Commentary

Reviewing the reviewers: the vague accountability of research ethics committees

Randi Zlotnik Shaul

Bioethicist, Department of Bioethics, The Hospital for Sick Children, and Department of Paediatrics and Joint Centre for Bioethics, University of Toronto, Toronto, Ontario, Canada

Correspondence: Randi Zlotnik Shaul, r.zlotnik.shaul@utoronto.ca

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Abstract

The role of research ethics committees (RECs) is currently strained by increases in the number of protocols that are in need of review, the scientific and funding complexities of the protocols, and a lack of clear standards for ethics assessment. This commentary describes the significance of these strains and calls for clarification of reviewer accountability. To maintain or, in many cases, to restore public and professional trust in the ethics of human research and in REC review of protocols, it is imperative that steps be taken to clarify the accountability of RECs and their individual members.

Keywords clinical trial, institutional review board, professional ethics, research ethics, research ethics committee

Although the need to review the ethics of research conducted in humans is generally accepted, there is less agreement over the extent to which reviewers are responsible or answerable for the decisions they make. What is the nature of reviewer accountability? RECs, like their US and Canadian counterparts (institutional review boards and research ethics boards, respectively), are responsible for assessing human research protocols for conformity to ethical principles. (For the purposes of this commentary, the term 'REC' will be used to refer to research ethics committees, institutional review boards and research ethics boards.) This role is currently strained by increases in the number of protocols that are in need of review, the scientific and funding complexities of the protocols [1,2], and a lack of clear standards for assessment of ethics [3]. To maintain or, in many cases, to restore public and professional trust in the ethics of human research, such as that done in critical care units, it is imperative that steps be taken to clarify the accountability of RECs and their individual members.

Attempting to learn from our past

Although human research has yielded phenomenal health and social benefits, the global scientific community has an unfortunate track record of harmful and exploitative research studies, in which the welfare of participants was sacrificed to competing interests of the investigators (for reviews of cases see Katz [4], Jones [5] and Weijer [6]). In recent years, even in some of the world's most prestigious research centres there have been many examples of noncompliance with ethical principles, resulting in preventable serious adverse events and inappropriate recruiting of subjects [7].

Since World War II there have been several attempts, at both national and international levels [8–13], to articulate ethical principles for the conduct of research that involves humans. These codes and guidelines typically call upon RECs to approve, reject, or demand modifications to protocols reviewed. In order to fulfil this mandate RECs must assess whether the research protocols demonstrate the following: sound scientific method and design; acceptable balance between risk of harm and probability of benefit; importance of scientific objective; adequate procedures to ensure that consent is informed and voluntary; protection of confidentiality; equitable selection of subjects; and adequate protection of vulnerable subjects. Although these principles and requirements are intended to be standards against which protocols are assessed, existing codes and guidelines include few provisions that ensure adequacy of the REC

REC = research ethics committee.

review process or reasonable application of principles. They are especially vague regarding how to weigh risks and benefits. The quality [14,15] of a REC's work depends largely on the values, conscience and commitment of its volunteer members [16].

Context for the physician research ethics committee member

Critical care physicians considering involvement in an REC may wonder what their liability might be for committee decisions. To date, courts have provided little useful guidance on the standard of accountability to which REC members can be held [17]. The standard of care that REC members are likely to have to meet is that of the reasonable REC member. That standard might vary from individual to individual, depending on the expertise of the member in the particular area under review. Those members with a greater degree of relevant expertise might be held to a higher standard of care [18]. Although REC members often undergo some form of education regarding research ethics, membership in a REC does not require that each member be an expert in research ethics. The current system is based on the presumption that decisions of appropriately constituted RECs will reflect thorough consideration of all relevant issues. Also, RECs do not serve as legal counsel for principal investigators. A lawyer is typically among the members of the REC in order to ensure that the law is appropriately included as one of several morally relevant factors that must be considered in REC deliberations.

It would be prudent for physicians serving on institutional RECs to satisfy themselves that the hospital or organization that they are serving will provide them with full defence and legal protection in the event that legal challenges arise from that role.

Looking to the future

The relationship between RECs and researchers can sometimes be quite divisive. The advancement of ethical research is curtailed if the efforts of RECs are perceived by well meaning researchers to be antiscientific and irrelevant hurdles over which they must needlessly jump. It is in everyone's interest to promote the perspective that the RECs, as well as the researchers themselves, have roles in protecting the safety of people participating in medical research studies.

The doctor–patient relationship is intended to be one of trust and confidence. Aspects of it have long been recognized in ethics and law as fiduciary in nature [19]. This means that doctors have an obligation to their patients to act with utmost good faith and loyalty, and must never allow their personal interests to conflict [20] with their professional duty (for a description of the general principles underlying fiduciary relationships, see [21]). This fiduciary relationship should not be abandoned when physicians and patients are involved in research. This fiduciary relationship should even be extended to RECs that are set up to protect individuals who participate in medical research [22].

The accountability of RECs may be clarified in a number of ways: statutory codification of detailed standards; an enhanced model of self-regulation; accreditation of RECs; and certification of REC members. Whether a single strategy or a combination of strategies is pursued, the goal should be to reinforce of the professionalism of human research review [23] in ways that acknowledge the separate [24–26] as well as the collective responsibilities of researchers and RECs. By specifying how relevant ethical principles are to be applied in REC deliberations, the procedures that RECs must adhere to in reviewing protocols and the level of expertise expected of each member, the overall accountability of RECs will be clarified and more transparent.

Conclusion

While the new millennium is well underway and we look forward to the health benefits that human research aims to achieve, we must take warning from the mistakes of the past. Vague notions of accountability, although well meaning and sentimental, offer little guidance to those they are intended to direct and little comfort to those they are intended to protect. Given the increasing pressures that face RECs in terms of volume of work and complexity of both protocols and funding relationships, it is imperative that the clarification of the roles and responsibilities of RECs is not delayed. One need not look far back to be reminded of the dangers of inadequate review processes or inappropriate risk–benefit analysis. For REC members, researchers, subjects and the public at large to have justifiable confidence in the ethics of human research and the role of RECs in reviewing protocols, issues of accountability will first have to be clarified.

Competing interests

None declared.

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