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Article

Applications and secretariat workload at the University of the Witwatersrand Human Research Ethics Committee (Medical) 2002 - 2011: A case study

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Objective. To examine trends in the numbers of new applications for ethics clearance of health research and associated research ethics committee secretariat activity.

Methods. Data were obtained from research ethics committee secretariat databases with ethics approval.

Results. General research applications increased from 440 in 2002 to 685 in 2011, all handled by one full-time staff member. This load is expected to increase by 250 per year for 2012, 2013 and 2014 before reaching a plateau. This new applications load per year is based on registered clinical postgraduates at the University of the Witwatersrand in a 4-year specialisation who must comply with the new Health Professions Council of South Africa requirement for completion of Master's level research in order to register as a clinical specialist. Sponsored clinical trials have remained and should remain at approximately 100 per year but require three staff members to attend to this workload.

Conclusion. The increased workload is a serious challenge and has to be tackled first by increasing the administrative staff number.

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Ethics screening of human research at the University of the Witwatersrand (Wits) began in October 1966 when John Hansen, head of the Department of Paediatrics, brought an important article in the June issue of the *New England Journal of Medicine* to the attention of the University authorities.[1] In this article, Henry Beecher, Emeritus Professor of Anesthesiology at Harvard University, had described instances of unethical research and recommended the establishment of committees to oversee the rights of those participating in research.[1] Wits agreed to form a human research ethics committee, which has functioned ever since and is currently registered for all types of research including clinical trials.[2,3]

The committee, based centrally in the Wits Research Office (WRO), was reorganised in 1998 when a secretariat for sponsored clinical trials was formed in the Wits Health Consortium Ethics Division (WHCED), a Section 21 company in the Faculty of Health Sciences. Both secretariats serve the same Human Research Ethics Committee (Medical) (HREC (Medical)).

The committee has 37 members of various disciplines, includes members from outside Wits, and meets on the last Friday of January through November. Member attendance at meetings varies from 12 to 27. The first part of the meeting deals with clinical trials through the WHCED followed by general research applications from WRO. If an application is submitted as required by the 7th of a month through either secretariat, it is discussed at the same month's meeting January through November.

During 2011, there was an increase in complaints from applicants about delays before hearing the outcome of general research applications – this prompted the 10-year review of application numbers and workload at both secretariats reported in this article.

Methods

The data for examination were obtained for 2002 through 2011 from the secretariat databases at the WRO and WHCED under ethics clearance number M120147. Graphs and linear regression analyses were made with GraphPad Prism (Version 4, GraphPad Software Inc., San Diego, CA, USA).

Results

Wits Research Office (WRO)

The secretariat for general research applications is in the Research Office on the University main campus and is staffed by one full-time employee. There has been an increase in new applications through this secretariat, from 440 in 2002 to 685 in 2011 (56% increase), as shown in Fig. 1, with a highly statistically significant linear regression line ($F=90.08$, $p<0.0001$).

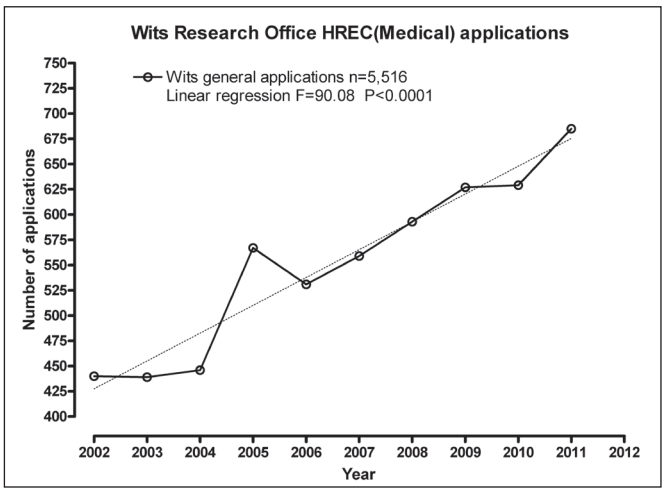


Fig. 1. X-Y plot of new general research applications by year.

In 2002 the number of applications per month was almost even (33 - 49) with a mean of 40 per meeting. In contrast, the range in 2011 was 41 - 94 (mean of 62 per meeting) but with an irregular pattern during the year (Fig. 2), with peaks in April, September and November influenced by departmental policies, research deadlines and a desire to begin projects early in the new year. In Fig. 2 the expedited applications are retrospective clinical record audits assessed in advance of a meeting by a Chair and one member, who provide a written report at the meeting for approval, which saves approximately a third of possible meeting time. The applications that are discussed (the second plot from the top) are the total applications less the expedited ones and occupy the majority of each meeting, which normally lasts from 12:30 to 17:30.

Wits Health Consortium Ethics Division

This secretariat is based at the Wits Health Consortium, about 1 km west of the medical school; it is staffed by three full-time employees. This secretariat operates in the same broad way as that in the WRO, with the same closing date for applications, and the same Wits application form with some minor modifications to suit clinical trials. However, an important difference is that applicants must pay specified charges for the management of an application as well as for any subsequent amendments (see www.witshealth.co.za/ethics).

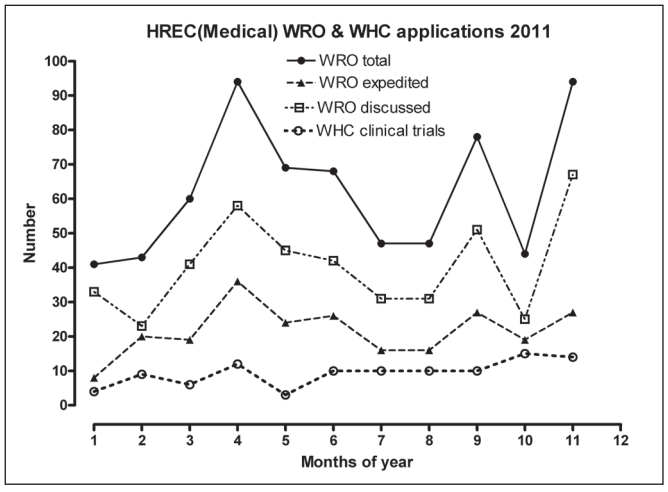


Fig. 2. Pattern of applications by month in 2011.

Despite receiving a lower number of submissions per year than the WRO receives, the WHCED secretariat has a heavy workload because of the administrative requirements for clinical trials specified by the Medicines Control Council in South Africa, the Food and Drug Administration in the USA, and other regulatory bodies elsewhere. Any change in a research proposal or information sheet or consent form, regardless of the extent, has to be approved through the secretariat. The complexity of the clinical trials produces many queries from members of the ethics committee to investigators and sponsors regarding the design or conduct of a trial. These must be scrutinised and approved by either one or more Chairs or reviewers or by the full HREC (Medical). Also, a close watch has to be kept on complaints and queries from participants in trials. The WHCED uses an advanced database to track applications and anything arising from them. The secretariat must keep this up to date and it is used for minutes of meetings as well as preparing lists of matters such as serious adverse events (SAEs). The Chair comes to the secretariat offices three mornings a week to sign letters, forms, help with queries, and so on. Staff members prepare documents for this in advance.

To illustrate workload in the WHCED, Table 1 shows five types of activity captured in the secretariat database for 2002 - 2011. For this article these have been grouped into 'documents for decisions' (initial clinical trial application evaluation, scrutiny of trial amendments and responses to queries) and 'other documents' (all acknowledgements and SAEs).

Fig. 3 shows X-Y plots of the three 'documents for decisions' frequencies by year considered. The numbers of clinical trials per year fluctuate slightly around 100. There is a highly statistically significant increase in amendments shown by the upper dotted regression line (F=76.65, p<0.0001). The middle fine-dotted line is a linear regression line for queries which, although upwards, has no statistical significance. Reasons for the significant increase in

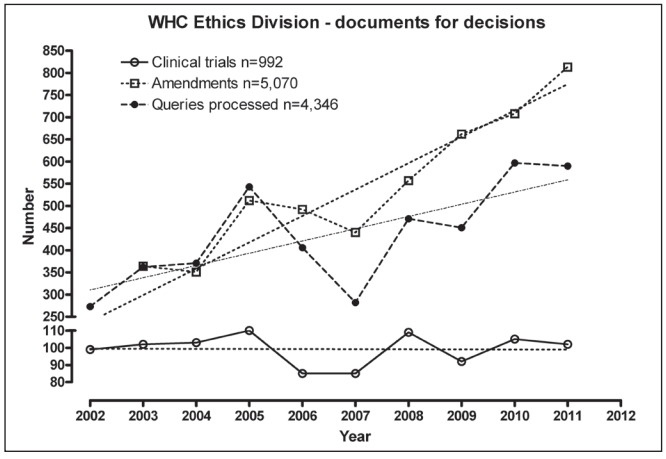


Fig. 3. X-Y plots for the frequency of 'documents for decision' by year.

Table 1. Frequency distribution of WHCED secretariat activities by year

	Documents for decisions			Other documents	
Year	Clinical trial applications	Amendments	Queries	Acknowledgement	SAEs
2002	99	171	273	1 123	2 530
2003	102	364	362	1 015	3 162
2004	103	351	371	2 317	997
2005	110	512	543	3 253	1 187
2006	85	492	406	3 382	1 401
2007	85	440	282	3 063	1 413
2008	109	557	471	3 714	947
2009	92	662	451	2 860	791
2010	105	708	597	2 583	624
2011	102	813	590	2 872	826
Total	992	5 070	4 346	26 182	13 878

amendments are the complexity of modern clinical trials and legal requirements to have every alteration approved by a research ethics committee.

The frequency X-Y plots for the 'other documents' are shown in Fig. 4. The rapid fall in SAEs is explained by a change in recording SAEs. Years 2003 and 2004 included international SAEs; from 2005 only South African SAEs have been recorded. Allied to this, international SAEs were not individually acknowledged but all South African ones were. After 2005 the rates have little variation.

Discussion

Current WRO workload

The current turn-around time in 2011 in this office was slower than in previous years, so frustration of applicants is understandable. The reason is that the workload for the single full-time staff member is now excessive – Table 2 lists the many responsibilities involved.

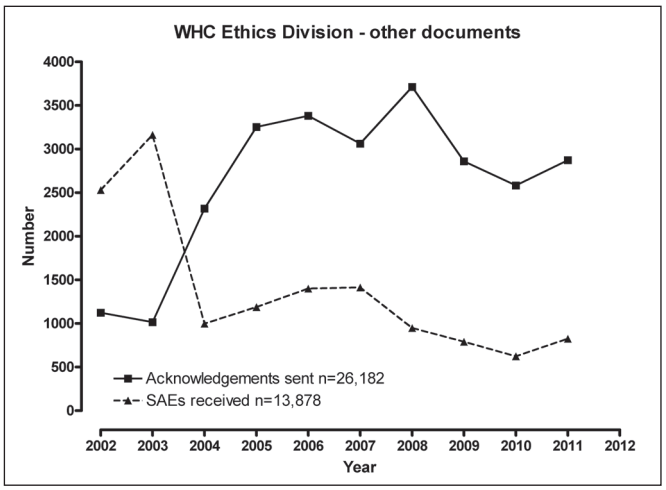


Fig. 4. X-Y plots for the frequency of 'other documents' by year.

What needs to be understood is that besides handling new applications, about 60% of reviewed applications have to be revised (Table 3). In a 1-year study sample of 586 applications (April 2008 - March 2009), 369 (62%) needed revisions or full re-application.[4] The proportions of process errors in these 369 applications were procedural violations 10%, missing information 43%, slip-ups 15%, discrepancies 7%, consent 55%, confidentiality 17%, study sample 15% and legal 3%.[4]

An estimate of the number of applications needing revision for 2011 is therefore 411/685. Experience has shown that when revisions are required, these are provided by applicants within 3 months of the initial month in which the application was considered, so that in addition to all the work associated with new applications there is a background of about 100 revised applications per quarter to be attended to.

Why have applications increased since 2002? The perceived reasons are:

- increased undergraduate research requirements by medical school departments in which new courses/degrees have been introduced since 2005 (Graduate Entry Medical Programme, Bachelor of Health Sciences, and Bachelor of Clinical Medical Practice)
- change in Health Professions Council of South Africa (HPCSA) policy from 2011 for registration as a clinical specialist: '... All specialist trainees will be required to complete a relevant research study ... research results are reported in a format of a dissertation …'[5]
- increased pressure from the university to do more research towards the Wits Strategic Plan for 2020 to be one of the world's top 100 research universities.

Typical complaints from applicants to the Chair include:

- 'I phoned the Research Office, no-one is ever there'
- 'I submitted my application last week (… month) and have not yet heard a decision'
- 'When will I receive my clearance certificate?', and so on.

Table 2. Responsibilities of the WHREC (Medical) secretariat staff member in the Wits Research Office

New applications:

- Receive new applications (685 in 2011) – 23 copies of each application and 4 copies of protocols
- Check each application is sufficiently complete for the meeting, return to applicants for revision if necessary
- Number applications, place into database and store hard copies in order for next WHREC (Medical) meeting
- Check which members will attend the next WHREC (Medical) meeting and make list for Chair
- Put together an agenda for the next meeting
- Give new applications to Chair to screen and assign reviewers
- Make a final agenda with names of reviewers
- Collate applications and protocols for reviewers
- Pack agenda and applications and arrange delivery to those attending the next meeting
- Print report on expedited applications reviewed by Chair and one member.
- Arrange lunch for the meeting

At each WHREC (Medical) meeting:

- Take minutes and collect reviewers' comments
- Table reports on expedited applications and any other documents
- Place expedited application comments at meeting entrance
- Keep attendance register
- Draft minutes
- Clear papers for shredding and arrange meeting venue clearance

After each WHREC (Medical) meeting:

- Write minutes for Chair to check
- Update checked minutes
- Update database with application outcomes
- Prepare clearance certificates for Chair to sign then dispatch these
- Prepare and dispatch queries and revisions to applicants not yet successful (60% at each meeting)

Constant background duties:

- Answer telephonic queries
- Print clearance forms for Chair to sign
- Receive and check revised applications
- Attend to application amendments together with an WHREC(Medical) Chair
- Issue revised clearance certificates
- Attend to SAE reports
- Send a copy of each application to Registry
- Get copies from Registry where necessary
- Deal with application amendments

With only one person in the WRO there is no one to answer the telephone if the single staff member goes to photocopy, to fetch a file from registry, or meet the Chair at medical school or the WHC. The single most common reason for delay of a decision is writing the meeting minutes – no certificate is released until the minutes have been checked by one of the Chairs (applicants often do not understand that the clearance certificate is a legal document, and so must be accurate). Minute writing is time-consuming, especially when there are as many as 94 applications for one meeting (April and November 2011) and interruptions by visits or telephone calls from applicants delay the writing.

Another common reason for applicants not receiving a decision or clearance certificate is provision of an incorrect contact e-mail or address or telephone number on the application form (for example a home address only used by individuals during university vacations).

Table 3. Comparison of HREC (Medical) decisions for general research though the WRO over three 1-year periods 2003 (*n*=439), 2007 (*n*=553) and April 2008 - March 2009 (*n*=586).[4] There are 11 meetings per year

	Initial decision (%)				Final decision (%)		
	2003	2007	2008/9		2003	2007	2008/9
Approved	27	37	37	Approved*	77	81	69
Minor revision	62	55	56	Removed from agenda†	19	16	28
Major revision	7	5	3				
Not approved	4	3	4	Not approved	4	3	3

*Sum of applications approved at initial consideration and those successfully revised.
†Removed from agenda if there is no response within three months for applications requiring revision or resubmission.

The expectation of many applicants is that they will know the outcome of their application on the first working day after a meeting, in spite of a notice in the application form that the earliest will be 10 - 14 working days after a meeting.

Current WHCED workload

At present the WHCED, with three full-time staff, is coping with its workload, albeit at full stretch. Having multiple staff ensures cover when a staff member is away for any reason. The typical new application rate of approximately 100 new clinical trial applications per year is expected to continue, as is the increasing number of amendments.

Combined statistics for WRO and WHCED secretariats

Fig. 5 shows X-Y plots for the frequencies of new applications to both the WRO and the WHCED, which shows the lower absolute frequency in the WHCED. This, however, is misleading. The amount of work per clinical trial is, in my opinion, six times that per general research application; this is illustrated in the plot of the estimated WHCED/WRO equivalent in office work. The rates in the two offices are then similar but what is handled by a single staff member in the WRO requires three staff in the WHCED.

When should an applicant expect a decision from a research ethics committee?

This is a matter of concern to every applicant worldwide. An Internet search produces a mass of regulations for obtaining ethics approval for research projects of many types, from interventional clinical trials to innocuous epidemiological information collection – but with vague mention of time scales. Here are three insights.

1. There are no figures to provide for the WRO – this information would have to be manually determined, which is not possible under present staffing. However, for retrospective record reviews of the type generally done by undergraduates and MMed candidates, a clearance for one of these projects approved through the 'expedited' method can be issued within 5 working days, because the written assessments presented to the HREC (Medical) are the final minutes for those applications.

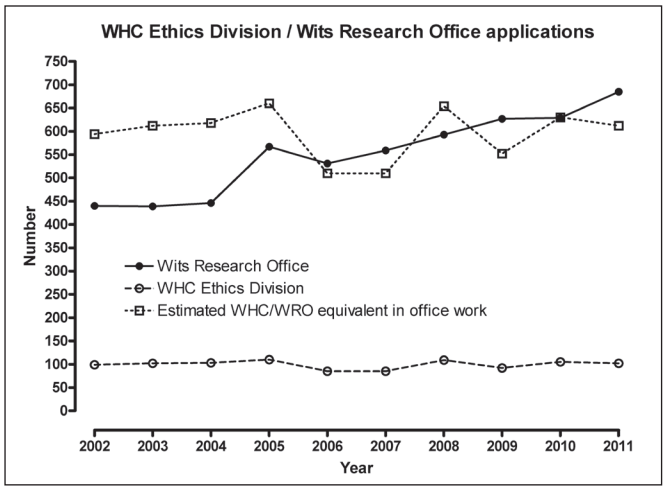


Fig. 5. Comparison of WRO and estimated WHC office workload.

2. At Wits, uncomplicated decisions on new clinical trials are generally completed within a month of submission through the WHCED; when there are queries this takes longer. A New Zealand Clinical Research Organisation says clinical trial application decisions in that country should take 2 - 3 months.[6]

3. For research electives the Human Research Ethics Committee of the Faculty of Health Sciences at the University of Cape Town recommends that planning with a supervisor should begin at least 6 months ahead to allow for ethics approval, and travel to South Africa should take place before this approval.[7] Uncomplicated applications to the UCT FHS HREC (with three staff) take approximately 6 weeks from submission to provision of a clearance certificate, according to the Chair (M Blockman – personal communication).

Comprehensive standard guidance on operating procedures is provided in a 280-page document of the UK National Research Ethics Service.[8] This states that a decision should be given to an applicant within 10 working days but certainly within 60 days un-

less more information is required, when the 60-day limit is suspended (this allows many interpretations!). An important regulation is that a research ethics committee should consider about six applications per meeting and certainly less than eight, something not possible in South Africa because of the high number of applications.

In the Wits HREC (Medical) application form there are two statements concerning timing:

'4. Please note that written clearances will not be available until approximately 10 - 14 working days after a Committee meeting – minutes must be checked, clearances printed and signed by the Committee Chair and only then despatched to applicants; this takes time.

'6. Researchers from abroad should obtain ethics clearance BEFORE arriving at Wits, a tight time schedule is not considered a valid reason for departing from Wits Standard Operating Procedure. A Wits collaborator may help obtain the clearance.'

Both these admonitions are usually ignored by applicants.

Forthcoming estimated workloads

Fig. 6 is the same as Fig. 5, but with the addition of an anticipated new application load to the WRO due to policy change of the Health Professions Council of South Africa (effective from 2011) that all clinicians wishing to register as specialists must have completed the equivalent of an MMed research project.

According to the Vice-Dean of the Wits Faculty of Health Sciences, applications from a cohort of 250 trainee specialists must be added for each of 2012, 2013 and 2014 after which such applications should plateau – this recommendation is based on the fact that specialisation is generally 4 years and on the number of registered clinical postgraduates in the Faculty (M Vorster – personal communication). By 2014 there will be more than double the number of new applications there were in 2011. Interestingly, it took 10 years, from 2002 to 2011, for yearly applications to increase by 245 – something that is now expected within 1 year.

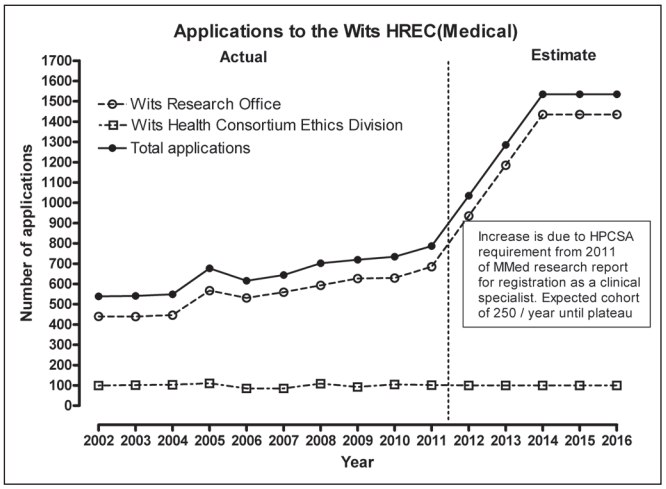


Fig. 6. Comparison of WRO and estimated WHCED new applications including the anticipated WRO application load due to new HPCSA policy.

For the WHCED, the number of new applications is likely to remain steady at about 100 per year but, as shown by the regression line in Fig. 3, amendments are expected to increase.

The new HPCSA requirements will affect all HRECs at medical schools in South Africa. The committees are in effect 'service committees' that must react to applications submitted in terms of South African research ethics requirements, whatever that number might be. The responsibility for providing staffing and facilities to enable the committees to function belongs to the home institutions. It is in the best interests of the institutions to do this because of the returns, both in recognition and finance, of increased research output and research grants awarded.

As a first stage in planning for the future a SWOT analysis was done for the Wits HREC (Medical):

Strengths

- Longest-established HREC (Medical) in South Africa and in Africa, and one of the 10 oldest in the world
- Experienced committee members across many disciplines and institutions
- Preferred South African HREC by many international research sponsors
- WHCED is an adequately staffed secretariat for clinical trials.

Weaknesses

- Inadequate staffing in WRO to cope with application numbers
- Committee members need to decide how to cope with the large expected application numbers per meeting while complying with South African law and regulations.

Opportunities

- The increase in research by clinical specialty trainees (registrars) should lead to an increased publication rate for the University bringing in more government funding and aiding the goal to be one of the world's 100 best universities by 2022.
- Online applications and management of applications may speed up turn-around time. iPads or notebooks will need to be provided.

Threats

The WRO as staffed at present will not cope with the large increase in applications due to the new policy of the HPCSA for specialist registration.

- The inability to cope with application numbers will affect deadlines for both undergraduate and postgraduate training.
- Delays in project approvals can adversely affect grant applications as a result of missing deadlines.

Conclusions

1. The HREC (Medical) is under severe and increasing strain due to new applications through the WRO which will increase from 2012 until 2014, by which time they will be double the current rate.

2. Bypassing applications is not possible due to legislation – the National Health Act, the South African Constitution and NHREC regulations.

3. Management of the new applications at meetings needs to be 'brainstormed' by the committee; based on the wide experience of members a solution is likely.

4. Without at least one extra full-time staff member in the WRO the management of the increasing application numbers will be impossible, with serious consequences for academic activities at Wits.

5. At the moment the status quo in the WHCED should be maintained but reassessed at yearly intervals.

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