What changes are there in decisions by the Wits Human Research Ethics Committee (Medical) and in process errors by research applicants between 2003 and 2015?

P Cleaton-Jones, MB ChB, PhD, DSc (Dent), FCD

Steve Biko Centre for Bioethics, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

Corresponding author: P Cleaton-Jones (pcleatonjones@gmail.com)

Objective. A retrospective examination of numbers of applications, decision rates, and process errors in 2015 was done for comparison with earlier studies to understand current ethics secretariat workload.

Methods. In December 2015 information from committee meetings of all the meetings (N=11) in 2015 (January - November) was collected to quantify change in application numbers and process errors. Statistical analysis used SAS for Windows (version 9.4). Statistical significance was set at p<0.05.

Results. There were 809 new general research applications considered in 2015. Monthly approvals at first evaluation ranged from 4 to 30% with an overall approval rate of 16%. Minor revision was required in 72%, major revision in 11% and 1% of applications were not approved. The χ² test for trend for initial approval showed a statistically significant decrease across the study periods (p<0.0001). However, the χ² test for trend for pending responses from applicants was also statistically significant (χ²=29.64). Informed consent and missing information process errors were the most frequent. There were statistically significant increases in lapses of confidentiality methods (p<0.0001) and discrepancies on application forms (p<0.005).

Conclusion. Applications to the Wits Human Research Ethics Committee (Medical) (HREC (M)) for ethics clearance almost doubled between 2003 and 2015 while approvals at first evaluation approximately halved. This has increased the workload on the HREC (M) secretariat. Process error rates are similar to those in an earlier study except that confidentiality and discrepancies have shown a statistically significant increase. Given limitation on the number of secretariat staff in the current stringent financial circumstances of South African universities, applicants need to improve the quality of their applications to increase approval at first review and reduce secretariat workload.


Methods

The study was done under Wits HREC (M) clearance M12014.

Minutes of the meetings from January through November 2015 were examined anonymously record: study number, initial HREC (M) decision, final decision (after modification or resubmission), and process errors if present.

The initial decisions were one of four: approved, minor modification, major modification, not approved. For final decisions the groups were: approved, pending (no response from applicants to comments from the committee within 5 months of the final meeting in the time period) and not approved.

The process errors were: procedural violation, missing information, slip-ups and discrepancies – all four were devised by Angell and Dixon-Woods[29] and an additional four are my categories, namely: informed consent, confidentiality, study sample, and legal[23]. Briefly they comprise:

- procedural violations[29] – failure to comply with application procedures
- missing information[29] – inadequate information to understand an application
- slip-ups[29] – minor errors
- discrepancies[29] – inconsistencies
- informed consent[25] – inadequate or poorly written consent documents
• confidentiality[2] – inadequate protection of participants
• study sample[2] – inappropriate choice, missing permission from relevant authorities

The data were analysed with SAS for Windows (version 9.4, Cary NC, USA) using the $\chi^2$ test, $\chi^2$ test for trend and Fisher’s exact test with statistical significance set at $p<0.05$.

Results

Percentage initial decision rates for 809 applications evaluated in 2015 are listed by month of meeting in Table 1. There was considerable fluctuation in application numbers per month, something influenced by academic deadlines for undergraduate and postgraduate students, closing dates for submissions of grant requests and university vacations. The busiest times are around Easter (usually the April meeting) when postgraduates who began their studies in January have designed a study, and in November that month’s meeting contains many applications for projects that researchers wish to begin in January of the following year. Approvals at the first evaluation of an application ranged from 4 to 30% with an overall approval rate of 16%. There is a reciprocal pattern per meeting: if the initial approval rate is low then the revision rate increases. Most revisions required are minor, and they are normally managed by a chair or the original reviewers of an application; the mean rate for the study year was 72%. Major revisions (mean rate 11%) have to be resubmitted to the committee. Non-approval rates were low (mean rate 2%).

In Table 2 the initial and final decisions in 2015 are contrasted with rates in the earlier four study periods. Initial approval in 2015 was at a lower rate than previously. For the same year revision rates required are minor, and they are normally managed by a chair or the original reviewers of an application; the mean rate for the study year was 72%. Major revisions (mean rate 11%) have to be resubmitted to the committee. Non-approval rates were low (mean rate 2%).

In Table 2 the initial and final decisions in 2015 are contrasted with rates in the earlier four study periods. Initial approval in 2015 was at a lower rate than previously. For the same year revision rates required are minor, and they are normally managed by a chair or the original reviewers of an application; the mean rate for the study year was 72%. Major revisions (mean rate 11%) have to be resubmitted to the committee. Non-approval rates were low (mean rate 2%).

In Table 2 the initial and final decisions in 2015 are contrasted with rates in the earlier four study periods. Initial approval in 2015 was at a lower rate than previously. For the same year revision rates required are minor, and they are normally managed by a chair or the original reviewers of an application; the mean rate for the study year was 72%. Major revisions (mean rate 11%) have to be resubmitted to the committee. Non-approval rates were low (mean rate 2%).

Discussion

This study was undertaken to understand recent workload in the HREC (M) secretariat and reasons for revision of applications. An extensive literature search showed that publications of this type of study are scarce.

Catania et al.[8] reported on a 2004 national survey in the US of Institutional Review Boards (IRB). They remarked on ‘...the need for research to (a) examine workload and its effects on review quality, research costs, and faculty morale ... ’. Interesting findings were an increase in the number of IRBs from 491 in 1995 to 3 853 in 2004. Regarding research applications, there were a quarter of a million in 2003. The researchers noted a significant increased workload for members of IRBs unaccompanied by an increase in the IRB labor

Table 1. Decisions at first evaluation of general research applications through the Wits Research office in 2015 ($n=809$, two withdrawals before evaluation were not included)

<table>
<thead>
<tr>
<th>Decision</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Jan</td>
</tr>
<tr>
<td>Approved</td>
<td>17</td>
</tr>
<tr>
<td>Minor revision</td>
<td>73</td>
</tr>
<tr>
<td>Major revision</td>
<td>8</td>
</tr>
<tr>
<td>Not approved</td>
<td>2</td>
</tr>
<tr>
<td>Total ($n$)</td>
<td>53</td>
</tr>
</tbody>
</table>

Table 2. HREC (M) decisions for general research applications through the Wits Research Office over five periods 2003 ($n=439$),[11] 2007 ($n=553$),[11] April 2008 - March 2009 ($n=586$),[12] January - June 2013 ($n=407$)[14] and the current 2015 study ($n=809$)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>27</td>
<td>37</td>
<td>37</td>
<td>24</td>
<td>16</td>
<td>Approved*</td>
<td>77</td>
<td>81</td>
<td>69</td>
<td>83</td>
<td>69</td>
</tr>
<tr>
<td>Minor revision</td>
<td>62</td>
<td>55</td>
<td>56</td>
<td>66</td>
<td>72</td>
<td>Pending†</td>
<td>19</td>
<td>16</td>
<td>28</td>
<td>17</td>
<td>31</td>
</tr>
<tr>
<td>Major revision</td>
<td>7</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>11</td>
<td>Not approved</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>0.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Not approved</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>6</td>
<td>1</td>
<td></td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>0.3</td>
<td>0.5</td>
</tr>
</tbody>
</table>

* Sum of applications approved at initial evaluation and after successful revision.
† No response from applicants within 5 months of the last meeting of the time period.
force’ and remarked that ‘… studies of investigator complaints about the long time lags associated with IRB application reviews … raise concerns about workload…’.

After more than 4 decades of experience on four SA HRECs my opinion is that the main criterion for applicant satisfaction with HRECs is the speed with which an ethics clearance is obtained. Committee workload and secretariat staff number as well as quality of applications affect speed.

New general research application numbers per year to the HREC (M) increased from 439 in 2003 to 809 in 2015, an increase of 84%. Administrative staff was one full-time person from 1966 until 2012. Currently there are two full-time administrators plus one temporary person. Many applicants, especially inexperienced ones, imagine that the only activity of the ethics committee secretariat is to receive and send out approvals for research. In reality the workload includes in-coming and out-going telephone calls, emails, direct visits from applicants, dealing with submission of amendments, updating databases, attending meetings and writing minutes, producing letters and clearances to applicants. The workload is increased by the number of applications requiring revisions. Concerning the latter, the percentages of revisions required (Table 2) indicate that the 439 new applications in 2003 were, in reality, 741 (439 + 302 revisions); while the 809 in 2015 increased to 1 489 (809 + 680 revisions). The revisions have to be considered by HREC (M) members with the same attention as the initial evaluation. This is overwhelming for the secretariat staff. Our estimate is that at least four full-time staff is required. However, finance for this is not available at the present time with pressures on university finances, so delays and frustration for researchers are inevitable.

Approval of research involving human participants prior to commencement is a legal requirement [9,10] that cannot be avoided. The longer a delay, the worse off are undergraduates, postgraduates and researchers who are applying for grant funding and who work with short deadlines. When workload exceeds capacity, secretariats and HRECs cannot be held accountable. Institutions have a responsibility to provide facilities and staff. In Catania et al.[8] study, in the US, heavy workload per IRB member was commented on but not the number of administrators.

The reasons for the high rate of pending responses to the HREC (M), 5 months after decisions were given to applicants, remain a mystery. The rates range from 16 to 28% between 2003 and 2013 increasing.
to an all-time high of 31% in the current study. The result of 31% of the 809 applications in 2015 meant that the HREC (M) secretariat staff and members of the committee wasted an enormous amount of time. No mention of this phenomenon was found in other publications.

While increasing the number of administrators would shorten the turnaround time, the more practical solution at the present time of financial stringency is for applicants to improve the quality of their applications. This would lead to the second objective of the current study, namely reasons for requiring application revisions or for not approving applications.

The pressure to increase research output and postgraduate degrees, mentioned briefly in the introduction, has affected students and staff alike. My belief is that nowadays a greater proportion of the applications received come from inexperienced researchers and inexperienced supervisors, with many having unrealistic expectations. To this one must add overworked heads of departments. Research planning well in advance of deadlines for ethics approval has, I believe, deteriorated, resulting in last-minute submissions and leaving much of a study’s weaknesses to be spotted by the HREC (M). Tables 3 and 4 show the weakness in compiling informed consent documents. Typical problems encountered by the HREC (M) are:

- absence of a greeting and explanation of who the researcher is and the purpose of the study
- using a coercive tone expecting compliance (I want, you will! instead of I want, will you?)
- promise of benefit when there is none
- weakness in outlining risks
- promising confidentiality without explaining how this will be achieved
- problems with clarifying the voluntary nature of participation and ability to withdraw at any time.

Concerning reasons for requiring revision of applications, a different approach was followed by Tsoka-Gwegweni and Wassenaar. They grouped ethics queries to applicants by eight principles in a framework described for the ethics review of biomedical research. The rates per grouped ethics queries to applicants by eight principles in a framework were as follows:

1. Absence of a greeting and explanation of who the researcher is and the purpose of the study
2. Using a coercive tone expecting compliance (I want, you will! instead of I want, will you?)
3. Promise of benefit when there is none
4. Weakness in outlining risks
5. Promising confidentiality without explaining how this will be achieved
6. Problems with clarifying the voluntary nature of participation and ability to withdraw at any time.

Conclusions

Applications to the Wits HREC (M) for ethics clearance almost doubled between 2003 and 2015 while approvals at first evaluation approximately halved. This has increased the workload on the HREC (M) secretariat. Process error rates are similar to those in an earlier study except that confidentiality and discrepancies have shown a statistically significant increase. Given a limitation on the number of secretariat staff in the current stringent financial circumstances of SA universities, applicants need to improve the quality of their applications to increase approval at first review and reduce secretariat workload.

Acknowledgement. The author is grateful to Mrs Zanele Ndlovu of the HREC (M) secretariat for tracing 2015 applications to check decisions.

References

15. Tsoka-Gwegweni JM, Wassenaar DR. Using the Emanuel et al. framework to assess ethical issues raised by a Biomedical Research Ethics Committee in South Africa. J Empir Res Hum Res Ethics 2014;9(3):36-45. DOI:10.1177/1556264614553172