

Streamlined research governance: are we there yet?

Despite the promise of a new streamlined process for gaining research ethics and governance approval, **Nina Fudge and colleagues** argue that the process is still dogged by delay and arbitrary decisions



JEAN PIERRE GAUZERE/THE IMAGE BANK/GETTY

In 2009 the UK National Institute of Health Research Coordinated System for gaining NHS Permission (NIHR CSP) for research studies was established. The aim was to provide a single point of access for investigators applying for permission to conduct research involving NHS patients.

Promotional literature for the new research governance systems across the UK suggests that they will reduce the bureaucratic burden and time taken to grant approvals, enhance the research process, and keep the UK at the forefront of health research.¹⁻² Investigators applying for research governance approvals before the introduction of the new NIHR CSP system have described a laborious process fraught with delays.³⁻⁶ However, in our experience of gaining approval for a national survey, the new system has not lived up to its promises. We describe our recent experience of using the NIHR CSP to gain research governance approval and seek to explain the delays we encountered using Lipsky's work on how policy is implemented.⁷

Integrated system

Shaw et al define research governance as the system of "administration and supervision through which research is managed, participants and staff are protected, and accountability is assured."⁸ A variety of historical and social causes (including abuses of research participants) have necessarily led to research world-

wide becoming a "highly formalised, regulated and institutionalised activity."⁸

Since November 2008 applications for UK health and social care research have been made through the integrated research application system (IRAS).⁹ On the IRAS website investigators register their studies and apply for various permissions. The system can be considered "streamlined" because investigators need only enter information about a project once. Using the information provided, IRAS automatically completes all forms required for a particular study (such as those for ethics committees, governance departments, the Medicines and Healthcare Products Regulatory Agency). These forms are then processed by the relevant bodies. Once global permissions are granted, investigators complete forms relating to permissions from local research governance departments associated with the centres undertaking research (see figure). IRAS generates a checklist of documents which need to be provided to local departments, such as CVs of local researchers and local versions of patient information sheets, and study documentation.

Approval for the Stroke Survivor Needs Survey

The Stroke Survivor Needs Survey (SSNS) is a national postal survey to assess the long term needs of stroke survivors living in the community one to five years after their stroke. The study was

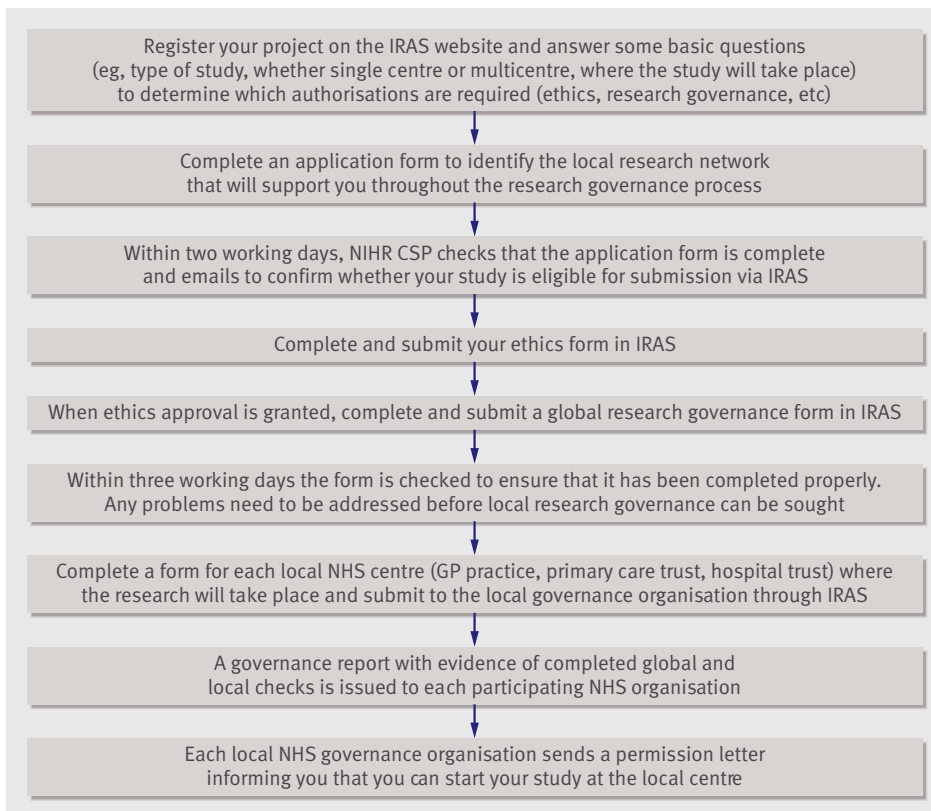
commissioned by the Stroke Association to help develop future campaigns and services. Questionnaires were administered by research nurses in 44 general practices in the four UK nations, recruited via the MRC General Practice Research Framework. The study was granted funding in February 2009, to be completed by September 2009 so that the results could inform the Stroke Association Trustees' meeting in November 2009.

We started the process to gain the required study approvals in February 2009. The process for gaining ethical approval was straightforward, with one application serving all centres within the four UK nations. Ethical approval was granted within 35 working days and subsequent changes to the study protocol were approved in a timely fashion. For research governance purposes this study was classed as a multisite study, meaning that permission had to be granted for each participating practice. The research governance approval process was further complicated by variation in application procedures in the four nations. Only England uses IRAS completely for research governance approvals. We could not use IRAS at all for research governance approvals in Northern Ireland. For Scotland and Wales we used IRAS to complete the research governance forms but submission was by email to each relevant research governance office (see table). It took until January 2010 for all 44 centres to be granted permission, with time taken ranging from seven to 135 days.

Table 1 | Research governance processes for the four devolved nations. Only research ethics was the same process for all four nations

Country	Initial contact	Global checks and approval	Local checks and approval	Duration*
Northern Ireland (14 GP practices)	Northern Ireland Primary Care Research Network (NI PCRN)	Each practice completes a 2 page form which is sent to NI PCRN		48 days
Scotland (15 GP practices)	NHS Research Scotland Coordinating Centre	Global research governance forms completed via IRAS but emailed to NHS Research Scotland Coordinating Centre	Local checks performed by local health boards but investigators not required to complete local research governance forms or equivalent	105 days
Wales (4 GP practices)	All Wales Primary Care Research Management Governance Office (RMGO)	Global research governance forms completed via IRAS but emailed to All Wales Primary Care RMGO	Local research governance forms completed via IRAS. IRAS generates checklists of required documents. Forms and documents have to be emailed to All Wales Primary Care RMGO	200 days
England (11 GP practices)	IRAS system NIHR CSP	Global research governance forms completed and submitted via IRAS	Local research governance forms completed and submitted via IRAS. Documents specified by IRAS emailed to local NHS organisations who undertook local checks	224 days

*Days counted as working days with bank holidays excluded, from the time global research governance form was submitted to the time last site was granted approval. The number of days includes delays caused by study investigators and local researchers (GPs) in providing research governance officers with additional information.



The NIHR CSP flow chart for researchers adapted from http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/CSP/Documents/csp_overview_diagram.pdf

Street level bureaucrats

This encounter with bureaucracy was frustrating and we turned to social theory to try to understand our experience. Lipsky's study of policy implementation, "street level bureaucrats," refers to public service employees who deal with members of the public and who have large caseloads to be processed quickly, constraints on resources (monetary, personnel, and time), ambiguous organisational goals and objectives, and clients who are non-voluntary—that is, they have limited or no choice over whether, where, or how they present to the service.⁷ Street level bureaucrats typically deliver public goods or confer specific status on citizens, and according to Lipsky have considerable discretion in decision making about this delivery. They use this discretion to manage workload and resource constraints so that "policy implementation in the end comes down to the people who actually implement it."⁷

In the case of research governance the public good delivered, or status conferred, is permission to carry out research. Ambiguous organisation goals are characterised by the need for the NHS organisation (primary care trust, NHS trust, local health board) to demonstrate an active research status yet at the same time to regulate potentially harmful research practices that could damage the organisation.

Discretion and autonomy

Local NHS organisations are legal entities in their own right. This in part explains the considerable variation in length of time it took to receive permission since the different organisations had different systems for approval. In Northern Ireland and Scotland the systems were relatively smooth, with much less paperwork and bureaucracy. In England and Wales differences in implementation between local sites was most stark. Similarly the discretion and autonomy afforded to local research governance officers varied, affecting the time taken to process applications.

IRAS is portrayed, and has been promoted, as a seamless, streamlined system.² At the initial stages of the research ethics and governance application process this is generally so. IRAS avoids the duplication of the same documents being sent to local research governance departments, as was the experience of Knowles et al.⁶ However, for several centres in England and Wales we had to respond to local requests for additional information and documentation beyond that listed in IRAS checklists (see box). In some cases local departments also requested changes to our study protocol or materials that in turn required further ethics approval. This meant that our applications were delayed since we had no way of anticipating local requirements for additional information.

Some additional requests appeared to have little to do with ensuring patient safety in research—for example, two research governance departments requested that NHS trust logos should be added to all study materials. In these cases the local officers used their discretion to give permission without the change having been made.

Some officers had clearly been granted some autonomy and could grant approval quickly. One NHS organisation in England took just seven days to grant permission because the research governance officer had autonomy to grant permission once he had completed the necessary checks. Others had to go to a committee for "sign off." If the next meeting was not for a couple of weeks, this inevitably contributed to delay. In another case an officer's autonomy had been curtailed when we discovered permissions were delayed while quality assessors were "checking the checks" performed by the research governance officer.

Inappropriate assessment of a study's risk to patients has been noted by others.¹⁰ One research governance officer recognised that our study was of minimal risk to patients and informed us that he would be able to process our approval quickly. By contrast, in other sites, no distinction appeared to be made between high and low risk studies.

Ambiguous objectives, large caseloads, constraints on resources

The government promotes the UK as being at the forefront of research and that research plays an important role in the knowledge economy.¹¹ However, our experience suggests there are tensions between different priorities: promoting research; ensuring patient safety; and other tasks, some of which are unrelated to research governance. On at least three occasions when we inquired about the progress of our study permissions we were told that there would be delays in granting approval because of "swine flu" (the epidemic reached its peak at the time our applications for research governance were being reviewed). In Wales we were told that local checks were being delayed as local health boards prepared for distribution of antiviral drugs at the direction of the Welsh Assembly. In England, a research governance manager told us of new tasks he was expected to prioritise in response to the swine flu epidemic at the expense of granting research permissions.

Non-voluntary clients

Although the original time frames for completing our study were tight, they were not so tight that a reasonable approval system, taking appropriate account of risks, could not have handled our applications for approval. Research should not be stymied by regulation, and nor should rapid investigations be prevented in anticipation of the lengthy research governance processes that will ensue. Investigators in NHS and university settings

are “non-voluntary clients” who have no choice but to apply to research governance departments for permission to carry out research.

Others have no such constraints, and there is the real possibility that research may be carried out in organisations that have less complicated systems for regulating quality and ethical standards. For example, early on in the study the National Audit Office expressed interest in using the results of our Stroke Survivor Needs Survey in their audit of stroke services.¹² However, when it became clear that the survey would be considerably delayed, they contracted a private research organisation to carry out a survey of stroke survivors sampled through stroke clubs/patient organisations. Such research is likely to be less representative of the population.

Our experience further suggests that even general practitioners who are active in research find the research governance system off putting and alienating. This is particularly a problem for GPs whose role in the research is minimal—for example, as in our case only providing access to patients.¹³ One GP withdrew his practice from our study citing bureaucratic procedures which made undertaking research not worth his while. Others were put off by the regulation but continued to participate in the study thanks to actions of individual research governance officers, who reduced the bureaucratic demands by reducing the numbers of forms the GPs needed to sign.

Conclusion

Authors commenting on the system before IRAS have speculated that medical research will be driven out of the UK.^{4 14} This year the Academy of Medical Sciences published a report criticising the strict regulation of research which was driving medical research abroad, citing concern over delays to research created by the requirement for each NHS organisation to provide its own research governance approval in multicentre studies.¹⁵ The new NIHR CSP system has gone some way to expedite the process for gaining research ethics

and governance approvals, but problems remain at the local level. For multicentre studies a burden remains on investigators and the time taken for permission to start a study remains lengthy. While accepting the need for research regulation, we propose some changes to the way research governance approval processes are currently managed.

Firstly, it should be made clearer to investigators that the streamlined aspect of IRAS refers only to gaining global governance checks, and that research governance policy will be implemented variously at the local level.

Secondly, investigators need to be aware of the documentation they are expected to supply at the local level beyond that specified by IRAS (see box). This would allow investigators to start collecting the necessary documents early on in the study to prevent delays.

Thirdly, debate is needed on whether all the documents asked for by local NHS trusts are necessary for ensuring patient safety in research studies. For example, is the request for NHS trust logos to be placed on all study materials related to patient safety or aimed at promoting the trust?

Fourthly, local research governance offices need to acknowledge the distinction that IRAS makes in the responsibilities of clinicians between those taking a minimal research role (such as allowing access to patients) and those taking a more active role (administering therapy, designing the research). In cases where clinicians are taking a limited research role, bureaucracy should be minimal so as not to dissuade them from taking part in research.

Currently most research governance policy assumes that all research studies present the same risk to patients. An agreed risk profile for studies would allow low risk studies to be approved with minimal paperwork, freeing up research governance officers to focus on studies with greater risk to patients. This would speed up approvals for all studies.

This variation between NHS organisations seems to be accepted at the national policy level. While there are time frames for research ethics and NIHR CSP to accept, validate, and approve documents, there are no such time frames at the local level owing to differences in required checks.¹⁶ Time limits for reaching a decision at the local level could be agreed based on the risk associated with a given study.

Research regulation is an evolving, iterative process. Changes at the local level may be hard to implement owing to the legal autonomy of NHS trusts. The Academy of Medical Sciences is reviewing research governance processes,¹⁷ and this may provide an opportunity to incorporate both the experience of local research governance officers and investigators who have been through the process of implementing and obtaining research governance approval for research studies.

Nina Fudge research associate

Judith Redfern lecturer in health services research

Charles Wolfe professor of public health

Christopher McKeivitt reader in social science and health, King's College London, Department of Primary Care and Public Health Sciences, 7th Floor Capital House, 42 Weston Street, London SE1 3QD

Correspondence to: N Fudge nina.fudge@kcl.ac.uk

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Box 1 | Requests for additional information made by local departments

- CVs of principal investigators (GPs, research nurses) that have to be signed and dated
- NHS Trust logos to be applied to all patient documentation (consent forms, questionnaires) and with ethical approval for this amendment to the documents
- Information about service support costs (sometimes involved completing a form, other times supplying the figures would suffice)
- Signed contract between general practice and MRC general practice research framework
- Local investigator agreement signed by GP in addition to the local research governance form the GP had already signed
- Welsh translations of study documentation with ethical approval for this amendment