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The Ethics Committee as Ghost Author

Ethics committees have a bad reputation for impeding, rather than facilitating research. Tales abound of delays and rejections of perfectly innocuous studies. Here, I argue that many committees actually improve the quality of the research proposal to such an extent that they deserve credit as authors in any resulting publications, or at least an acknowledgement of the contribution made.

One of the reasons that applicants are often angry at ECs is that they question the science of the proposal. Many researchers believe that this is not the role of the EC, and indeed the recently revised GAFREC document states that:

A REC need not reconsider the quality of the science, as this is the responsibility of the sponsor and will have been subject to review by one or more experts in the field (known as 'peer review'). The REC will be satisfied with credible assurances that the research has an identified sponsor and that it takes account of appropriate scientific peer review.[1]

However, in many cases this advice simply cannot be followed. The job of an ethics committee is to protect participants, and exposing patients to potential harm for the sake of a study that simply cannot answer its own research question is deeply unethical. It might be argued that ECs should not intervene where there is no risk of harm, but the research question cannot be answered; I believe that wasting people's time and making them think they're contributing to research is not to fully respect them or safeguard their rights. In any case, an EC would look rather stupid if it gave a favourable opinion to a study with serious scientific flaws, and it is difficult to see how a REC would be "satisfied with assurances" when there are obvious flaws in the design.

Equally, however, ECs tend not to simply reject such studies outright; rather, they offer constructive criticism and often suggest ways to improve recruitment, statistics and trial design. This can lead to some delay, but the result is frequently approval of a study that is a significant improvement on what was originally submitted. In one recent study I reviewed, the research in question was intended to provide evidence that a particular intervention worked; had we approved it as it was originally submitted, we would have wasted the participants' time and the results might have been used to justify the use of public funds for such an intervention when the evidence was deeply flawed. Instead, we suggested major revisions to the design which were implemented. In such cases, the committee has made a substantial contribution towards the design of the study; if a colleague of the principal investigator were to make such a contribution, and her name was not included when the results were published, she would have been treated badly. The phenomenon of ghost authorship is ongoing despite widespread condemnation; why should the input of ethics committees be treated any differently?

At present the only credit ethics committees receive is the statement that "this research was approved by XXXX" in small type on the published paper. I would suggest that the ethics committee should be listed as an author in cases where they have significantly improved the design of the study. This might be embarrassing for the main authors, but credit should be attributed where it is due, and this would not be necessary if the original proposal had really undergone proper scientific review or been designed properly in the first place. Given that authorship is frequently attributed to people who have had only marginal involvement in the design of the study, it does not appear unreasonable to give credit to the EC. At the very least, an

acknowledgement should be made of the input of the ethics committee, even if it is not listed as an author.

My recommendation is based on current practice in authorship in many universities and companies. However, if we wish to adhere to the highest standards (which many are not doing yet), it would appear that ethics committees would not qualify as true authors. The ICJME states that:

authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. [2]

The ethics committee clearly meets the first of these criteria in some cases, but will not meet the second or third. But how many people who have been listed as authors can truly say that they have met all three criteria? Furthermore, the same guidelines state that contributors who do not meet the above criteria should be mentioned in the acknowledgement section: “editors should ask corresponding authors to declare whether they had assistance with study design...If such assistance was available, the authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article.”

Therefore, ethics committees (in the UK) and IRBs (in the USA) should either have full authorship attribution (going by current standards) or at the very least an acknowledgement (going by the highest standard). The ICMJE suggests acknowledgment of “scientific advisers” and those who “critically reviewed the study proposal”; the latter is probably the most appropriate. An example acknowledgement would be “Thanks to NHS West of Scotland Research Ethics Committee 2, who critically reviewed this proposal and suggested improvements to the design.” Once again, though, there must be many academics who have done just this and been listed as a full author. Ironically, ethics committees are currently being treated unethically by researchers who deny them credit for their input.

References.

1. Department of Health. Governance arrangements for research ethics committees: a harmonized edition. 5.4.2 <http://www.nelm.nhs.uk/en/NeLM-Area/News/2011---May/10/Governance-arrangements-for-research-ethics-committees-a-harmonised-edition/> (Accessed 11/7/11.)
2. International Committee of Medical Journal Editors. Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship. http://www.icmje.org/ethical_1author.html (Accessed 11/7/11.)

Conflicts of Interest: the author is a member of an NHS research ethics committee and chair of the Research Ethics Committee of the College of Medical, Veterinary and Life Sciences at the University of Glasgow.