

Written work: The social functions of Research Ethics Committee letters

Mary Dixon-Woods^{a,*}, Emma Angell^a, Richard E. Ashcroft^b, Alan Bryman^c

^a*Social Science Group, University of Leicester, Leicester, UK*

^b*Queen Mary, University of London, UK*

^c*School of Management, University of Leicester, Leicester, UK*

Available online 8 May 2007

Abstract

Research Ethics Committees (RECs) are increasingly institutionalised as a feature of research practice, but have remained strangely neglected by social scientists. In this paper, we argue that analysis of letters from RECs to researchers offers important insights into how RECs operate. We report a traditional content analysis and an ethnographic content analysis of 141 letters to researchers, together with an analysis of the organisational and institutional arrangements for RECs in the UK. We show that REC letters perform three important social functions. First, they define what is deemed by a REC to be ethical practice for any particular application, and confer authority on that definition. They do this actively, through comments on particular aspects of proposals, and passively, through silences about other aspects. Second, they provide an account of the work of the REC, and function as a form of institutional display. Third, they specify the nature of the relationship between the REC and the applicant, casting the applicant in a supplicant role and requiring forms of docility. Writing and reading REC letters require highly specific competences, and engage both parties in a Bourdieusian “game” that discourages challenges from researchers. The authority of RECs’ decisions derives not from their appeal to the moral superiority of any ethical position, but through their place in the organisational structure and the social positioning of the parties to the process thus implied. Letters are the critical point at which RECs act on researchers and their projects.

© 2007 Elsevier Ltd. All rights reserved.

Keywords: UK; Research Ethics Committees; Ethical dilemmas; Organisations; Qualitative

Introduction

Research Ethics Committees (RECs) have become increasingly institutionalised as an element of re-

search practice worldwide and are charged with heavy responsibilities in the regulation and ethical conduct of research. In healthcare settings they are now commonplace, yet surprisingly neglected by sociologists as an object of study. Much of the commentary has come from health researchers, traditionally in the form of complaints about bureaucracy, delay, and stifling of research (Ahmed & Nicholson, 1996; Harries, Fentem, Tuxworth, & Hoinville, 1994; Meade, 1994; Redshaw, Harris, & Baum,

*Corresponding author. Tel.: +44 116 2297262.

E-mail addresses: md11@le.ac.uk, nuffield92@yahoo.co.uk (M. Dixon-Woods), elj1@le.ac.uk (E. Angell), r.ashcroft@qmul.ac.uk (R.E. Ashcroft), ab302@le.ac.uk (A. Bryman).

1996; Watling & Dewhurst, 1993). A particular focus of criticism has centred on apparent irrationality, incompetence, and “inconsistencies” in REC decision-making (e.g. Edwards, Ashcroft, & Kirchin, 2004; Hannigan & Allen, 2003; Lux, Edwards, & Osborne, 2000). It is only more recently that a social scientific analysis of RECs has begun to emerge, as the social science community itself has moved towards increased ethical oversight of research (e.g. Hammersley, 2006; Lincoln & Tierney, 2004; Van den Hoonaard, 2001).

Notwithstanding the intensity of the debates, systematic empirical evidence about RECs and their operation is mostly lacking. Current evidence tends to be anecdotal, sometimes deriving from wounding encounters. An understanding of the role of RECs and their significance cannot be derived from such accounts alone; closer attention to the normal processes of REC functioning is much needed. In this paper, we explore some of the ways in which RECs might be understood by taking up Prior’s (2002) proposal that documents are an important (though often ignored) source for social science theorising. In particular, we examine letters written by RECs in response to submissions from applicants. In asking “what do REC letters do?”, we propose that letters function socially in a number of important ways, and we suggest some of the consequences of this. In particular, we will argue that letters are acts themselves rather than mere reports of acts.

Research Ethics Committees in the UK

The European Clinical Trials Directive (Directive 2001/20/EC) makes it a requirement that applications to conduct clinical drug trials be considered and approved by an ethics committee. However, the UK Research Governance Framework (Department of Health, 2005a) requires every research project—whether a clinical trial or not—to be conducted in the NHS to receive advice from an NHS REC. This framework effectively prevents those that do not receive a “favourable opinion” from proceeding, as such an opinion is necessary in order to gain permission from local NHS organisations to conduct the research.

In the UK, REC activities are coordinated by COREC (the Central Office for Research Ethics Committees), an organisation whose aims are to develop and implement operating procedures and standards for RECs that are consistent across the

UK. Governance arrangements for RECs (known as GAFREC, Department of Health, 2001) define the remit and accountability of RECs, and give guidance on membership and the process of ethical review. Standard operating procedures (SOPs) were introduced in 2004, mainly to meet the obligations of the EU Directive. Under the SOPs (Central Office for Research Ethics Committees, 2005), RECs in the UK are obliged to register each application they consider onto COREC’s Research Ethics Database (RED). Applications are reviewed at REC meetings, where applications that have been scheduled for review are discussed by the committee. Applicants are invited to attend, and if in attendance may be invited to answer specific questions. The committee may further discuss privately any matters arising from the discussion, and a decision is made. RECs must record the decisions made about applications, and may upload the letters written to applicants, onto the RED. Opinions, favourable or otherwise, must be given in writing. GAFREC states:

7.9 The REC should always be able to demonstrate that it has acted reasonably in reaching a particular decision. When research proposals are rejected by the REC, the reasons for that decision must be made available to the applicant.

To fulfil the requirements of 7.9 might be thought to require that decisions be supported by documentation to show that each part of the decision has been arrived at through explicit consideration of the criteria described either in GAFREC or other relevant guidance, but in practice this would be impossibly onerous. One important question therefore concerns which specific issues are critical in arriving at a decision, or in justifying it formally.

GAFREC further specifies that:

9.21 Advice that is not binding may be appended to the decision.

9.22 In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

9.23 An unfavourable decision on an application should be supported by clearly stated reasons.

The guidance thus emphasises accountability to the researcher for the decisions reached, and moreover that reasons are required for unfavourable, but not for favourable, decisions.

Download English Version:

<https://daneshyari.com/en/article/954588>

Download Persian Version:

<https://daneshyari.com/article/954588>

[Daneshyari.com](https://daneshyari.com)