

## **Bureaucracy, trust and time: getting a research foot in the door at a time of organizational change**

### **Authors:**

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### **Abstract**

#### **Background:**

The twentieth century saw changes which transformed unregulated and unethical research in ways which could only be welcomed. The burden of paperwork, however, risked the near universal buy-in to ethical governance being seen as an obstacle rather than a facilitator.

#### **Objective**

We sought to record and understand delays, variations in practice, and time costs in relation to research governance approval of a low-risk study during a time of organisational change.

**Design:** Review of recruitment notes.

**Setting:** Research and Development (R&D) departments UK National Health Service hospital trusts.

**Main outcome measures:** Number of contacts required to achieve an interview with NHS employee(s)

#### **Results**

The ratio of contacts to interviews was 16.5:1. Although we did not formally cost the time taken to (under) achieve our sample, we estimate that it doubled the time we had budgeted for this relatively small low-risk project. Once we reached a contact in an R&D department, colleagues were risk averse, but helpful in trying to make this study work, in some cases, suggesting workarounds.

**Conclusions** Our difficulties in securing relevant permissions for interviews suggest that a report contributing to the literature on checks and balances in good research governance during a time of organisational change, and possible mitigation is worth undertaking. The 'bureaucracy busting' measures in *Best Research for Best Health* remain a work in progress. Drawing on notions of trust and proportionality, we suggest that, for low risk studies, the costs to researchers, to R&D colleagues and to R&D funders could be reduced without increasing risks to participants. A postscript to our conclusion comes from the Health Research Authority, who currently have a major programme of change designed to enable the kinds of change which both protects participants and enables research.

### **Background**

Much of the discussion about the burden of paperwork in ethical approval of research studies has been around the need to balance timely research and encouragement of innovation with the need to protect participants and prevent research fraud. The worst outcome of attempts at improving governance, as one of us has pointed out in a different context, is that research becomes more difficult to undertake.<sup>1</sup> In a climate of austerity combined with rising research costs, it also becomes more expensive. There are, of course, wider implications of the growth of bureaucracies, limits to trust and professionalism, and the costs to

academics, clinicians, research participants, some of which were set out in a recent evaluation<sup>2</sup> of the delays and variations in practice attributable to research governance approval of clinical trials in the United Kingdom. The authors concluded that: *The UK research governance system incurs unacceptably long and costly delays...*' suggesting that urgent reform, including uniform implementation of the 'bureaucracy busting' measures in Best Research for Best Health, were needed.<sup>3</sup>

### *Our study*

A decade on from Best Research for Best Health, and following further reports on increasing efficiency and reducing bureaucracy in research governance,<sup>4 5 6</sup> we carried out a low-risk, non-clinical study of paediatric policies in the public domain. The aim of the study was to understand the ways in which particular guidelines operated and were interpreted on the ground. This was a two stage study: the first comprised documentary review (which did not require formal ethical review); the second, interviews with NHS staff who wrote the policies, implemented them on the front line as clinicians or administrators and/or had responsibility for strategic implementation of the policies. We gained ethical approval for the project from UCL Ethics Committee, who permitted us to seek verbal consent only in approaching interviewees. We were, in addition, required to secure two other forms of approval, one relating to data protection/information governance, and the other from Great Ormond Street Hospital for Children/UCL Institute of Child Health/ (GOSH/ICH) R&D office. The latter required us to secure permission from leads in R&D offices of each Trust before we approached prospective interviewees.

Having searched for guidelines on the topic of interest in the public domain in all English trusts, we identified 24 guidelines that met our inclusion criteria. We downloaded and described the contents of these, and then set about trying to contact potential interviewees.

We contacted the relevant trust R&D offices by email using contact names on the R&D forum (<http://www.rdforum.nhs.uk>). In all, 47 organisations were contacted over a three month period and experienced significant recruitment problems at the commencement of this stage. The current report, in which we describe the delays, variations in practice, and time costs we experienced, is a by-product of the original study (UCL Ethics Committee agreed that we did not need to seek additional ethics permission to report on our difficulties).

Method: Review of recruitment notes collected during the second stage of our study. This involved a review of both electronic and paper-based records.

## **Results**

We encountered significant problems with recruitment at the interview stage. To interview eight respondents, we initiated 131 contacts, giving a ratio of contacts to interviews of 16.5:1.

Our difficulties were undoubtedly exacerbated by the re-organisation brought about by the Health and Social Care Act (2012), within the NHS, but many of our difficulties replicated those encountered by previous researchers. Difficulties in making the initial contact were experienced at both the R&D approval stage, and in relation to approaching prospective interviewees.

In respect of the first, a common problem we experienced was email messages returned as 'unknown addressee'. Table 1 shows the full range of responses. Briefly, these included:

- Multiple first R&D contacts forwarding our message to colleagues, and suggestions of who else might be approached;
- Requests for Integrated Research Approval System (IRAS) or other written information;
- In principle approval, so long as we only conducted a telephone interview;
- Only one R&D office declined our approach to interview staff on the basis of volume of studies they needed to consider. They too made helpful suggestions;
- One query about whether the study was part of NIHR portfolio;
- A query about whether the study needed to come to R&D for approval (and, in some cases, a suggestion that that the study might be re-defined as 'not research' to facilitate faster progress;
- Although only one R&D department declined, others simply ran into the sands as our attempts to contact R&D departments by telephone and email – and the contacts we were then passed onto, became increasingly unproductive.

Once an R&D department had agreed to let us go ahead (sometimes providing us with contacts in addition to, or instead of, those named in the guidelines), the remaining delays related in the main to the workloads of those we were interviewing, although all respondents were generous with their time. Our poor ability to recruit resulted in our extending our search through snowballing in the trust with which one of us (HR) holds an honorary contract. This was an approach for which had ethical approval but one which we had hoped to avoid on the grounds of potential bias. This method was rapidly productive of 3 illuminating interviews.

Table 1 describes our contacts with R&D departments.

## **Discussion**

The history of the formal ethical oversight of research both within and outside the clinic is relatively recent in terms of its formal structures. Previous reports <sup>7 8 9 10</sup> have described what can be a heavy burden of requirements, and our data on the difficulties of tracking down the right people (and variations in what R&D departments consider to be the 'right' answer) suggest that bureaucracy-busting has some way to go. As Macdonach et al <sup>7</sup> point out, over-regulation may result in

undesirable side effects – including the temptation by researchers or R&D colleagues to re-nominate work as ‘not research’ as a ‘workaround’ measure.

All approaches to R&D were made by the investigators themselves rather than delegated to colleagues who were newer to the field. We were experienced researchers doing a low-risk study. Those we were interviewing are busy people, and it is right that they should have the right to turn down participation, but what we were requesting from R&D departments was not permission to *interview* their staff, but permission to *approach* staff to request an interview. This itself raises ethical issues about the appropriate level for decision-making in organisations and the nature of trust.

At a meeting to celebrate 50 years of the National Children’s Bureau,<sup>11</sup> a young person was reported as having said “If you stopped doing stupid stuff or doing stuff in a stupid way, you would have time for the important stuff.’ Ethics and good governance, is not, of course ‘stupid stuff,’ But an increasing distance between the core business of academic, NHS and other public sector organisations and their governance carries risks. This is a relatively minor example, but a costly one.

## **Conclusions**

Our experience suggests the following, most of which in one form or another, have also been raised by other researchers over the last couple of decades. However, despite the need for originality, repeated messages (as Coca Cola and the tobacco and alcohol industries have found) may be helpful in implanting an idea.

- The need for continuous dialogue with both researchers and researched on fine-tuning systems in the light of the everyday research practice.
- Whilst the requirement for R&D departments to be involved in addition to ethical approval may make the governance trail for research which hits the headlines clearer, judgement is needed on proportionality.
- Cost consequences studies of the very substantial time invested in research governance in low or no risk studies needs to be assessed.
- Ethics reviews for low-risk, non-clinical studies are now streamlined. (Ours was granted chair’s approval).

The time taken in tracing and following up R&D contacts during a period of considerable churn in the NHS was substantial for both researchers and R&D colleagues. This is not a new problem, and one can acknowledge the reasons for risk aversion whilst deploring some of its consequences.

In her 2002 Reith lectures<sup>12</sup>, Onora O’Neill pointed out that every day we read of untrustworthy action by politicians and officials, by hospitals and exam boards, by companies and schools. ... Everyday we also read of aspirations and attempts to make business and professionals, public servants and politicians more accountable in more ways to more stakeholders. Her conclusion is that we need to think less about accountability through micro-management and central

control, and more about good governance. If we are to restore trust we shall have to start communicating in ways that are open to assessment.

In thinking about these problems, HR and TS made contact with the Health Research Authority (HRA). As a result of our discussion, we add a cautiously optimistic response and illustrative case study from JW.

*The HRA was established in December 2011 to promote and protect the interests of patients and the public in health research and to streamline the regulation and governance of research. Its establishment was part of a response to the Academy of Medical Sciences review of the regulation and governance of health research, which called for the removal of barriers to research where researchers had to navigate complexities to get permission to conduct research in the NHS.*

*HRA Approval is a new operational service which will streamline the process through which permission is achieved from the NHS in England. HRA Approval brings together the assessment of governance and legal compliance, with the independent REC opinion.*

*Value can be demonstrated by learning from case studies. The HRA in the course of exploring how systems might be improved, found examples where inefficiencies resulted in inexcusable and unjustifiable delays and burdens for researchers seeking to deliver studies without clinical interventions, and where these studies provide insights into the change of approach and culture required.*

*The study described above will be a familiar story to readers, but how would we expect it to have fared as an HRA Approval study? I respond with reference to a study that went through HRA Approval in the first cohort of a move to streamline systems.*

*The study: A short online survey sent to the Senior Nurse, Chief Nurse or Director of Nursing*

*Target: All secondary care Trusts in England*

*There was no requirement for a principal investigator or local collaborator and no support was required locally*

*HRA Approval was issued 15 days after submission and the HRA determined that participating NHS organisations in England did not need to confirm capacity and capability to host the research. It was expected that each NHS Trust would become a participating NHS organisation 35 days after submission by the sponsor to the HRA, unless justification could be provided to the sponsor and the HRA as to why the organisation could not participate. All NHS Trusts in England automatically became sites unless they opted out with clear justification.*

*NHS Trusts were sent the HRA Approval letter and Statement of Activities via contact details on the R&D forum website. In addition, as a study coming through very early in the roll out process the HRA provided change leads notified their local*

*change contacts in advance (this is additional support to facilitate change to the new processes).*

*The HRA received a number of requests for further information and for copies of the study documentation. Requests for the study documentation were refused in all cases, gently with explanation as to why they were not required locally. There were a number of requests for clarification and assurance e.g. confirming the staff involved and the HRA agreed to provide the IRAS form so that locally there could be confidence in our assurance. Some wanted these details so they could fulfil roles to support the study and encourage participation.*

*From all secondary care Trusts sent the information only 5 declined to participate. Accepting that this was local facilitation by the change leads it is nevertheless a very encouraging result which shows great promise for a radically simplified approach of genuine and considerable benefit for researchers conducting these non-clinical studies.*

*So, what of the 5 that declined? The duties in the Care Act that established the HRA as a Non –Departmental Public Body provide a platform through which others have duty to regard our guidance. In due course we may look to rely on these duties more directly. For now we seek to work with colleagues to understand and learn, to build on relationships and expertise to change culture and ensure that we build a platform for the new approach that has a shared understanding and support. Interestingly, the 5 that declined were largely based on policies that did not empower a sensible interpretation. We know it is early days but the signs are good and we welcome feedback from all that are working through the new processes. Early feedback is essential whilst we have the additional programme resources in place to address the issues we fully expect to be raised for and that we will need to resolve.*

## References

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**Table 1: Contacts to harvested interview**

Organisations	Number of contacts	IRAS or other info required	Interview yield
Acute Trust1	4	IRAS + additional Information	N
Acute Trust2	4	IRAS + additional Information	N
Acute Trust4	7	Additional information	N
Acute Trust5	3	Asked for original information to be re-sent	N
Acute Trust9	6	IRAS	N
Acute Trust10	3	No – passed on to R&D manager	N
Acute Trust12	10	Passed to additional colleagues including information governance manager	Y
Acute Trust13	6	Very interested and passed onto 3 colleagues	N
Acute Trust14	5	Declined on grounds that organisation receives too many requests	N
Acute Trust15	5	Requested further documents	N
Acute Trust16	8	Department short staffed and our contact away	N
CCG2	10	Passed through several contacts and phone numbers	Y
CCG3	1	Unproductive contact	N
CCG4	2	Unproductive contacts	N
CCG5	4	Unproductive multiple contacts	N
CCG6	3	Suggestion to contact provider services	N
MHT1	9	Multiple follow ups	N
MHT2	1	IRAS required	N
MHT3	4	3 interviewees (one paired)	Yx3
MHT5	5	Multiple contacts	N
MHT7	7	Multiple contacts; IRAS required	N
MHT8	6	Multiple contacts	N
MHT9	6	Asked if project will become part of NIHR portfolio given DH funding	N
HCT1	7	Multiple contacts	N
Other trust	5	Snowballing contacts	Y x3



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