

**An examination of timelines in the expedited ethics review process at the University of
KwaZulu-Natal, Biomedical Research Ethics Committee**

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**Submitted in fulfilment of the requirement for the degree of Master of Social Science
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DECLARATION

This is to declare that the work is the author's own work and that all the sources have been honestly reported and acknowledged, and that this document has not in its entirety or in part been submitted at any university in order to obtain an academic qualification.



Brightness Cebisile Nxumalo
November 2017

I confirm that the work reported here was carried out by the above-named candidate under my supervision.

Supervisor Prof D. Wassenaar

Signature...  Date.....23rd Feb 2018.....

Abstract

Purpose

This study examined the timelines of the expedited ethics review process at the University of KwaZulu-Natal Biomedical Research Ethics Committee. The purpose of the study was to evaluate timeframes of BREC review processes for expedited ethics applications and identify specific phases in the review process associated with delays in the time taken to obtain ethical clearance.

Method

A sample of 200 cases of research proposals submitted to BREC for expedited review in two consecutive years, 2013 and 2014, were reviewed. The researcher drew 100 cases from 2013 and 100 cases from 2014. The research took every third referenced expedited review application in the year 2013 and 2014 until the sample of 200 cases was reached.

Results

There were noticeable delays in the BREC review process, mainly from the applicants. The descriptive statistics show that it took a mean of 24.22 days and a median of 18.00 days for reviewers to respond to applicants. It took a mean and mode of 65.66 and 14.00 days, respectively, for applicants to respond to reviewers. These were the longest phases of the UKZN/BREC expedited ethics review process. The modal time it took for the protocols to receive final approval was 140 days.

Conclusion

The study showed that the BREC expedited review process had a slow turnaround time of 140 days. The phase that contributed most to delays was the time it took applicants to respond to queries. This phase is not under the control of BREC.

Recommendations

This data highlights the slowest elements of the ethics review process. Researchers and the UKZN/BREC should identify why these are the slowest phases and make efforts to improve these data in a future follow-up audit of these timelines. A forthcoming electronic document

management system might also assist, and hopefully future data will show improvements in the slowest phases illuminated by the current study.

ACKNOWLEDGEMENTS

I give thanks to the Lord! He has never let me down.

To my supervisor, Prof D Wassenaar, thank you for being patient with me; your guidance and your expertise really anchored me. You are an inspiration! God bless!

The SARETI project manager, Ms Carla Pettit, you are an inspiration! Thank you.

The BREC staff for welcoming me and for your guidance and support.

Mummy, MaNtuli! Thank you, I now see the fruits of your prayers.

My Husband uZwide! Your motivations and belief in me. God bless!

My Daughter, Zibusiso Nxumalo; you did not understand why mummy did not have undiluted time for you, but you are the reason I completed this study. All the best in life, my angel.

To my son, Luminjalo; I love you, ungukuKhanya.

Research reported in this report was supported by partial funding from the Fogarty International Center (FIC) of the US National Institutes of Health (NIH) under award number 3 R25TW001599-15 to the South African Research Ethics Training Initiative (SARETI). The content is solely the responsibility of the author and does not necessarily represent the official views of the US National Institutes of Health.

ACRONYMS AND ABBREVIATIONS

CIOMS - Council for International Organisations of Medical Sciences

DOH - Department of Health

GCP - Good Clinical Practice

HSRC - Human Sciences Research Council

IRB - Institutional Review Board

MRC - Medical Research Council

NHREC - National Health Research Ethics Council

REC - Research Ethics Committee

UKZN/BREC - University of KwaZulu-Natal/Biomedical Research Ethics Committee

WHO - World Health Organisation

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CHAPTER 1: INTRODUCTION

1.1 Introduction

Ethics review is progressively becoming mandatory for social science and health science research. Ethics review is increasingly accepted as adding value to how studies are conducted in that they are required to address issues like protecting the rights of participants, safeguarding researchers from unwanted costs, and fairness. To comply with the South African Department of Health's Research Ethics Guidelines of 2015, the majority of South African universities and research institutions require that an independent research ethics committee reviews all health and social science research that involves human participants prior to collection of data (Mamotte & Wassenaar, 2009).

1.2 Rationale of the study

Scholars have complained that ethics review processes delay research unnecessarily (Warlow, 2005). This study, therefore, intends to review and evaluate the expedited ethics review process timeline at the University of KwaZulu-Natal's Biomedical Research Ethics Committee (BREC). Such a study has the potential to assist in revising the current ethical review procedures adopted by BREC at the University of KwaZulu-Natal. The interest for such a study is further motivated by complaints students usually have for the delays in their ethical clearance. This research project is intended to help identify areas of potential delay in the process and to highlight possible ways to circumvent and reduce these delays.

1.3 Objectives

The objectives of this study are:

- a). To evaluate current timeframes of BREC review processes for expedited ethics applications.
- b). To identify specific phases in the review process associated with delays in the time taken to obtain ethics clearance.
- c). To make recommendations on how the timing of the ethics review process can be improved.

1.4 Research questions

- a). What are the modal, mean and median times taken for BREC review of expedited applications?
- b). Which phase of the review process takes the longest?

1.5 Definition of terms

Expedited: means review by the REC chair and one or more experienced reviewers, rather than review by a scheduled meeting of the research ethics committee.

Expedited Ethics Review Process: “research may qualify for expedited review if it is judged to involve only minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. For example, the collection of physical data through non-invasive procedures is eligible for an expedited review, including: Height and weight, ECG, MRI and Ultrasound, Moderate exercise, Blood or other bodily fluids” (45 CFR 46. 110).

Minimal Risk: “the prospect and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46. 102).

Phases: the time taken to progress from each stage of the review process.

Research: a class of activity designed to develop or contribute to generalizable knowledge.

Taxonomy: the practice and science of classification of things or concepts, including the principles that prompt such classification.

Timeline: the time taken to complete the expedited ethics review process.

Vulnerability: a significant incapability to protect your own interests due to barriers such as lack of capability to give informed consent, privation of means to obtain medical care or other exclusive needs, or being a junior or subordinate member of a hierarchical group. Accordingly, exceptional backing is necessary to protect welfare and rights of vulnerable persons (CIOMS, 2016).

1.6 Delimitation and scope of the study

The study examined the timelines in the expedited ethics review process at the University of KwaZulu-Natal, Biomedical Research Ethics Committee (UKZN/BREC). This study is therefore limited to this region in its scope. Its outcomes cannot be extended to other RECs beyond the one explored.

1.7 The scope of REC

“The National Health Act, 2003 (Act No. 61 of 2003), proposes that the functions of research ethics committees will include: Reviewing research proposals and protocols to ensure that research will be conducted in the spirit of endeavouring to promote health, and to prevent or cure disability and disease; ensuring that humans involved in research are treated with dignity and that their well-being is not compromised, and that animals involved in research are treated compassionately; Ensuring that informed consent is obtained in the case of human participants; granting approval in instances where research proposals and protocols meet ethical standards”.

1.8. The scope of UKZN/BREC

“The Biomedical Research Ethics Committee (hereafter referred to as "BREC") (international equivalent titles: Institutional Review Board (IRB), Independent Ethics Committee) is mandated to fulfil its function by the Senate of the University of KwaZulu-Natal through the University Research and Ethics Committee, to which BREC will report annually in writing” Source: (<http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>). The essential purpose of BREC is to protect the dignity, rights, safety, and well-being of all human participants in health-related research. BREC will do this through independent, prospective and ongoing ethics review of all health research projects undertaken by members of staff, registered students and affiliates of the University. Special attention will be paid to research that may include vulnerable participants. The Committee is available to review, advise on, and approve or reject research protocols involving human participants submitted to it by researchers at UKZN and, at the discretion of the Chair, in the province of KwaZulu-Natal or any other province in the Republic of South Africa who are not UKZN staff members, students or affiliates. Research to be reviewed will be in accordance with the provisions of the National Health Act. In addition, when the University undertakes non-exempt human participant research that is supported by the US Department of Health and Human Services (HHS), the University and BREC will ensure that the HHS protection of human participants’ regulations are adhered to (UKZN/BREC ToR & SOPs, 2014). Source: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

A requirement of conducting health and social science that involves human participants in South African universities and research institutions, is that before data collection can take place, an independent research ethics committee (REC) reviews the proposed research (Mamotte & Wassenaar, 2009).

2.2 Ethics review processes

The bureaucratization of processes of ethics approval of research has meant that delays and expenses in doing research are prominent (Clarke, 2012). In South Africa, research with human participants has to be authorized by a registered research ethics committee (REC) before data collection can begin (Mamotte & Wassenaar, 2009). This is a universal requirement for researchers. In the United States, the governing federal regulation, 45 CFR 46, maintains that only human participants research that is federally funded should get IRB approval (Howe & Dougherty, 1993). However, in practice most US universities require IRB approval for all human subjects studies (Howe & Dougherty, 1993).

The South African National Health Act of 2003 requires that a NHREC-registered REC reviews all health-related research, including social and behavioural research that is done in South Africa. Furthermore, it should adhere to the provisions of the South African research ethics guidelines (DoH, 2015). Clinical trials must also comply with the South African guidelines on good clinical practice (GCP), (2006). According to UKZN/BREC's standard operating procedures (SOP) (<http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>), studies differ in the ethical review processes they must undergo; some studies obtain expedited ethical review and others have to undergo a full ethics review, depending on their levels of risk.

A study conducted by Clarke (2012) reviewed the ethics approval process of Master of Medicine (MMed) degrees (mostly by expedited ethics review) at UKZN to ascertain whether the process of obtaining ethics approval was functioning optimally and to detect areas where it may be improved. In his study, he found that "a total of 53 proposals for MMed degrees for the year 2010 were

obtainable for study” (Clarke, 2012, p. 24) These proposals included varieties of studies such as: “retrospective chart audit (29), prospective audit (14), questionnaire (9), cross-sectional study (1), randomised interventional study (nil), and cadaver based anatomical study (1)” (Clarke, 2012, p. 24). According to Clarke’s (2012, p. 24) analysis, “BREC took an average of 14.8 weeks (103 days) to approve to each of the 53 protocols (range 3-32 weeks). Of these, 21 (39%) received provisional approval in the first reaction”. For about 56% required major amendments and two were rejected. Clarke’s (2012) findings can, however, be critiqued in that he did not calculate or take into consideration the mode, to enable a reader to judge how often these incidents occurred. However, his conclusion was that obtaining ethics approval for a MMed study was a lengthy process. He also reported that concerns about scientific validity was the most frequent cause of queries.

Other related studies have also asserted that getting ethics approval takes more time than expected. Other REC chairs do not grant approval for studies that are approved somewhere else without a full submission made for local correspondence. Specifically for multi-center studies, overall one-third of RECs, as asserted by Ahmed and Nicholson (1996), were unable to approve the project within three months, and three of the 36 (8%) took longer than six months. These delays in obtaining approval were evidently linked to the regularity with which ethics committees met, and their workload. Although these data were reported 21 years ago, it suggests that obtaining ethics approval has always been difficult and time consuming.

A study conducted by Mamotte and Wassenaar (2009) showed that the same problems and frustrations that are faced by developed countries’ researchers are also faced by South African researchers. However, empirical evidence collected in various published studies showed that IRBs in the US differ in the way they apply federal regulations, their review turnaround time, and in the decisions they make (Abbott & Grady 2011). Mamotte and Wassenaar (2009) found that ethics review issues in South Africa are not due to the underdevelopment of the country, but are due to common review practices inevitably arising in institutions. South Africa and all other developing countries have the advantage of learning from developed countries’ frustrations and blunders, so they can custom their own review processes in standards that are more strategic to crucial ethical

issues that arise in research and avoid procedures that have delayed developed countries' ethics review processes.

It is further noticeable that very few ethics applications are approved at the first review. In review of 1 180 protocols to the HREC (Medical) of the University of the Witwatersrand (Wits) in 2003 and in 2007, 21% of the protocols received approval on the first reaction of HREC, 72% needed slight or considerable amendments, HREC did not approve 5% of these protocols, and 2% were withdrawn, (Cleaton-Jones, 2010). Angell and Dixon-Woods (2009) reported on a review of 141 letters written by UK National Health Service RECs in a period of four months. The decision percentages were: 15% for approved, 64% for amendments, 8% for not approved, and 13% for withdrawn, percentages just about comparable to those at Wits University.

Researchers often complain that the REC's review process is incompetent and research ends up being delayed for what seem to be insignificant concerns (Whitney, Kemper, Bauman, Rosene, & Blatt, 2008). Literature further reveals that strain and objections to the REC's approval processes at times results in sites and researchers being hesitant to take part in research (Mansbach, Acholonu, Clark, & Camargo, 2007). On the other hand, the public learns about problems surrounding the process of conducting research and fears that research is perhaps perilous and maybe the provisions made to protect them (participants) are not efficient (Lemonick, Goldstein & Park, 2002, cited in Abbott & Grady, 2011). In this sense therefore, research ethics committees (RECs) encounter various complications while attempting to achieve their goal of ensuring protection of research participants (Abdel-Aal, Ghafar & El Shabawy, 2013).

Silaigwana and Wassenaar, 2016 conducted a collective review of empirical studies examining the structure, functioning, and review outcomes of African RECs to describe what is known in these areas and to identify gaps in the knowledge about RECs. Their review showed that the functioning of RECs was undermined by inadequate financial resources, inadequate training of members and few resources to review and monitor studies within an acceptable timeframe. Their interpretation of these results was that "while some RECs have well-established structural and functional status, additional financial support and training would be beneficial to enhance the capacity of African RECs" (Silaigwana and Wassenaar, 2016, p. 12). Silaigwana and Wassenaar (2016) further assert

that efficiency of an REC depends upon many factors including the complexity of the proposed research, the quality of the submitted application, and the size and capabilities of the REC staff. Although many studies report the overall time to IRB or REC approval, there is no outlining of the time each party (e.g., researcher, reviewer) contributes to the overall review time. There are no data on the quality of the applications, the time it takes research ethics committee members to review, or the time it takes the researchers to respond to queries.

According to Sonne *et al.*, (2018) REC staff do not have sufficient time to devote to the correction of severely deficient applications. However, their mandate remains as that of ensuring that human participants' research is conducted in ways that minimize risk of harm and balance risks with minimal benefits.

2.3 RECs in South Africa

South African guidelines on ethics in health research were first issued by the Medical Research Council in 1979 (revised 1987, 1993, 2002 - 2005). This sequence is not different from other unions outside of South Africa. Previous research shows that seeking ethics approval for health research was initially a natural decision of acting in good faith for South African researchers, reinforced by internal regulations of the various host institutions (Cleaton-Jones & Wassenaar, 2010). In 1996 this improved with the introduction of the Constitution of South Africa, which states: "Everyone has the right to bodily and psychological integrity, which includes the right: a) to make decisions concerning reproduction; b) to security in and control over their body; and c) not to be subjected to medical or scientific experiments without their informed consent" (Constitution of the Republic of South Africa, 108 of 1996, 12(2)).

The National Health Act became law in 2005; this legally requires that ethics approval of research should be sought by researchers from a registered REC prior to research commencement. The South African Health Act mandates that, every health-related research together with social and behavioural research that is done in South Africa has to be reviewed by an NHREC registered research ethics committee, and must adhere to the stipulations of the South African Research Ethics guidelines (2015) and with the South African guidelines on good clinical practice if it's a clinical trial (GCP) (2006).

In South Africa, all proposed research studies with human participants, irrespective of its nature or discipline, require ethics review. However, according to section (2) of 46.101 of the Common Rule in the United State of America; interviews, surveys, and behavioral studies, if not potentially harming, are exempt from ethics review in the USA. Studies using existing data already in the public domain are also exempted from ethics review. Section 2 of the Common Rule further exempts research on diagnostic and pathological specimens, but in South Africa each research use of specimens is scrutinized afresh to ensure that it is in accordance with the protocol and informed consent before they are approved by RECs. Another significant difference regards informed consent, as in South Africa the likelihood of getting a waiver is small (Cleaton-Jones & Wassenaar 2010). Furthermore, consent documentation and age of consent for minors is not the same, as South African requirements are more rigid (Hebert & Saginur, 2009).

2.4 Research ethics guidelines

Research ethics is concerned with how human beings are treated when participating in research. Most of the time, scientific activities or anything to do with research is achieved with an involvement of human beings as research participants. Hence, it is vital that researchers be acquainted with ethical issues and the possible effects of their scientific work, and act accordingly. This includes fashioning ethical judgements that are contextually informed by literature, relevant guidelines and morality.

The Nuremberg Code emerged as a part of international disapproval of violence by Nazi physicians. It concentrated on the issues of consent and a favourable risk-benefit ratio in clinical research (Emanuel *et al.*, 2004). The research scandals of Tuskegee and Willowbrook, led to the development of the Belmont Report. Belmont Report similarly emphasized the importance of informed consent (Beauchamp, 2008). Then, the Declaration of Helsinki, emphasized the need for favourable risk-benefit ratio in research as well as independent ethics review, and delineated the ethical guidelines for doing biomedical research (Emanuel *et al.*, 2004).

The Second World War and the Nuremberg trials of doctor-researchers revealed biomedical research that was unethical. After World War II, scientists started to be more responsive to ethics

in biomedical research. The validity and quality of unethical research was critiqued, and participants' human rights were recognised and respected, leading to the formation of ethical codes. The Nuremberg Code (1947) was followed by the Declaration of Helsinki in 1964, which was modified many times afterwards (World Medical Association, 1989). The Council for International Organisations of Medical Sciences (CIOMS) and the World Health Organisation (WHO) also proposed guidelines in 1983 and adapted them in 1992, 2002 and 2016. These international developments motivated many initiatives at the national level and in countless fields of biomedical research.

The Declaration of Helsinki, issued by the World Medical Association in 1964, has been looked up to as an ultimate manuscript in the field of ethics, especially in biomedical research and has inspired the construction of worldwide and local legislation and codes of conduct. It has been revised a number of times, of late in 2013. It sets out ethical guidelines for practitioners engaged in both clinical and non-clinical biomedical research. According to the Declaration of Helsinki, “the research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified” (Declaration of Helsinki, 2013, paragraph 23)

Research ethics committees are expected to reflect the regulations of the country where research is conducted. Relevant international norms and standards should also be considered but not dropping or abolishing any of the protections for research participants set forth in the Declaration. The committee should have a right to monitor studies that are in progress. However, ethics review in health-related research is occasionally antagonistic, with contemporary mediations arguing that most ethics review of health research is complacent. According to Angell and Dixon-Woods (2009, p. 797), RECs are struggling to accept the “quality of science from peer review conducted before applications are seen by RECs”

CIOMS foresaw that it is imperative that guidance is provided to researchers, sponsors, members of research ethics committees, and other stakeholders in dealing with these challenges; thus a revision process was started.

2.4.1 Revision of CIOMS guidelines

As an overall reaction, the scope of the CIOMS guidelines has been extended from purely biomedical research to include health-related research; this is because the term biomedical research would not cover research with health-related data. In addition, the 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects were combined with the CIOMS 2009 International Ethical Guidelines for Epidemiological Studies, which included topics such as bio-banking and research with health-related data.

Changes have been made as a response to the specific challenges that have risen during the last decade. First, the “2016 CIOMS guidelines put an emphasis on the scientific and social value of research: the prospect of generating the knowledge and the means necessary to protect and promote health (guideline 1)” (van Delden & van der Graaf, 2017, p. E1). “Researchers and sponsors should see to it that research addresses significant and mysterious queries to improve health and increase the reliability of scientific information and reduce research waste” (van Delden & van der Graaf, 2017, p. E1).

“CIOMS (2016) now sets forth the responsibility to make obtainable the interventions that have been proved to be operative in research as part of a broader responsibility to care for participants’ health needs (guideline 6)” (van Delden & van der Graaf, 2017, p. E2). This broader responsibility requires, for example, that before the commencement of the study, researchers and sponsors make provision for transitioning participants, who continue to need treatment after their participation in research to appropriate health services. Moreover, the revised guidelines “require researchers and research ethics committees to evaluate the specific context-dependent characteristics that may place study participants at increased risk of being harmed or wronged” (van Delden & van der Graaf, 2017, p. E2). “Researchers and research ethics committees can formulate special protections for groups considered to be vulnerable, including allowing for no more than minimal risks for research procedures that offer no potential individual benefits for participants” (van Delden & van der Graaf, 2017, p. E2).

According to guideline 23 (CIOMS, 2016), RECs may function at a local and/or a national level. Their establishment must be in accordance with regulations set by a national or other recognized authority. Institutions must encourage undeviating standards for committees within a country. There should be sufficient resources allocated for the ethical review process. “Committees should either carry out a proper scientific review, confirm that a knowledgeable expert body has accepted the research as scientifically rigorous, or consult with competent experts to ensure that the research design and methods are appropriate” (CIOMS, 2016; guideline. 23, p. 87). If RECs do not have expertise to judge science or feasibility, they must co-opt persons with relevant expertise.

2.5 What is ethical?

RECs are faced with situations where there is no answer that is particularly ‘right’ to most ethical issues, especially when it comes to medical research (Dixon-Woods, Angell, Ashcroft & Bryman 2007). Even if there was common ground on other issues, there would be opportunity for analysis and diverse verdicts (Dixon-Woods *et al.*, 2007). Studies show that RECs’ ethical opinion varies when deciding about the same protocol. As much as reviewers may try to consider all ethical issues relating to proposed research, ethical guidelines also contradict one another.

However, assuming that ways to approach ethical issues are many (utilitarian versus human rights, for example), different outcomes are likely to be reached (Angell, Sutton, Windridge, & Dixon-Woods, 2006; Angell *et al.* 2007; Edwards, Stone, & Swift, 2007). Without an ultimate ethical authority in determining what is deemed as ethical, it can be hard to lay down what should be the ‘correct’ reaction to any perused research proposal. “In the face of the unclear nature of ethical decision making, the purpose of the REC response is to guide the connotation of ‘what is ethical’ for each application” (Dixon-Woods *et al.*, 2007, p. 795). Significantly, thus, RECs’ responses function to outline what is reasoned by a REC to be ethical practice, and deliberate reliability on that definition.

RECs’ responses may guide the meaning of ‘what is ethical’ in two distinctive ways (Dixon-Woods *et al.* (2007). First, they find those aspects of the protocol relating to ethical themes or subject enquiry and concern. Occasionally, it is obvious what one can judge as an ethical issue; i.e., the informed consent process. Tsoka-Gwegweni and Wassenaar (2014) found that informed

consent was the most common ethical issue considered by the biomedical REC that they studied. This shows that RECs pay attention to consent because this is an obvious way of protecting potential participants and an obvious platform for understanding most of ethical issues of that particular study. In other cases, it is less obvious what counts as an ethical issue, or why it might engage the attention of the REC and this is where available guidelines are helpful.

Secondly, RECs actively or passively put forward what ethical compliance entails. If the REC does not respond to researchers' projected provisions, it is passively accepting the researchers' proposals. If the REC comments, it actively suggests amendments from the researchers. In so doing, responses may impose a number of vastly changing or unpredictable requirements on researchers, for example, in prescribing the period of time that data should be stored for.

The quality of ethics review within RECs is questionable. The fact that an Ethics review committee approves debatable studies might not necessarily be an indication of competence nor incompetence; it may be a result of a counterbalanced contemplation of social value and scientific validity, and examination of risk-benefit ratio. South Africa is transforming into a free country, in which autonomy, fairness, and the exploration of human rights are appreciated, encouraged, and safeguarded by the South African Constitution Act, 1996 (Act No. 108 of 1996). Particularly, section 12(2) of the Bill of Rights provides that "everyone has the bodily and psychological integrity, which includes the right (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent".

2.6 The meaning of risk

The multiplicity of approaches that are used in biomedical science creates a number of risks that biomedical scientists and RECs have to manage. According to Brink, Van der Walt and Van Rensburg (2006), risk is often understood with reference to the possible physical or psychological harm, distress or strain to human participants that may be generated by participating research. This is commonly accepted in the perspective of health-related research but, additionally, social science brings about a different range of risks that need to be taken into consideration by RECs (Wassenaar & Mamotte, 2012). These comprises of risks such as; personal social standing, confidentiality, personal beliefs and views, occupations, their links to family and the community, emotional

distress, and stigma attached to revealing information that relates to socially stigmatised or non-conforming behaviour (Wassenaar & Mamotte, 2012).

Research that has no physical risk could bring about concerns and risk to research participants either as individuals, groups or as entire communities, because, as much as that particular research may not be physically threatening, it may carry psychological risk such as stigma. It may be complex get these risks quantified before the commencement of a research study. Nonetheless, researchers are expected to try their best to determine all possible risks and have relevant solutions for potential risks prior to the start of a project. Furthermore, after identifying risks, they should then be discussed with research participants so that appropriate informed consent can be obtained (Pope, Ziebland & Mays, 2000). Ordinarily, researchers have a duty to maintain that research participants are knowledgeable of and agree, by consenting, to the provisions in place for the anticipated risks.

2.7 Ethics review as a tool of power

It has been argued that RECs somehow influence researchers and participants in ways that may be opposing to the conduct of 'ethical research'. Halse and Honey (2007) argue that research ethics committees are changing their goal of promoting good research through ethics review. They argue that ethics is becoming "a system of governmentality generating its own discursive systems, meanings and representations of the world" (Halse & Honey, 2007, p. 339). This discourse is the product of principles and actions employed by institutions for researchers to practice within the requirements of ethics. It functions "as both an ideology and an instrument of governmentality, that encompasses an ever-expanding suite of technologies, structures and practices, including a new class of professional committed to its political ethos" (Halse & Honey, 2007, p. 341). These dispositions of governmentality, fundamental to the establishment of strategic discourse about ethical research, are characterized by REC practices and requirements.

Lincoln and Tierney (2004) maintain that RECs, most of the time, block studies which employ unconventional methods. Research ethics' governing practices might certainly have effects on the likelihood of alternative approaches and ultimately, the construction of new knowledge. This discourse may also unknowingly nurture the very unethical research it seeks to do away with. As

Halse and Honey (2007, p. 344) asserted, “there is always a danger that what is taken to be ethical research within institutions will be reduced to no more than a performance by researchers of a suite of textual competencies deemed necessary and desirable within the discourse’s governing conditions”

2.8 Summary

The chapter reviewed studies that looked at ethics review approval times, to confirm whether there was any trend in ethics review approval times. Several studies confirmed that there were excessive delays in ethics approval turnaround times. The chapter outlined the ethics guidelines in relation to ethics review processes and discussed what is ethical and the meaning of risk. The current study sought to understand the turnaround of the UKZN/BREC expedited review process. The following chapter describes and discusses the study methodology.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter focuses on the approach and the research design adopted for this study. This is followed by a description of sampling and data recording. The chapter concludes by reflecting on the ethical issues relating to the study and a description of the data analysis conducted.

This was a quantitative exploratory study. Firestone (1987) asserts that, quantitative methods adopt a positivist perspective that says that one can interpret actions quantitatively. The reason adoption of this method was to clarify information through unbiased dimensions and quantitative analysis (Firestone, 1987). The design, being exploratory, was chosen to allow for an inductive tactic to research (Terre Blanche, Durrheim & Painter, 2006). Quantitative scholars such as Ayer (1959), Maxwell and Delaney (2004), Popper (1959), and Schrag (1992) have argued that social studies have the potential to be studied the same way as scientific studies and hence should be studied the same way (Johnson & Onwuegbuzie, 2004).

Quantitative methodology and the use of exploratory design are used in order to reduce error and bias that may compromise the study's validity (Firestone, 1987). A study such as this, that seeks to explore the timelines of the expedited ethics review process, is best approached using a quantitative exploratory research design. Two instruments were used in this study, one was the data pro forma (Appendix A) to document and measure the timelines of the expedited ethical review process and the other was a taxonomy (Appendix B) to categorise the acceptability of the period of time taken for each phase of the review process. The development of taxonomy was informed by previous literature on ethics review turnaround time. For example in the study conducted by (Adams, Kaewkungwal, Limphattharachoen, Prakobtham, Pongsaa & Khusmith, 2014) the customary duration from the submission of protocol submission to the time of approval was set at 60 days. This was based on protocol submissions for the monthly REC meetings. The average number of days from submission to first notification was about 30 days, plus on average another 30 days until final approval (making the total average from submission to approval about 60 days). A period of >60 days was considered "above target duration".

In contrast, the qualitative research paradigm does not accept positivism; it argues for interpretive and constructionist approaches to research (Johnson & Onwuegbuzie, 2004). Researchers who adopt this paradigm have confidence that there exist several constructed truths and that the knower and what can be known are inseparable (Guba, 1990; Terre Blanche, Durrheim, & Painter, 2006). Despite the significance of being able to discover multiple accounts of a given phenomenon that qualitative methods make possible, the purpose of this study, which is to review and quantify the time it takes for the expedited review process, it was most appropriate to use quantitative methodology.

According to Johnson and Onwuegbuzie (2004), quantitative research has strengths and weaknesses. A thorough perusal of the following strengths and weaknesses led to the quantitative methodology used in this study. The first of these strengths, as discussed by Johnson and Onwuegbuzie (2004), is that data collection can be speedy. Because of time constraints pertaining to conducting this research, this research method was assessed and deemed to be appropriate in meeting the objectives set for the study. Secondly, a quantitative research method is expedient in its ability to offer accurate numerical data. Another strength of the quantitative research method is that it is useful when working with large numbers, given the large number of cases that were included in this study.

However, there are some weaknesses associated with quantitative research that Johnson and Onwuegbuzie (2004) identified, and these were also noted when choosing and using this method. The most relevant of these to this study was that it is a narrow research method that can miss other important information related to the phenomenon under investigation. Exploring the expedited review process has the danger of missing other important internal and underlying variables, for example, administration, filing, etc., which may be contributing to ethical review delays. However, important as it is to explore all explanations of human phenomena, it is not always practical. Methodological approaches such as the one used in this study seek only to explore, describe and understand one area.

3.2 Sampling

This section will describe how sampling was done and offer a justification for the choice, given that numerous sampling methods are available for studies like this. De Jongh (1990, p. 46) refers to a sample as “a model of the population or a subset of the population that is to be used to gain information about the entire population”. A population can be defined as the entire list of cases that the study is interested in (Monette, Sullivan & De Jong, 1989). According to Monette *et al.* (1989, p. 132), a representative sample is one that “accurately reflects the distribution of relevant variables in the target population”.

The first step in sampling was to decide what population one plans to study and according to Kish (1965), selection of the population should be based on four factors: content, units, extent, and time. ‘Content’ refers to a distinguishing feature that all members of the population of interest have in common. The unit refers to what the study is interested in studying, i.e., individuals, groups or organisations. This study was interested in examining the timelines in expedited ethics review process at the Biomedical Research Ethics Committee, University of KwaZulu-Natal. Extent refers to the geographical coverage of the study, which was the University of KwaZulu-Natal, Biomedical Research Ethics Committee. Time refers to a period that the units possess, and the characteristics that qualify them for participation in the study.

The sampling method used in the study was a convenience sampling method and will be described below. Sampling has a substantial role in determining the statistical validity of a study. The statistical validity of the study is furthermore determined by sample size (De Jongh, 1990). In this study, a large enough sample was hopefully used in order to reduce the possibility of statistically invalid results. A convenience sampling method was judged to be the most appropriate for this study after careful scrutiny of the following sampling methods. Probability sampling is one sampling method that allows for randomness, which maximises the chances that most members of a population of interest are included in sample for the study (Bryman, 2001). This type of sampling is deliberately structured to reduce researcher bias in the way he/she selects the sample.

Non-probability sampling is less structured than probability sampling and incorporates human judgement in the sample selection process (De Jongh, 1990). There are six types of non-probability

sampling designs (Henry, 1990). The first is *convenience/availability* sampling. With this sampling method, cases are selected based on their availability. The second is most *similar/dissimilar* cases. According to this method, cases are selected based on their apparent similarity or dissimilarity with the conditions of interest.

The third design is *typical* cases. Cases using this design are selected based on their known usefulness and lack of extremity. The fourth design is the *critical* cases design; for this design, only the essential and key cases for what is being investigated are selected for the sample. The fifth design is the *snowball* design. With this design, sample members that have already been judged to be appropriate for the study recommend to the researcher other similar cases known to them. The sixth design is the *quota* design; with this method, the researcher selects a representative sample for the study based on readily identifiable characteristics. Non-probability sampling often makes the results of the study hard to generalize because they usually reflect the views of a restricted sample.

To minimize error discrepancy, it would have been ideal to use probability sampling in the current study. However, due to time constraints, non-probability convenience sampling was employed. Convenience sampling was found to be useful because the investigator in the current study had easier access to UKZN/BREC database.

3.3 Data collection

The design of the study was exploratory. Data was readily available from the UKZN/BREC database subject to the permission of the UKZN Dean of Research, the chair of UKZN/BREC, and the UKZN Registrar (Appendix C). Gatekeeper permission was sought and obtained through letters to the above respective officers. Ethical clearance Ref number BE 347/16.

The researcher sampled and reviewed 200 records of research proposals submitted to BREC for expedited review in two consecutive years, 2013 and 2014. The researcher drew 100 cases from 2013 and 100 cases from 2014. The researcher extracted every third referenced BREC expedited (coded as 'BE') application sent in for BREC review in the years 2013 and 2014, until the sample size of 200 cases was reached. Expedited review is a process applied to research that involves no

more than minimal risk. It requires review by one or two reviewers and does not serve at full REC meetings, and should thus reach a decision before having to wait for a monthly meeting. Expedited review is intended to be faster than full review and is justified by the lower level of risk (BREC, 2010).

The following information was extracted from each case: a) the application reference; b) the date on which BREC received the proposal; c) the date on which the application was sent to reviewers; d) the date on which it was received back from the reviewers; e) the date on which applicants responded to queries; and f) the date that full ethics approval was granted. A pro-forma for data collection (Appendix A) was used to record the dates respectively. Data was readily available from the BREC records which limits bias; in this manner therefore, validity and rigour are ensured.

The results will be related to current and emerging local and international literature on the efficiency of the ethics review process, ultimately with a view to identifying blocks in the system so that remedies can be designed.

3.4 Ethical considerations

It is significant that each time research is conducted, applicable ethical guidelines and considerations must be adhered to. For the purposes of this study a brief review and consideration of these different guidelines was done to ensure that the study is conducted ethically. Below are the eight ethical requirements as asserted by Emanuel *et al.* (2004) which were considered for this study.

1. Collaborative partnership - this means that there should be ongoing partnerships with researchers, makers of health policies, and the community (Emanuel *et al.*, 2004). Everyone should be involved in sharing responsibilities for determining the importance of that particular research, assessing the value of research, etc. In this study, there has been ongoing supervision, the BREC chair and Dean of research deemed the study to be necessary and of potential value to the REC.
2. Social value - research must result in some value for people, for example, institutional improvement, better health or wellbeing, etc. According to this requirement, studies that are not implementable are probably neither valuable nor ethical (Emanuel *et al.*, 2004). The current study was intended to identify specific phases in the review process

associated with delays in the time taken to obtain ethical clearance. This could possibly help the ethical review process be improved.

3. Scientific validity - this requirement calls for studies to be methodologically sound in order to be regarded as ethical (Emanuel *et al.*, 2004). The objectives of the study must be clear, the design principles and methods reliable and able to test the objectives of the study. The current study adhered to widely accepted research methods and processes that addressed the objectives of the study and were judged to be so by independent reviewers of the School of Applied Human Sciences at the University of KwaZulu-Natal. The methodological process was regularly revisited and reviewed throughout the duration of the study to ensure that it remained sound and consistent with the objectives of the study. This study was also supervised by an experienced researcher. This supervision ensured that the scientific rigor of the study was monitored and maintained throughout the duration of the study and that the researcher remained objective at all times.
4. Fair subject selection - selection of participants or data must address the scientific goals of the study. Only sound scientific reasoning can justify the exclusion of participants from the study. This study did not use any human participants and non-probability convenience sampling was used; as discussed earlier, this was because it is the scientifically accepted method of sampling when one takes advantage of the accessibility and availability of the data of interest as was the case in this study.
5. Favourable risk-benefit ratio - this requirement highlights the need for clinical studies to minimize risk for participants and increase the benefits; benefits should always outweigh the risks (Emanuel *et al.*, 2004). Extraneous benefits like money are not included in this definition of benefits, as increasing how much one pays participants will not necessarily reduce the risk that the study poses (Emanuel *et al.*, 2004). There were no risks identified in this study, since there were no participants involved. Confidentiality of the identifiers in the BREC records accessed was assured and maintained and a confidentiality form was signed by the researcher. Only aggregated data are reported.
6. Independent ethics review - this requirement refers to the oversight role of an independent research ethics committee that ensures that all studies adhere to acceptable ethical standards. Independent reviewer(s) can help ensure that scientific rigor and principles are not clouded by researcher interests (Emanuel *et al.*, 2004). The Biomedical Research Ethics

Committee at the University of KwaZulu-Natal, whose responsibility it is to ensure that all research done by registered students is ethical, approved this study BE 347/16 (Appendix D).

7. Informed consent - providing information in culturally and linguistically appropriate formats is very important for a research study to be judged ethical (Emanuel *et al.*, 2004). Although in this particular study, informed consent was not applicable (since there were no human participants), thorough information about the study was given and permission was sought and obtained from relevant gatekeepers.
8. Respect for recruited participants and study communities (Emanuel *et al.*, 2004) - although there were no recruited participants in the study, procedures and measures to protect the confidentiality of the collected data were taken. The researcher did not record or use any identifying information from the protocols accessed and only uniquely coded protocol numbers were created and used.

3.5 Data analysis

Data analysis was done using SPSS. The researcher had to first quantify the collected data. Data was quantified into the number of days taken for each of the phases in the ethics review process. There were no formulas required. The researcher calculated the days it took for each phase of the ethics review to be completed. The researcher calculated this independently and then entered values into SPSS to obtain descriptive statistics: Mean, Median and Mode. Researcher left blank the spaces for the ethical review phases that did not have any dates and for the studies that were not approved to date. Of the 200 cases that were drawn, 100 expedited (BE) cases were from 2013 and other 100 expedited (BE) cases were from year 2014. However only 87 cases from the year 2013 ended up being used for 2013 due to missing values and extreme outliers; extreme outliers were data that was unable to be traced, cohort and longitudinal studies that were still not approved for more than five years which was prone to distort the data. Such cases were probably not revised and resubmitted to the REC after the initial review and should have been closed by after six months. A Taxonomy (Table. 3.5.1.) was developed in discussion with an experienced REC member, and was used to categorise the acceptability of the periods of time taken for each phase of the review process. No international benchmarks for these phases could be located.

Table. 3.5 Taxonomy

Time taken to complete each phase of the review process	Acceptability
3-4 weeks	Highly Acceptable
4-6 weeks	Acceptable
6-8 weeks	Less than acceptable
8-10+ weeks	Unacceptable

Data was then analyzed with descriptive statistics. Mode was examined, this was because considering only the mean is problematic because it is easily distorted by extreme outliers. There were no anticipated problems during the implementation of the study. However, during data collection the researcher encountered difficulty in obtaining data randomly as some files were not clearly recorded as expedited applications, files with inconsistent information and refile of applications. Results are intended to be published as a thesis and submitted to a peer-reviewed journal and a copy made available to the UKZN Research Office and BREC.

The findings are related to current and emerging local and international literature on the efficiency of the ethics review process, ultimately with a view to identifying blocks in the system so that remedies can be designed. Data was readily available which limits bias, in this manner therefore, validity and rigour was hopefully ensured. The information explored in this study was gathered by a person permitted (Appendix C and D) to access the research data. Almost all data that the personnel looked for was quantitative. Therefore, the person who extracted data did not need to exercise any subjective judgment. The duration of the ethics review process, from submission to final approval of each protocol regarded as ‘highly acceptable’, was set at ≥ 30 days, 3-4 weeks in the devised taxonomy.

3.6 Summary

This chapter has provided a description and motivation for the exploratory quantitative design used in this study. This was accompanied by a description of data collected and why convenience sampling was judged to be appropriate for this study. All ethical considerations as discussed by Emanuel *et al.* (2004) were addressed and monitored throughout the duration of the study. The chapter that follows will present the results of this study.

CHAPTER 4: RESULTS

4.1 Introduction

This chapter describes the study findings based on the research questions and the taxonomy (Appendix B) that was developed for this study. The researcher considered 187 usable protocols of the 200 expedited protocols that were initially drawn from the years 2013 and 2014. Of the 187 protocols, 163 protocols had been given full approval and, at the time of this research, 24 protocols were still either not yet approved, or not recorded as approved. The results are accepted as accurate as they were quantified and analysed in exact number of days per stage of review.

Mean, median and mode are all valid measures of central tendency, but when subjected to different circumstances, some measures of central tendency are more appropriate than others. The mean has one main disadvantage: it is particularly susceptible to the influence of outliers. On the other hand, one of the problems with the mode is that it is not unique, so it leaves problems when there are two or more values that share the highest frequency (Groth & Bergner, 2006). The median also has a disadvantage in that it may be difficult to calculate in a large set of data, like in this study; however, it is a good measure of central tendency in that a very big value or a very small value do not affect it (Thompson, Diamond, McWilliam, Snyder, & Snyder, 2005). Mean, median and mode are all considered in this research because they all contribute certain figures that are relevant to the data and present different ways of examining and describing the data (Groth & Bergner, 2006). The results are presented in the section that follows according to the standard sequence in which BREC processes expedited applications.

4.2 Results

Table 4.2: Phase 1: The duration from the date on which BREC received the proposal to the date on which the application was sent to reviewers

<i>Valid cases</i>	178
<i>Missing cases</i>	9
<i>Duration in days</i>	
Mean	11.93
Median	8
Mode	1(25)

Table 4.2 presents the data relating to Phase 1, which is the duration from the date on which the ethics office received proposals to when they were sent to reviewers. The obtained mean was 11.93 days. The median was eight days and the mode was one day. The mode in this phase tells us that mostly it took one day for the ethics office to send proposals to reviewers. According to our guiding taxonomy, the modal time it took for this phase is ‘highly acceptable’ as it is shorter than the 3-4 weeks specified in the taxonomy.

Table 4.3: Phase 2: The duration from the date on which the application was sent to reviewers, to the date on which reviewers returned their reviews

<i>Valid cases</i>	171
<i>Missing cases</i>	16
<i>Duration in days</i>	
Mean	24.22
Median	18
Mode	1(12)

Table 4.3 shows Phase 2 which is the duration it took the reviewers to review protocols. This records the number of days between the date on which it was sent to reviewers to the date on which the reviewers returned their reviews. It shows that it mostly took only one day for reviewers to review and send feedback as the mode was equal to 1. However, the mean and median, although affected by the extreme outliers, show that it took a mean of 24.22 days and a median of 18 for the reviewers to return their reviews. According to our guiding taxonomy, the time it took this phase is ‘highly acceptable’ as it ranges below 3-4 weeks of the taxonomy.

Table 4.4: Phase 3: The duration from date on which the reviews were returned by reviewers, to the date on which applicants responded to queries

<i>Valid cases</i>	163
<i>Missing case</i>	24
<i>Duration in days</i>	
Mean	65.85
Median	42
Mode	14(8)

Table 4.4 presents the data relating to Phase 3, which is the duration from the date provisional approval was given to the date on which applicants responded to queries. This phase was for finding out how long it took the applicants to respond to queries. The mode was 14 which means that most of the time it took applicants 14 days to respond to the reviewers’ feedback. The mean was 65.85 days and median was 42 days. For this phase, although the mode of 14 days means this phase falls under the ‘highly acceptable’ category, the mean shows that it took almost three months for applicants to respond to queries. According to our guiding taxonomy, the time it took this phase is thus ‘less than acceptable’ as it ranges above the 6-8 weeks specified in the taxonomy.

Table 4.5: Phase 4: The duration from the date on which applicants responded to queries to the date on which ethics approval was given

	<i>Valid cases</i>	153
	<i>Missing cases</i>	34
<i>Duration in days</i>		
Mean		41.20
Median		17
Mode		1(16)

Table 4.5 presents Phase 4, which is the duration from the date on which applicants responded to queries to the date on which ethics approval was given. This is the final phase of the expedited BREC review process and its turnaround time is highly dependent on how fast the committee reviews necessary amendments. It shows that after applicants have fully responded to queries, full approval is usually granted, with the mode as one day, although the mean and median were 41 and 17 days, respectively. According to our guiding taxonomy, the time it took this phase is ‘acceptable’ as it ranges above the 3-4 weeks specified in the taxonomy.

Table 4.6: The duration period it took the entire ethics process to be completed

	<i>Valid cases</i>	163
	<i>Missing cases</i>	24
<i>Duration in days</i>		
Mean		155.72
Median		136
Mode		140(8)

Table 4.6 shows the duration from the date on which protocols were received from the applicants to the date on which they were finally approved by the BREC. It shows a mode of 140 days (5 months or 20 weeks), and a mean and median of 155.72 and 136 days, respectively. According to the results, shown in Table 4.2.5, the total duration of the UKZN/BREC expedited review process falls under the ‘unacceptable’ (more than 8-10 weeks) category of the taxonomy.

Table 4.7: The turnaround times (in days) of the expedited review process at UKZN/BREC

	Phase 1	Phase 2	Phase 3	Phase 4	Total duration of the entire UKZN/BREC expedited review process
<i>Valid cases</i>	178	171	163	153	163
<i>Missing cases</i>	9	16	24	34	24
<i>Duration in days</i>					
Mean	12	24	66	41	156
Median	8	18	42	17	136
Mode	1(25)	1(12)	14(8)	1(16)	140(8)

Fig 4.2.1: The turnaround time (in days) of the expedited review process at UKZN/BREC

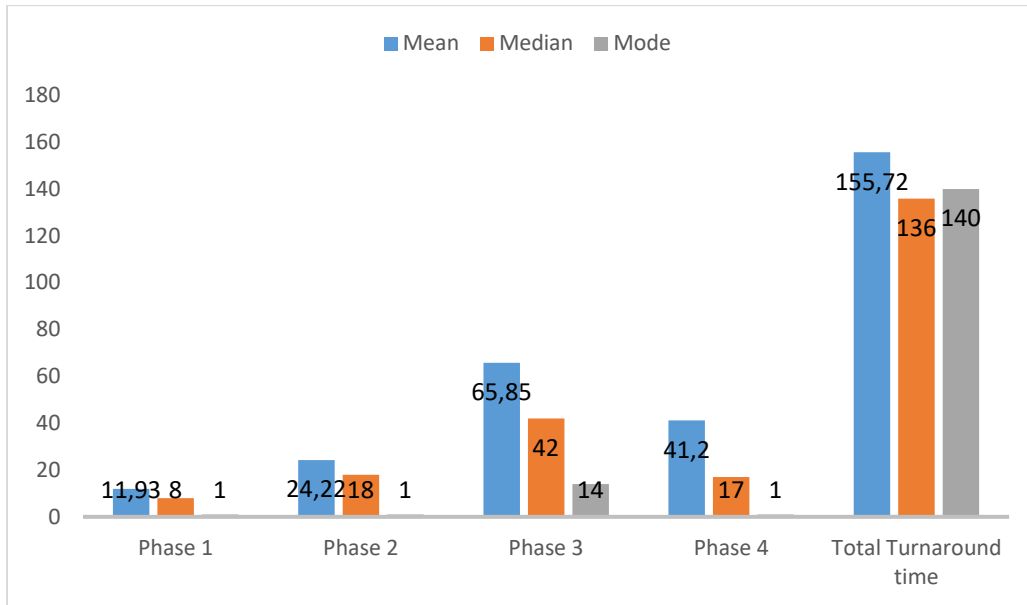


Fig.4.2.1 shows that Phase 3 of the UKZN/BREC expedited review process took the longest, compared to other phases. In terms of duration, these phases can be ranked in descending order as follows: Phase 3 > Phase 4 > Phase 2 > Phase 1. According to this study, Phase 3 shows the duration between the provisional approval and the responses of applicants to queries. Thus, this phase records how much time it took applicants to respond to queries. The results showed that it took a mean of 65.85 days, a median 42 days and a mode of 14 days for applicants to respond to reviewers’ feedback.

Table 4.8: Pre-review versus Post-review

	Pre-review (Phase 2)	Post-review (phase 4)
mean	24	41
median	18	17
mode	1(12)	1(16)

Table 4.8, show the difference between the time it took initial phase of the review process and the time it took the final phase of the review process. The results show that it took a mean of 24 for the first review and the mean of 41 for the final review. The median was 18 and 17 respectively and the mode of 1 for both phases.

According to this study, Phase 4 was the second longest phase of the UKZN/BREC expedited review process. Phase 4 shows the duration from the date on which applicants responded to queries to the date on which ethics approval was given. In this study, this phase was for finding out how much time it took the committee to issue to give full approval after applicants had responded to queries. The results showed that it took a mean of 41.2 days, a median of 17 days and a mode of one day for reviewers to give full approval after queries had been responded to by applicants.

According to this study, Phase 2, was the third longest phase of the UKZN/BREC expedited review process. Phase 2 reflects the duration from the date on which the application was sent to reviewers to the date on which reviewers returned their reviews. In this study, this phase was for finding out how long it took the reviewers to return reviews. The results showed that it took a mean of 24.22 days, a median of 18 days and a mode of one day for the reviewers to return their reviews.

Phase 1, according to this study, was the shortest phase of all other phases in the UKZN/BREC expedited ethics review process. Phase 1 is the duration from the date on which BREC received the proposal to the date on which the application was sent to reviewers. In this study, this phase was for finding out how much time it took reviewers to receive applications after applications had been sent to the BREC office. This phase showed that it took a mean of 11.93 days, a median of eight days and a mode of one day for the BREC office to send applications to reviewers.

4.3 Summary

It can be said that most results for each phase of the ethical review process fell into the 'highly acceptable' category of the taxonomy; however, the total duration of the entire UKZN/BREC expedited review process showed that it took a mean of 155.72 days, a median of 136 days and a mode of 140 days, which means that, it often took about 140 days (20 weeks) for the entire UKZN/BREC expedited ethics review process. This seems slow for expedited review. The results also show that the longest portion of the review process was the time taken by applicants to respond to queries reviewed by the REC. The results are discussed more fully in the following section.

CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter covers the main findings relating to the two research questions in line with the study objectives. The findings show that for the entire expedited review process, the modal time it takes is 140 days with a mean of 155.72 days. This finding concurs with several studies that looked at RECs' duration to approve studies, especially in the US (Abbott & Grady, 2011; Mamotte & Wassenaar, 2009). As also confirmed by Ashcraft and Krause (2007), 50% of the 'slow' documented times went beyond a five-week turnaround time, and 20% went beyond three months. This was further confirmed by Clarke (2012, p. 24) as he concluded that "obtaining ethics approval for MMed studies was a lengthy process" and Cleaton-Jones (2010) who found that few studies received full approval at the first review, which prolongs the duration of the ethics approval process.

5.2 What are the modal and average times taken for BREC review of expedited applications?

The results show that the modal time taken by BREC review of expedited applications was 140 days and the average time taken by BREC review of expedited applications was 155.72 days. This finding is not unusual, as there is considerable literature verifying the bureaucratic deferments relating to ethics review. For example, Cleaton-Jones (2010, p. 21) 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". Cleaton-Jones (2012) 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. Angell et al (2009) in the UK 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. No data was provided by these authors on actual days involved.

5.2.1 *Negative impact on academic progress and knowledge generation*

Results showed that the modal and average for the time taken by UKZN/BREC review of expedited applications were 140 and 155.72 days, respectively. This, at most was a duration of

five months. Five months is a significant amount of time for applicants to be anticipating their study's ethics approval. This delay had previously been confirmed by other scholars. For example, according to Clarke (2012, p. 24), it took an average of 14.8 weeks (103 days) for BREC to approve "each of 53 proposals (range: 3-32 weeks). Of these, 21 (39%) received provisional approval in the first response". Specifically for multi-center studies, Ahmed and Nicholson (1996) assert that, overall, one-third of local RECs were unable to approve a project within three months, and three of the 36 (8%) took longer than six months. Although these figures were reported twenty-one years ago, they suggest that obtaining ethics approval remains difficult and time consuming.

According to Ashcraft and Krause (2007, p. 12), "time (i.e., waiting time for approval) appears to be the main reason for violating federal regulations about prior REC approval. In fact, time was even mentioned by three respondents". The same applies to the current study. The slow turnaround time presented in this study has the potential to affect researchers' choice of research. Researchers might resort to research that requires no external gatekeeper permission or even research that involves no human participants, in order to avoid ethics approval delays. This, therefore, can result in research value being diminished, and important and critical research not being done (Cleaton-Jones, 2010). According to Baarts (2009), research ethics is based on the researcher's understanding of the subject of inquiry: "both scientific knowledge of the topic and insight into the role and status of the subject matter. However, the inevitable uncertainty involved always makes an ethical decision 'greater' than the researcher himself" (Baarts, 2009, p. 433).

While researchers have a responsibility to familiarize themselves with the ethics review process at their institution, there is also a need for institutions to actively educate their academic staff and students on the ethics review process. Not only in terms of the requirements that need to be fulfilled, but in terms of the purpose, goals, process, and practices of the research ethics committee (Wassenaar and Slack, 2016). The ethics education of researchers should not only be at the level of relating documentations, but should show how distinctive ethical issues are resolved in areas where there is much uncertainty. For example, workshops could be scheduled in which specific research problems are examined or in which simulated good and poor protocols

are presented and discussed with the opportunity for mutual learning. According to Wassenaar and Slack (2016, p. 310), “applicants should use a systematic framework to think about ethical issues in their research and application. The framework that is most applicable and all-inclusive is that, proposed by Emanuel, Wendler, Killen, and Grady, (2004)”

5.3 Which phase of the review process took the longest?

There is an often overlooked distinction, when discussing turnaround time, between pre-review delays and post-review delays. The pre-review is the review that results in provisional approval and the post-review is the review that follows after applicants have responded to provisional approval queries; post-review typically results in full approval. In this study, the results showed that Phase 3, the time taken by researchers to respond to provisionally approval queries, was the largest component of the pre-approval delay period and this ended up affecting the whole review process turnaround time. More research is needed to verify and explore this element of slow approval times.

As argued above, Phase 3 is the duration from the date on which the review was returned to the applicants from the reviewers, to the date on which applicants responded to queries. As shown in Table 4.2.3, this was the phase that took the longest, with a mode of 14 days and a mean of 65.85 days. This can be interpreted as applicants taking almost three months to respond to queries. It is highly noticeable that there is a lack of association between protocol submission and approval time, as much as results of this study show that applicants are the ones who delay. However, factors around the applicants’ delays in responding cannot be assumed to be solely associated with laziness. Further investigations on what makes applicants respond slowly to reviewers’ queries is recommended, because if it is a matter of straightforward amendments, the turnaround time for this phase should have been no more than four weeks.

5.3.1 Pre-review versus post-review

When one compares the turnaround time of the two review phases (the pre-review which in this study is Phase 2 and the post-review which is Phase 4), the results showed that Phase 2 took a mean of 24.22 days while Phase 4 took a mean of 41.20 days. This shows that the pre-review Phase 2 took a much shorter time than the post-review Phase 4. One would expect that the

turnaround time for the pre-review and the post-review would be similar or slightly different. It can be further expected that the pre-review would be longer than the post-review; however, in this study, the pre-review phase had a shorter turnaround time than the post-review.

The question to ask is why the post-review phase took longer than the pre-review. Generally, post-review should have a shorter turnaround time than pre-review because, with the post-review, reviewers are already familiar with the applications and may recall all issues that were posed as queries in the pre-review. The lack of an electronic review management system or understaffing could typically account for post-review period delays. However, “RECs cannot be held accountable for delays caused by researchers themselves while responding to legitimate REC queries and requirements” (Wassenaar & Slack, 2016, p. 312). A longer post-review turnaround time is also seemed more likely to occur when revised applications are assigned to different reviewers who were not assigned for the same application in the original review. This has a potential to prolong post-review turnaround time as the reviewers would be faced with a situation where they have to review a previously reviewed application for the first time, and this may introduce endless queries resulting in a slow turnaround time of the UKZN/BREC expedited review process.

As much as RECs should see to it that research is scientifically and ethically sound, they should not be the reason that research ends up being done late or not done at all due to their bureaucratic review procedures. The main concern of a REC should be to ensure that ethical standards are maintained, both in theory and in practice, and operate within the ethical and legal frameworks of its host country. It is possible that applicants delay in responding to queries due to discouraging or perhaps unachievable demands that reviewers request (cf. Tsoka-Gwegweni & Wassenaar, 2015). This could provide one explanation for the long delays of about three months that applicants take to respond to queries.

5.3.2 Lack of ethics review knowledge

A lack of knowledge of the principles and practices that govern REC decision-making and perhaps uncertainty of REC members may result in poor review. Halse and Honey (2007) assert that long turnaround times may unintentionally nurture the type of ‘unethical’ researcher that the

ethics process is seeking to exclude. According to Ashcraft and Krause (2007), The REC was in short of members that were knowledgeable in the researcher's field of study so that timely and necessary responses could be given. In their study, 22% of participants confirmed the statement that "My REC always takes a long time, regardless of the specifics of the proposal" (Ashcraft & Krause, 2007, p. 322). Furthermore, according to Ogunrin *et al.* (2016), the decision made on the first review of the protocol is strongly associated with the time the protocol is going to take in the ethics process. A provisional approval means that applicants must go through their protocols and resubmit them, and have it reviewed again by the REC. According to this study, revision and resubmission of applications potentially resulted in a considerable period of three months passing before a constructive judgment was achieved. Therefore, it can be said that provisional rather than immediate approval was associated with delays in timeous ethics approval.

Researchers' resistance and frustrations concerning the ethics review process can be separated into principled and pragmatic objections (Wassenaar and Mamotte, 2012). Principled objections are from those who assert that ethics review restricts academic freedom (Oakes, 2002; Wassenaar and Mamotte, 2012) and those who feel that there is an intrinsic responsibility in researchers and therefore ethics review is unnecessary and offensive (Whittaker, 2005). According to Dada and Moorad (2001), delays resulting from proposals being returned for revision are said to be the result of incompetence or poor ethics knowledge on the part of the researchers. This is also argued by Sieber (1992) who said that if researchers were more knowledgeable in the ethical dimensions of research, their applications would be unlikely to require revision. However, RECs may also be accused of incompetence in their reviews (Oakes, 2002; Whittaker, 2005). Various frustrations linked to ethics review, could be reduced if applicants were motivated to get their protocols 'right' on the earliest time of submission (Wassenaar & Slack, 2016).

5.3.3 Clearly regulate turnaround times

Slow turnaround time of REC review affects researchers' satisfaction with the ethics review process and their ethics compliance (Ashcraft & Krause, 2007; Liddle & Brazelton, 1996, Mamotte and Wassenaar, 2009). RECs should give researchers clear advance indication of typical review turnaround timelines and adhere to these wherever possible. RECs should also

ensure that researchers are familiar with REC submission dates and turnaround time so that researchers can factor the ethics review process into their schedules. Inadequate review may make researchers feel powerless and inclined to sabotage the review process (Seahloli, 2015). The Principles of Research Ethics Framework states that “research should be designed, reviewed, and undertaken to ensure integrity and quality” (Faden *et al.*, 2013, p. 12). Some variations are allowed in exceptional research contexts.

5.4 Summary

Slow turnaround time of the UKZN/BREC appeared to be mainly influenced by the time applicants took to respond to queries and secondly by the time reviewers took to review and respond to revisions. The results established that the time it took the applicants to respond to queries was the longest phase of the UKZN/BREC ethics review process. The entire UKZN/BREC ethics review process took a mean of 155.72 days, a median of 136 days, and a mode of 140 days. This is a notably long and unacceptable duration for expedited studies to be approved.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The timeframes of a sample of expedited reviews at the UKZN/BREC were identified and evaluated and the phases in the review process associated with major delays in obtaining ethics clearance were identified. The study showed that the UKZN/BREC expedited review process had a slow overall turnaround time. The phase that contributed most to the slow turnaround time was Phase 3. This is the time it took applicants to respond to queries. In other words, the time applicants took to submit amendments to the UKZN/BREC. This phase is not under the control of BREC. The applicants' delay in responding probably has many contributing factors. Some of these factors could be inefficiency of applicants, discouragement by reviewers' queries, receiving gatekeeper permission very late and other factors that could be confirmed by further research. Therefore, further research is necessary to establish what made applicants respond later than expected, and to confirm or disconfirm the above assumptions. Recommendations can then be made based on this outcome.

In conclusion, according to Allen (2009), RECs reflect a system of control which guides researchers and the process of research. UKZN/BREC should improve administration and governance that empowers good research by collaborating with researchers in the ethics review procedure. An electronic review management system is likely to reduce those sections of the review and approval process that are under the REC's own control. Researchers should also be willing to accept temporal realities that may not accord with their research anticipations and ideals. For example, an electronic ethics review management system like RHInnO Ethics. RHInnO Ethics aims to speed up the review process by improving efficiency. The system provides RECs with a secure, web-based solution for tracking research applications throughout the entire life-cycle of the research project. This will improve control of research activities by RECs and could contribute to safer and more reliable management of submitted materials and minimize delays in the ethics review process at UKZN/BREC (<http://www.rhinnolabs.com/>).

6.2 Study recommendations and further research

This study showed that obtaining expedited ethics approval at the UKZN/BREC took an average duration of 155.72 days, with a mode of 140 days. The ethics review phase that took the longest was the period from the return of reviews to the time applicants responded to queries, with a mean of 65.85 days and a mode of 14 days. Reviewers also took time to review protocols - the average duration they took to pre-review protocols was 24.22 days, while for post-review the duration was 41.20 days. However, the longest delays were from the applicants themselves failing to respond to queries within an acceptable period of time. An in-depth qualitative study to look at factors contributing to these different delays is recommended as there are many studies that confirm that there are delays in the ethics review process. For example, a study by Ashcraft and Krause (2007) showed that some researchers end up doing modifications without going back to REC for approval, with the reason given being: “Yes, because I knew it would take the IRB too long to act on the modifications” (p.12) Specific studies on what makes researchers respond so slowly to ethics review queries are highly recommended as it appeared in this study that the time it took the researchers to respond to queries was the longest phase of the ethics review process. Furthermore, studies on understanding the pre-review and post-review turnaround times are recommended, as in this study the post-review phase happened to be longer than the pre-review.

6.3 Recommendations for interventions

6.3.1 Clarify the requirements for expedited review

UKZN/BREC should make clear to researchers, through clear and appropriate channels of communication (e.g. standard operating procedures and guidelines), what research qualifies for expedited review. Researchers and UKZN/BREC should, whenever possible, be mindful of the timelines within which they need to work and plan accordingly. UKZN/BREC should assign members whose expertise most closely matches the methodology of the study to conduct expedited review. Electronic submission and review systems should be implemented for expedited reviews, so that reviewing can be done quickly through online communication.

The rate of first-time approved protocols can be increased if researchers improved the ethical standard of the initially submitted protocols. Improving the standard of protocols can assist in

moderating administrative workload. With lower REC administration workload, protocols will have the potential to be given priority and hence shorter turnaround time may be achieved (Cleaton-Jones, 2015). Furthermore, to avoid misunderstanding and misinterpretation of protocols, once reviewers are assigned to specific protocols, they can conduct 'video call reviews' with researchers through skype or any other possible video call application. This would mean that every researcher applying for expedited review will be required to have a skype account or any other similar account so they can clarify with reviewers where there seem to be complications. This could reduce misunderstanding of the protocol between the researcher and the reviewer and hence speed up the turnaround time at the UKZN/BREC.

6.3.2 Assist researchers with protocol development and submission.

UKZN/BREC should give regular workshops for researchers to help them to understand research ethics and protocol development (Wassenaar & Slack, 2016). There should be trained research ethics academics in every research-oriented department who are prepared to consult with investigators preparing a protocol, and wherever possible, there should be a senior BREC member in each research-oriented department who can consult informally in the project and protocol development stages. There should be ongoing improved training for REC members. This is not solely recommended for UKZN/BREC; rather, it is legal requirement (DoH, 2015), because it is not necessarily a matter of how well resourced a certain REC is, but rather it is a matter of how efficient it is in its review turnaround time. In addition, it is also a South African NHREC guideline requirement that "all REC members receive initial and ongoing training in research ethics" (p. 59), no argument is necessary for this point as it is a clear requirement for RECs.

6.3.3 Undergo periodic evaluation

"The RECs process is too important not to undergo periodic evaluation" (Office of the Inspector General, 1998a, p. 20). It is furthermore a requirement from the (DoH, 2015), that all South African RECs should be regularly audited. Audits can help UKZN/BREC to determine whether applications are reviewed within an acceptable period of time. In addition, they can help identify what slows applicants' responses to the initial reviews, and whether slow turnaround times are

preventing critical, socially valuable research from happening (Office of the Inspector General, 1998).

6.4 Limitations of this study

The sampling approach adopted in this study may have had a bearing on the reliability and validity measures. Further studies using a diverse, randomly selected and stratified sample and using additional qualitative methods could perhaps have shed more insight. Furthermore, this study was restricted to a single university, and cannot be generalized across institutions. This study did not attempt to identify whether any specific types of minimal risk studies or research designs took longer to be approved than others. It must also be acknowledged that the taxonomy of acceptable and unacceptable review periods (Table. 3.5.1) was rather arbitrary and could be criticised. It was, however, constructed in the absence of any relevant guidance or international benchmarks for expedited review.

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APPENDIX A: DATA PRO-FORMA.

Ethical review process	1. Date Application Received	2. Date Application sent to reviewers	3. Date Application back from reviewers	4. Date Feedback sent to Applicants	5. Date Revision Received from Applicants	6. Date of final Approval	7. Total days to approval	
						Provisional Approval	Full Approval	Total full approval
Time		Days	Days	Days	Days	Days	Days	Total days

APPENDIX B: TAXONOMY

Time taken to complete each phase of the review process.	Acceptability
3-4 weeks	Highly Acceptable
4-6 weeks	Acceptable
6-8 weeks	Less than acceptable
8-10+ weeks	Unacceptable



18 May 2016

Mrs Brightness Cebisile Nxumalo (SN 208526094)
School of Applied Human Sciences
College of Humanities
UKZN
Email: cebincube@gmail.com

Dear Mrs Nxumalo

RE: PERMISSION TO CONDUCT RESEARCH

Gatekeeper's permission is hereby granted for you to conduct research at the University of KwaZulu-Natal (UKZN), towards your postgraduate studies, provided Ethical Clearance has been obtained. We note the title of your research project is:

"An examination of timelines in expedited ethics review process at the University of KwaZulu-Natal, Biomedical Research Ethics Committee".

It is noted that you will be constituting your sample by obtaining institutional data from UKZN/BREC database.

Data collected must be treated with due confidentiality and anonymity.

Yours sincerely

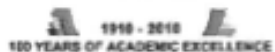

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20 June 2016

Mrs Brightness Cebisile Nxumalo (208526094)
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PMB Campus
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Dear Mrs Nxumalo

Protocol: An examination of timelines in expedited ethics review process at the University of KZN, Biomedical Research Ethics Committee.

Degree: Masters

Your correspondence dated 12 May 2016 refers.

Please note that the Chair of BREC has considered your request and granted permission to access and sample UKZN BREC "BE" records.

Yours sincerely

Ms Anusha Marimuthu
Senior Admin Officer: Biomedical Research Ethics Committee

cc supervisor: Prof D Wassenaar