

## RESEARCH ETHICS

# Proportional ethical review and the identification of ethical issues

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Presently, there is a movement in the UK research governance framework towards what is referred to as proportional ethical review. Proportional ethical review is the notion that the level of ethical review and scrutiny given to a research project ought to reflect the level of ethical risk represented by that project. Relatively innocuous research should receive relatively minimal review and relatively risky research should receive intense scrutiny. Although conceptually attractive, the notion of proportional review depends on the possibility of effectively identifying the risks and ethical issues posed by an application with some process other than a full review by a properly constituted research ethics committee. In this paper, it is argued that this cannot be achieved and that the only appropriate means of identifying risks and ethical issues is consideration by a full committee. This implies that the suggested changes to the National Health Service research ethics system presently being consulted on should be strenuously resisted.

and the seemingly unnecessary scrutiny given to some hardly risky research projects.<sup>5 6</sup>

## THE CASE FOR THE INTRODUCTION OF PROPORTIONAL ETHICAL REVIEW

The case for the introduction of proportional ethical review is succinctly made within the implementation plan, which states in reference to the research ethics service whose primary role will be to carry out the proposed triage<sup>4</sup>:

This concept of a Research Ethics Service is fundamental to the plan proposed here and would, we believe, lead to significant efficiencies and a reduction in time taken for many ethics applications to be processed. This would not be at the expense of appropriate assessment.

The notion of proportional ethical review seems inherently attractive primarily because it seems highly efficient. With it in place, each application would receive no more scrutiny than it needs. This should have two benefits:

- for uncontroversial applications, as these would be processed extremely rapidly; and
- for controversial applications, as these would receive an appropriate level of scrutiny.

Several problems have been pointed out for this new model of ethical review, including concerns about whether it will be compliant with the requirements of the World Medical Association's Declaration of Helsinki.<sup>7 8</sup> The Scottish Ethics Advisory Group has rejected the proposal that some applications can be approved without committee approval by a national ethics adviser because they believe that this would break the requirement that ethics review include committees. Likewise, there has been concern about whether the new model will genuinely increase efficiency. However, I am focusing here on the notion of proportional ethical review and whether it is indeed sound. Although I will use the suggested changes to the NHS research ethics system as a focus, the implications of this discussion are intended to apply more generally to the concept of proportional ethical review wherever it is applied.

The idea of proportional ethical review has recently become popular in the UK research governance framework. This notion of proportional ethical review appears in the recent Department of Health report of the Ad Hoc Advisory Group on the Operation of National Health Service (NHS) research ethics committees, the Economics and Social Research Council Research Ethics Framework and the adoption by some UK universities of a tiered system of ethical review.<sup>1–3</sup> The University of Ulster, for example, divides research into categories based on risk level and the quality of consent obtained. The low risk or good consent applications are then approved at a local level and the higher risk or poor quality of consent applications are dealt with by a university-wide ethics committee. It is also prominently present in the current suggestions of the Central Office of Research Ethics Committees as regards implementing the suggestions of the Ad Hoc Advisory Group (henceforth referred to in this document as the implementation plan).<sup>4</sup> One of the primary thrusts of the implementation plan is the institution of national research ethics advisors who will have the authority to approve research that is identified as containing no material ethical issues. (This is referred to as the triage system within the implementation plan<sup>4</sup>) This is intended to create a system of proportional ethical review. This move is driven both by researcher complaints about the inefficiency of the present NHS system

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**Abbreviations:** NHS, National Health Service; REC, research ethics committee

## IDENTIFICATION OF ETHICAL ISSUES

The possibility of effective proportional ethical review relies on the possibility of identifying the ethical issues and risks inherent in an application without it going through a full research ethics committee. If this is not possible or if it is a time consuming and laborious task, then either uncontroversial applications will not be processed rapidly or, more worryingly, some controversial applications will slip through without being scrutinised to an appropriate level. Before we accept the implementation of a system of proportional ethical review, we ought to be convinced that ethical issues and risks can be identified without recourse to a full ethics committee. In other words, can the ethics committee review process and the identification of ethical risks be meaningfully and sensibly separated?

Using the example of the proposed changes to the NHS research ethics system, how confident can we be that ethical issues and risks can be identified without recourse to full committees?<sup>4</sup>

Under the present system all completed applications go straight through to an NHS ethics committee where they are considered by the full committee. In the suggested system of triage, it is proposed that coordinators will read through all applications first and identify those without serious ethical issues. These will then be passed on to senior coordinators to be reassessed. If they are convinced there are no material ethical concerns, the application will be passed on to National Research Ethics Advisors. The National Research Ethics Advisors will then check through the application and finally decide whether there are in fact any material ethical concerns, and approve the application if there are none. If at any point in this process it is thought that the application does raise material ethical concerns then it will be sent on to a research ethics committee (REC).<sup>4</sup> Several types of applications will automatically be directed for consideration by a full committee, such as applications to conduct clinical trials. This is not the only method of proportional review available—for example, a chair person allowing an application to bypass a committee due to time constraints or the lack of ethical concerns is an informal means of proportional review—as would be a small committee or subcommittee making a decision on behalf of the full committee before the application is seen by a full committee. However, the system proposed by the NHS is a useful example because it typifies the problems of proportional review; each of the alternative varieties of proportional review will have similar problems to a greater or lesser extent depending on how close the decision makers' approach is to being constituted in the same manner as that by a full ethics committee.

There are four interrelated concerns that I will raise which in combination show that the identification of ethical risks cannot be appropriately separated from a committee-based ethics review process.<sup>1</sup>

### Concern 1: expertise

The first concern is whether the coordinators, senior coordinators or National Research Ethics Advisors have or are likely to gain the necessary expertise to determine whether an application raises serious ethical concerns.

To have sufficient expertise to identify all of the potential ethical issues in an application, you must first understand the science and the methodology proposed. Secondly, you need to be aware of all the points of process that need to be taken care of, the sorts of things which should be in the participant

<sup>1</sup> I should note here that I do not intend to imply that ethics committees will necessarily identify all of the risks or ethical issues with an application; simply that generally they will do a better job than an individual or a small group.

information sheets and consent forms, for example. Finally, you need to have some understanding of the ethical principles that guide research ethics review, ideally of the different ethical theories and the conflicts between these theories and principles.<sup>ii</sup> Clearly, this requires considerable knowledge and expertise.

Of course, this concern is tempered by the fact that an application will be checked by three different people (the coordinator, senior coordinator and National Research Ethics Advisor) and that the last of these people, the National Research Ethics Advisor, will presumably be as qualified as anyone is to make these sorts of judgements. Nonetheless, as the comments received from existing REC members—as regards the report of the AD Hoc Advisory Committee—suggest, there is good reason to be doubtful that any one person could have the necessary range of experience and familiarity with different research techniques to be competent to assess the risks posed by the wide variety of research that is currently seen by an NHS committee.<sup>9</sup>

Committees, in contrast, can have several different members who together have the necessary expertise to identify the ethical issues raised and the methodological backgrounds to predict risk posed by very different kinds of studies. The expert members can then bring their knowledge to bear appropriately according to the application.

### Concern 2: ethical icebergs

We all see things from different perspectives and have different sensitivities to different ethical concerns. In my experience on ethics committees, this can sometimes lead to ethical issues being initially unnoticed when I have read through the applications before the meeting. It has certainly been my experience that, sometimes, applications may at first seem uncontroversial until another member points out a—sometimes serious—ethical issue with regard to the application. This seems to be a widespread phenomenon as is shown by this comment made in the consultation response from the Association of Research Ethics Committees, summarising the views of their members as regards the triage suggestion<sup>10</sup>:

A commonly expressed opinion, which applies to this recommendation, and many other instances in the implementation document, is that it is a frequent experience, as a lead or back-up reviewer, to believe that their submission is sound and ethical, only to discover during the ensuing committee discussion, that your fellow members think nothing of the sort.

The explanation of this experience is simple. Although individuals may try to pick up on all the issues with an application, we are sensitive to and aware of different issues depending on our background, experience and ethical beliefs. Inevitably, this is going to cause us to be blind to some issues and very sensitive to others. Furthermore, ethics applications are long and complicated documents (often more than 50 pages long). To miss an issue or concern, even if an application is read through several times, is hardly surprising. This is part of the reason why ethics committees aim to have members from different backgrounds, including lay members. The different

<sup>ii</sup> I do not intend to imply here that, typically, NHS RECs contain ethicists; indeed they do not, and the standard operating procedures do not currently contain any requirement in this regard, in contrast with the requirements of the Economics and Social Research Council as regards university-based social science research ethics review. Nonetheless, members of RECs have often received some training as regards research ethics and, in combination, have considerable expertise on research ethics.

perspectives that different kinds of members bring are often invaluable. Likewise, multiple sets of eyes going over an application are more likely to identify more issues.

Clearly, however, this points to further difficulties for separating the identification of ethical issues from the ethics committee process. The National Research Ethics Advisor's background is going to make her or him more sensitive to certain issues and less sensitive to others. Likewise, if people on committees presently miss ethical issues when they read through an application, there is no reason to believe that individual National Research Ethics Advisors will not also miss issues. Again, this concern is tempered by the coordinator and the senior coordinator having already looked over the application; nonetheless, the final decision is in the hands of one person who may miss something, especially when he or she knows that two other people have already individually decided that there are no material ethical concerns. Now, of course, ethics committees are not necessarily going to pick up on all of the ethical issues or risks posed by an application, but surely they will be more reliable than a single individual or a small group in this regard.

### Concern 3: ethical diversity and pluralism

There is a more theoretical reason why one person or a small group of people cannot be expected to pick up on all the risks and ethical issues posed by an application. This is because of the plurality of ethical positions available. At the very least, we have the big three of consequentialism, deontology and virtue ethics and then these can be supplemented by other approaches common in bioethics, such as the four principles approach or the ethics of care approach and many others. Obviously, these different theories are concerned about different features of moral experience and followers of a particular theory are going to be sensitive to different aspects. So, crudely put, a utilitarian may be more sensitive to concerns about risks to participants and the possible benefits of a piece of research, whereas a deontologist might be more concerned about the quality of the consent that is obtained and how well informed the participant is.<sup>11</sup> Although I do not intend to imply that RECs often overtly debate ethical theory, the subtext of several common debates that take place at REC meetings is a background clash of different ethical theories. So, for example, whether the committee should be mainly concerned to protect participants from harm or to just ensure that the participants are only involved when they give fully informed consent, regardless of the risk of harm, seems to indicate a clash between a broadly consequentialist viewpoint and a deontological viewpoint.<sup>12 13</sup>

I believe it is fair to say that we do not currently know which ethical theory, if any, is the correct position to take, although different people will have their own views.<sup>14</sup> Although some applications will be straightforwardly problematic on any ethical theory, for others, the decision on whether or not they are ethically controversial will be theory dependent. As each of us has our own beliefs about morality, people will inevitably make different judgements about the same applications.

Now, of course, this can also happen with committees and two different RECs might, for example, come to different judgements about the same application.<sup>15</sup> However, there is an important check present when a committee makes a decision that is not present when an individual makes a decision. Given a sufficiently large and diverse committee, there will almost always be people who represent the different ethical viewpoints present and each perspective will, at least, get a chance to make its case—whether or not it is ultimately accepted by the committee. Given that in the suggested triage system three people will individually make the decision on whether there are any major ethical concerns, all or even most ethical viewpoints will it is unlikely be represented.

### Concern 4: uncertainty

There are, of course, some clear-cut applications which do not present ethical issues that come before ethics committees, and the implementation plan gives several examples of these in appendix F.<sup>4</sup> Likewise, there will be some applications that obviously require review by a full committee. However, there will also be some applications where this is unclear. Furthermore, there will be applications in which it is unclear whether there are ethical issues or not. Fundamentally, there will always be uncertainty about the risks and concerns posed by a research application precisely because it is research. Research concerns the unknown and as such always includes a substantial measure of uncertainty. This point was vividly and tragically shown by the recent events at a research unit based at Northwick Park Hospital. Six volunteers participating in a stage 1 clinical trial of an anti-inflammatory drug had multiorgan failure, despite the fact that the animal testing did not indicate the likelihood of severe adverse reactions.<sup>16</sup> Although, as this case shows, review by a committee may not be sufficient to avoid tragedy, as I will show, it is the best bet available to do so in a situation of uncertainty.

Uncertainty makes it inappropriate for any person or small group—no matter how well qualified—to make the decision on whether a piece of research has risks or other ethical issues that require it to be considered by a full committee. This is the case because committees will be more reliable in making decisions in these situations of fundamental uncertainty. We know this is the case because mathematically we can show this to be true. One of the classic arguments for the superiority of democracy, the Condorcet jury theorem predicts that “the collective performance of a group in arriving at a correct judgment on the basis of majority rule will be superior to the average individual performance, provided that certain conditions hold”.<sup>17 18</sup> The main relevant condition is that each person has a greater than 50% chance of making the best decision.<sup>iii</sup> You can see how this would work; the more times something is iterated, the more likely it is that the average (modal) result will tend towards the probable result. Or, to put this another way, the more times you run a test the more likely it is that the actual results you obtain will resemble the probable results.

Imagine you had a weighted coin that 75% of the time landed on heads. If you flipped it 100 times and it landed on tails 50 times, you would be surprised; if you flipped it 1000 times and it landed on tails 500 times, you would be amazed; and if you flipped it 10 000 times and it landed on tails 5000 times, you would believe someone had swapped the coin! The reason the appearance of tails gets less and less plausible each time the numbers increase is that, statistically, the greater the numbers the more likely the probable overall outcome will result. Now imagine that instead of a coin toss we have people voting in a majority rules style election between two alternatives and that these people each individually have a 75% chance of picking the best option. The more people who vote, the more likely that the outcome of the election will be the best option. This occurs for precisely the same reason that the more times you flip a weighted coin the more likely it is that the probable overall result will be obtained. This is a simple consequence of the law of probability. If the probable answer is also likely to be the best

<sup>iii</sup> I am assuming it is plausible that the decisions whether there are ethical issues or risks entailed by a research project can be answered as a yes or no question so that there are only two values. That said, it has been argued that Condorcet's jury theorem is also applicable in cases where there are more than just two possible outcomes as long as the participants' chance of a right answer is better than average.<sup>19</sup> I have also been assuming that there is just one best answer, not often the case in research ethics review, as it frequently includes trade-offs. Nonetheless, as long as there are better answers, the theorem still holds.

answer, then the more people who decide, the more likely that their collective decision is best.<sup>iv</sup> If people making the decision are competent in the area in which the decision is being made, then the probable answer is likely to be the best answer. This gives us some reason to believe in the safety of numbers in grey areas.

Now, it might be objected that we have no reason to presume that members of ethics committees have a better than 50% chance of getting the best answer. However, this seems unlikely because it implies that a coin toss is going to be a better decision maker than a trained member of an ethics committee with considerable information about the project at hand. Nonetheless, I must concede this is a possibility. If this is the case, however, it does not support proportional review; it supports no review at all because, on the whole, any ethics review is going to get it wrong more often than they get it right.<sup>v</sup> On this view, then, tossing a coin would do a better job of ethics review.

## CONCLUSIONS

Arguably, the notion of proportional ethical review presupposes that some process other than review by a full committee can effectively and efficiently identify the risks and ethical issues in an application. If it is not possible to do this, then either low-risk research will not be markedly quickened up or higher risk research will not receive an appropriate level of scrutiny.

I have argued that the appropriate and effective identification of ethical issues and risks is unlikely to be achieved without recourse to a full ethics committee because of four reasons:

- the technical expertise needed to properly judge risks posed by applications of considerably different research areas and methods;
- the effect of individual experiences on our perceptions and judgements, and how this leads people to be insensitive to certain ethical issues;
- the existence of a major dispute about which moral theory should guide our behaviour, the theory dependence of some ethical risks and issues and how this leaves an individual unable to represent all relevant ethical perspectives; and
- the inherent uncertainty implicit in research and the superiority of a committee approach in making decisions in circumstances of uncertainty.

A variety of alternative methods of proportional review are available to the one suggested in the implementation plan and are discussed in this paper. These range from informal structures such as the occasional chair person's action, to consideration by a subcommittee, a mini-committee or a virtual committee (who meet via email). Likewise, guidelines can be drawn up to ensure that only some types of projects are dealt with in this manner (ie, student projects or questionnaire only-based research, etc), whereas more troublesome classes of projects are dealt with by a full committee. In each of these cases, however, there will be a relevantly similar trade-off between efficiency and effectiveness; in general, the closer the decision-making body is to being and operating like a properly constituted REC, the more effective it will be at identifying

<sup>iv</sup>Formally, this may be expressed as "Let  $(X_1 \dots X_n)$  be  $n$  independent identically distributed binary random variables, such that  $Pr(X_i = 1) = p > 1/2$  and  $P_n = Pr(\sum X_i > n/2)$ . Then, (a)  $P_n > p$  and (b)  $P_n$  is monotonically increasing in  $n$  and  $P_n \rightarrow 1$  as  $n \rightarrow \infty$ . If  $p < 1/2$  then  $P_n < p$  and  $P_n \rightarrow 0$  as  $n \rightarrow \infty$ . Finally, when  $p = 1/2$  then  $P_n = 1/2$  for all  $n$ ."<sup>20</sup>

<sup>v</sup>I am presuming here that research ethics advisers in general will not be considerably better decision makers than individual members of RECs.

ethical issues but the less efficient it is likely to be, and vice versa.

Therefore, there is good reason to believe that any system based around the decisions of an individual or a small group will be less effective than a full research ethics committee at identifying possible ethical issues and risks in an application. As such, if we are concerned primarily with having the highest possible standards of protection for research participants, a system of proportional ethical review that separates the identification of ethical issues and risks from the process of ethical review ought to be rejected. This has serious implications both for the current suggested changes to the NHS system and for those universities which have adopted a system of proportional review. It might well be argued that the gains in efficiency represented by a system of proportional review could offset and outweigh any losses in the effectiveness of the system of ethics review. Properly, this is a debate for another paper; however, it would seem to me difficult to justify to the individual research participant who is harmed or treated unethically that while it is a shame, nonetheless, this is the price we pay for an efficient system.

A final word is appropriate about the scope of this argument as it is potentially wide ranging. In particular, an implication of this argument is that if we are serious about protecting the rights of research participants, then all human subjects research, NHS or otherwise, ought to be considered by an appropriately constituted ethics committee, NHS or otherwise. Finally, because of the uncertainty inherent in the nature of research and indeed the uncertainty about what counts as research, we should adopt a policy that when any doubt or controversy arises, then a project should be submitted to an ethics committee for review.<sup>21</sup>

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Competing interests: DH presently sits on one of the ORECNI (Office for Research Ethics Committees, Northern Ireland) research ethics committees. He also sits on the University of Ulster research ethics committee.

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