# CHALLENGES ENCOUNTERED WHEN APPLYING FOR THE ETHICS AND PERMISSION TO CONDUCT THE NON-CLINICAL TRIAL STUDY IN THE HOSPITALS AND CLINIC

*Article Review by Michael Sello Seahloli, South Africa*
*(M.Sc., Ph.D., in Clinical Research Student of Texila American University)*
*Email: - sellos@onqsa.co.za*

## ABSTRACT

A case study on the process of applying for ethical and provincial clearance to conduct a medical informatics research for a PhD programme in South African Hospitals. The programme was looking for current status of medical informatics and implementing electronic healthcare record, challenges, and future direction in South Africa. Nine provinces were contacted and all approved the study, however, the approval was obtained after averaged of 9 months which was longer than expected. The public hospital CEOs and medical managers were also contacted to acknowledge participation and give clearance for the study to be conducted at hospitals. After an average of 3 months to give clearance and out of 40 hospitals contacted only 70% acknowledged. Overall the process took longer than expected to approve a non-clinical trial study for academic purpose. This has delayed the start of the PhD research program and the challenges encountered in the provinces applications are due to autonomy and lack of standardisation of procedure between the provinces, lack of understanding the procedure of the study by the province personnel and hospitals, lack of expertise in handling electronic submissions and non-clinical trial submissions. IT is still a challenge to most of government employees and the infrastructure that can accommodate amount of information.

## KEY WORDS

Ethics committee, South African Provincial clearance, Hospital clearance.

## INTRODUCTION

This case study report was developed from the process when the researcher tried to apply for ethical and provincial clearance to conduct a medical informatics research for a PhD programme. The programme was looking for current status of medical informatics and implementing electronic healthcare record, challenges and future direction in South Africa. During this process the researcher encountered challenges when trying to obtain approval from the provinces. In

South Africa, there are new requirements for formal research component and this increases the workload for health research ethics committees (HRECs) which all so affect the approval and processing of study approvals. This also affects the postgraduate curriculum timelines [1]. An average time taken by The University of Kwazulu-Natal ethics – Biomedical Research Ethics Committee (BREC) took 15 weeks to respond to a proposal. According to Clark report only 43% of studies received provisional approval on the first review and 53 % did not get provisional approval and he felt that the ethical approval for Masters Projects are taking too long to be approved [2]. There are few articles published on provincial clearance and hospital clearance in South Africa and other countries. Majority of articles published refers mainly to ethics committee. Prof. Cleaton-Jones also reported that only 27% of proposals received provisional approval on the first review and 69% requires a revision at Wits University ethics committee [2]. At the United Kingdom (UK) National Health Services Ethics committee, only 15% of the proposals received provisional approval and 64% needed revision [3].

Regulatory and ethics review of clinical trial projects are important to ensure that research that is conducted is ethical and safe on humans [4]. The process of approving projects for academic institution and non-clinical trial project are prolonged and there were different reasons for the delay [1,2,3,4]. The delay is mainly caused by: 1. The procedural violation whereby essential item required are not enclosed in the application including approval from the head of the department, signature of the applicant and lack of supporting signatories, the standard of the proposed investigation and financial support of the project. 2. Missing information. 3. Slips up like failing to specify age of the participants and sample size. 4. Discrepancies that lead to inconsistencies between the sections. 5. Consent issues 6. Participant confidentiality. 7. In appropriate choice of study population or studies cause psychological discomfort and there is no counselling planned in the study and lastly legal issues where like obligation to provide information on the study. [1,2,3]. These also affect the approval of the low risk and non-clinical research projects [1,4]. The long time in delaying approval of research in general will increase the costs, delay academic programs, impede the conduct of research critical areas and frustrate the researcher [1,2,3,4,5,6,7].

Geldenhuys et al supported that the delays in regulatory approval is caused by protocol factors and or by the capacity of the ethics or regulatory body reviewing the proposed research project. The delay regulatory approval in South Africa is not significantly influenced by the complexity of the proposed project or safety risk associated with the proposed research project. The capacity and administrative limitations are major cause of regulatory approval. The other factors that a noteworthy are lack of correlation between project submission and approval time that require resubmission or clarification [5, 6]. Clinton-Jones and Voster confirmed that since 2007 to 2013 there was unexplainable increase in general research workload and may be this was due to emphasis on staff research by the University [8]. Mostly delayed studies are those involving nobel vaccines, microbicides and combination drug treatments and probably they require to be

reviewed by the regulators before the protocol is finalized [9]. However, the non-clinical trials should be impacted by these processes and issues regarding approval of these studies.

Despite relatively low risk associated primary care practice-based research networks (PBRNs) and non-clinical trial projects, challenges remain for the researchers seeking provincial, ethics and regulatory approval for these investigations or researches [10 11]. Publications dealing with process errors in ethics applications are few and are limited to some departments [3, 12,13] but none were found that are related to process and request to conduct studies in the 9 provinces of South African to archive a post graduate curriculum or non-clinical trial research.

The objective of this case study is to report the challenges encountered when applying for the South African provincial clearance and permission to conduct a medical informatics research in the hospitals and clinics for fulfilment of PhD degree.

## METHODOLOGY

The researcher started by developing the protocol for the research and performed a search for the contact details of the department of health Head of Departments (HODs) in each province in South Africa. The provinces offices were contacted, the researcher received several responses where the researcher was advised on whom to contact to get approval to conduct a study and the procedure to be followed. The researcher followed all the guides given and also submitted the study to the private ethics committee as guided by provincial offices. Responses and queries from the Ethics and the provinces were received by the researcher and the researcher responded to all queries. Researcher prepared all the documents requested by the provinces. During the process of preparing of the documents, there were number of communications, between the researcher and institutions including the hospital chief executive officers (CEOs) and ethics committee.

The hospitals were randomly selected from the list of hospitals in South Africa in the 9 provinces. The contact details of the CEOs were searched through the internet, from the province and by contacting the hospitals directly. The CEOs of the selected hospitals were contacted and the researcher sent a formal letter requesting permission to conduct a study at their hospitals. The researcher tracked all the contacts made with the province personnel and the hospitals.

## RESULTS

All provincial health departments were contacted for information seeking to approve a medical informatics from 27 February2014. The province gave information to the researcher and most of the information. Some of the provinces were not sure where to refer the research to for information regarding the application to conduct a medical informatics research. Requirements provided by the provinces are present in Table 1 below. The process of proving this requirement took about three months to get all the requirements and the relevant personnel that deal with application to conduct studies. The provinces requested the application to be accompanied with

the protocol, participation information leaflet, ethics approval from any registered ethics committee in South Africa. Some of provinces requested application form to be completed and to submit. Kwa-Zulu Natal was the only province requested the researcher to first get permission from the hospitals and once approved to attach the approval letters to the application and sent to the province.

The ethics approval was not available and the researcher obtained provisional approval in June 2014 and final approval in September 2014. The pending ethics committee approval was sent to the department who gave the relevant person to be contacted and most took longer than expected to respond. The procedure for application is not the same in all provinces. Each province followed its own procedure to approve the study.

**Table 1: Requirements of provinces**

| Province No | Ethics | Hospital Permission | Application form | Participant Informed Consent |
|---|---|---|---|---|
| P01 GP | Yes | No | Yes | Yes |
| P02 LP | Yes | No | No | Yes |
| P03 NW | Yes | No | No | Yes |
| P04 FS | Yes | No | No | Yes |
| P05 MP | Yes | No | Yes | Yes |
| P06 ZN | Yes | Yes | Yes | Yes |
| P07 NC | Yes | No | Yes | Yes |
| P08 EC | Yes | No | No | Yes |
| P09 WC | Yes | No | Yes | Yes |
| | 9 | 1 | 5 | 9 |

## *GAUTENG HEALTH DEPARTMENT (GP) (P01)*

Province Number 01 Health Department (P01) was followed up on the 25 March 2014 after having no response on the initial contact. There was still no response on the 2nd attempt and the third follow-up was done on the 6 June 2014. On the 17th June, the researcher contacted the secretary of P01 telephonically and the secretary told the researcher that the request was forwarded to Departmental doctor handling the applications and approvals. On the 18 June 2014 the first response was received from P01 requesting ethics approval. The approval was pending

and it was sent to the P01 on the 4 September 2014 with all other documents requested. P01 was followed up on the 29 September 2014. P01 responded and promised that they are in discussion with other department and will get back to the research as soon as possible. The researcher followed up on the 15 October 2014 and there was no response and another follow-up was made on 24 October 2014. The researcher sent a complaint to the province officials on the 7 November 2014 to complain about the slow process of processing the application to conduct a medical informatics research in P01. On the same day P01 responded and apologized for a slow process and requested the researcher to complete the additional document (application form which was never sent the researcher before). On the 10 November 2014 the researcher sent the completed application form. The researcher followed up on the 14 Nov 2014 and the approval was sent to the researcher on the 17 November 2014.

Letter to requests to conduct a study in 6 (six) P01hospitals were sent to all hospitals on the 18 November 2014. On the 27$^{th}$ of November, none of the hospitals acknowledged the request. A follow up was done on the 27$^{th}$ November 2014 for hospital Charlotte Maxeke Hospital (P01-H02). The rest of the 5 hospitals (Zola Jabulani hospital (P1-H01), Tembisa Hospital (P01-H03), Steve Biko Hospital(P01-H04), Sebokeng Hospital (P01-H05) and Natalspruit Hospital (P01-H 06)) were followed on the 30 Nov 2014.Hospital P01-H05 referred the researcher to another person and the mail was sent and till the end December 2014 there was no response. After several communications and follow-ups, the following hospitals approved the conduct of the study in their hospitals: Zola Jabulani (P01-H01), Charlotte Maxeke (P01-H02), and Natalspriut Hospital (P01-H06). Tembisa Hospital (P01-H03) and Steve Biko (P01-H06) was still pending. Sebokeng hospital refused to participate. Results of hospitals contacted, approved and number of months taken to get approval from the hospitals are presented on Table 2 and 3 below.

**Table 2: Number of months taken by the hospitals to approve the study**

| Province No | No of contacts | No of Tel contacts | No resend docs | Redirected to new | No of Months of com | No of approvals | No of Months to approve | No of Months since actual person | No of Months since Ethics |
|---|---|---|---|---|---|---|---|---|---|
| P01 GP | 10 | 9 | 3 | 2 | 9 | 1 | 9 | 6 | 3 |
| P02 LP | 7 | 3 | 1 | 0 | 8 | 1 | 8 | 6 | 2 |
| P03 NW | 6 | 3 | 1 | 0 | 7 | 1 | 7 | 6 | 2 |
| P04 FS | 5 | 4 | 1 | 1 | 6 | 1 | 6 | 6 | 1 |
| P05 MP | 6 | 4 | 1 | 1 | 7 | 1 | 7 | 5 | 1 |
| P06 KZN | 8 | 3 | 2 | 1 | 12 | 1 | 12 | 9 | 1 |
| P07 NC | 10 | 3 | 2 | 1 | 12 | 1 | 12 | 10 | 6 |
| P08 EC | 15 | 3 | 3 | 2 | 11 | 1 | 11 | 10 | 5 |
| P09 WC | 15 | 3 | 3 | 0 | 11 | 1 | 11 | 8 | 5 |
| Sum | 82 | 35 | 17 | 8 | 72 | 9 | 83 | 66 | 26 |
| SD | 3.77 | 1.96 | 0.93 | 0.78 | 2.33 | 0 | 2.33 | 1.94 | 1.96 |
| Median | 8 | 3 | 2 | 1 | 9 | 1 | 9 | 6 | 2 |
| Average | 9.11 | 3.89 | 1.89 | 0.89 | 9.22 | 1 | 9.22 | 7.33 | 2.89 |

**Table 3: Number of months took by the hospitals to approve the study**

| Province No | No of Months Hospital took approve research | | | | | average | median | SD |
|---|---|---|---|---|---|---|---|---|
| P01 GP | 3 | 4 | 2 | 5 | 5 | 3.8 | 4 | 1.30 |
| P02 LP | 2 | 0.2 | 0.2 | | | 0.8 | 0.2 | 1.04 |
| P03 NW | 6 | 5 | 1 | 6 | 1 | 3.8 | 5 | 2.59 |
| P04 FS | 4 | 1 | 5 | 7 | 7 | 4.8 | 5 | 2.49 |
| P05 MP | 4 | 4 | 3 | 3 | | 3.5 | 3.5 | 0.58 |
| P06 KZN | 4 | 5 | 2 | 4 | 1 | 3.2 | 4 | 1.64 |
| P07 NC | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 0 |
| P08 EC | 3 | 5 | 3 | | | 3.67 | 3 | 1.15 |
| P09 WC | 0 | 0 | 0 | 0 | | 0 | 0 | 0 |
| | | | | | | 3.17 | | |

## *LIMPOPO HEALTH DEPARTMENT (LP) (P02)*

Limpopo Health Department (P02) was followed up on the 5 June 2014 and responded to the request, where it requested ethics approval from any ethics committee and by then the ethics approval was not obtained. The researcher applied for the ethics and the approval was forwarded to P02 on the 4 September 2014. On the 29 September 2014, P02 was followed up to check if they received the ethics approval and they have processed the application. P02 secretary responded and informed the researcher that the application was sent to the reviewers. On the 15 October 2014, a follow-up email was sent to P02 and the application was still with the reviewers. The approval was received on the 21 October 2014.

Letters to request to conduct a study in 4 (four) P02 hospitals were sent to Louis Trichardt Hospital (P02-H02) and Tshilidzini Hospital (P02-H04) on the 27 October 2014. On the 01 December 2014, Polokwane hospital (P02-H01) and Warmbath Hospital (P02-H03) were contacted to request participation to the study and hospitals P02-H02 and P02-H04 were followed up on the same-day. All hospitals were followed up on the 4$^{th}$ December 2014 and hospitals P02-H02 and P02-H04 gave verbal approval to visit the sites. The researcher requested the letter of acknowledgment which the email was sent. P02-H01 approved the study on the 4

February 2015 and P02-H04 was difficult to get hold of the CEOs office and never responded to the email but the researcher received read confirmation of emails.

## *NORTH WESTHEALTH DEPARTMENT (NW) (P03)*

North West Health Department (P03) was followed up on the 20 May 2014 and P03 requested to resend the letter and on the 21 May 2014 the acknowledgement of received was sent to the researcher. On the 6th June 2016, P03 requested additional documents including the ethics approval. Researcher sent other documents pending ethics approval. On the 12 August 2014, P03 requested ethics approval and it was sent on the 4 September 2014. On the 29 September 2014, P03 was followed up to check if they received and processed the application. The approval was received on the 3 October 2014.

Letters to request to conduct a study in 5 (five) P04 hospitals were sent to all hospital on the 16 October 2014. On the 13 November 2014 Gelukspan hospital (P03-H02) acknowledged the request and approved the study on the 13 November 2014. A follow up done on the 30th November 2014 to rest of the 4 hospitals (Klerksdorp Hospital (P03-H01), Moses Kotane hospital (P03-H03), Job Shimankana Tabane Rustenburg (P03-H04) and Joe Morolong Memorial Hospital(P03-H05) were followed on the 30 Nov 2014. The hospitals were also contacted by phone on the 4 December 2014 and Both P03-03 and P04-04 requested documents to be resent. The researcher tried several times to send the mail and the box of P03-03 hospital blocked the mail as spam email. The researcher reported the problem to P03-03 personnel and requested an alternative email and there was no alternative email. P03-H01 approved the study on the 2nd February 2015, P03-H03 on the 2nd March 2015, P03-H05 on the 25 March 2015 and P03-H04 still pending approval.

## *FREE STATE HEALTH DEPARTMENT (FS) (P04)*

The researcher followed up Free State Health Department (P04) on the 20 May 2014. P04 requested that the documents to be resend and the researcher sent the documents on the same day. On the 21 May 2014, P04 send further instructions and documents to be submitted by the researcher. Researcher collected documents required and were sent to P04 on the 6 June 2014. On the 17 June, the study was approved.

Letters to request to conduct a study in 5 (five) P04 hospitals were sent to all hospitals on the 12 October 2014. On the 14 November 2014, all the hospitals did not respond and were followed up on the 17 Nov 2014. Only Tokollo Hospital (P04-H06) acknowledged the request. On the 2nd December all other hospitals were followed up through a phone call and Pelonomi (P04-H01) and Parys (P04-H05) hospitals stated that they have not received the mail. The mail was resent to all hospitals again and the researcher followed up to check if they were received. P04-H05 hospital confirmed the receipt and P04-H01 and Universitas Hospital (P04-H02) did not receive the mail. Second email address was given for both P04-H01and P04-H02 hospitals and both

confirmed the receipt of the request. Bongani Hospital (P04-H04) was not sure if they received the mail and promised to check and was followed up the followed up for several days and weeks the phone was no available. Botshabelo Hospital (P04-H03) CEO was on leave and was referred to the acting CEO and the request was resent on the 4 December. All pending hospitals were followed up on the 9 Dec 2014 and Hospitals approved the study on the following dates: P04-H01 on 5th March 2015, P04-H02 4th Feb 2015, P04-H03 on 14th November 2014, P04-H04 on 5th March 2015 and P04-H05 on the 6th February 2015.

## *MPUMALANGA HEALTH DEPARTMENT (P05)*

Mpumalanga Health Department (P05) responded the same day (27 February 2014) requesting further documents including ethics approval. The researcher collected requested documents pending ethics approval and sent to P05 on the 17 Mar 14. P05 responded on the 18 March 2014 putting the application on hold till submission of the Ethics approval but at the meantime the application form was submitted on the 28 March pending ethics approval. Researcher sent the ethics approval on the 4 September 2014 with all other documents sent before. The researcher followed up P05 on the 29 September 2014 and there was no response. Another follow-up was done on the 15 October 2014 and there was still no response. The researcher contacted P05 personnel via a telephone and the researcher was told that the study is approved and the letter is waiting for a signature. Approval was received on the 24th October 2014.

Letters to request to conduct a study in 4 (four) P05 hospitals were sent to all hospitals on the 27th October 2014. By the 30th of November, none of the hospitals acknowledged the request and were all followed up via email. On the 1st December, the researcher called all hospitals and Ermelo hospital (P05-H01) confirmed that their email systems are down and will be up and running soon. After two days the email was still down. The rest of the hospitals did not respond. The researcher followed-up in January 2015. After several follow-ups the study was approved as follows: P05-H01 on 5th March 2015, Witbank Hospital (P05-H02) on the 12th March 2015, Piet Retire Hospital (P05-H03) on 5th March 2015 and Evander Hospital (P05-H04) on 12 March 2015.

## *KWA-ZULU NATAL HEALTH DEPARTMENT (KZN) (P06)*

Kwa-Zulu Natal Health Department (P06) never responded to the request, the researcher followed up on the 18 June 2014 and was referred to another department. On the same day the other department was contacted and all documents were sent. Researcher sent the ethics approval on the 4 September 2014 with all other documents sent before. On the 5 September 2014, P06 send further guidelines to the researcher to follow and to also get approval from hospitals. The researcher contacted all the six selected hospitals to request permission to conduct a study in 6 (Six) P06 hospitals were sent to all hospitals on the 12 October 2014 and on the 14 November 2014, Umzimkhulu Hospital (P06-H06) acknowledged the conduct on the study. On 30 November 2014, all the other hospitals were followed up and there was no response. On the 7th

December another follow-up was sent and the approval were received as follows: Addinton Hospital (P06-H01) approved on 12 February 2015, Inkosi Luthuli Central Hospital (P06-H02) on 4th February 2015, Madadeni Hospital (P06-H03) on 9 December 2014, Eshowe Hospital (P06-H04) on 12 February 2015 and Murchison Hospital (P06-H05) never responded and was excluded from the study.

On the 12 October 2014, the application was resent with the cover letters sent to the hospitals requesting permission to conduct the study in the hospitals. The researcher sent the hospital approval to P06 on the 12 February 2015 and the approval was received on the 25 February 2015.

## *NORTHERN CAPE HEALTH DEPARTMENT (NC)(P07)*

Northern Cape Health Department (P07) never responded to the request, the researcher followed up on the 6 June 2014 and P07 requested the researcher to resubmit the study documents. The researcher resubmitted the study documents on the 9 June 2014. The P07 requested the ethics approval and it was submitted on the 4 September 2014 with all other documents. On the 8 September 2014, P07requested to resubmit all the documents again which were submitted the same day. On the 15 October 2014, the researcher sent a follow-up email. No response was received. On the 13 November 2014, another follow-up was sent. On the 18 November 2014, P06 sent details of new personnel to send the study application. The new personnel was contacted and stated that he did not receive the mail. An alternative email was requested and the researcher sent to the alternative email. The new personnel was followed up and said he does not remember the password for the alternative email but will find the password. The researcher followed up on the 1st December 2014 and there was no response. The researcher contacted P08 telephonically on the 3rd Dec 2014 and requested the documents to be resubmitted again. The new personnel confirmed receipt and told the research to expect approval on the 10th March 2015. The approval was received on the 13 February 2015.

Letters to request to conduct a study in 3 (Three) P07 hospitals (Kimberly Hospital (P07-H01), Prof. ZF Mathews Hospital (P07-H01), Harry Surtie Hospital (P07-H01)) were sent to all hospitals on the 3rd December 2014 and the approval from P07 was sent on 15th February 2015. On the 16 March 2015, all the other hospitals were followed up and there was no response which was received from these hospitals.

## *EASTERN CAPEHEALTH DEPARTMENT (P08)*

Researcher followed up Eastern Cape Health Department (P08) on the 22 May 2014 and on the 23 May 2014. P04 acknowledged receipt of the application. The researcher followed up on the 6 June2014 and the personnel at P04 stated that the request has been sent to the study committee (SC) for recommendation. The researcher sent the ethics approval on the 4 September 2014. There was no response and the researcher sent another follow up email on the 13

November2014. P04 responded on the 14 November 2014 and informed the researcher that the request was referred to the new person in the research committee. The new personnel was contacted on the 24 November 2014 for follow-up and did not receive the documents. Researcher resent the document to the new personnel. On the 15 Jan 2015, the researcher called to follow-up and was told that the papers were not processed yet. The researcher sent email to the head office to complain about the slow process and the approval was received on the 30 January 2015.

Letters to request to conduct a study in 3 (Three) P05 hospitals were sent to all hospitals on the 15 October 2014. By the 3rd December, none of the hospitals acknowledged the request and were all followed up via email. On the 7th December all hospitals Cecilia Makiwane Hospital (P08-H01), Port Elizabeth Provincial Hospital (P08-H02), Nelson Mandela Academic Hospital (P08-H03)) were followed up again and still no response. The researcher followed up all the hospitals in February and P08-H01 and P08-H03 approved the study on the 05 March and 23 February 2015. P08-H02 was still pending.

### *WESTERN CAPE HEALTH DEPARTMENT (WC) (P09)*

Researcher followed up Western Cape Health Department (P09) on the 22 May 2014 and there was no response. On the 5th June 2014 another follow-up was done and P09 requested resubmission of documents. On the 6th June 2014, further documents were requested including completion of Annexure 2 which was completed and submitted on the 9th June 2014. P09 requested ethics approval on the 9th June 2014 and was not available yet. Researcher sent the ethics approval on the 4 September 2014 and all other documents were sent again. Researcher followed up on the 15 October 2014 and there was no response. The researcher followed up again on the 13 November 2014 and still there was no response. On the 28 Jan 2015 the researcher called to follow-up and left a message then sent a follow-up email. Approval was received on 2 February 2015 but the letter was dated 10 Sep 2014.

There three hospitals (Mossel Bay (P09-H01), Beaufort West (P09-H02) and Khayelisha (P09-H03)) were contacted in February 2015 and for all of them the approval was still pending.

## DISCUSSION

This case study describes the challenges and the experiences encountered by the researcher when requesting permission to conduct a medical informatics research in 45 Public hospitals in South Africa. It describes the challenges and the barriers encountered when communicating with the department of health personnel, public hospital CEOs and public hospital research managers.

In all the provinces, the process of provincial ethical approval for this PhD project was prolonged. It took average of 9 months for the provinces to approve the study; however, the three months were taken by the ethics approval application. The average time taken to approve the study was 6 months to approve a non-clinical trial study. Time taken seems to be long for

approval of a non-clinical study. Mpumalanga Province took 5months to approve and was the shortest time to approve in this case study and the longest was Eastern Cape and the Northern Cape provinces with 10 months to approve. It took an average of 9 email contacts and 4 telephone communications before the approval. The average time of response from the first contact took and the first of response was 3.2 months. The research had to resend the documents at least twice to the approved provinces.

Letters sent to the hospital to request a permission to conduct the study also took long to be processed by the Hospital CEOs and medical managers. Gauteng hospitals took average of 4 months to approve the study. Limpopo hospitals took 3 months to approve the study and it was shortest time taken to approve the study amounts all the provinces. Free State took 6 months and they were the worst in time to approve the study at the hospital level. The process was started in October 2014 and out of 40 public hospitals requested to participate only 19% acknowledged participation within two months. Some of the CEO of the hospitals did not understand the request of the researcher and the researcher has to explain why the study is needed to be done at their facility, even though the information was supplied. Some hospitals came back requesting information that was already sent with the request. The issues encountered in the provinces mentioned above were also experienced when requesting permission from the CEOs of the hospitals

According to the researcher the delay was caused by:

1. Lack of proper policies that handle clinical and non-clinical trials in the provinces. There is no standard procedure for the country and each province follows its own procedure. The non-clinical studies still has to follow the process of clinical studies and full process must be followed.

2. There is a lack of expertise and experience in handling applications to conduct trials in the hospitals in the provincial level. E-mails sent to the health departments HOD office are not handled properly or read by the recipient. This is either due to lack of administration skills or capacity. Most of the communications are lost and the senders are requested to resend.

3. Lack of proper facilities or expertise to use the facilities. Information technology is still a major issue in the provinces. Some of the provinces emails are down for days. Some of the email systems are too secured and when you send email with number of attachments, it rejects email as spam and when department of those hospitals or departments do not understand what are you talking about since IT is a challenge to some of them.

4. In some of the provinces, there were capacity issues since you will find one person handling the process of application of study also do other functions. Capacity issues were also experienced in the hospitals.

The delays discussed above, are not unusual as they were presented by several researchers whereby they found that the delay is not caused by the complexity of the trial but by the capacity of the body to review and process the application [4, 6, 8]. This study confirms that the major issue is administrative limitations, IT limitations and lack of capacity by the bodies approving the application. These finding also applied to the CEOs of the hospitals. The delay to start the PhD research was delayed for more than 9 months which was nearly an academic year.

In conclusion, the challenges encountered in the provinces applications are due to autonomy, lack of standardisation of procedure between the provinces, lack of understanding the procedure by the province personnel and lack of expertise in handling electronic submissions and non-clinical trial submissions. IT is still a challenge to most of government employees and the infrastructure that can accommodate amount of information. This case study suggests that South Africa need to develop more efficient mechanisms and common procedures or policies for provinces to follow when processing application to do clinical trials or non-clinical trials. To also train the relevant staff on these procedures and IT skills. To invest in good infrastructure and to increase capacity in the departments processing clinical and nonclinical trial applications. These finding also apply the hospitals in South Africa.

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