

# Ethical Issues Surrounding the Use of Modern Human Remains for Research in South Africa

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## Abstract

Chapter 8 of the South African National Health Act 61 of 2003 (NHA) that deals with the donation of human tissue was promulgated in 2012. The new Act is perceived to impose restrictions on low-risk research involving human remains. This study aimed to identify the issues raised by a research ethics committee (REC) when reviewing protocols where human remains are used as data source. REC minutes from 2009 to 2014 were reviewed, and issues raised by the committee were categorized. In total, 127 protocols submitted to the committee over 6 years involved human remains. Queries relating to science (22.2%) and administration (18.9%) were the most common, whereas queries relating to legal issues constituted only 10.2%. Ethical issues centered on informed consent regarding sensitive topics such as HIV, DNA, and deceased children. The change in legislation did not change the number or type of legal issues identified by the REC.

## Keywords

research ethics, human remains, National Health Act, research ethics committee, review process, legislation, South Africa, developing

## Introduction

All researchers at medical schools across South Africa are required by the South African National Health Act 61 of 2003 (NHA) to submit protocols to their faculty's research ethics committees (RECs) every year. The increased pressure on academics to publish and obtain ratings for promotion that would improve the national and international standing of academic institutions has led to a surge in the number of postgraduate protocols and self-initiated research projects submitted to RECs for approval (Cleaton-Jones & Vorster, 2008).

Although some of these research protocols are granted ethical clearance after first submission, a considerable number are deferred for revision and resubmission. Infrequently, the researcher prefers to retract the protocol rather than to amend the protocol, often not stating specific reasons (Cleaton-Jones, 2010). This trend is of concern, as valuable information that will contribute to generalizable knowledge for societal benefit is lost. From the institution's perspective, potential publication units are forfeited after much effort by the student and supervisor to prepare the protocol. Even though there is literature on the review process and prominent issues noted by different RECs in South Africa (Clarke, 2014; Cleaton-Jones, 2010; Cleaton-Jones & Grossman, 2015; Cleaton-Jones & Vorster, 2008; Tsoka-Gwegweni & Wassenaar, 2014), no reports are available in

cases where research specifically involves modern human remains (fresh or embalmed cadavers and decomposing or skeletal remains) as data source.

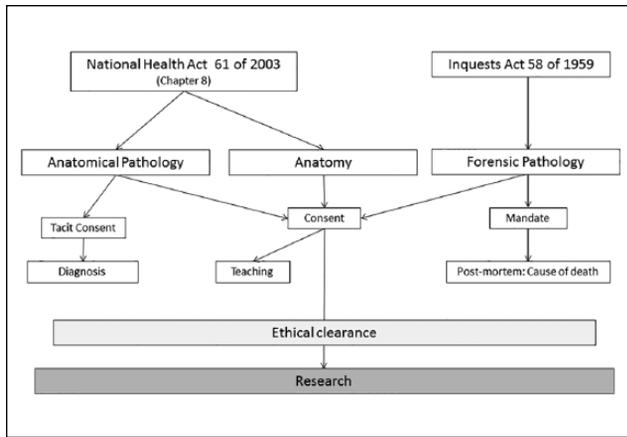
University researchers using human remains are predominantly from the fields of anatomy, anatomical pathology, and forensic pathology (also known as Forensic Medicine at some tertiary institutions) and are faced with a particular set of challenges. These challenges include the availability of research material (which is also used for teaching purposes), safety issues, security concerns, and legal matters.

All three disciplines are governed by law: the South African NHA of which Chapter 8 replaced the now defunct Human Tissue Act (HTA) 65 of 1983, as well as the Criminal Procedure Act 51 of 1977 and the Inquests Act 58 of 1959. Despite these diverse laws that govern the different disciplines, the South African NHA ultimately provides legal guidelines as to the conduct of research. Figure 1 presents the legal rules of the handling of tissue in South Africa.

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**Figure 1.** Legislative framework and consent requirements for each discipline dealing with human remains.

From Figure 1, it is clear that the NHA requires consent for both teaching and research to be given when a living person bequeaths his or her body (or by the next of kin of the deceased in absence of bequeathal prior to death) to an anatomy department. In contrast, different considerations come into play in the case of tissue samples. Tissue samples pose a problem because these samples are often accompanied by information that identifies the individual. According to the South African Department of Health (2015) ethics guidelines, consent or re-consent may be waived by RECs under certain conditions. These conditions depend on the level of risk and potential benefit to the participants while considering the rights of the participant. More explicitly stated, RECs may grant waivers where research poses minimal risk; in cases where secondary data analysis is performed when the risk is minimal; when the information could not be obtained otherwise; where the information will be disseminated to the individuals or, in case of the deceased, to their next of kin; or when the person's rights would not be harmed (Department of Health, 2015).

The collection of tissue samples to deduce the cause of death, where indicated, in forensic pathology is mandated by the Inquests Act, while the NHA provides tacit consent for the collection of samples to aid diagnosis in anatomical pathology. However, when tissue is subjected to testing that is not indicated to determine the cause of death (forensic pathology), when tests are done that are not part of the diagnostic process and tacit consent no longer applies (e.g., genetic testing and HIV testing), or when further work is done in anatomy that is not covered in the original donation documentation, the NHA requires additional consent (Figure 1), as the collection of unsolicited samples may adversely affect the rights of deceased persons (Chamberlain, 2008).

Nienaber (2011) and Mahomed, Nöthling-Slabbert, and Pepper (2013) raised the question whether general consent (for training, research, and postmortem examination) should

be viewed differently to consent for a specific purpose in the future research involving human tissue. When applied to anatomy, forensic pathology, and anatomical pathology, the question is problematic as there is no certainty of how the tissue will be used prior to the person's death. While Kenya and Nigeria have legislation in place for such eventualities, currently no similar laws govern this practice in South Africa (Nienaber, 2011). The main issues regarding research involving human remains are ownership and respect for a person's autonomy. Worldwide legislation and legal interpretations differ, creating practical difficulties for researchers and RECs during the ethical review process when human remains are involved (Chamberlain, 2008). This is also thought by Nienaber (2011), Satyapal (2012), and Mahomed et al. (2013) to be the case for the South African NHA.

The South African NHA attempts to set a new standard for the application of policies related to health, health ethics, and health research in South Africa. Despite being updated in 2012, the detail provided in terms of regulations of health research in Chapter 11 of the NHA contrasts with the less clear regulations provided to researchers in Chapter 8 of the Act. The practical implications and effects filtered into the interpretation of these regulations by different parties, specifically in relation to education and research in the health sciences.

As a result, although the NHA legal framework aims to improve health research, it also serves as the basis of potential sources of incongruence between RECs and researchers as it is perceived to give power to RECs but fails to inform the researchers of their rights while holding them accountable for their actions.

In the United Kingdom, the introduction of a new HTA 2004, implemented 2006, was thought by the Royal College of Pathologists to introduce constraints and could lead RECs to be overly cautious in their review and therefore prevent "low-risk" studies from being conducted (Angell, Tarrant, & Dixon-Woods, 2009). After reviewing REC letters to researchers pre- and post-legislation change, Angell et al. (2009) found that informed consent for obtaining, using, and storing human tissue for research was the main query from the REC, specifically if the tissue was to be used in future projects. More importantly, they found that the REC did not unduly pursue the issue of consent or inflate risks but operated within the legal guidelines of the HTA 2004 (the United Kingdom) and that their approach was more consistent when reviewing protocols involving human remains, providing advice rather than criticism alone to researchers.

One of the questions that needs to be answered is whether the change in South African health research legislation also affected South African RECs' view of protocols using human remains as a data source differently from the way they did when the old HTA of 1983 was still active. Although Satyapal (2012) alluded to this as far as consent issues are

**Table 1.** Taxonomy for Categorizing Types of Queries and Reasons for Each Based on Clarke (2014) and Emanuel, Wendler, and Grady (2000).

Category	Reason
Ethics	Fairness, risk–benefit ratio, independent review, consent, funding, confidentiality, authorship, reimbursement
Science	Validity, methodology, statistics, title changes
Editorial (stylistic/grammar)	Writing style, references
Legal	Compliance with NHA
Administrative	Permissions, documentation

Note. NHA = National Health Act 61 of 2003.

involved, the impact can only be seen when viewing comments from the REC and responses from researchers.

An investigation into the reasons for deferrals, requests for revisions, amendments, repeated submissions, and retraction of protocols seemed warranted to assist researchers (who use human remains for data collection) to address legal and ethical issues pertinently in their projects before submission to the REC, and to determine whether the promulgation of Chapter 8 of the South African NHA in 2012 might have affected RECs' typical judgments on such applications.

The first aim of the study was to conduct a review of the minutes from January 2009 to December 2014 of a REC to identify issues, decisions, and outcomes of the ethical review process regarding protocols where human remains were used as data source. The second aim was to determine whether additional issues were raised by the REC after the applicable section of the NHA (2003) was promulgated in 2012.

## Method

A REC that regularly receives protocols from the fields of anatomical pathology, forensic pathology, and anatomy was selected for the study. A retrospective review of the minutes of the REC, which consented to take part in the study, was performed to identify all protocols involving human remains (fresh or embalmed cadavers and decomposing or skeletal remains) submitted from January 2009 to December 2014. This time period encompasses the era before and after promulgation of the South African NHA. Protocols not adhering to the criteria listed above were excluded from the study.

### Time Period, Acceptance Rate, and Revisions

First, the number of protocols (involving human remains in data collection) submitted from 2009 to 2014 was reviewed per year, field of study, and purpose (degree or non-degree). Second, the number of protocols that were accepted without

revision, and with minor and major revisions, and the number rejected and/or resubmitted were noted and summarized according to type of study design, type of query, and reason(s) for the decision in cases of revisions and rejections. The time period taken to obtain ethical clearance was also noted. The actions of the researcher after the protocol had been rejected, or amendments suggested, for example, abandonment of the project, rewrite, and the outcome of each (ethical clearance obtained or deferred) were documented as well as the number of amendments.

## Taxonomy

Recurrent themes in the comments of the REC, and taxonomic classification and reasons for each, were noted. Taxonomy as described by Clarke (2014) and principles by Emanuel, Wendler, and Grady (2000) were used to classify type of study (prospective, retrospective, descriptive, or qualitative) and type of query (legal, scientific, ethical, editorial, or administrative; Table 1).

Reasons for each type of query were the qualitative aspect of the study to enrich data. The deductive approach to framework analysis was used (Ritchie & Spencer, 1994). In terms of ethics queries, reasons for queries were categorized as pertaining to fairness, risk–benefit ratio, consent, funding, confidentiality, authorship, reimbursement of participants/patients, and whether the research was subjected to independent review. For science-related queries, the categories were validity, methodology, and statistics. Methodology also included the selection criteria for the study population as described by the protocol submitted to the REC. Title changes were added to the science category as most title changes were not editorial but involved scientific aspects to be added to the title. Referencing and writing style were part of the editorial category. In terms of the legal category, comments involved compliance with and interpretation of the South African NHA. Administrative queries mainly related to permissions not provided and lack of documentation or incompleteness of documentation submitted.

Responses from the researchers were noted and categorized as “amended” or “retracted.” Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences, version 22.0; IBM Corp., Armonk, New York) to derive descriptive statistics and presenting proportions by associated factors of interest.

Ethical clearance was obtained from the institutions involved prior to commencement of data collection.

## Results

### Sample

Over a 6-year period, 127 protocols were submitted to the study REC, with the intention of using human remains as a

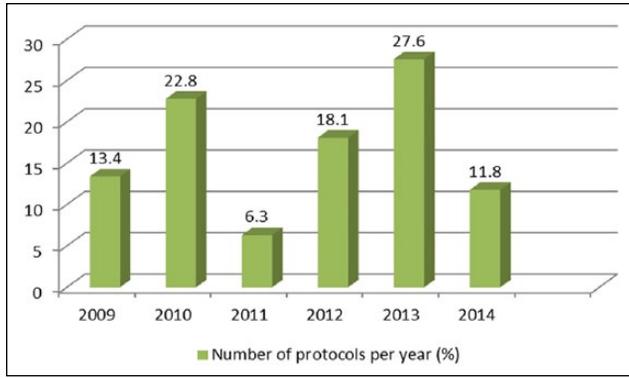


Figure 2. Number of protocols per year (%).

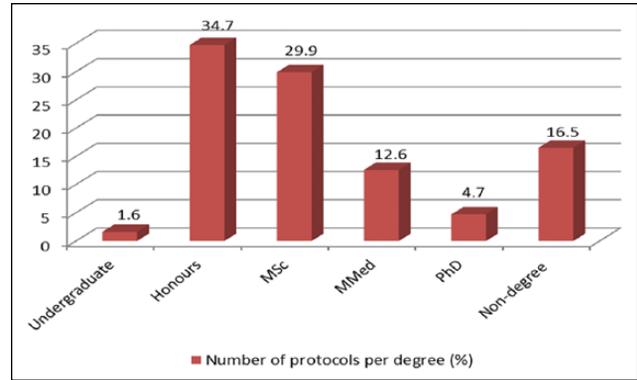


Figure 4. Number of protocols per degree (%).

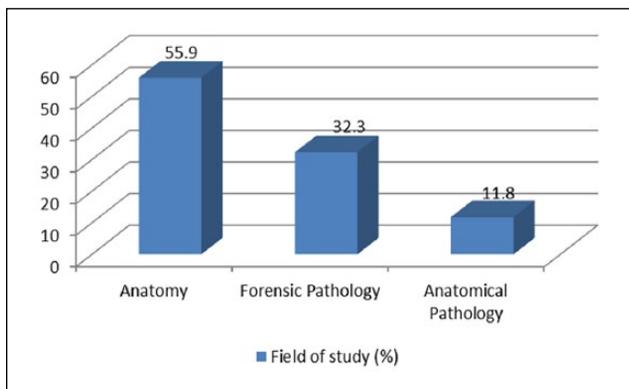


Figure 3. Field of study (%).

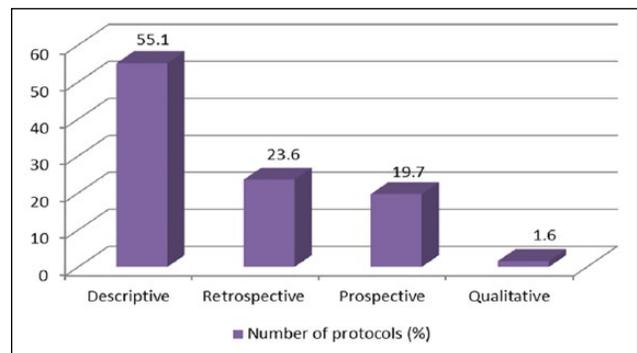


Figure 5. Type of study (%).

data source. The highest number of protocols was submitted in 2013 (27.6%) and 2010 (22.8%), and the lowest number of protocols (6.3%) was submitted to the REC (Figure 2) in 2011.

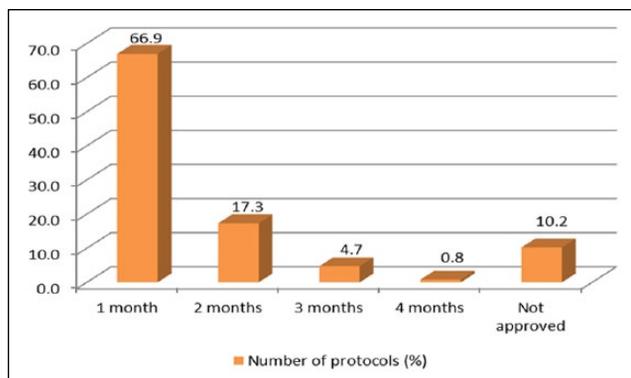
In total, 55.9% of the protocols submitted were from the field of anatomy and were mostly descriptive and cross-sectional in nature, mainly involving embalmed human material and skeletal remains. Protocols from forensic pathology comprised 32.3% of the total sample, whereas 11.8% of the 127 protocols were from anatomical pathology (Figure 3). Figure 4 shows that the majority of protocols were for research undertaken toward honors (34.6%) and master’s degrees (29.9%). The percentage of protocols submitted by staff as self-initiated non-degree projects was 16.5%, considerably higher than 4.7% of PhD protocols submitted. From the total, 12.6% of protocols were submitted by MMed students in forensic pathology or anatomical pathology. Only two undergraduate protocols were submitted (1.6%), as students are not expected do research at undergraduate level at the evaluated institution. Protocols pertaining to forensic pathology and anatomical pathology also included descriptive studies but mostly concerned retrospective record reviews, prospective investigation regarding samples already collected, or additional samples to be

collected by the researchers. As a result, 55.1% of the protocols were descriptive studies, 23.6% were retrospective, and 19.7% were prospective/investigational. Only two studies (1.6%) involved qualitative research, and both were based on questionnaires (Figure 5).

### Time Period and Acceptance Rate

In 66.9% of cases, it took 1 month to obtain ethical clearance from the REC after submission, and in 17.3% of cases, it took 2 months (Figure 6). In 4.7% of cases, the time period was delayed to 3 months, with 0.8% of the cases taking 4 months for approval.

Of all protocols submitted, only 24 (18.9%) were accepted at first submission, whereas the vast majority were deferred for revision (81.1%) (Table 2). Of the revised protocols (second submission), 13.6% did not respond satisfactorily and were once again deferred for revision. After resubmission, only 5.8% of protocols were deferred for a third revision, and of these, 9.7% were met with non-approval. Of all protocols initially submitted, 10.2% met with non-approval. This number included both rejections by the study REC and withdrawals of protocols by the researchers. Reasons for withdrawals varied from deregistration of students due to personal circumstances after the protocol



**Figure 6.** Time period for ethical clearance.

**Table 2.** Acceptance Rate.

Acceptance rate	Number of protocols (n)	%
Accepted at first submission	24/127	18.9
Deferred for revision	103/127	81.1
Deferred for second revision	14/103	13.6
Deferred for third revision	6/103	5.8
Not approved <sup>a</sup>	10/103	9.7

<sup>a</sup>Includes retracted and rejected protocols.

was submitted for review (3.1%) and withdrawal of the protocol by the researchers with the intention of rewriting, but without resubmitting due to funding difficulties or the researcher/supervisor resigning from the university (2.4%). In one case, the researcher did not state a reason (0.8%), and in another case, the researcher repackaged two protocols into one large blanket study with subdivisions after consultation with the study REC (1.6%). Only in two cases (1.6%) did the REC reject the protocols based on poor research design. As only records from January 2009 to December 2014 could be accessed by the current study, we could not determine whether the research design of these two protocols was changed to meet the criteria of the REC. It is possible that both protocols eventually received ethical clearance after resubmission in 2015 or 2016.

### Taxonomic Classification of Issues

The taxonomy of Clarke (2014) was used to classify REC reasons for deferrals (Table 3). However, it was necessary to add another category, “Administrative,” to accommodate aspects such as outstanding permission from the academic advisory committees approving master’s and doctoral protocols on scientific merit, as well as permissions from CEO of the local academic hospital, director of the National Health Laboratory Service, and curators of skeletal collections. The “administrative” category also included a

subsection named “documentation” as it was noted that in several cases, the pages were not numbered, the table of contents was omitted, consent forms were incomplete, and so forth.

In Table 3, it is clear that the REC queries relating to science (22.2%) and administration (18.9%) were the most common, whereas queries relating to legal issues only constituted 10.2% of queries. Ethical and editorial issues were on average 7.5% and 5.1%, respectively. When reviewing the subsections of each category, 14.2% of queries under “ethics” related to participant information and informed consent of the next of kin. The issue of confidentiality was only raised by the REC in 6.3% of queries. In terms of the science category, most reasons behind science-based queries were methodological (44.1%) and related to statistics (29.9%) of which sample size and data analysis were most often problematic. Outstanding permissions and approval from academic advisory committees resulted in 29.9% of problems in the administration category. The interpretations of the South African NHA by researchers and REC members constituted 15% of queries in the “legal” category. Difference in interpretation of the NHA by REC members and researchers was related to consent, specifically who is able to give consent on behalf of the deceased and whether “low-risk” studies should be subjected to re-consent by the next of kin. In Table 4, it can be seen that the recurrent theme pertaining to research protocols with human remains as source, in the category of “ethics,” was consent. The term “recurrent theme” in this context refers to themes repeatedly identified by the REC that led to reasons for deferral. In this regard, consent was specifically raised by the REC when sensitive themes such as race, HIV, DNA, and non-therapeutic research in children were involved. The issue of race was also closely linked to selection criteria and fair selection in the science category. In addition, the source of human material (donation, part of routine sample collection, additional sample collection) was queried which relates to the legal category (regulations of the NHA and its subsequent amendments) as well as ethics (informed consent).

### Discussion

With the promulgation of Chapter 8 of the South African NHA in 2012, researchers feared that it restricted use of human remains as a source of information because it effectively limited access to cadavers available for research and it strengthened consent requirements in cases where samples were to be collected. These fears were also based on a similar situation, which occurred in the United Kingdom where the Royal College of Pathologists objected to the introduction of the HTA 2004 (the United Kingdom) in 2006, stating that it imposed restrictions that would result in “low-risk” research being rejected by RECs (Angell et al.,

**Table 3.** Taxonomic Classification of Queries Raised by the REC.

Category	Reason	<i>n</i>	% of total sample	<i>M</i> per category (%)
Ethics	Unacceptable risk–benefit ratio	7	5.5	7.5
	Consent (participant information, informed consent)	18	14.2	
	Funding (budget, resources)	5	3.9	
	Confidentiality (privacy, anonymity)	8	6.3	
Science	Validity and viability	1	0.8	22.2
	Methodology (study design, selection criteria)	56	44.1	
	Title changes (content related)	18	14.2	
	Statistics (sample size, data analysis)	38	29.9	
Editorial (stylistic/grammar)	Writing style	8	6.3	5.1
	References	5	3.9	
Legal	Compliance with legislation	7	5.5	10.2
	Interpretation of NHA	19	15.0	
Administrative	Permissions	38	29.9	18.9
	Documentation	10	7.9	

Note. REC = research ethics committee; NHA = National Health Act 61 of 2003.

**Table 4.** Recurrent Themes Pertaining to Research Protocols With Human Remains as Data Source, and Taxonomic Classification of Queries Raised by the REC.

Recurrent themes identified	Category and reason	<i>n</i>	% of total sample
Race	Ethics: Fairness	4	3.1
	Science: Selection criteria	6	4.7
HIV	Ethics: Consent	4	3.1
DNA	Ethics: Consent	4	3.1
Data source (donation, residual samples, prospective sampling)	Ethics: Consent	6	4.7
	Legal: Compliance and interpretation of NHA	5	3.9
Non-therapeutic research in children	Legal: Compliance and interpretation of NHA	5	3.9
	Ethics: Consent	4	3.1

Note. REC = research ethics committee; NHA = National Health Act 61 of 2003.

2009). However, the contrary was proven by Angell et al. (2009) who determined that the researchers benefitted from the new law as the RECs could make more consistent judgments and advise researchers on how to improve their protocols to meet the legal requirements.

The current study focused on issues raised by a REC regarding protocols that involved data collection from human remains in the fields of anatomy, forensic pathology, and anatomical pathology. In South Africa, the HTA of 1983 was replaced with the NHA in 2012. As the current study spanned a six-year period from 2009 to 2014, it included the change in legislation. This part of the legislation took almost 10 years to be promulgated after it was initially published in 2003. During this time, researchers were aware of the suggested changes and most likely adapted their research strategies accordingly. As a result, the current study showed an average 10.2% of legal queries from the REC from 2009 to 2014. Only in 5.5% of cases was compliance with the NHA problematic with regard to

informed consent. In 15.0% of the total number of protocols, interpretation of the NHA by the REC and researchers was different. These differences were related to consent. Documentation from the REC indicated that one question that was debated between the REC and researchers was who should give consent in terms of the NHA when tissue samples that have been harvested as part of the postmortem examination are to be part of future research. The other question was whether reconsent from the next of kin was needed for “low-risk” studies if the person has been deceased for several months. The REC determined that the next of kin should be approached when additional tests were to be performed, whereas the researchers argued that the research was “low risk” and the next of kin would experience further distress should they be approached to give consent for the research. The RECs instructed the researchers to provide counseling for the next of kin in such cases and proceeded to require consent based on their interpretation of the NHA.

**Table 5.** Comparison of the Number of Legal Queries Before and After Change in Legislation in 2012.

Period	Year	Number of protocols per annum	%	Number of protocols per period	%
Time period before legislative change	2009	2	7.7	12	46.2
	2010	6	23.1		
	2011	4	15.4		
Time period after legislative change	2012	3	11.5	14	53.8
	2013	7	26.9		
	2014	4	15.4		
Total		26	100.0	26	100.0

When comparing the time period before change in legislation (2009-2011) to the time period after legislation was changed (2012-2014), almost an equal number of protocols had legal-type queries (12 cases from 2009 to 2011, and 14 cases from 2012 to 2014; Table 5). Therefore, the change in legislation did not significantly change the number and type of legal issues identified by the REC. This lack of new legal issues may be partly attributed to the similarity of the projects and that submissions were made by the same supervisors to a REC with a membership of 20 that remained largely unchanged during this period. Furthermore, RECs and researchers learn from previous interactions and therefore may have been able to preempt problematic issues.

Angell and Dixon-Woods (2009), Cleaton-Jones (2010), and Tsoka-Gwegweni and Wassenaar (2014) identified informed consent as the major recurrent issue raised by RECs. Tsoka-Gwegweni and Wassenaar specifically mentioned gatekeepers' permission, respect for autonomy, context of the consent process, and permissions from legally authorized representatives as issues under their informed consent category. In the current study, consent was also the main legal and ethical issue, specifically when consent was required from the next of kin. This was specifically so when research involved deceased children and when the source of samples might require additional consent, for example, autopsy samples to be subjected to genetic testing, the use of residual pathology samples, or requests to take additional samples for non-routine testing such as HIV and secondary data analysis. In 30% of these cases, the REC determined the studies as being "low-risk" and waived consent. Examples of such "low-risk" studies include the sensitivity testing of different chemicals to detect tuberculosis in body fluids, measuring of stature of deceased persons, and analysis of standard procedures in forensic pathology to improve service delivery. In cases where genetic and HIV testing were requested, re-consent was needed. In research involving deceased children, consent from at least one parent was required. The REC also instructed that ancillary care in the form of counseling was to be provided by the researchers as the researchers had the capacity to do so.

Research involving human remains seemed to enjoy faster review times than reported review times for general protocols at other institutions. Clarke (2014) reported that the average number of months for a protocol to be reviewed at the University of KwaZulu-Natal (UKZN) was 3 months. Cleaton-Jones and Grossman (2015) indicated that at the University of the Witwatersrand (WITS), the period was 4 months. In contrast to results from Clarke (2014) and Cleaton-Jones and Grossman (2015), the current study showed that at the study REC, the time was 1 month as 66.9% of protocols were approved within 1 month and only 0.8% of protocols approved after 4 months. The 1-month approval included review by the REC and revisions by the researchers in response to comments and suggestions by the REC prior to the main meeting at the end of the month where the protocol is tabled. This suggests that the review process at the REC involved in the study was efficient despite the process generally being perceived as laborious by researchers. The implementation of the electronic South African Research and Information Management Programme (RIMS) submission system in 2013 by the REC also contributes to the smooth operation as revisions are sent to reviewers immediately once uploaded. If reviewers find the changes in order, approval is given at an interim REC meeting. The decision is then ratified at the monthly committee meeting. This process decreases approval times considerably. Furthermore, the majority of studies were descriptive (55.1%) or retrospective (23.6%) which poses less risk than other types of studies in accordance to observations by Clarke (2014) and Cleaton-Jones and Grossman (2015). In addition, most protocols were part of BSc honors (34.6%) and MSc (29.9%) degrees, which are not as complex in terms of research methodology, compared with the smaller number of doctoral studies (4.7%) and self-initiated research projects (16.7%) that were submitted by senior-level researchers. Protocols that took longer than 2 months to obtain clearance usually had major scientific or legal issues which required resubmission by the researchers.

Notwithstanding the shorter approval time of the study REC, 9.7% of protocols that underwent full review (excluding protocols withdrawn by researchers) were not approved,

compared with non-approval rates between 3% and 8% reported by others (Angell & Dixon-Woods, 2009; Clarke, 2014; Cleaton-Jones, 2010). Furthermore, only 18.9% of protocols were accepted at first submission without revision, compared with 24% (Cleaton-Jones & Grossman, 2015) and 37% (Cleaton-Jones, 2010) reported at WITS.

Revisions after first submission can be classified as either being “minor” or “major.” The criteria for each are similar to those listed by Cleaton-Jones (2010) and Cleaton-Jones and Grossman (2015). In cases of minor revision, the revisions are referred back to a REC member or the subcommittee for approval. In cases of major revisions, the revised document is reviewed again by the full committee. When comparing cases requiring minor and major revisions, the general trend showed that minor revisions (55%-66%) far outweighed major revisions (3%-13%; Angell & Dixon-Woods, 2009; Cleaton-Jones 2010; Cleaton-Jones & Grossman, 2015). This trend was also seen at the study REC where 58.2% of cases needed minor revisions and 15.1% of protocols required major revisions. The exception to these trends was Clarke (2014) who reported that 43% cases required minor revisions and in 53% cases, major revisions were necessary at UKZN. Approval rates of protocols submitted at the study REC are similar to other institutions, despite passing more rapidly through the review process.

Clarke (2014) and Cleaton-Jones (2010) found that 28% of protocols that required major revision were never resubmitted, which contrasts significantly with the current study, in which only 3% of protocols were not resubmitted. Possible reasons for this low number are the open communication between the REC and the researchers and the numerous ethics workshops held in faculty that encourage active engagement with the REC on complex issues.

Scientific issues, rather than ethical or legal problems, were the most common reasons for revisions (22.2%). In particular, study design and selection criteria (41.1%) as well as sample size and statistics (29.9%) were often listed as being problematic. This finding correlates with the results of Tsoka-Gwegweni and Wassenaar (2014) who determined that 21.4% queries raised by the South African biomedical REC in their study concerned scientific validity of which most queries related to appropriate design and methods as well as study design feasibility. Clarke (2014) also identified scientific queries rather than the grammatical and stylistic problems identified by Cleaton-Jones (2010) as being predominant. One explanation that can be offered is that the REC members are more knowledgeable regarding scientific review as opposed to changes in the legislation and therefore more focused on the former.

The results of the current study are limited to one REC and cannot be extrapolated to all RECs in South Africa. However, it provides insight into the way in which the NHA

has shaped the research environments within the domains of anatomy, forensic pathology, and anatomical pathology.

## **Best Practices**

Based on the results, it is recommended that researchers should be more rigorous regarding the scientific design of protocols. Postgraduate students should adhere more closely to the administrative requirements of the REC.

## **Research Agenda**

The active participation of multiple stakeholders is required to further understand the complexities imposed by lawmakers. Therefore, future investigations should be directed at obtaining similar information for other RECs within South Africa and to combine it with the knowledge and attitudes of REC members and researchers toward the NHA. The latter is important as it will highlight the shortcomings of the legislation for future law reform, preferably in consultation with academics and RECs.

## **Implications for Ethical Guidelines**

This study suggests that researchers and RECs might be experiencing confusion with regard to the exact implication of the law concerning ethically acceptable research involving modern human remains. The legislation is perceived as vague, as some sections (cf. Chapter 1) of the HTA 65 of 1983 that directed such activities have been omitted in the NHA. However, despite this perception, the major reasons for REC queries were scientific in nature. It seems as if researchers do not address the scientific component appropriately or that REC members are more familiar with the scientific process than ethics (or possibly legislation) when assessing a protocol.

The review process followed by RECs should align with the ethical guidelines of the South African Department of Health (2015) which emphasize dual review of any protocol submitted to a REC (S 1.6.7) assessment of both scientific integrity (S 2.3.2) and ethical standards (S 1.6.7). One of the priorities of the South African National Health Research Ethics Council (NHREC), a national body that oversees all RECs in South Africa, is the refinement of ethics guidelines to improve the review process and protect the rights of all involved (S 1.3.3, Department of Health, 2015). Guidelines of local RECs should therefore also offer direction for specific categories of research, one being research that involves modern human remains. This refinement in the guidelines will assist the growing number of researchers in the fields of anatomy, anatomical pathology, and forensic pathology toward improving the ethical practice of health-related research using modern human remains.

## Educational Implication

It is imperative that researchers and REC members should be aware of legislative changes. The promulgation of new laws may impact on research in terms of the sample (availability, accessibility), methodology (type of data to be collected), and ethics considerations (informed consent from the next of kin). It is not only the REC that has to remain abreast of the content of such laws but also researchers who work within the realm of human remains have a responsibility to keep up to date with legislative changes. As the South African Department of Health (2015) guidelines (S 4.4.1.2) require all registered South African RECs to have a legally qualified member, RECs should thus be more aware of pending changes. RECs therefore should consider organizing interactive forums in this regard, and researchers, even seasoned ones, should attend these information exchange sessions.

## Conclusion

The current study suggests that scientific rather than legal issues were the predominant basis of revision requests by the REC on protocols involving use of modern human remains. Furthermore, legal issues, that is, the interpretation of the current NHA and other governing legal principles, were not perceived as problematic by REC members and researchers in the field because our data show that the number of legal queries raised by the REC before and after the promulgation of Chapter 8 of the NHA in 2012 was virtually unchanged after the legislation changed. The average time period for obtaining ethical clearance for studies involving human remains after submission and revision was 1 month, faster than turnaround time frames reported at other South African RECs. It is possible that the minimal risk and relatively innocuous nature of these studies may be the reason for this observation. Scientific issues relating to methodology and administrative matters such as outstanding permissions were more frequently problematic than legal issues and should be attended to carefully by researchers before submission of protocols for ethics review.

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## Authors' Note

The views contained in this article are not necessarily the views of the supporting institutions. N. Briers conceptualized the study, collected the data, performed data analysis and interpretation, and wrote the article. J. J. Dempers contributed to the conceptualization of the study, provided guidance, and edited and approved the final manuscript.

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