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RESEARCH ETHICS REVIEW

EDITOR: DR ROGER RAWBONE

ASSOCIATE EDITORS: DR MICHAEL BONE & PROFESSOR PAULA MCGEE

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Humphrey briefly suggests that a change of study design and a resubmission to the same REC is one possible option. But JM is confident in the appropriateness of his design. This suggests an appeal. However, Humphrey advocates going further and complaining to the NRES REC manager. Where an appeal is accepted, the appeal REC will carry out an independent review on the basis of the existing application supported by a statement from the researcher. JM can, thus, readily address the objections raised by the first REC and argue why his chosen methodology is the most appropriate to his participant groups and the study objectives.

But Stephen Humphrey advocates that a wide range of information about the individual members of the REC, and the review process, should also be sought. However, the opinion expressed is the collective opinion of the committee. Of the various types of information to be sought:

- the following information is made available routinely to the applicant in correspondence:
 - o a list of the names of those present and their capacities;
 - o officer status.
- the following information is contained in the annual report and, therefore, available in that format or would be released on request:
 - o date of appointment and training received by the members;
 - o member attendance record.
- the following information is not available and would not be released:
 - o copies of written submissions by absent members – such comments form part of the discussion of business at the meeting and are destroyed once the meeting minutes are written;
 - o contemporaneous notes made by the coordinator – again, these are destroyed once the minutes are written.

Additionally a copy of the full minutes will normally be made available in response to Freedom of Information requests although they will be appropriately redacted. Detailed declarations of interest made at meetings by members appear in the formal minutes and a summary is recorded in the letter to the applicant.

Humphrey proposes gathering such information which may be useful in a judicial review of the opinion of the REC. This appears unnecessarily formal where robust processes already exist to deal with complaints about the ethical review process and to appeal decisions which the applicant feels are incor-

rect. It is also suggested that the investigator be accompanied to the REC meeting by a solicitor – whilst NRES SOPs permit, and encourage, attendance by researchers in order to respond directly to requests for further information, clarification or reassurance about their application, attendance by a solicitor would not fulfil this objective and we would not expect it to be agreed.

From **JOAN KIRKBRIDE**

Head of Operations, England, National Research Ethics Service (NRES).

References

1. Humphreys S. Case study 18.: discussion. *Res Ethics Rev* 2010; 6 (2): 62-64.
2. McGee P. Case study 18. Dealing with complaints to the REC. *Res Ethics Rev* 2010; 6 (1): 22.

The problem of proliferation: reply to McCrae and Murray

We wish to reply to the letter by McCrae and Murray [1] in response to our article on the ‘problem of proliferation’ of digitally held qualitative data [2]. We agree with McCrae and Murray that part of the way in which rigour can be maintained in qualitative research across a range of disciplines should involve the preservation of an audit trail from data collection (including, for example, voice recordings) through to findings. We concur too with their observation that the proliferation of (often contradictory) messages given to researchers when obtaining ethical approval for their research can result in confusion about appropriate ethical and scientific standards that can and should apply to qualitative research data.

Nowhere in our guidelines do we recommend however, as McCrae and Murray glean from our article, the permanent destruction of audio-recordings as the ideal or only strategy for improving the security of qualitative data. The original ethical protocol for our ethnographic research on youth gangs, as approved by our University Research Ethics Committee, did indeed promise that we would delete non-anonymized voice recordings. But our original ethical protocol, as the article set out to demonstrate, was insufficient in a range of ways, and ultimately untenable. (For example, our initial strategy for anonymizing data after collection proved to be practically near impossible, and to result in impoverished and misleading data.) It was for these reasons that we proposed the guidelines we did for researchers to improve the security of digital qualitative data. Although many of the guidelines we offer refer to the deletion of data, it is in relation to the deletion of the

many copies of data files (voice files and text transcriptions of these, for example) that proliferate during the course of research, particularly in team working environments, that our guidelines are directed.

Although we concur with McCrae and Murray that retaining rather than deleting potentially valuable data is preferable in the quest for research rigour, we should like nevertheless to retain the possibility for researchers in particular contexts to reserve the right to argue for the deletion of data if this is seen to be appropriate. For example, researchers collecting information from active criminals about unsolved crimes may feel that the best way to protect their respondents is to permanently delete all non-anonymized data files, thus preventing (for example) the seizure of these files by police [3]. We argue that the decision permanently to delete original data is one that researchers should have the right to make a case for, in light of the context of specific research context particulars. Retention, however, should be the norm, and not a special case that qualitative researchers should be repeatedly forced to justify to their institutional research ethics committees.

From: **JUDITH ALDRIDGE, JUANJO MEDINA, ROBERT RALPHS**

School of Law, University of Manchester, UK.

References

1. McCrae N, Murray J. The problem of proliferation. *Res Ethics Rev* 2010; 6(2): 69.
2. Aldridge J, Medina J, Ralphs R. The problem of proliferation: guidelines for improving the security of qualitative data in a digital age. *Res Ethics Rev* 2010; 6(1): 3-9.
3. In the United States, researchers may apply for a 'Certificate of Confidentiality' from the National Institutes of Health to protect them from being compelled to disclose identifying information about their research participants, thus minimizing the risks to research participants and to themselves.

Re-branding RECs as NRES Committees: a case of the emperor's new clothes?

The Government has issued its report on the Review of arm's-length bodies [1]. The future of the National Research Ethics Service (NRES) will be the subject of special consideration. Its parent body, the special health authority known as the National Patient Safety Agency (NPSA), will be abolished. The question is whether the functions of NRES should be transferred to a single regulatory body for research. The review will be informed by the consultation currently being undertaken by the Academy of Medical Sciences [2].

In the course of its second call for evidence at Annex II [3], the Academy lists NRES among other statutory bodies responsible for giving approvals in research. This is a plain error of law and function. All the other statutory bodies detailed in the schematic are responsible for delivering a statutory approval which stands as a condition precedent to the commencement of a research study. The Medicines and Healthcare Regulatory Agency (MHRA) is a clear example of that. NRES has no such duty or function. In fact, NRES has no statutory identity at all. NRES is a sub-department of the NPSA. It was selected by the United Kingdom Ethics Committee Authority (UKECA) to discharge duties that would normally fall to UKECA to perform, but which were delegated to the NPSA as a matter of administrative convenience. As a matter of law, NRES cannot exceed the statutory functions of its principal, from whom such powers were delegated. The statutory functions of UKECA are set out by law [4]. They relate solely to the establishment, recognition and monitoring of the research ethics committees themselves. UKECA can deliver no approval for the commencement of a medical research study. So the same is true for NRES. NRES is merely an oversight and scrutiny body for RECs.

The NRES Director will shortly invite the Department of Health to rename RECs as 'NRES Committees' [5]. Her stated intention is to demonstrate to researchers the identity of 'those RECs that are within the Service and operate to the NRES standards and principles'. This proposal reveals a basic misunderstanding or misapplication of the current legislative schema. The REC has a statutory identity under the 2004 Regulations and it has a statutory function in the delivery of an ethical opinion that is the condition precedent for the commencement of a clinical trial of an investigational medicinal product. The 2001 Clinical Trials Directive also requires the REC to be an 'independent body in a member state' [6]. To describe a REC as a NRES Committee is therefore to misrepresent the functional independence of a REC by assimilating it to a non-statutory body that has no legal power to do that which it plainly seeks to do. NRES would thereby purport to reduce the REC members to the level of agents of a currently unauthorised principal. A similar effect would be achieved, albeit on a more grandiose scale, if the Care Quality Commission were to insist that henceforth all National Health Service Hospitals should be re-branded as 'CQC Hospitals'. A point of distinction might be that under the current terms of reference of the arm's length review, the future of the Care Quality Commission is assured.

As I have demonstrated in earlier submissions to this journal, the REC must follow the law and if there is conflict between the law and the operational