Auditing the process of ethics approval for Master's degrees at a South African university

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Objective. This study audited the process of ethics approval for Master's research at the Nelson R Mandela School of Medicine, Durban, KwaZulu-Natal, South Africa.
Methods. After obtaining the appropriate ethical approval, all the correspondence surrounding each Master's proposal for the year 2010 was reviewed.
Results. A total of 53 proposals for Master's degrees were available for review. All the proposals were for low-risk studies, and all were subjected to expedited review. It took an average of 15 weeks (range 3 - 32) for the institutional ethics review board (the Biomedical Research Ethics Committee (BREC)) to respond to each of the 53 proposals. Twenty-three studies (43.4%) received provisional approval on the first response, 2 proposals (3.8%) were rejected, and 28 proposals (52.8%) were sent back with major queries. For the 28 proposals that required major revisions, 11 responses had been submitted by the time the data were collected. The average length of time to receive a response from the applicants to BREC queries was 4 weeks.
Conclusion. This study suggests that there is a potential cumulative delay of over 4 months before data collection for low-risk clinical audits can be commenced. Any system designed to improve this situation must ensure that high standards of vigilance are maintained, but must be flexible enough to allow for a faster review and approval process.

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The new requirement for a formal research component of specialist training in South Africa means that the workload for health research ethics committees (HRECs) will increase. This increased ethics review workload will be set against the backdrop of an already pressurised postgraduate curriculum and the need for medical schools to continue to produce high-quality specialists to meet the country's ever-increasing health needs. I audited the process of ethics approval for Master's level research at the Nelson R Mandela School of Medicine, Durban, KwaZulu-Natal, to classify the type of research being undertaken and identify common reasons for delay in the process of ethics approval.

Methods

The HREC at the University of KwaZulu-Natal is called the Biomedical Research Ethics Committee (BREC). After obtaining the appropriate ethical approval from the BREC (ref. no. BE 217/09) to perform this audit, all correspondence surrounding each Master's proposal for the year 2010 was reviewed. The following information was retrieved: the BREC number, the date at which the BREC received the proposal, the date of the BREC's first response, and the dates of all subsequent responses until full ethical approval was given. Low-risk studies are sent for expedited review, which is quicker than full review. Proposals that are appropriate for expedited review are sent by the chairperson to two reviewers and are not formally discussed at a full meeting of the BREC. Provided the reviewers are satisfied with the protocol, their comments are documented and the decision to approve the study is recorded in the minutes of the next meeting. The nature of the response from the BREC was recorded – this could be provisional approval, full approval or declined. If a study was granted provisional approval but still required some changes, it was classified as requiring minor revision. If a proposal was returned with queries but was not granted provisional approval, it was classified as requiring major revision. Whether the study underwent expedited approval or had to undergo the full ethics process was also noted. Studies were classified as retrospective chart reviews, prospective clinical audits, cross-sectional studies, questionnaire-based studies, cadaver-based studies or randomised interventional-type studies. Two separate taxonomies were used to classify the nature of the queries raised by the BREC (Tables 1 and 2).

Taxonomy 1

A simple taxonomy was used to divide the queries into four broad groups (Table 1). The ethical queries were divided into major and minor queries.

Table 1. Taxonomy 1

Ethical queries
Scientific queries
Stylistic/grammatical queries
Legal queries

Taxonomy 2

In this taxonomy I further categorised the reasons for the queries from the BREC under categories based on Emanuel *et al.*'s criteria for ethical research[1] (Table 2).

Results

Type of study

A total of 53 proposals for Master's degrees were available for review. All the proposals were subjected to expedited review. The types of studies are listed in Table 3. There were 43 audits, and the remaining methods consisted of 8 questionnaires, a single cross-sectional study, and a single cadaver-based study from the Department of Anatomy. There were no interventional studies.

Response times

It took an average of 15 weeks (range 3 - 32) for the BREC to respond to each of the proposals. Twenty-three studies (43.3%) received provisional approval on the first review. Two proposals (3.8%) were rejected. One of these was rejected because of consent and confidentiality issues. It involved a study designed to audit patterns of sick leave use among staff at a hospital, and would have required consent from the nursing staff and the nursing unions as well as the hospital management. The reviewers felt that this study was a gross invasion of privacy and the potential benefit was too small to justify this. The other study that was rejected did not declare its source of funding, had confused methods, was badly written and was unclear as to how tissue samples were to be stored. It also had major statistical deficits. Twenty-eight proposals (52.8%) did not receive provisional approval, and were sent back with major queries.

Eleven responses to the initial queries had been submitted by the time the current data were collected. The average length of time before a response to BREC queries was received from the applicants was 4 weeks. All these 11 studies received provisional approval at the second sitting. At the time of data collection 17 studies (32.1%) requiring major revisions were still outstanding. The average length of time for a response to BREC queries to be received from the applicants was 5 months (range 1 - 8). By June 2011, of the 53 proposals that were audited, 21 (39.6%) had completed the entire review process and had full approval. Table 4 compares the results of this study with the published literature. A total of 142 queries were raised by the BREC (Table 5). There were 84 scientific queries, 45 ethical queries, 13 stylistic/grammatical queries, and no legal queries.

Table 2. Taxonomy 2

Reason for query	Category[1]
Fairness	Ethics
Risk benefit	Ethics
Independent review	Ethics
Consent	Ethics
Funding issues	Ethics
Confidentiality	Ethics
Authorship	Ethics
Reimbursement	Ethics
Human tissue storage issues	Ethics
Validity	Scientific
Method	Scientific
Statistics	Scientific
Stylistic concerns	Stylistic/grammatical
References	Stylistic/grammatical
Legal	Legal

Table 3. Methods of the proposed studies reviewed

	n
Retrospective chart audit	29
Prospective clinical audit	14
Questionnaire	8
Cross-sectional study	1
Randomised interventional study	-
Cadaver-based anatomical study	1

Table 5. Queries raised by the Biomedical Research Ethics Committee (*N*=142) and their taxonomic classification

Query	*n* (%)	Taxonomic classification
Fairness	3 (2.1)	Ethics
Risk benefit	4 (2.8)	Ethics
Appropriate investigators	6 (4.2)	Ethics
Consent	13 (9.2)	Ethics
Human tissue	1 (0.7)	Ethics
Funding	3 (1.4)	Ethics
Authorship issues	7 (4.9)	Ethics
Confidentiality	6 (4.3)	Ethics
Reimbursement	2 (1.4)	Ethics
Statistics	14 (9.9)	Scientific
Validity	10 (7.0)	Scientific
Study design	31 (21.8)	Scientific
Methodology	29 (20.4)	Scientific
Stylistic issues	10 (7.0)	Stylistic/grammatical
References	4 (2.8)	Stylistic/grammatical

Table 4. Approval rates (%) – Cleaton-Jones[2] v. Angell *et al.*[5] v. the present study

	Cleaton-Jones, 2003[2]	Cleaton-Jones, 2007[2]	Cleaton-Jones, 2010[2]	Angell *et al.*, 2005/6[3-5]	Present study, 2011
Approved at first sitting	27	37	37	15	-
Minor revision	62	55	56	64	43
Major revision	7	5	3	-	53
Not approved	4	3	4	8	4

Discussion

The process of ethical approval of Master's projects at our institution seems to be a prolonged one. It takes 3 months on average for a first review to be completed, and only 43% of studies receive provisional approval at this first review. Student response to the queries raised by the BREC is poor, and by the end of this study only 40% of the proposals had completed the entire review process. This delay is especially problematic in the context of a defined 4-year period for registrar training.

This finding is not unusual, and there is an increasing body of literature documenting the bureaucratic delay associated with ethics review.[2-9] Cleaton-Jones[2] reported that in 2003 and 2007, out of 1 180 ethics applications at his institution, 27% were approved at the first sitting, 69% required revision, and 5% were rejected. He looked at this again in 2010, and found that 37% of proposals were accepted at the initial sitting, 59% required revision, and 4% were rejected.[2] Angell *et al*. in the UK[3-5] had similar rates. They reported that over the period July 2005 - April 2006, 15% of proposals were approved at the initial review, 64% required revision, and 8% were rejected. Table 4 compares the approval rates for these authors and the current study. Both Cleaton-Jones[2] and Angell *et al*.[3-5] were reporting on all the studies reviewed by their respective HRECs and did not provide any assessment of the level of the proposals they were reviewing. The proposals in the present audit were all for low-risk studies.

There appears to be a difference in the nature of the queries between this study and the reported literature. In the study by Cleaton-Jones,[2] ethical, stylistic and grammatical concerns predominated, whereas in this series the majority of queries were of a scientific nature. This difference is difficult to explain, but may reflect lack of appropriate supervision of the protocol writing process.[2]

Cleaton-Jones[2] was concerned about the high rate of non-response, i.e. papers sent back for major revision that were never resubmitted for review. He found that in 2008 this had increased to 28% from 19% in 2003 and 16% in 2007. A similar tendency was documented in the present study. Cleaton-Jones[2] thought that the most likely reasons for failure to respond were either that the applicants could not secure financial support to continue, or that they were intimidated by the bureaucracy involved and abandoned their projects. The reasons for these delays need to be studied further.

Conclusion

This study suggests that there is a potential cumulative delay of at least 4 months prior to ethical approval for low-risk research projects. The compulsory research project creates a number of challenges around both the drawing up of research protocols and the ethical and scientific review of these protocols. A balance needs to be struck between the need to protect participants and the need to undertake research as part of the 4-year training programme. Attention must be given to improving the scientific quality of the submissions.

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