Research ethics paperwork: what is the plot we seem to have lost?

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The standardisation of applications to local research ethics committees seems likely to make ethical approval less efficient and more time consuming for everyone

Editorial by Warlow

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Researchers in the United Kingdom now have to submit their study proposals to local research ethics committees using a nationally standardised form. The form overcomes the problem of inconsistencies in the paperwork required by different committees.[1 2] It is incredibly long, however, and threatens to overwhelm both committees and investigators with paperwork.[2–4] The administrative burden is likely to be increased by the advent of a research management and governance framework for health and social care[5] and the requirement for ethical clearance for all research by students on humans, including their tissues or data.[6] Current trends are not sustainable in terms of time, money, or their impact on the environment, and it seems we have lost the plot. In this article, I examine how we can streamline the process.

Basics of ethical review

The first step is to determine the essential information required for ethical approval. Based on my experience as a member of three ethics committees in two countries, I think that members ask themselves four basic questions:

- What hazards are raised by the research protocol?
- Can the protocol be redesigned to reduce these hazards without compromising its ability to answer the research question?
- Have the investigators taken reasonable steps to minimise the chances that the (remaining) hazards result in harm?
- Are either the hazards or the risk of their resulting in harm disproportionately great in relation to the apparent importance of the knowledge to be gained?

What are the hazards?

It is relatively easy to identify broad classes of hazards that are commonly encountered in health and social care research. Invasive procedures, ionising radiation, and untried drugs are obvious, as are breach of confidentiality and capacity to give, and adequacy of, informed consent. Committees will also be mindful of relevant statutory provisions—for example, regarding protection of data—and of public concern about instances such as retention of body parts after postmortem at Alder Hey.

Many proposed studies have inadequate designs that might lead to an invalid or uninformative answer to an otherwise useful question, but ethics committees can also create hazards to scientific validity. A common example is the requirement for written, informed consent to participation in a postal survey; the additional paperwork threatens to undermine participation and therefore to increase selection bias in responses. Inappropriate insistence on informed consent in a behavioural intervention study can increase contamination between groups in a controlled trial, resulting in a greater chance of a type II error.

Reducing the hazards

Local research ethics committees effectively match their collective wits against the applicant's to see whether the study question can be answered with equal or greater validity at lower risk to the participants. These deliberations require not only knowledge of ethical principles but also familiarity with the strengths and weaknesses of different study designs and at least some insight into the research topic. Single members of an ethics committee rarely have expertise in all of these domains for a given application, but the combined membership of many committees will.

Strategies to minimise the realisation of risks

Even if the study protocols cannot be refined, the study may fail to gain approval if the investigators do not show sufficient awareness of the pertinent ethical sensitivities or have adequate strategies to avoid the potential harm becoming a reality. Sometimes applications are rejected because the investigators regard the ethical hazards intrinsic in their work as blindingly obvious and have not bothered to describe the relevant harm minimisation strategies that are in place. This often occurs because they cannot conceive of a reputable investigator failing to organise their work and team in such a way. Sometimes, however, familiarity and routine have led to blindness to hazards, increasing the risk of harm occurring through absence of, or failure to enforce, appropriate safeguards.

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Proportionality between risks and potential gains

Even well crafted applications cannot be passed without some consideration of the balance between the chances of harm and the value of the new information to be gained. This assessment again requires an understanding of the research topic, but it is made easier if the applicant has provided a lucid rationale for undertaking the study. The summary for the intelligent layperson, which is required on many grant applications, will often fulfil this role. There is no guarantee, however, that the investigator and the ethics committee will agree on the importance of the work in view.

Improving applications

It is unclear whether the extraordinary amount of detail sought by the new application form is intended primarily to alert investigators to potential ethical difficulties or to ensure that committees have all the information they might need to consider the submission. Whatever the explanation, the result is a lengthy and cumbersome document that is ill suited to several common types of investigation such as descriptive epidemiological analyses of routinely collected data or qualitative studies using in-depth interviews. In addition, the new form risks either slowing the process of ethical review or, through making relevant information more difficult to find, reducing the scrutiny given to each application.

From the committee's point of view, the ideal applicant is one who submits a succinct protocol that makes the rationale and methods of the proposed study clear, together with an insightful and focused document that identifies the likely points of ethical sensitivity, explains why the study is required and must be conducted as designed, and describes the steps that will be taken to minimises the risk of harm.

To submit such an application, researchers require thorough training in both the methods and the ethical issues relating to research in human subjects or their tissues or data. Almost half of the applications that come to the ethics committee of which I am a member fail to obtain approval at the first submission. This suggests that appropriate training is either not widely available or not taken up. Elsewhere I have argued for training and certification of research investigators and for simplifying the process of approval of new projects.[7] This would allow ethics committees to spend more of their time checking that approved research is conducted properly. The new national ethics form, however, seems likely to take up more rather than less of committees' time.

Summary points

The new application form for ethical approval is too long and cumbersome

Research ethics committees need enough information to ensure that potential hazards are minimised and balanced by the benefits

Researchers need training in the methods and ethical issues of research

Such training would improve applications, making the committee's task easier and reduce the number of rejections

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Competing interests: KJ is a member of the Riverside Local Research Ethics Committee, to which he provides advice on study design and statistical matters on a paid contract basis.

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The truth is not always a beautiful thing

I answered my emergency page to be informed that my presence, as the on-call neonatology senior house officer, was required for an instrumented delivery. On my arrival in the obstetric theatre, three apparently vital pieces of information were offered: the baby was being delivered by mid-cavity forceps, labour had been prolonged, and both parents were veterinary surgeons.

The scene was familiar, with a sweaty, exhausted looking woman in stirrups. At her cranial end sat her husband, perched awkwardly on a stool, his discomfort heightened by the cumulative effect of the "one size fits all" surgical scrubs and the actions of the obstetrician at his wife's caudal end. I checked the resuscitaire and waited for the impending delivery.

The baby girl was delivered "flat," and the theatre echoed with her silence. As I cleaned and dried her, I felt the father's presence at my shoulder. This was the first anxiety provoking moment of his new-found fatherhood, but thankfully it was not to be the last. The theatre rang with the tumultuous sound of crying, and the relief was tangible. The infant's body turned bright pink as her lungs went through postpartum transition, but patches of her head and face remained varying shades of dark blue, the trauma from the forceps already closing her left eye.

The obvious question followed; "Is she beautiful?" the mother cooed from the bed. The father and I looked at each other and then down at his grimacing, bruised, screaming daughter.

The pause should have lasted longer for him to have thought of a more appropriate response than the one that will inevitably haunt him—"I prefer baby lambs."

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