Navigating Digital Health Research Ethics: Insights from a South African Context

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Abstract. Research ethics committees are responsible for promoting academic integrity in research projects. They must ensure that researchers abide by the code of ethics that are relevant to the type of research being conducted. Digital Health research, which is at the intersection of information systems research and health research, is categorized as health research by South African research ethics committees. This results in researchers following often unnecessary research ethics processes prior to commencing their research project. This research uses the first author's PhD research as a case study to set the scene for Digital Health research ethics processes. A content analysis of three ethics policy documents revealed that there is no concrete definition for Digital Health research, which consequently leaves a gap in the research ethics processes. This led to recommendations aimed at research ethics committees and the relevant research ethics policy makers.

Keywords: Digital Health research, research ethics committees, information systems research, gaps in research ethics processes.

1 Introduction

The definition of Digital Health is expanding, with researchers now including medical terms such as genomics, software related components such as Artificial Intelligence (AI), clinical practice techniques such as telemedicine, and hardware devices that interact with people such as wearables [1]. This definition supplements those used in 2011 [2] which placed more emphasis on the virtual health record as well as associated hardware and technology devices. The extension of Digital Health's definition can be considered a contentious issue due to the research ethics implications of Digital Health research. Digital Health's adoption into healthcare settings globally [3] has consequently sparked an increase in Digital Health research projects in recent years [4]. Apart from the expansion of the definition of Digital Health, it could be argued that the term Digital Health is being mis-used or mis-understood. In some cases, Digital Health is sometimes used inter-changeably with health informatics which is a separate field that combines healthcare and information systems with a stronger focus on healthcare data [5] rather than placing a focus on technology design elements.

Research ethics committees are tasked with ensuring that research is conducted in a manner that protects research subjects whilst promoting the beneficence of the study

Smuts, Hanlie & Hinkelmann, Knut (2024). Proceedings of the 4th Conference Society 5.0 - Innovation for Sustainable and Inclusive Social Good, Volume 2, Mauritius, 26-28 June 2024, DOI: 10.5281/zenodo.11612759

DOI: 10.5281/zenodo.11661107

within the relevant context [6]. Due to the inconsistent use of the term "Digital Health research", Digital Health can sometimes be gravely misunderstood, resulting in increased ethics approval turnaround times and frustration for the researchers who are conducting low risk projects which do not involve interaction or collecting data from patients. Committees tend to enforce unnecessary and excessively strict requirements on Digital Health researchers to the extent that it could be described as "the weaponization" of research ethics committees.

This research, based in South Africa, used a qualitative approach by considering the first author's current PhD research (henceforth referred to as "the PhD"). The PhD was used as a case study to set the scene of this research. A content analysis, which is a method used in healthcare research [7], was used to analyze three research ethics policy documents to determine whether there is an adequate definition for Digital Health re-search and whether it should be regarded as health research. The results of the content analysis, which used three cycles of coding, were combined with the insights from the health research application enforced by the research ethics committee on the PhD.

Recommendations were then formulated to simplify the ethics processes for Digital Health research projects. The recommendations, which include a decision chart were formulated for research ethics committees and policy makers. The recommendations were formulated with cognizance to the critical role that research ethics committees play in ensuring scientific integrity and participant safety.

2 Background

A Ghanian PhD candidate reflected on an experience with ethics review processes related to Digital Health [8]. That author explains the lengthy ethics application process which applies even to "non-clinical" research. The ethics application process was described as inconsistent and duplicated in some situations. This research uses a similar approach by using the PhD as a case study. Case studies present problems with real life contexts [9] which supports the interpretation of pragmatic research.

2.1 Case study

The case study with the working title "Digital Health: A Live Healthcare Console for Public Health in Gauteng, South Africa" focuses on the development of an information systems design model to make non-patient related information such as hospital bed occupancy available in real time to key stakeholders for the public healthcare system in South Africa. The research does not involve the development of a software artefact, nor does it investigate any sensitive data stored on existing healthcare systems.

The case study utilized three literature review phases, which led to an understanding that there is a lack of real time information available to key stakeholders. An evaluation of existing Digital Health design models was then conducted to determine whether an existing model could be used to solve the challenges experienced within the Digital Health systems implemented in Gauteng (South Africa). Once it was determined that a

contextually relevant model does not exist, it was decided to create a new model using lessons learnt from existing models.

To create a contextually relevant and actionable model, it was necessary to engage with key stakeholders within the public healthcare system. Semi-structured interviews were designed to engage with relevant stakeholders, which included healthcare workers and managers. No patients or otherwise vulnerable members of society were included in the study and no patient data were consulted. Supported by the worldwide adoption of online meetings, MS Teams was used to conduct all the interviews, preventing the need for the first author to physically visit any healthcare facility. The ethics and gatekeeper permission application steps are presented in the next section.

2.2 Ethics approval process

It would be reasonable to assume that the first author should apply for research ethics clearance from the University's college ethics committee at which he is registered. The first author's prior experience with Digital Health research however, led to the conclusion that "healthcare related research matters" are dealt with through another college within the University due to the nature of the research. **Table 1** is an explanation of the question categories that were asked on online research ethics application form.

Table 1. Digital research ethics application form question categories

Group	Category
General[1]	Proposal summary
General[1]	Gatekeeper permission
General[1]	Application forms
General[1] and health[2]	Research design
Health[2]	Health research
Health[2]	Health specific questions
General[1]	Population and sampling
General[1]	Data collection instruments
General[1]	Data collection methods
General[1]	Procedures for consent
General[1]	Vulnerable participants
Health[2]	Health related activities
General[1]	Participant incentives
General[1]	Human participant risk category
General[1]	Human Participant Ethics Considerations
General[1]	Human Participant Conflict of Interest
General[1]	Data management plan
General[1]	Protection of Personal Information

[1]Applies to other forms of research and is not specific to health research.
[2]Specific to health-related research.

There are five health research committees in Gauteng, one for each of the five districts in the province [10]. Health researchers should be aware of this as each health district follows unique approval processes. The health research ethics application process has

been documented on https://profmoosa.com/ [11]. It must be noted however that the documented process refers to the University of the Witwatersrand Health Research Ethics Committee and is not necessarily generalized to other universities. **Table 2** provides a summary of the research ethics application process that the first author intended to use. The steps presented are a mixture of the processes described by the sources noted above as well as from the author's previous research ethics applications.

Table 2. Anticipated ethics application steps

Step	Description
1	Create ethics application via the University's research ethics portal [12]
2	Register the research project with the National Health Research Database [10]
3	Upload proof of National Health Research Database registration to the University's research ethics portal
4	Request letter of support from gatekeepers (hospital or department managers)
5	Receive final approval from National Health Research Database
6	Receive final approval from the University
7	Receive final approval from the relevant gatekeepers

The actual research ethics and gatekeeper application process presented in Supplement [13] was a 38-step process. The research method of this paper is discussed in the next section.

3 Research method

Pragmatism has been described as a research paradigm that renegotiates reality [14]. Three methodological fundamentals of pragmatic research are presented below [15]:

- Emphasis on actionable knowledge – the results of the research should display elements of practicality and should be actionable,
- Inquiry as an experiential process – people will question how problems are solved. Reference in this case is made to the solving of organizational problems. It must accordingly be noted that though this research does not focus on any one research ethics committee, from an organizational perspective, it does consider research ethics as being bound by research ethics committees or organizations, and
- Recognition of the interconnectedness of experience, knowing and acting – this contributes to the contextualization of problems and how they can be solved.

The PhD was presented as a case study in conjunction with the anticipated ethical clearance and gatekeeper permission processes. The actual process that was followed is presented in Supplement [13]. A content analysis of three governing ethics policy documents, presented in **Table 3** was conducted to identify the definitions and rules that regulate healthcare research. Using three cycles of coding, underlying themes within these documents were identified and related to the case study. Once all the data were analyzed, recommendations were identified and presented.

Table 3. Three ethics governance policy documents selected for analysis.

Document name	Rationale for analysis
Policy on Research Ethics [16]	As a PhD student, the first author had to become familiar with the research ethics policies and guidelines prior to initiating the ethics review process. It is safe to assume that researchers (including students) should be familiar with their institutions research ethics policies through consulting their institution's documentation. The policy document provides the definitions for research which includes healthcare research.
Ethics in Health Research [17]	The Policy on Research Ethics document provides guidelines on ethical research practices, but it refers the reader to the National Health Act for further detail. Since this document provides detail aimed at healthcare research it was deemed necessary to analyze the document.
National Health Act, 61 of 2003 [18]	The Policy on Research Ethics and Ethics in Health Research documents refer to the National Health Act document for definitions and further information. This document focusses on the overall healthcare system and refers to healthcare research.

The content of the three policy documents were analyzed using ATLAS.ti version 23.4.0.29360. This version of ATLAS.ti is integrated into OpenAI and can perform coding on the uploaded documents using AI [19–21]. The integration of AI coding in qualitative analysis has shown an increase [22] however the stand-alone use of AI for coding is still novel. To ensure rigor in this research, the three documents were analyzed using three cycles of coding with a hybrid approach of AI and human-centered coding. This hybrid approach was followed in a related study which analyzed twenty-one documents using three cycles of coding done by AI and the researchers [23]. The three cycles of coding led to the identification of themes which were then related to the research ethics processes described earlier. Recommendations relating to Digital Health research were then formulated and presented.

4 Results

The policy documents were first investigated to determine whether Digital Health research was clearly defined. It was found that policy documents provided a hierarchical definition where Digital Health research which was not precisely defined. The definitions are illustrated in **Fig. 1**.

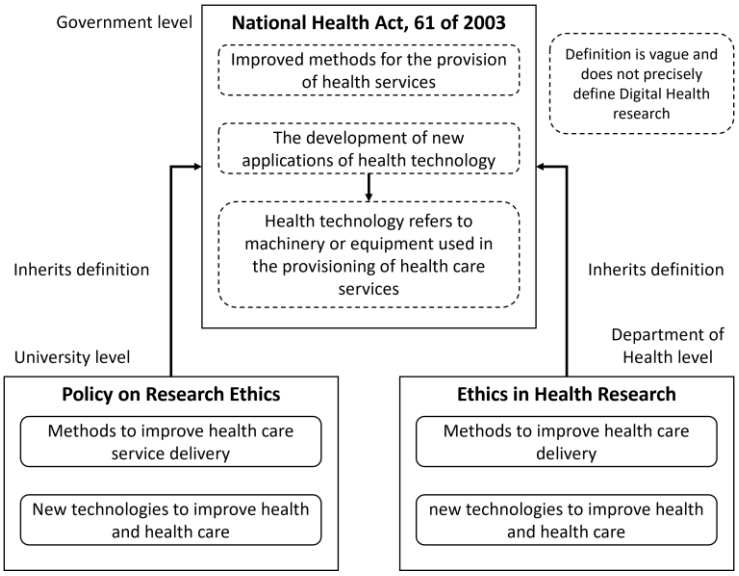

Fig. 1. Health research definitions according to the relevant policy documents

A qualitative content analysis of the three essential research ethics policy documents was done using three cycles of coding. The first coding cycle adopted a hybrid approach of human-centered and AI coding (ATLAS.ti integration into OpenAI). The human-centered coding revealed 73 codes and the AI coding revealed 122 codes. In the second coding cycle, the human-centered codes were grouped into 11 code groups and the AI generated codes were grouped into 9 code groups. The 9 AI code groups formed a subset of the human-centered code groups resulting in a total of 11 code groups. The 11 code groups were then associated with each other during the third cycle of coding revealing the relationships illustrated in **Fig. 2**.

	Healthcare service delivery	Definition of healthcare research	Committees	Data handling	Medical research	Non human participants	Research ethics	Research planning	Rights of participants	Vulnerable groups
Academic Integrity	promotes	is bound by	is verified by	requires	is related to	is related to	is verified by	requires	protects	protects
Healthcare service delivery		is indirectly related to	is indirectly related to	is indirectly related to	is promoted by	is indirectly related to	is indirectly related to	is indirectly related to	is related to	is related to
Definition of healthcare research			is promoted by	is indirectly related to	defines	is indirectly related to	regulates	influences	protects	protects
Committees				require	regulate	is related to	verify	is indirectly related to	protects	protects
Data handling					is required by	is related to	is required by	is part of	is related to	is related to
Medical research						is related to	is regulated by	requires	must protect	must protect
Non human participants							are protected by	are protected by	are protected by	are protected by
Research ethics								requires	must protect	must protect
Research planning									must include	must include
Rights of participants										includes

Fig. 2. The relationships identified amongst the 11 code groups.

Fig. 2 illustrates the 55 identified relationships. The relationships highlighted in orange and yellow were regarded as subtle relationships and were consequently omitted from the analysis. Once the 18 subtle relationships were removed, 37 relationships remained. The remaining relationships and code groups were then associated with each other using the ATLAS.ti network function. This is illustrated in Supplement [24].

The four themes were then derived using a combination of the code group relationships illustrated in Supplement [24] and the associations of the quotations, codes and code groups presented in Supplement [25]. AI-derived and human-derived quotations were carefully considered.

As presented in Supplement [24], the four themes are described below:

- *Participant rights* – Participants have rights that need to be protected by researchers. Rights can include their safety and anonymity. Since participant groups can include vulnerable groups (minors, women and people living with disabilities), researchers need to take extra precautions to ensure that the rights of vulnerable groups must not be violated. It must however be noted that individuals who are deemed to be part of a particular vulnerable group may not see themselves as being vulnerable. This theme applies to all forms of research that involve human or non-human participants.
- *Healthcare research* – This can consist of medical research which can involve clinical trials and the use of medication or medical equipment. The provisioning of healthcare services is also included in healthcare research however its definition is not clearly articulated. This theme applies to healthcare research and may apply to Digital Health. This will be argued in the next section.
- *Research integrity* – This theme, which applies to all forms of research, refers to the integrity of the researcher as well as the governing committees. Researchers must be

adequately qualified to conduct the research and must uphold the ethical standards as set out by the relevant committees.
- *Research preparation* – Prior to the initiation of the research, the researcher must present a detailed proposal to the relevant committee. This proposal must include details regarding research ethics (this is a broad topic which includes how human and non-human participants will be interacted with) and how the research data will be handled. This theme applies to all forms of research.

The four themes were then associated with each other and with the concept of Digital Health research. The results of this together with the recommendations are presented in the next section.

5 Discussion

Digital Health research, which is at the intersection of information systems research and medical or health research, requires researchers in South Africa to follow the health-related research ethics application process instead of the standard processes that would apply to information systems research. It was anticipated by the first author that the ethics and gatekeeper application process would follow seven steps to obtain full approval however this proved to be a 38-step process with elements of process entanglement which left the first author often uncertain about how to continue with the application.

The Policy on Research Ethics contains six definitions for Health research, four of which are purely medical with the remaining two being potential options for Digital Health research projects. The fourth definition from the Policy on Research Ethics states "methods to improve health care service delivery" however the document provides no specifics on the definition of "methods to improve health care service delivery" [16]. The Ethics in Health Research contain the same options but also does not provide a thorough definition of health care service delivery [17]. The National Health Act, 61 of 2003 refers to "improved methods for the provision of health services".

The Policy on Research Ethics provides another definition which states "new technologies to improve health and health care". The definition for technologies is provided by the National Health Act, 61 of 2003 which defines it as "machinery or equipment that is used in the provision of health services…".

The definitions of Health research provided by the guiding documents do not clearly define Digital Health research, which as mentioned earlier focusses on digital systems and does not necessarily include healthcare technologies. Three out of the four themes identified in this research refer to principles that are applicable to all types of research, with healthcare research being the only theme that refers to healthcare service delivery. **Fig. 3** illustrates the relationships between the four themes and Digital Health research. It can be observed that Digital Health research must follow the same ethical standards as healthcare research, yet it defers from medical research, does not meet all the criteria of healthcare research and does not necessarily relate to healthcare service delivery.

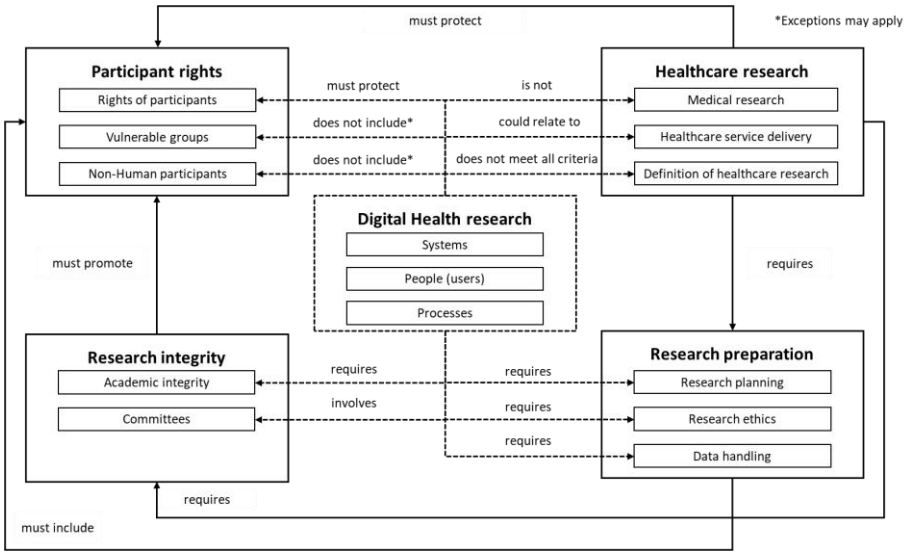

Fig. 3. The relationships amongst the four themes and Digital Health research

The first author was expected to select health research for a PhD study on Digital Health, on the online ethics application. All the answers relating to health research were however recorded as "No". If you consider the lack of a precise definition for Digital Health research, the deficiency of clear linkage between Digital Health research and Health research, the absence of patient interaction, the absence of medical data, the exclusive use of online interviews and the responses to the health research questions on the online ethics application, it is unclear why the research was categorized as health research.

Admittedly, the research sought to investigate healthcare related processes from healthcare workers, however the minimal risk of the study should have resulted in a different ethics application route. Research ethics committees and policy makers should therefore take note of the following recommendations.

- Due to the proliferation of Digital Health research projects, Digital Health research should be clearly defined in all necessary ethics policy documents. A possible definition could be "Digital Health research is a subdiscipline of Information systems research and is concerned with the healthcare context. Digital Health research considers the structure, layout, and integration of healthcare related information. Human participants and technology may be involved in the research however should medical tests, medical data or medical procedures be involved then the research may be classified as Health related.",
- The ethics application process for Digital Health research should be posted on the appropriate University's website so that researchers can plan their application process accordingly,
- The definition of Digital Health research should make clear use of parameters such as whether there will be patient interaction or the use of sensitive data,

- The ethics application systems should display elements of fluidity in the response to questions:
  - If the researcher answers "No" to all Health research questions, then the risk level should be automatically downgraded, or
  - If the researcher states that all interactions will take place online, then this reduces the risks associated with a researcher visiting a healthcare facility and should result in a downgrading of the risk level,
- Based on the scenarios described above, research ethics committees should be empowered with the ability to allow a researcher to avoid the district level approvals and be allowed to obtain direct gatekeeper permission based on the recalculated risk category, and
- A decision chart such as the one illustrated in **Fig. 4** should be used by Research Ethics Committees to guide them on how to differentiate between Health related research and Digital Health research. The decision chart was discussed with two ethics chairs who saw merit in this approach to differentiating between the research types.

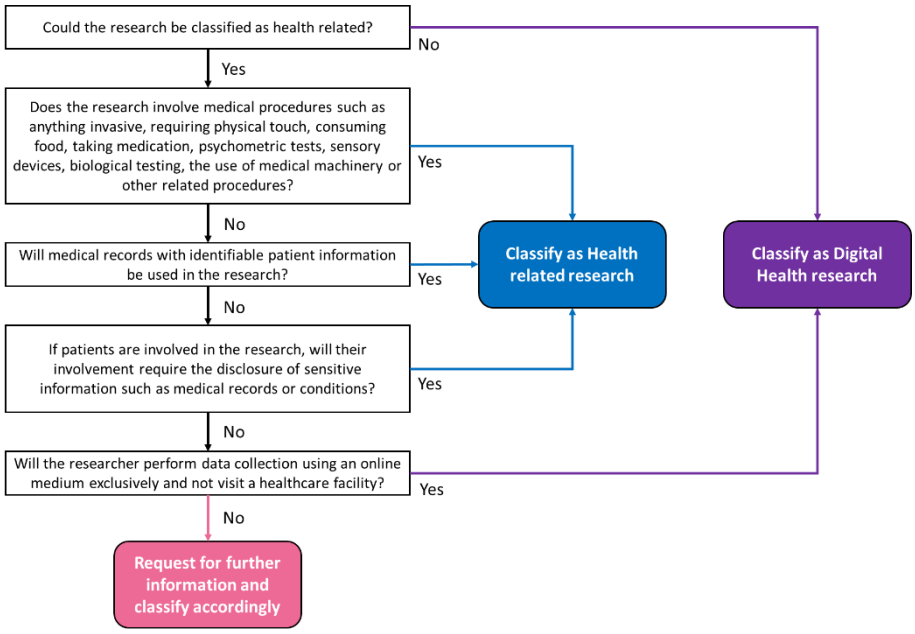

Fig. 4. Decision chart to guide research ethics committees.

The decision chart illustrated in **Fig. 4** is an initial version. Further research will be conducted to convert the decision chart into a more comprehensive decision tree containing more permutations. Research ethics committees have important responsibilities to research participants, communities and to the researchers. The generalized inclusion of all Digital Health research projects into the health research category, however, results in unnecessary processes being followed for otherwise low risk research. This not only

lengthens the ethics application process but also puts a strain on the committees and gatekeepers themselves. Digital Health research should therefore be reclassified or be included in a unique research category to promote the optimization of the research ethics processes.

Acknowledgments. The authors would like to thank the research ethics chairs and committee members who supported this idea. For ethical reasons, they remain anonymous.

Disclosure of Interests. There are no interests to declare.

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