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Ethics Review of Research Projects Involving Human Subjects

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Maltreatment of subjects has led to the introduction of an ethics review process for research involving humans. There is a feeling that the bureaucratization of the process is too restrictive and that it may be hampering research. The function, duties, and effectiveness of ethics committees are examined, and it is contended that there are problems with the way that committees operate. The remit of committees needs to be clarified, and the paper presents guidelines for making decisions on ethical matters, with deontological considerations taking precedence over consequentialist ones. It is concluded that the functions and processes of ethics committees need to be modified.

The origins of this paper lie in my perception of a growing sense of disquiet among researchers at the bureaucracy surrounding ethics review practices. I explicitly recognize the moral necessity and scientific utility of ethics review but will suggest some changes to the way in which the system currently operates.¹

Sports science research, like other forms of investigation involving human participants, has experienced rapid growth. In biomedical and behavioral research, past abuses and scandals resulted in legislative and regulatory responses such as the Nuremberg Code and the Helsinki Declaration. Subsequent to this, Institutional Review Boards (IRBs), or Ethics Review Committees, were formed on a widespread basis. These developments changed the face of research by requiring investigators to justify their research on humans to a peer review group prior to recruiting participants (Annas, 1991).

The composition, structure, function, and accountability of these committees varies widely. This variance applies to research in sports science, with different approval requirements across institutions and countries. This means that researchers are faced with diverse requirements of stringency and accountability.²

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IRBs in the USA are required to review and approve, require modifications to, or withhold approval of research involving human subjects (Department of Health & Human Services, 2001).

It is generally accepted that such committees are of crucial importance in regulating research and preventing abuses, since investigators should not be the sole judges of whether their research conforms with generally acknowledged ethical codes and practices.

No investigator can be totally objective in the sense of being free from personal belief and conceptual bias, and the distancing and isolation of an IRB, coupled with a wide range of membership, serves to improve the objectivity of ethical decision making (Brodie & Stopani, 1990). These sentiments recognize the benefits of impartiality implied by external scrutiny, and there is little to argue with here, as the principles are sound. However, it is worth examining the practices and procedures of ethics committees.

Composition of IRBs

It has been advocated that a wide variety of expertise and skills be represented on an IRB, which can include statisticians, administrators, lawyers, ethicists (who may be members of the clergy), and lay members (Brodie & Stopani, 1990). The following could be added to this list: medical members (including experienced clinical investigators and a general practitioner), nonmedical workers or scientists, a nurse, a social worker, and at least one person not practicing or trained in any medical or paramedical discipline (MRC, 1993).

It has been argued that an ethics committee should include in its membership someone trained in philosophy. However, a recent USA-based study found that less than a third of IRBs surveyed had a formally trained bioethicist or philosopher in their membership (Hoffman, Tarzian, & O'Neil, 2000).

If we were to accept the preceding recommendations (and many of our institutions do!), then we will have committees of unmanageable size, meeting for extraordinarily long sessions, endlessly debating a variety of opinions that are not always relevant to the advancement of knowledge. I would contend that it is considered desirable to establish smaller IRBs that are staffed by well-trained individuals,³ rather than by a large number of merely well intentioned ones. The committee should preferably be of manageable size (i.e., not more than 8 members—USA Federal Regulations require at least five members with varying backgrounds), should have the power to coopt additional members with specific expertise for particular meetings,⁴ and should be provided with adequate administrative support. In an ideal world, membership of IRBs should be taken into account by institutions when calculating workloads and remission given where possible. Duration of membership should be a renewable period of 3–5 years. This seemingly lengthy period would assist new members to absorb the ethos and to develop the skills of ethical review. Where possible, each IRB should have at least one senior, experienced researcher as a member. Such an individual's knowledge of regulations, processes, and decision making will not only expedite proceedings, but will hopefully also serve as an educative process for less experienced members. The success of the ethics review process depends on the standards and capability of the decision makers, and IRBs should be trusted by society and by the research community.

Functions and Duties

It is worth questioning the extent to which evaluating the technical (e.g., methodological) merit of a study is within the purview of IRBs. In this sense, the role of IRBs has changed. Historically, they were primarily concerned with issues surrounding the preservation of subjects' autonomy, such as the informed consent process and confidentiality. The role of research project approval committees has, however, expanded to include issues not specifically related to participant autonomy to the extent that a broad range of design issues is now included in many discussions (Rosnow, Rotherham-Borus, Ceci, Blanck, & Koocher, 1993). They may, for example, conduct a scientific peer review, a statistical review, an examination of compensation claims or subject complaints; they may need to enforce sanctions against offenders and perform any combination of these and other related functions. So IRBs are paying increasing attention to the methodology of the studies and the relevance/significance of the topic, as well as the competence of the investigator/s in the proposed areas of study.

The shift from a narrow ethics evaluation to a broader methodological scrutiny is reflected by Jago and Bailey (2001). They contend that an important part of submission to an IRB is the scientific validity of the study, including the statistical analysis. Public scrutiny, accountability, and increasing concern for individual rights means that the functions of IRBs will continue to expand. These committees, for example, are the bodies that will have to deal with sensitive issues introduced by developments in knowledge and technology in sports science, e.g., drug use or genetic engineering.

To avoid over-bureaucratization and to streamline the approval process, ethics committees must clarify their remit—are they an “ethics” committee or a “research methods” committee, or both? The types of questions that they address must be clearly communicated to those who submit proposals to avoid unnecessary delays between submission and the commencement of projects.

Effectiveness and the Restrictive Nature of IRBs

It has been contended that a sort of “cost-benefit” process dominates ethical decision making in research and that due consideration is seldom given to the ethical implications of the failure to conduct research that may be ethically ambiguous (Rosnow, 1990). This supports the view that in our proper concern for the welfare of subjects, the pendulum has swung so far that it sometimes may seriously prejudice the ability of the study to yield the correct result (Kabat, 1975). This sort of concern may, at least in part, be due to the increase in legal and administrative constraints that severely limit the autonomy of university administration and the freedom of research workers (Price, 1978). Among such constraints are included the existence and machination of IRBs, which have been perceived by some researchers as impeding research by introducing unnecessary delays and constraints (Azar, 2002).

Social responsibility and sensitivity to individual rights must be recognized in scientific inquiry, but the general principle is plagued with difficulties regarding decisions on specific issues (Kroll, 1993). Given the heterogeneous composition and size of IRBs (see earlier), legislated policies or guidelines are difficult to interpret

and apply consistently. There appears to be great variability in the standards invoked, and in turn the recommendations put forward, among IRBs (Rosnow et al., 1993). Such inconsistencies may be the result of the composition of the committee, differing levels of technical expertise, or may stem from the nature of committee action and interaction. Inconsistent standards create the appearance, if not the possibility, of injustice. It seems that “different local ethics and research committees viewed similar research in different ways . . .” (Jago & Bailey, 2001, p. 534). The above reflects a perception of inconsistent judgments on the part of IRBs,⁵ but the issue goes deeper than that, with a growing point of view among researchers being that IRBs are increasingly acting as a “police force” (Rosnow et al., 1993). This point of view is strongly propounded by Mosher (1988), who states that “the institutionalization of IRBs or HSCs creates a growing bureaucracy that chills science by reducing creative nonconformity” (p. 379).

If ethics committees are to play a positive role in advancing science, caution should not be abandoned. However, the likelihood of dangers and harms should also not be exaggerated. This is particularly the case for research that generally poses little physical or mental risk, which might include much of the research performed in sports science. For example, Jago and Bailey (2001) seem to imply that before making a submission to an IRB, an investigator should be satisfied that the project involves no more than negligible risk. I am not quite sure what negligible risk entails. Should we, for example, not expose subjects to procedures that are more risky than those they face traveling to the laboratory, such as crossing the road? This is ludicrous, and implementation of such guidelines would mean that very little research gets done. A more useful instruction to both researchers and IRBs would seem to be to perform a cost-benefit analysis. Naturally, we should take great pains to quantify and then minimize risk, but to insist on no more than negligible risk would surely retard the advancement of knowledge.

When a research project is delayed, either through unnecessary bureaucracy or exaggerated caution, it could be argued that the principle of human subject protection has been misappropriated. As Mosher (1988) states, “Cover your ass is not an ethical principle” (p. 379). The principle of respect for persons should in cases such as these be applied to both subjects and scientists. The argument then is that the oppressive outside legislation represented by IRBs will cut down on both the quantity and quality of research. Scientists claim that the spectacular growth of the “ethics business” has resulted in its exploitation, to the point where the application of ethics has become unethical. Bok (1978) states the following:

The bureaucracy of regulation of research can weigh as heavily as all other bureaucracies, and impede legitimate activity as much. Paradoxically, it can then allow genuine abuses to slip by unnoticed in the flood of paperwork required and minute rules to be followed. (p. 118)

The preceding sentiments are strongly supported by Pettit (1992), who feels that not only is ethical review endangering valuable research on human beings, but it is also endangering the very ethic that is needed to govern such research. He is pessimistic about the direction that the ethical review process is taking and feels that the reactive dynamic in operation will lead to a serious reduction in the scope of research and to a substantial compromise of the ethic that currently governs research practice.

With ethics committees becoming increasingly conscious of litigation, many types of research projects are endangered, including biomedical experiments, studies dealing with any sort of confidential information (no matter how secure the measures are), those that involve some invasion of privacy, those that include deception in the methodology, and those where subjects are unable (for a variety of reasons) to give personal consent. Pettit (1992) feels that given this intrusion into research by IRBs, there will be increasing resentment and alienation on the part of researchers, who may come to scorn whatever restrictions are laid down. In this way, the restrictions insisted on by IRBs will demoralize researchers and will lead to a restriction in the commitment of researchers to the ethic, which currently prevails.

There is thus some pessimism about the effect of IRBs on research practice, and Pettit (1992) feels strongly that “there is no regulation like self-regulation” (p. 107). It is tempting to agree with this, and self-regulation is of course a necessary condition for the effective functioning of research ethics, but unfortunately not a sufficient one. Given that “. . . professionals have exhibited a pervasive inability to regulate themselves . . .” (Bok, 1978, p. 118), self-regulation does not suffice. Researchers should be held accountable, not only to their colleagues, but to all who are at risk or their representatives (Bok, 1978).

So, we need outside scrutiny and regulation. The disadvantages of IRBs are outweighed by the benefits of careful planning, close adherence to the scientific ethic, and protection for subjects and researchers. The positive benefits should, however, be supplemented by realization on the part of committees that part of their remit is the advancement of research.

IRBs should protect research participants and encourage the pursuit of new knowledge. An over-emphasis on the former when it is not necessary will retard the latter. The remit and submission requirements of committees should be clear and should be communicated to researchers. The principles on which they are founded are universally acknowledged. The way that their business is conducted is not always accorded the same respect.

Challenges and Responses

The nature of research is changing, as is the ethics system that regulates it. For example, large multicenter experiments and collaborative research projects are now more common. This has imposed additional stresses on the review system. In the UK, regional multicenter research committees were established in 1997. Unfortunately, there is some evidence to suggest that this has neither alleviated administrative delays nor reduced financial costs (Tully, Ninis, Booy, & Viner, 2000; Lux, Edwards, & Osborne, 2000; Flynn, Dixon, Amos, & Appleby, 2000).

In the USA, there has been an increase in federal regulatory actions taken against IRBs. Federal review panels have also called for major modifications to the regulations governing IRBs. A recent editorial in *The Lancet* (2001) contends that the increased regulatory efforts have been misdirected and that IRBs have become preoccupied with procedural matters.⁶ “If the modified system remains bureaucratic, the problems will remain” (*Lancet*, 2001, p. 2067). When concerns such as these are allied to those of inconsistent judgments, it becomes clear that we need to reevaluate the role and functions of IRBs.

Rosnow et al. (1993) feel that not only should IRB decisions be more consistent, but also that the power of these committees should be limited. IRBs should take into consideration not only the costs of doing research, but also the potential costs of not doing it. This would go some way to ensuring that there will be no cessation of studies that need to be done to answer important scientific and societal questions (Rosnow et al., 1993).

This supports the view of Stetten (1975), who contends that because a problem may be difficult, or that its solution may prove politically embarrassing or unpopular, there is insufficient ground for invoking constraint. Further, he holds that a science that shies away from a line of inquiry merely because the result may be difficult to manage is in a sorry state.

Different strategies are needed in the face of moral problems posed by scientific investigations involving humans. First, we need agreement on what forms of research are risk-free, and then unnecessary bureaucratic impediments must be removed from such research. This approach is in line with the plea by Rosnow et al. (1993) for consistency in decision making and is also strongly supported by Pettit (1992), who feels that it is important that ethics committees concern themselves only with research projects that raise genuine difficulties.⁷ Second, we need agreement on what forms of research involve clear-cut abuse or recklessness, and we need to set clear standards so that scientists can know beforehand when experimentation is too intrusive or too dangerous to be undertaken.

This of course leaves us with a third set of research proposals—those complex problems where disagreement persists. The challenge of the first two strategies is to “. . . press the limits of the clearly intolerable and the clearly innocuous so as to make this middle group as small as possible, in order to avoid as much unnecessary dispute as we can” (Bok, 1978, p. 126).

Making Ethical Decisions

Ethics committees might be well advised to incorporate a mixture of teleological (consequence-based) and deontological (rights-based) approaches in their deliberations. Included in evaluations as to the ethical merits of studies should be the following: the results should be important (teleological); the benefit/risk ratio should be favorable (teleological); voluntary informed consent should be obtained (deontological); and considerations such as privacy, cultural factors, confidentiality, and deception should set limits on the conduct of research (deontological).

As presented above, the utilitarian conditions could be viewed as necessary but not sufficient conditions for research to proceed. The unjustified absence of any of the deontological concerns may morally invalidate research that satisfies the utilitarian criteria.

The practical implication of this is that in any codification of research ethics for sport science, priority ought to be assigned to principles based on duty, rights, and obligations. This deontology-loaded approach is consistent with Zelaznik's (1993) contention that the use of humans in research is a privilege and that the rights of research participants ought to outweigh the desire of researchers to conduct research.

One of the potential problems identified earlier in the way IRBs operate was the unequal distribution of reward and punishment for decisions. Pettit (1992)

suggests that this might be overcome by some sort of appeal procedure, whereby a researcher can gain review of a negative decision. This would not only strengthen the position of researchers (and, necessarily, research per se), but would also combat the trend of IRBs becoming over-restrictive.

A practical problem here is that of time, with researchers often feeling rightly aggrieved at a delay over a relatively insignificant issue, perhaps, for example, related to design or statistics. Particularly at tertiary institutions, where research is often "in house," committees should give some thought to granting a right of appearance to researchers if there are any questions that need clarification.⁸ Where such procedures are practically possible, the researcher becomes relatively empowered, and unnecessary delays may be avoided. Of course, if a researcher elects to not be available for consultation at the time of a specific meeting, then culpability for delays shifts away from the committee and toward the researcher.

Conclusion

There are problems with the ways in which IRBs operate. Perhaps the ethos of IRB decision making needs to be reshaped so that, primarily through educative efforts, an ethos of research ethics, partially independent of committees, is nurtured. The remit and composition of IRBs needs to be examined, and all scientists would support measures that introduce consistency and limit gray areas. The autonomy of research participants should continue to be highly valued, but the cost of not performing valuable research should also be factored into the decision-making process. Within the framework of the above, individual professions/disciplines could have ethical codes or guidelines that, if carefully formulated and applied, would reduce the number of potential problems. Deontological and utilitarian considerations should shape the decisions of ethics committees. In the decision-making process, duties and rights must be accorded primacy, but the consequences to all concerned should not be ignored. The practices of these committees may be restrictive and should be evaluated and perhaps reshaped, but the imperfections of the concept should not lead to the process being discarded.

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Notes

¹Recognizing the international readership of this Journal, the terms ethics committees and IRBs are used interchangeably. Ethics committees in the USA serve to resolve dilemmas regarding patient care (clinical settings), but similarly named committees elsewhere serve the same function as IRBs do in the USA (research settings). Here, the two terms both refer to the process of research approval.

²In the USA, Federal Regulations (Title 45, Part 46), while allowing for regional differences, provide for consistency of regulation and operations. This is not necessarily the case outside the USA.

³By well trained, I mean someone formally trained in moral philosophy or bioethics. I acknowledge that, as with other aspects of ethics review, consistency of training and implementation will be difficult if not impossible to achieve. Nevertheless, I contend that a knowledge of moral philosophy improves the ethical decision-making process.

⁴For example, this refers to where specialist knowledge may be desirable, such as particular medical knowledge relating to pregnancy when pregnant women are utilized as research subjects.

⁵An example would be a collaborative study in two countries, where one committee retarded the project because a member did not agree with the proposed statistical analysis. The committee, however, glossed over the issue of obtaining written first-person consent from illiterate subjects who subscribe to a notion of community rather than individual rights (an ethical issue).

⁶An example would be requiring researchers to submit essentially the same information in different formats for different committees. While desirable from a committee point of view, it increases the administrative burden on researchers.

⁷I acknowledge that most IRBs in the USA have policies that expedite the review process where research is classified as having minimal risk. This is by no means, however, a worldwide procedure.

⁸In the USA, this is relatively common practice, but this is not necessarily the case elsewhere.