



Governing health services research: is it working?

Mary Dixon Woods and Karen Yeung



The Health Services Research Network

The Health Services Research Network (HSRN) is a network of over 100 organisations dedicated to promoting health services research. HSRN aims to be the voice of the health services research community and is working as part of the NHS Confederation to create greater alignment between the research and NHS communities.

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Contents

Foreword	4
Introduction	5
The research governance system	6
Reflecting on the current system of research governance	10
Research governance as a system of prior approval	12
Proportionality and frustration of the goal of promoting research	14
Conclusions	17
References	18
The authors	19
Acknowledgements	20
Annex A	21

Foreword

The Health Services Research Network (HSRN) is the independent membership network for organisations interested in health services research and acts as the voice for the health services research community.

Research governance is an issue that constantly troubles our members who feel that a system that has been set up to deal with clinical research unfairly places an excessive level of regulatory burden on much lower risk health services research, which is largely non-clinical and non-invasive.

As part of HSRN's programme of work looking at this issue, we commissioned Mary Dixon Woods and Karen Yeung to write this viewpoint to help us understand and provide some questioning of how the current system operates. This paper provided an important aid to a seminar, co-hosted with the Society for the Study of Organising for Healthcare (SHOC) and the Society for Social Medicine, that looked at problems with the regime from a health services research perspective and proposed some ideas for improvements.

Introduction

The Research Governance Framework (RGF) undoubtedly has good intentions, and it is clear that some form of governance is needed, not least because of the need to secure the social licence for research. But it is also clear that the RGF as it currently operates does not deliver on all of its goals:

- it often gets in the way of serving the public interest function of health services research
- it fails to provide clarity
- the regulatory requirements it imposes are often disproportionate to the risks it is intended to safeguard against
- goals relating to transparency and to detection and investigation of adverse events and misconduct are poorly served.

By looking at how the current system operates, and then reflecting on its aims, the level of regulatory intervention and its subsequent advantages and disadvantages, this paper reflects on the merits of this argument and of the current system as a whole. It does not discuss in any detail many of the other aspects of the regulation and governance of health services research, including issues relating to research ethics committees.

This paper sits alongside the HSRN briefing, *The new research governance landscape*, that describes how the landscape has changed in recent years.

The views expressed are those of the authors and not necessarily those of the HSRN.

The research governance system

We start by looking at the specific form that the Research Governance Framework (RGF) for Health and Social Care takes.¹ The RGF may be described as a code of practice issued by the Department of Health that is intended to direct NHS organisations and those who wish to conduct research in the NHS as to their obligations, and to clarify lines of responsibility. The perceived need for the RGF was influenced by high-profile controversies involving research in the NHS in the late 1990s, at around the same time as scandals about clinical performance and misconduct also erupted. It was modelled very closely on policy documents about clinical governance, including language and ideas relating to risks, standards and systems.

European Clinical Trials directive 2001

A second important context for the RGF was the European Clinical Trials directive 2001, which was implemented into UK law by the Medicines for Human Use (Clinical Trials) Regulations (2004). The Regulations established standards relating to clinical trials of investigational medicinal products (CTIMPs), provided a statutory basis for Research Ethics Committees (RECs), and laid down the legal responsibilities of investigators and sponsors. Standard operating procedures (SOPs) for RECs were introduced in 2004 to meet the requirements of the Regulations. The Department of Health decided to apply the same SOPs to all other research and, crucially, this model of using the same broad standards to deal with all types of project applied generally to research governance as well as research ethics. Many complaints about the current process focus on disagreements about whether it is appropriate to treat all types of research as posing, in principle, the same risk and requiring the same level of governance as CTIMPs.

The legal basis of RGF

A further important but rarely noted point is that there is some ambiguity about whether the RGF rests on a sound legal basis, particularly in seeking to extend the legal duties of NHS organisations to research projects that do not directly affect the healthcare of individuals or are not governed by specific legislation (for example, the Clinical Trials Regulations). The general legal duty of NHS organisations in relation to quality arises under section 45 of the Health and Social Care Community Health and Standards) Act 2003. This refers to a duty in relation to the quality of healthcare provided to individuals, defined as services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness and the promotion and protection of public health. Section 46 of the Act allows the Secretary of State to prepare and publish standards in relation to the provision of NHS care.

This is currently operationalised as 24 core standards^{2,3,4} organised into seven domains defined by the Department of Health. Core standard C12 relates to research governance. It requires healthcare organisations that either lead or participate in research to have systems in place to ensure that the principles and requirements of the RGF are consistently applied. The legal basis for Core Standard C12 seems to rest on sections 45 and 46 of the Act. However, this appears to assume that any health research legally constitutes part of the provision of healthcare in the sense defined by the Act. Because the legal foundation of this assumption has not yet been tested, it is debatably whether health services research that does not affect patients' care should be regulated under the Health and Social Care Act 2003. However, further legal analysis is required to clarify this.

The role of the sponsor

Under the RGF, each research project must have a sponsor. The sponsor is often (though not always, and not by requirement) the employer of the chief investigator on a project. The sponsor must be satisfied that a research proposal respects the dignity, rights, safety and well-being of participants; ensure that the study has undergone an independent expert review which has demonstrated the proposed research to be worthwhile; be satisfied with the arrangements for management and monitoring of projects; and ensure indemnity arrangements. If an investigation or audit of a project is initiated, sponsors are to help with this.

Formally, it would appear that the sponsor is a key agent in the governance system, and it is indeed true that no project can proceed without a sponsor. In practice, however, NHS organisations (such as NHS trusts) operate as the critical point of entry. All research to be undertaken within trusts must be notified to, and approved by, any NHS organisation 'hosting' the project by virtue of providing access to information or research participants. In effect, NHS organisations function to regulate both the sponsors and the researchers.

Research governance permission from NHS organisations

The system of gaining permission from NHS organisations arises because the RGF specifies that:

"Organisations providing care are responsible for satisfying themselves that they have adequate arrangements that any research involving their patients, service users and carers, or staff to meet the standards set out in this framework."

The introduction of the RGF caused many problems initially because the Department of Health did not specify exactly how the system should be implemented, leaving it up to individual organisations to devise their own research governance processes. As a result, a diversity of systems emerged, often with contradictory requirements. Since the publication of *Best research for best health* in 2006⁵ and the establishment of the NIHR, efforts to address some of these issues have been made.

The NIHR, as well as functioning as a major funder of health research, allocates funding for research, produces standard operating procedures for elements of research governance and has established 25 comprehensive local research networks (CLRNs) throughout England. NHS research studies that are eligible for support through these networks can be included in the NIHR portfolio. The portfolio automatically includes NIHR-funded research, and other studies that fulfil certain criteria (for example, competitively funded via a national funding scheme and having been peer-reviewed for quality) may also be eligible for inclusion.

An important feature of the portfolio is that, since November 2008, a coordinated system for gaining NHS permission (CSP)⁶ for studies on the portfolio now exists. CSP standardises, and has the potential to greatly speed up, the process for gaining NHS permissions in England. However, the CSP itself is complex. Its operating guidelines⁷ extend to 170 pages, including a six-page glossary. Central to NIHR CSP is the notion of governance checks. These are intended to provide assurance that studies are legal, compliant with applicable regulations and comply with the key domains of the Research Governance Framework (i.e. ethics, science, health and safety, information and finance, and intellectual property).

Moreover, something of a two-track system operates depending on whether studies are portfolio or non-portfolio (see Annex A). Although the Department of Health expects that NHS trusts will in the long term adopt NIHR procedures or equivalent for non-portfolio studies, for the present research that is not eligible to be included in the NIHR portfolio is currently managed by healthcare organisations using their local research governance and assurance mechanisms, and many projects thus persist with the 'old' system and its associated frustrations. Regardless of whether projects are portfolio or non-portfolio, NHS permissions depend on demonstrating compliance with multiple specification standards – i.e. standards that either compel someone to conduct an activity in a particular way, or prohibit some ways of conducting the activity.⁸ As Harlow and Rawlings point out, these are the most interventionist standards, and are the classic target of criticism of fussy or legalistic command and control regulation.⁹

Approval of researchers to conduct research

Some of the checks aim to determine whether researchers are appropriately qualified and otherwise fit and proper persons. Many problems arose in the past because of locally imposed requirements in relation to honorary contracts

for non-NHS staff. A research passport system has been introduced to allow researchers not employed by the NHS to engage in a single pre-engagement process where all the necessary checks, including those relating to health, criminal record, and qualifications, are carried out once only, and then the information shared with all of the trusts where the research is to take place. The checks are initially undertaken by researchers and employers, and are then validated by an NHS organisation.

The Care Quality Commission's (CQC) inspection guide for standard C12 makes it clear that:

researchers who will not foreseeably affect patients' care, treatment or diagnosis etc (for example those conducting social research in NHS settings) are not required to hold honorary contracts. Indeed such a requirement would be disproportionate to risk and not in line with the Research Governance Framework.

Researchers not requiring honorary contracts are not, however, exempt from a formalised relationship with NHS organisations. They now require 'letters of access'. The legal distinction is that in most cases when a letter of access is issued, liability lies with the researcher's employer, whereas the NHS organisation that issues an honorary contract acquires liability for the researcher. Higher education institutions retain primary accountability and liability for the actions of their researchers.¹⁰

Monitoring, learning from adverse events, preventing misconduct, promoting good practice

The RGF expresses a general commitment to monitoring of research, standards-based assessment, statutory inspection (by what is now the CQC) and adverse events reporting. In addition:

- organisations providing care are responsible for reporting “adverse incidents in the context of research” to the National Patient Safety Agency (NPSA)
- the Director of Counter Fraud Services has responsibility for all work to counter fraud and corruption within the NHS, but NHS organisations are expected to ensure that universities and others with whom they develop partnerships have appropriate systems for detecting, investigating and addressing fraud by their employees
- NHS organisations employing researchers accept liability for these individuals and may use their disciplinary procedures to investigate and deal with any misconduct
- non-NHS employees may require an honorary contract if their research has a direct impact on patients’ care. Higher education employers are responsible for discipline of researchers they employ, but NHS organisations retain vicarious liability for harm due to clinical negligence

and would be liable for paying compensation to patients who suffer harm due to negligence in research

- non-NHS employees who do not require an honorary contract require a letter of access, but vicarious liability for the actions of the individual lies with their substantive employer, which can use its disciplinary procedures in the event of alleged misconduct or other failings in the conduct of research
- in the case of alleged misconduct, members of some professional groups (for example, medicine, nursing, midwifery and other registered professionals) will be subject to disciplinary action by their professional bodies.

It appears that the CQC would be the likely candidate for conducting an investigation into alleged problems in research if deemed necessary. The CQC may inspect compliance with the Department of Health’s core standard C12 (which relates to research governance). Organisations are expected to ensure that they detect non-compliance with the RGF (for example, fraud, scientific or professional misconduct) and must also ensure that they systematically identify, protect and exploit intellectual property arising from research. If an organisation fails to meet the standard for research governance, the CQC should offer proposals for improvement in negotiation with its strategic health authority and can recommend taking special measures in relation to significant failings.

Reflecting on the current system of research governance

In reflecting on the current system, it is useful to begin by identifying the goals that the regulatory regimes seems to be aiming to serve, so that we can then identify the extent to which the system is achieving its own aims. Five high-level goals can be distinguished.

Goal 1: Promoting research in the public interest

The importance and public benefits of health research have been repeatedly emphasised in government policy documents, including the Research Government Framework, Best Research for Best Health, the NHS Constitution, and the Operating Framework for the NHS in England for 2009/10, which emphasised that “all providers of NHS care will need to increase their participation in research”.

Goal 2: Protection from risks of harms or wrongs to patients, the public and research participants

The commitment to promoting research is balanced against a number of other goals, including those relating to ensuring adequate control of any risks, and those related to securing the ‘social licence’ for health research¹¹, that is, maintaining its standing as a

legitimate and socially valuable activity for which there is broad public and institutional support. Although members of ‘the public’ are framed as beneficiaries, the principal focus of the governance system is on the need to safeguard them from risks as research participants.

However, identifying the risks that are being regulated in health services research is not always easy, and there is (often intense) disagreement about the nature of these risks and their significance. For many HSR studies, the risks are frequently vague and difficult to measure, and are often concerned with various types of possible ‘wrongs’ and indirect harms, concerning for example potential invasions of privacy. There is often extreme contestation between different groups as to what constitutes a harm or wrong, or whether risks should be tolerated in order to serve the aim of advancing knowledge or serving the public interest.

Goal 3: Enhancing quality and promoting good practice; reducing adverse incidents and ensuring lessons are learned; ensuring research integrity

The RGF makes a commitment to promoting good practice in research and high performance in health research. However, efforts to promote good practice have to confront contestation about what constitutes ‘good’ science in the face of legitimate differences of opinion about the best design or methodology for tackling particular research questions as well as about the ethics of particular research designs. There are often significant disagreements about situations where ethical rulings have implications for scientific quality (for example, requiring consent before using anonymised patient records). How differences of opinion are settled is often the subject of dispute and resentment, because researchers may argue that administrative rulings on issues favour defence of individual institutions rather more than they serve the interests of science or the public. On the other hand, institutions may argue that researchers are bound to

The current system of research governance

The governance system aims to serve five high-level goals:

- promoting research in the public interest
- protection against risk to patients, the public, and research participants
- promoting quality and good practice
- protecting against organisational and reputational risk
- maintaining a system of good governance, including satisfying principles of legality, proportionality and accountability and transparency

argue for the most liberal regime possible, that their arguments are self-serving, and that appeals to the public interest should be treated sceptically.

Distinct from these disagreements about what might define 'good' practice is the issue of misconduct, including falsification of research data, plagiarism, and so on. Misconduct may be difficult to prevent and intentional misconduct is inherently difficult to detect, but its control is likely to be important to securing the legitimacy of the research enterprise.

Goal 4: Protection against reputational and organisational risk

When something goes wrong in research, there is a risk that organisations' reputations may be adversely affected. They are also faced with a range of other risks, including the risk of time, resource and effort being diverted to managing problems, and unwelcome challenges of dealing with what may be uncomfortable or unpleasant situations. Organisations will also wish to ensure that involvement in research does not pose financial risks. Risk perception may have a chilling effect on organisations' willingness to host research.

Goal 5: Maintaining a system of 'good governance'

A 'generic' aim of any regulatory regime is to ensure that the regulatory regime itself satisfies the demands of good governance. Although there is no universally agreed set of good governance principles, there are various important values that recur in scholarly and policy-based literature, including concerns that governance should be lawful, accountable, transparent, efficient, effective, responsive, flexible, timely, proportionate, consistent and fair.¹² Three are perhaps particularly salient in the governance of health research: legality; proportionality and accountability; and transparency.

Ensuring the legality of health research is clearly important, but challenges arise because of the many

areas of legal uncertainty in this area. For example, the application of the rules to privacy, confidentiality and consent remains complex and confusing, not least because of uncertainties about the interpretation of the Data Protection Act in the NHS.

If the principle of proportionality is to be satisfied, there should be a reasonable relationship between the aims of the regime and the means to achieve these aims.⁷ Proportionality involves some idea of balance between competing interests and objectives, and the appropriate relationship between means and ends, as well as a commitment to consistency. Consistency reduces the existence and appearance of arbitrariness, promotes stability and certainty in regulatory decision-making, and provides firm guidance to those likely to be affected. Proportionality further requires that sanctions should be calibrated with the gravity of the offence.^{13, 14}

Accountability and transparency, which are directly linked, are also important features of democratic governance. Accountability requires people to explain or justify – against criteria of some kind – their decisions or acts, and then to make amends for any fault or error.¹⁵

Transparency describes the extent to which the reasons or basis for particular decisions can be identified. Those affected by regulatory decisions are entitled to an account of the reasons for the decision so as to demonstrate to them that the decision was made properly and that they were fairly treated.¹⁶

Finally, regulatory schemes must be capable to providing useful and reliable guidance to the regulated community concerning the scope of permissible conduct and the consequences of non-compliance. Clarity and predictability in both the content and the application of regulatory rules are therefore important. Guidance is provided most directly and completely by a system of precise rules that are stable, applied consistently, not changed too often, known publicly, and not unduly complex.¹⁷

Research governance as a system of prior approval

The summary above suggests that the governance of health research is likely always to be fraught. This is because of the nature of the enterprise, where all of the parties involved – including researchers, NHS organisations, funders, employers, and patients/the public – have important and legitimate interests at stake that may be highly contested and sharply conflicted. For example, the interests of the different stakeholders may not converge on a single standard on many areas of legal uncertainty (for example in relation to privacy), perhaps encouraging some stakeholders to adopt the most defensive position available. Nonetheless, any regulatory regime should seek to achieve a balance of interests, and to do so with the minimum of regulatory overhead to achieve the goals of the regime. The level of intervention should be suited to the objectives of the regulatory regime, and the lowest level of intervention necessary to achieve the objectives should be chosen; to avoid using a hammer to crack a nut, regulatory action should not go beyond what is necessary to achieve the objectives of the regulation.¹⁸

Regulatory techniques can be classified in a spectrum according to the degree of intervention. The lowest level of intervention is regulation involving information provision, where suppliers are made to disclose details about their goods and services to enable consumers to make informed choices. In the middle are techniques involving standards. These allow an activity to take place subject to its meeting certain standards, and people or organisations are liable to sanction (or prosecution) if they fail to meet the standards. Systems of prior approval involve the highest level of intervention. Prior approval means that a licence or permit must be obtained from

an authorising agency, which will require certain conditions to be met, before allowing an activity to take place. Under such a system, only those who are licensed can carry out a particular activity, and under a particularly restrictive regime, each individual activity must itself have prior approval and be specifically certified or authorised before it may proceed.

From the description earlier, it is clear that the present system of research governance system operates, in regulatory terms, as a system of licensing. It involves prior approval and authorisation both of each individual project and of most researchers. Entry to the system is strictly controlled, with multiple points in the system empowered to limit entry to those who can demonstrate compliance with pre-set standards. Notably, no system of prior approval operates at the level of an organisation – thus, for example, a particular unit in a university cannot be approved to conduct research; each project requires individual approval. It is therefore a very high intervention form of regulation. As it currently functions, it can therefore be seen to involve both the advantages and the disadvantages characteristic of prior approval or licensing regimes.

Advantages of research governance as a system of prior approval

Licensing, as Scott and Black point out,¹⁹ is a powerful tool of control. Being denied the right to undertake an activity is a powerful deterrent against breach of standards. Prior approval has a number of other justifications, particularly as a tool of consumer protection:

- it helps to ensure that vulnerable consumers do not make errors of judgement
- only those who are fit and proper to operate are permitted to do so
- dangerous interventions and unsafe or unscrupulous practitioners are weeded out.²⁰

In the research governance system, NHS approvals are intended to ensure that any risks of the research are properly assessed; that those engaged in working on the project are properly qualified; and that assurance can be provided to the public that any risks associated with research are well controlled. Many of the advantages of the current system accrue to NHS organisations, since operating detailed systems of prior approval offers a very high level of control and allows them to demonstrate that they are compliant with core standard C12. The system may also provide crucial benefits and protections for researchers, in particular by helping to secure the social licence for research and providing defences if something does go wrong.

Disadvantages of research governance as a system of prior approval

The research governance system is prey to all of the disadvantages of licensing systems:

- the administrative costs of scrutinising all applications is very high, making research governance, like all licensing systems, expensive to operate
- opportunity costs arise because of the time and resources diverted to applying for and granting of licences
- investment may be discouraged both by commercial interests and by charitable or public interest agents who find the costs of entry too high
- the benefits associated with activities may be delayed.²¹

Proportionality and frustration of the goal of promoting research

As already noted, if the principle of proportionality is to be satisfied, there should be a reasonable relationship between the aims of the regime and the means to achieve these aims. Regulation of health services research gives rise to particular difficulties because what it is that is being regulated in terms of risks is not always easy to discern, because there is (often intense)¹³ disagreement about the nature of the risks being regulated and their significance, and because multiple and potentially conflicting regulatory objectives may co-exist. Health services researchers frequently argue the current system of governance is disproportionate, that it obstructs and disrupts research which involves minimal risk, and that it operates counter to the public interest. A particular focus of criticism concerns the application of the same standards of risk aversion to different kinds of research. Researchers argue that all research is inappropriately treated as being due critical and sceptical scrutiny, as being equally rich in the potential for harms, and as requiring the same standards and processes of review. Thus, the argument goes, the weight of scrutiny and intervention should be more closely matched to the level of risk involved. Further, what is notably absent is a location for any authority that might be able to settle some of the more substantive questions that trouble the research community, such as those concerning the public interest, the motives of researchers, and so on.

Though recent positive initiatives under Best Research for Best Health were intended to simplify and standardise processes of research governance, much complexity remains. It is still the case that each NHS organisation is a separate legal entity, and NHS permission for research is required from each

NHS organisation for each project on a per-site basis. Neither NIHR CSP nor the CLRNs can give NHS permission for a research study; their role is to facilitate and support the process in a coordinated way.

Further disadvantages of the current system may be less evident but are nonetheless important. Prior approval provides incentives for both regulators and users/consumers to be less than rational. Regulators (or NHS organisations in this case) may be incentivised to be too cautious because they can easily be blamed for things that go wrong; and users/consumers may be incentivised to assume that all is well with a licensed activity, rationally decide to take little care in making judgements about safety.²⁰ There is some evidence that both of these problems have occurred in relation to research governance.

Protocolisation

The current system tends to default to a bureaucratic focus on procedure, to assess formal compliance with prescribed procedures rather than attend to more substantive aspects of performance, and to suppress discretion, even when the disciplined exercise of discretion might better deliver on aspirations for regulation and be more efficient. This is because, when faced with challenges to their activities and legitimacy, and demands for accountability, transparency and openness over the handling of risk, a frequent strategy on the part of organisations involves 'protocolisation'.²² Such efforts may be directed towards reputation management and

organisational defensiveness rather than being genuine efforts to manage real risks. But once 'governance' has been converted into procedural form, rigidities and limitations are inescapable. With NHS organisations and research sponsors defined as sites where blame can easily be located, and where lapses of procedural compliance take on particular significance, rule generation and observance may become engaged as 'blame prevention engineering'.²² Efforts at managing blame and liability may encourage compliance-orientated behaviours, including a rigid adherence to rules. 'Rituals of verification'²³ may become the focus of activity, and the original goals of risk management may be displaced in favour of rigid rule compliance in the interests of maintaining consistent standards and behaviours. Researchers' complaints about the research governance system can, in many ways, be read as surfacing these kinds of processes.

A further problem is that the current system of governance is essentially coercive²⁴ in form; researchers do not conform because they necessarily share the same values, ethics, and role expectations of the governance system, but rather because displays of compliance with those qualities are required in order to gain approval. This may have the effect of degrading researchers' own moral sensibilities, and of reducing ethical or safe behaviour to conformity with procedural requirements. This is important because scholars suggest that in any complex system control cannot be effected by simple steering alone, but must to a large extent consist of self-controlling mechanisms, and that 'command and control' styles of regulatory intervention can produce unintended side effects or even perverse effects.²⁵

Problems in achieving the goal of securing the social licence for research

Despite the weight of regulatory intervention, it is not clear that the system fully succeeds in controlling risks associated with research, including the risk that patients or the public may be duped into taking part in research that has not been approved, or that is not taking place in accordance with the approved protocol. One key deficiency with the current system is that there is still no central registry either of researchers or of research projects. It may therefore remain difficult for a member of the public to identify a research project relevant to his/her condition; to determine whether any given project is a bona fide study that has been approved by the NHS; or to identify whether any individual is authorised to conduct research through the NHS. The case of Peter Green, a GP in Loughborough who used a claim that he was conducting research into back pain as a veil for committing sexual assaults on patients, highlights this issue.²⁶

Problems of achieving the goal of dealing with poor performance and misconduct, learning from adverse events, and promoting good practice

Although the risks of 'adverse events' and research misconduct are part of the motivation for the RGF, the arrangements for monitoring, investigation and enforcement would appear to be inadequate in several respects:

- Outside of clinical trials of medicinal products and a few other well-defined areas, systems for detection and correction of non-compliance with regulatory requirements for research are generally ill-specified and poorly coordinated.
- Sponsors do have a responsibility to ensure the research is properly managed and monitored, but how this is to be done is not defined, nor is it clear that sponsors such as higher education institutions have the expertise and resources to manage this effectively. It is also unclear how NHS organisations exercise their responsibility to audit research projects, particularly in relation to 'low-risk' HSR projects.
- Although 'adverse events' relating to research are supposed to be notified to the NPSA, there is little evidence that this happens.
- It is not clear how many complaints there are about research conducted in the NHS each year, and whether any of these complaints concern HSR.
- It is not clear how many applications for research governance approval are permanently declined each year, or the reasons why a project with REC approval and a sponsor would be declined.

Systems for detecting and investigating research misconduct or other allegations of failures or problems in research remain poorly developed. Investigations of this nature typically require a high level of expertise and resource if they are to be fair, consistent, transparent, and legitimate. In recognition of this, the USA has implemented legislation on the conduct of research sponsored¹⁶

by the US Public Health Service, and the Office of Research Integrity supervises and ensures compliance by institutions. The UK Research Integrity Office was recently established with a brief for promoting effective systems for research integrity. But it has no statutory basis, and no regulatory or policing powers.²⁷

Responsibilities in relation to research conduct and investigations into allegations of misconduct depend upon a whole series of often complicated arrangements between NHS organisations and employers. The CQC does appear to have some powers to conduct reviews of research projects, but it is unclear whether this has been tested as yet. Where misconduct is detected, a range of different types of investigation and sanctions may follow depending on who committed the misdemeanour and the gravity of the offence. Different standards apply depending on the professional group to which a researcher belongs.

In practice, learning about adverse events is likely to rely primarily on complaints from research participants, members of the public or colleagues, and the oversight is exercised by medical journals, especially those that are members of the Committee on Publication Ethics. These problems frustrate the goal of learning from adverse events and promoting good practice. Moreover, they feed back as legitimacy problems to the research community, since in the absence of good evidence that there are real risks associated with their research activities, they may continue to regard the governance system as disproportionate.

Conclusions

The research governance framework undoubtedly has good intentions, and it is clear that some form of governance is needed, not least because of the need to secure the social licence for research. But it is also clear that the RGF as it currently operates does not deliver on all of its goals. It often gets in the way of serving the public interest function of health services research; it fails to provide clarity; the regulatory requirements it imposes are often disproportionate to the risks it is intended to safeguard against; and goals relating to transparency and to detection and investigation of adverse events and misconduct are poorly served.

These problems are compounded because research in health care is a fraught area, where there is considerable contestation about how the conflict between the multiple goals of the regime should be resolved. Given this, it is especially important that the system should be clear, capable of authoritative resolution in a transparent, accountable and democratic manner. The system as it currently operates faces multiple challenges in achieving this,

in part because health services research represents a diverse field with multiple different actors. For the NHS, trying to control non-NHS personnel is always going to be difficult and it is perhaps unsurprising that the administrative manoeuvres that have been introduced to deal with this problem are naturally inclined to complexity.

The NIHR's recent effort to deal with some of these issues and reform the research governance environment is very encouraging. We hope the plans to reconfigure R&D departments into research support services with standard operating procedures and produce clear guidance around the handling low risk research will deliver real and noticeable improvements for health services researchers. But in considering the way forward, a broader range of solutions may need to be considered.

For more information about the issues covered in this report, please contact Stephan Groombridge, Senior Policy and Research Officer at stephan.groombridge@nhsconfed.org

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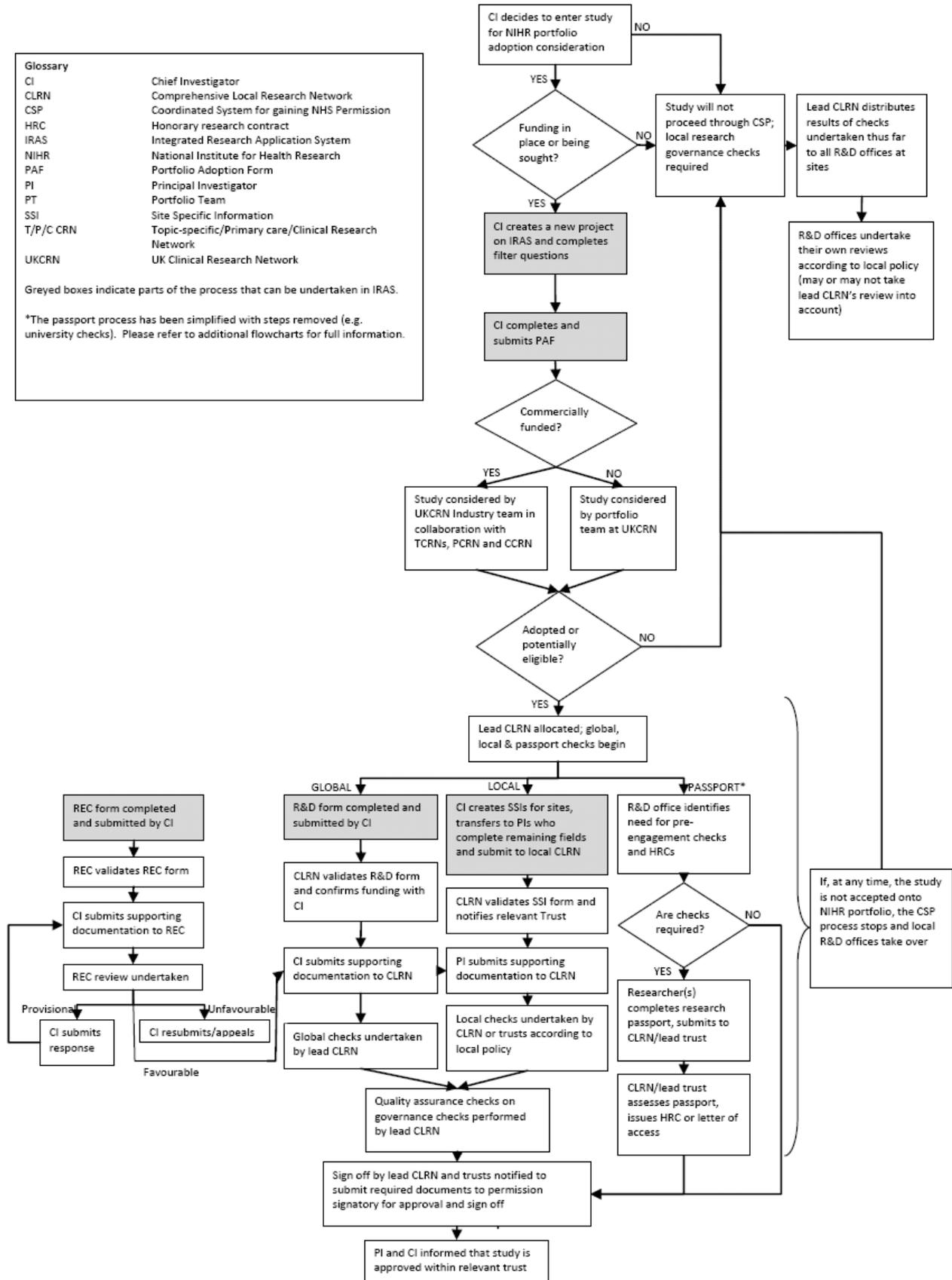
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Annex A

Glossary	
CI	Chief Investigator
CLRN	Comprehensive Local Research Network
CSP	Coordinated System for gaining NHS Permission
HRC	Honorary research contract
IRAS	Integrated Research Application System
NIHR	National Institute for Health Research
PAF	Portfolio Adoption Form
PI	Principal Investigator
PT	Portfolio Team
SSI	Site Specific Information
T/P/C CRN	Topic-specific/Primary care/Clinical Research Network
UKCRN	UK Clinical Research Network

Greyed boxes indicate parts of the process that can be undertaken in IRAS.

*The passport process has been simplified with steps removed (e.g. university checks). Please refer to additional flowcharts for full information.



Governing health services research: is it working?

Research governance is an issue that constantly troubles our members who feel that a system that has been set up to deal with clinical research unfairly places an excessive level of regulatory burden on much lower risk HSR, which is largely non-clinical and non-invasive. As part of HSRN's programme of work looking at this issue, we commissioned Mary Dixon Woods and Karen Yeung to write this viewpoint to help us understand and provide some questioning of how the current system operates.

The views expressed are those of the authors and not necessarily those of the HSRN.

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