some respondents commented that staff were helpful and that guidance and systems are improving. Others commented on the increasing availability of data.

But even in response to this question which sought positive experiences, the largest category of responses was "nothing" or "very little" (n = 32).

Table 12: What works well about the current systems for information governance?

Theme	Count	Key quotation(s)
Data protection	16	That there is a system in place for safety purposes and insurance.
Helpful IG staff/clear roles	15	I think that IG leads are generally much more integrated with the needs of their staff in terms of research, evaluation, audit QI. That said they still do not have enough specific understanding and local process are completely divorced from RECs and what they do. We have an excellent IG team and a lead for governance within our profession (at consultant level) in the new system.
Robust/respected	12	The external assurance granted that research has been thoroughly assessed and deemed legal and ethical should not be underestimated. In my early research days, it felt like bureaucracy. Now it feels like robust assessment and assurance. It is thorough.
Positive generic	11	looks to be getting clearer - sort of - in clarity of process and accessing data. But net effect is probably unrealistic expectations in terms of delivery! It is straightforward.

continued

Table 12: What works well about the current systems for information governance?

Theme	Count	Key quotation(s)
Guidance/support	8	There is now a bit more training and online help. The guidance and support has been clarified to a much better standard recently.
Data availability	6	Data coverage is continually improving.
Integrated/user friendly system	6	Regional systems have streamlined governance and it is possible to amend applications to ask for additional years of data, for example, or variables omitted in primary application, without going back to the start.

3.4.2 Information governance: problems

There were many more comments in response to this question than the previous one (n = 127), although again the area of Information Governance was only relevant to a subset of respondents.

Problems cited most frequently were: complicated system/bureaucracy, lengthy delays and a lack of clarity or understanding about requirements. Data sharing agreements were described as very time consuming and challenging to negotiate. Variations in requirements or decisions between partners were reported by 12 respondents. The high cost of accessing routine data was highlighted by 9 respondents. Systems and processes were described as inflexible and disjointed.

Table 13: What problems, if any, have you encountered?

Theme	Count	Key quotation(s)
Complicated system/bureaucracy	34	Huge amount of red tape in getting access and navigation through data protection.
Lengthy processes/delays	26	Some sites have now introduced IG documentation prior to approval. …. This delays start up. Vastly time consuming. Requiring resilience, determination and patience. The lead time required to obtain data from NHSD precludes a great deal of responsive, policy-relevant research.
Complicated system/bureaucracy	34	Huge amount of red tape in getting access and navigation through data protection
Lengthy processes/delays	26	Some sites have now introduced IG documentation prior to approval. …. This delays start up. Vastly time consuming. Requiring resilience, determination and patience. The lead time required to obtain data from NHSD precludes a great deal of responsive, policy-relevant research.
Lack of clarity/understanding/training	21	Poor understanding of the law around IG, resulting in conflicting advice and policies even within the same organisation. Some IG departments are poorly set up to work with research. A lack of knowledge and understanding leads to extensive delays in gaining approval. This is due to some reinventing the wheel each time.

continued

Table 13: What problems, if any, have you encountered?

Theme	Count	Key quotation(s)
Agreements to share data	14	IG departments can be very slow to process applications to conduct research. Data sharing across NHS Trusts can be extremely bureaucratic.
Variations in understanding/requirements	12	Non standard approaches to conducting this across sites, you end up doing a completely different IG questionnaire/ process with each site, very time consuming. What is acceptable in one site will not be acceptable in another site. Different IG/ IT policies can mean you have to change study procedures between sites, can add additional unforeseen costs. Unwarranted variance in interpretations of differing Information Governance teams.
Expensive	9	Obtaining data from NHS Digital is an ... expensive process. Expense of accessing datasets sometimes means that research is not feasible.
Access to data e.g. for scoping	6	There is no scope for exploring datasets. You need to have a hypothesis or question first. This does not facilitate preliminary scoping of the evidence.
Lack of integration of systems	5	Lack of interoperability between systems. A lot of the information has to be submitted and approved by ethics before IG and they often take different stances. Funding is approved before ethics and IG and the amount of time to get approval by IG and Ethics is always under-costed and if IG or ethics make recommendations to change something then often the money is not available to make these changes as it wasn't a known cost.

3.4.3 Information governance: impact on research delivery

There were 136 comments about impact of information governance on research delivery – with by far the largest category being delays, sometimes for months or years. The increased workload and stress on research and other staff was raised by twenty respondents. Respondents also highlighted changes to research methods, in some case compromising quality to meet information governance requirements, even after research ethics approval had been gained. Delivery of projects was reported to be directly affected by issues with this part of the research process. As for the other sections of the survey, information governance was reported to impede or block research as deadlines were missed or researchers ran out of steam.

Table 14: What impact, if any, has there been on research delivery?

Theme	Count	Key quotation(s)
Delays	69	Massive.. Funded projects running years over schedule. For one trial the publication of the primary results has been delayed by 5 years because of on-going issues accessing the data from NHS Digital/NRS. Studies that have been delayed or abandoned because of the delays or problems securing access to data. We've had studies that we have been trying to do for >3 years without success.
Workload	15	Taking up ridiculous amounts of my time which could be spent making more use of my clinical academic skill set. Major administrative burden.
Project delivery	13	Huge delays in research - over a year. Needing to request no-cost extensions to research which has knock on effects on retention of researchers. Massive, and massively wasteful. Funded projects running years over schedule, in some cases arriving at stalemate, with no over-arching body apparently in a position to sort out the catch-22, and with the distinct possibility that the years of work done prior to the stalemate will have to be written off.. My funding ran out while I was waiting for the data to arrive, so now I cannot do anything with it.

continued

Table 14: What impact, if any, has there been on research delivery?

Theme	Count	Key quotation(s)
Research methods/quality	12	Less complete data analysis. It is easier to do a low quality small observational study of own (~3 months end to end) than access this large population data (>1 year) , so people quite wisely give up and do that instead, reducing the quality of the research. Ethically I don't think we should be conducting population level research without making the data available - what is the point of this if we do. Forced to make trial -wide revisions to documents after REC/HRA review to satisfy local IG requirements.
Inability to produce timely high-quality evidence to inform policy	8	Massive, massive delays …. Consequently, investment decisions continued to be made, without any information about effectiveness.
Costs	8	Huge … costs.
Restricts/prevents research	6	Wastes time, restricts what evidence you can access or construction of new concepts and enquiries. I avoid these projects - life is too short.
Conflict/stress	5	Worry and anxiety that we will be reported for something we don't really understand. .. demoralisation is not worth it. Most stressful part of my work and well outside my comfort zone.

3.4.4 Information governance: differences during COVID-19 pandemic

Only thirty-one comments were made in this section to this question, with some reporting that things were more difficult (n = 15), other reporting the opposite (n = 11) and a few reporting that their experience had been variable, largely dependent on whether the research was COVID related or not.

Table 15: In the last 12 months has your experience of these systems been different due to the COVID-19 pandemic?

Theme	Count	Key quotation(s)
More challenging	15	Worse - because of staff shortages, people off sick, home schooling etc and academic/NHS morale is rock bottom. We do not need this governance mess! Non-Covid related research was pushed far lower on the list, which is a shame as much of our work could still have been done (remote studies is something we have developed over the years), but timelines and regulations, funding prioritisation in terms of CRN support etc. meant that this was not always feasible.
Better	11	Generally the COPI regs have allowed data sharing and linkage on an unprecedented scale, but access to that (eg ONS, OpenSAFELY) is constrained and healthcare data sets are limited. Need to hold onto easing of regulations while maintaining public trust and confidence I can see that the speed of data linkage has been rapid during the pandemic and that has been important.
No difference	5	Not particularly. The same issues have continued with some organisations.

3.4.5 Information governance: suggestions for improvement

There were 105 suggestions for improvement made – with again the majority of these being around the need for reducing bureaucracy and duplication (n = 12), and even a complete overhaul to improve communication, responsiveness and speed (n = 11). Some respondents suggested that higher level review was required, and a change in attitude or approach so that risks are considered in a less defensive, proportionate and more balanced way (n = 16). Suggestions were made around provision of more training, guidance and templates to improve clarity of expectation and reduce variation between organisations (n = 26). Six respondents indicated the need for availability of more expertise. Moving away from project specific to system or organisation level agreements was recommended by some (n = 5).

Table 16: Looking forward, do you think these systems should change and if so, how?

Theme	Count	Key quotation(s)
Reduce bureaucracy	24	Again, making it clear that getting these [data sharing] agreements cannot take up the full term of the grant - projects and research teams are on short contracts and need to have time to complete the actual research project. Yes, there is significant room for improvement in efficiency …. and communication. Smoother and more transparent CAG process. Better responsiveness from NHS Digital.
Change of attitude/approach	15	Of course safeguards required, but proportionality needs to be applied. Being proportionate to what is requested would be really helpful, instead of having one pathway for all things. A change in attitude and culture that aims to be more permissive and enabling - focussing on how the use of data for public good as opposed to what you can't do
Guidance/templates	14	Clear guidance of good practice. Although this is constantly evolving at least provide questions/points to consider when thinking about what software/platforms to use for research. Standard IG template and processes, sharing of acceptable methods of working with info between sites.

continued

Table 16: Looking forward, do you think these systems should change and if so, how?

Theme	Count	Key quotation(s)
Clarity	12	Again, clear processes for all involved. As an applicant, if I have ticked all the boxes and met the requirements, I should be given IG approval. Clear understandable requirements so you know if you are meeting the regulations or not.
Complete overhaul	11	The whole system needs to be streamlined and speeded up. The whole system just needs a complete overhaul. As it stands, it poses a significant risk to us being able to conduct timely research that meets the needs of the NHS, with all the implications that has for the public purse and so on. Again, co-design the system with those who use it and those who work within it.
More expertise	6	More ... expertise is required to facilitate contractual processes to enable research to commence. It feels like a huge amount of time and resource is being wasted waiting to resolve contractual/governance debates. we need to bring these specialists in this community and make the knowledge sharing more integrated. REC resources that can be shared with IG leads, sharing of common issues and resolutions, how others are tackling issues, basic sharing learning stuff.
Organisation level agreements	5	Organisational-level agreements for data sharing could be a sensible move, by this I mean that my employer (University) applies once for access to routine data held in NHS that can then be available to researchers within the institution without separately making individual applications. Yes, the forms required for permission for each project are not necessary if there is a system wide approval.

4 Discussion

4.1 Summary of key findings

Across the three sections of the consultation questionnaire, similar themes emerged:

1. There were many more responses to the questions related to problems encountered and suggestions for improvement than questions about "What works well?"
2. Aspects which were reported to work well were: online centralised systems e.g. IRAS; virtual meetings; confidence in having the approval of a rigorous and robust, respected system; helpful staff. Processes for gaining ethical approval were reported to have improved over time.
3. Workload, frustration and delays related to processes which were viewed as overly bureaucratic, unclear, repetitive, inflexible and inconsistent between areas and over time were reported as the main problems across research ethics, governance and information governance.
4. A theme which was raised across areas by many respondents was the perceived lack of fit - or disproportionality - for low-risk studies such as observational or non-interventional studies (where there was no change to practice); qualitative studies; and studies using routine (existing) data only.
5. Systems for approvals across the three areas were reported as tending to be risk averse, defensive and lacking a balanced approach to risk assessment – for instance not taking account of the harms of clinical practice without evidence until research can go ahead; or a lack of research evidence to inform important public health or other health policy.
6. Some requirements were reported across themes to have unintended effects on inclusion and diversity, and to be a very difficult fit with Patient and Public Involvement and engagement processes. Inflexibility, the need to have everything ready at the outset with every small change requiring a lengthy amendments process and overlong, complicated Patient Information Sheets were highlighted again and again as off-putting, particularly for potential participants in already marginalised groups.
7. Existing processes and requirements were reported to cause stress and demoralisation for those involved in trying to produce research, particularly as most research is contracted for fixed time periods, and many researchers are employed on fixed term contracts.
8. Impact on research delivery was reported to be high, in terms of timescales for completing studies, deterrence of research, particularly for clinicians and students, quality of outputs and costs.
9. Respondents' experiences of differences during the COVID-19 pandemic were varied, with some reporting not much change, or things overall being worse (even grinding to a complete halt) and others citing positive impact, particularly on COVID related studies and the efforts of staff involved in the HRA processes.
10. Many suggestions were made for improvements in each section of the questionnaire, related to system level changes / overall approach and specific refinements to existing systems. Many suggestions were made about how to try to streamline and integrate systems in order to reduced workload and speed up processes for approvals at set up stage.

4.1.2 Study limitations

In this online survey we used a snowball approach to try to gain views and experiences from a wide range of people working in HSR in the UK. Because of this approach we do not have any data about response rate or representativeness of respondents. We report characteristics of respondents in terms of place of work; role; whether the respondent had led externally funded research; type of research methods used and populations included in research.

We used mainly open-ended questions which resulted in a large amount of narrative to code across areas. We discussed and validated codes but this was not an in-depth piece of qualitative research, rather a descriptive analysis task in order to present results in a coherent manner, and we carried out one level of coding only.

4.1.3 Implications for policy and practice

Despite long recognised concerns with over-bureaucratic processes and structures in research and information governance affecting HSR, and several attempts to streamline systems and requirements, we found that delays are routine. Levels of frustration are high and inflexible, interdependent – but not integrated - systems have negative impacts on research delivery, quality, inclusion, training of future research workforce (particularly clinicians) and costs.

The result of these delays means, inevitably, that rigorous research evidence is not available to inform development and implementation of health care policy in a timely manner. Many interventions lack an evidence base. Health Services Research endeavours to provide evidence about not only whether a treatment – be it device, drug or model of care – works in the lab, but whether it works in the real world. This requires gaining information from patients, the public, NHS staff and other stakeholders about how the intervention is implemented, its uptake, costs and effects in practice – benefits, risks and harms. This evidence is collected through a variety of study designs – both experimental and observational and methods both quantitative and qualitative.

Health services researchers work with other disciplines to produce evidence that is policy and practice relevant. Close cooperation is required across the various component parts of the research ethics, governance and information governance system in order to set up and deliver studies. Currently, high levels of familiarity with the system and key partners – 'inside knowledge' - is necessary to negotiate this system. Highly skilled academic and clinical researchers are spending their time form-filling, repeating information in different formats for different parts of the process. The system tends to be risk averse, and to only consider some risks. Safeguards and lack of flexibility within the system can result in vulnerable groups being excluded from research.

Processes which were set up for the approval of clinical trials have been modified for a wider range of research designs and methods but this has not always been successful as trials by their nature include much tighter pre-specification than other research designs. Study designs and populations that are frequently covered in HSR that are different from the standard randomised trial and that may be prioritised for fast tracking would include:

- NHS workforce
- Evaluations running alongside implementation (such as some in the Health and Social Care Delivery Research (HSDR) rapid centres)
- Qualitative studies in populations that are not 'high risk'.

Research permissions processes can be sped up – we have seen that during the COVID-19 pandemic with impressively fast approval of some urgent public health research, most notably the vaccine trials. The work now is to take through these expedited processes, and develop others which are suited to low risk research in which care delivery is not changed during the study (non-intervention studies).

5 Conclusions and next steps

This consultation with those involved in health services research in the UK revealed a story of overwhelming and increasing bureaucracy, delays, costs, reduction in quality, avoidance and burnout related to gaining approvals necessary to begin research in the NHS.

Suggestions for improvement across all three areas focused on reducing duplication and unnecessary paperwork/form filling; instilling a sense of balance in risks of harm through research, loss of data and prevention of research to inform clinical practice.

We hope that the HRA will work in partnership with HSR UK and others involved in 'busting bureaucracy' initiatives to develop an increased understanding that in order to thrive in the long term, research needs to be carried out responsibly, sustainably and efficiently.

Our next steps, following the production of this report, will be:

- Publication and dissemination of findings of HSR UK consultation survey
- Feedback meetings with HRA and other relevant leaders
- Workshop with stakeholders including research commissioners and facilitators to discuss how to make improvements in:
    - Approvals timelines
    - Bureaucracy (integrate and trim to reduce duplication and workload)
    - Costs
    - Inclusion
    - Fit for low risk/non-interventional studies
    - Levels of stress amongst researchers
    - Avoiding deterrence of necessary and desirable research

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HSR UK

HSR UK is an independent charity dedicated to the promotion of health services and care research in policy and practice. We aim to be the collective voice of UK health services research and our members include universities, research centres, think tanks, NHS organisations and NIHR Applied Research Collaborations.

By convening and connecting producers and users of health services and care research we support evidence-based policy and practice in the NHS and social care, helping to mobilise research, build capacity and make an impact. We also influence policy leaders and funders to improve the profile and landscape of health services research, enabling it to thrive.

Authors' names and affiliations

Prof Helen Snooks
Professor of Health Services Research and Senior Research Leader, Swansea University. HSR UK board member

Dr Ashrafunnesa Khanom
Senior Research Fellow, Swansea University Medical School, PRIME Centre Wales (Wales Centre for Primary and Emergency Care Research)

Rokia Ballo
Administration and Communications Officer, HSR UK. PhD student, UCL Science and Technology Studies dept

Prof Kieran Walshe
Professor of Health Policy and Management, The University of Manchester. Chair of HSR UK board

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HSR UK c/o The Nuffield Trust
59 New Cavendish Street
London
W1G 7LP

info@hsruk.org
www.hsruk.org

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