Research governance:

assailing a paper mountain

Here is a personal view of the rigmarole I have been experiencing as a PhD student applying for local Research and Development (R&D) approval to conduct my relatively low-risk study. The very mention of 'ethics' and 'R&D' elicits sighs all round from the PhD office and this is not without good reason. I, for one, have found the application system complex, inconsistent and at times, rather discouraging.

Since 2008, an online Integrated Research Application System (IRAS) has been in operation for the purpose of seeking ethical approval nationally and facilitating local research governance approval. The creation of IRAS followed a Department of Health advisory group report calling for a streamlined ethics application system. My first challenge on embarking on this supposedly simpler process was navigating my way around the National Research Ethics Service (NRES) website and its obvious penchant for acronyms.

Once I knew my CAS from my SSA, I faced the 70-question ethics form. The nature of my research (a qualitative organisational study of low QOF scoring general practices) placed it at odds with the hypothetico-deductive format the form takes. Yet despite it being difficult to specify exactly what my exploratory research might involve from the outset, and finding the form inflexible at times, it rightly prompted me to reflect on the ethical implications of my work. Finding that local ethics committees were fully booked for a number of months ahead, I travelled 60 miles to attend the next available meeting. The experience of this meeting was very encouraging and I found the panel supportive. Approval without amendments was granted swiftly. So far, so good.

But my excitement about starting fieldwork soon after was, in retrospect, rather naïve. NRES advises that researchers do not wait for ethical clearance to be approved before seeking

local research governance approval through PCT R&D offices. However, the R&D requirement to identify a local collaborator at the GP practice research sites I would be visiting, left me in a chicken or egg predicament. Approaching GPs at this stage in the case of my study svnonvmous with participant recruitment prior to gaining ethical approval to do so. Additionally, I felt that the label 'local collaborator' may hold burdensome connotations for GPs, whom it was already hard enough to persuade to take part in my project as research participants.

At the time of writing I had applied to three PCT R&D offices. There was nothing 'integrated' about this experience. Each office required at least 10 different documents to be emailed through, in a variety of formats (pdf, xml, three large envelopes filled with old-fashioned paper). I was also asked to provide documentation which was not listed on the checklist, such as a financial breakdown of study funding arrangements. Some emails bounced back due to attachment size. At this point I was climbing a mountain of paperwork, which might have honed my administrative skills, but did little for my academic development as a postgraduate researcher. One could say that I was on the receiving end of what Haggerty² coined the 'ethics creep'. The unique skills required for negotiating the ethical complexities of researching health services were being substituted by cumbersome bureaucracy.

Yet, most importantly, I believe that the research governance process lacks the transparency of the national ethical review. Information about who makes the decision about R&D approval is not made available to the researcher, and it is unclear on what grounds a decision is reached. Indeed, I have been faced with an unfavourable decision which I believe is not consistent with the checks stipulated in the Research Governance Framework for Health and Social Care.³ As justification, I was provided with an inaccurate statement of

my study aims to support the decision of the office in question. There was no mention whether I could appeal.

My experience is not atypical and raises issues such as the lack of research governance consistency and transparency. There is a clear requirement for a greater balance in addressing the needs of the research process, as well as of those being researched. Impeding health services research through excessive bureaucracy cannot be in the public interest. Just one suggestion for improving the IRAS online system would be an integrated function for uploading attachments submitting the same documents to all R&D offices at the push of a button. At a time of financial austerity, this would no doubt be a time-saving and therefore cost-cutting solution. Furthermore, the composition of the panel behind the R&D decision and the criteria they use for evaluating applications should be made explicit to the researcher. Behind such changes should lie the ultimate goal of removing the frustrating bureaucratic burden faced by health service researchers, while endeavouring to maintain the highest ethical standards throughout the research process.

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