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The complexities of human procedural nursing research ethical approval processes in Indonesia

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ABSTRACT

Introduction: Research requires high quality ethical practices. However, research approvals vary between developed and developing countries resulting in additional challenges for researchers wishing to participate in collaborative research projects. The aim of this paper is to describe and discuss three nursing research ethics application processes in different locations in Indonesia that had an Australian university overseeing them. The first research project aimed to identify the health needs of women and their families in the Surabaya region. The second project aimed to interview women with breast cancer in the Bandung region and the third project aimed to examine empowerment issues in diabetes care in supporting patient self-management in Jakarta.

Methods: Three nurse researchers provide a reflective account of the ethics application processes of their qualitative research projects conducted between 2014 and 2021. A collective case-study methodology using descriptive analysis was applied where the information was collated and compared for similarities, differences and challenges.

Results: Ethics and site approvals varied at each Indonesian site. The ethical and approval application processes were time-consuming at all levels. which delayed the start of all the projects, which varied from between one to six months. As a result, all three projects experienced delayed completion.

Conclusions: Ethical approval is required for medical research prior to any data collection. Approval processes need to be consistent so that delays in the application processes are avoided. Any delays in approval to conduct research has implications for research projects. It is essential that timeframe factors need to be considered when applying for grant funding, gatekeepers are identified early, and payments are identified and planned for. It is recommended that, to improve consistency with ethical application processes, streamlining of applications and approvals in Indonesia needs to be reviewed, particularly since the introduction of the WHO March 2022 Standard Operating Procedures.

Keywords: developing countries, ethics, nursing, research methods

Introduction

With increasing worldwide demand for the use of evidence-based practice, collaborative international research partnerships are continually being forged, particularly in nursing. This type of collaborative research is viewed highly within the research community and beyond (Serguga et al., 2014) . Positive outcomes of global health research partnerships include the development of research capacity and improvements in the production and use of evidence to improve global health equity (Murphy et al., 2015). In the Asia-Pacific region for instance in Indonesia, there has been increased interest in research partnerships with other countries, particularly in the area of primary

care research which aims to explore medical issues in relation to individuals, families and the community and may also include evaluation of the effectiveness and efficiency of healthcare practices and health policies (Ichsan et al., 2018).

By increasing research capacity and improving the evidence base used to inform clinical practice, improvements in health outcomes can be achieved, especially in developing countries such as Indonesia (Ichsan et al., 2018). Additional benefits include knowledge sharing between partners, generation of new knowledge, capacity development leading to strengthened capacity among individuals, institutions, and systems where all partners can benefit from improved cultural competencies, improved research design and methods, enhanced pedagogical capacity, and access to unique opportunities for mentorship (Murphy et al., 2015). Potential positive impacts from the benefits of collaborative research may include improved quality of medical research outcomes, effective problem-solving for healthcare issues, and improved nursing practices particularly in Indonesia (Wutzke et al., 2017; Nyström et al., 2018) . However, partnerships formed between developed and developing countries can face many challenges, with power and resource differences. Additionally, there are many hurdles and barriers that need to be overcome including regulatory demands, particularly in developing countries (Serguga et al., 2014).

One area of challenge in particular is that of gaining ethical approval to conduct research. Academics from a range of different countries and institutions have expressed frustration of the intricacies of the ethics application procedure (Davis et al., 2022). Conducting medical research involving humans requires stringent ethical practices to protect participants and researchers. But these practices vary from country to country with consideration needing to be given to legal and statutory frameworks, discipline codes of practice, local cultural norms of ethical conduct and formal ethics committee reviews (Green and Thorogood, 2018) . In addition there are regulations to be considered, which are usually advisory rather than mandatory, that provide frameworks for high-quality ethical research governance (Green and Thorogood, 2018). Furthermore, there are Standard Operating Procedures (SOPs) that need to be followed in some regions such as the Asia-Pacific Region (World Health Organisation (WHO) South-East Asia, 2022). The SOPs provide guidelines and other procedural issues concerning ethic applications (World Health Organisation (WHO) South-East Asia, 2022). Procedural ethics refers to research ethics approval processes that may include developing research protocols, participant information sheets, informed consent forms, and other procedural documentation (Chiumento, Rahman and Frith, 2020). These types of standardized documents can provide a shared reference between those involved in the research process, such as researchers and research participants, which can be tailored for research practice (Chiumento, Rahman and Frith, 2020) . However, there remain many challenges for researchers in gaining ethical approval to conduct research.

In Australia, a developed country, the National Health and Medical Research Council Act 1992 (NHMRC Act) provides governance to the National Health and Medical Research Council (NHMRC) (National Health Medical Research Council (NHMRC), 2022) . This council is the statutory body and has powers and obligations to oversee the guidelines in the National Statement that are applicable to the conduct of medical research involving humans (National Health Medical Research Council (NHMRC), 2022). The National Statement, which was developed jointly by the NHMRC, the Australian Research Council and Universities Australia, guides researchers conducting medical research, ethical reviewing bodies, research governance and potential research participants (Pollacsek, Boardman and Mccann, 2017) . Research committees in Australia are required to include scientists, non-scientists, institutional representatives, lay people who do not engage in medical, scientific, legal or academic work and a person who performs a community pastoral role (Davis et al., 2022) . Australian universities have a responsibility to ensure that any research conducted by their researchers, students or associated funding bodies is ethically acceptable, safe and of an appropriate level of quality and that their Human Research Ethics Committees (HRECs) have reviewed and approved all projects (Davis et al., 2022). There can be concerns by researchers and others, such as international post-graduate students from developing countries, regarding decisions made by HRECs as a result of differences in previous experiences in gaining ethical approval for projects in their developing country (Davis et al., 2022). Challenges in gaining ethics approval is reported to be a common experience for many (Davis et al., 2022). This is particularly so for Indonesia.

In Indonesia, a developing country, the National Commission for Research and Development of National Health committee assists the Health Minister of the Indonesian Republic in providing regulations and

guidance for enforcing ethical research and health development involving humans (Fourianalistyawati et al., 2018). Even though universities in Indonesia are starting to include research ethics committees (REC), the number of committees is small (Fourianalistyawati et al., 2018). Hence, there are likely to be no human research ethics committee procedures for social research (Davis et al., 2022). This means that alternative permissions to conduct research are required to be sourced in many instances (Fourianalistyawati et al., 2018). This may result in researchers and students encountering difficulties adapting to differing cultural expectations due to differences in approval processes (Davis et al., 2022). For instance, previous approval may have been granted by an Indonesian government education official who may have directed researchers to undertake particular activities were they were allowed to make their own ethical decisions about the research project (Davis et al., 2022). This can be problematic for researchers, including post-graduate students from developing countries such as Indonesia that have a less developed research ethics tradition, including absence of university topics encompassing ethical research principles and, therefore, they face challenges when undertaking coursework that assumes knowledge, skills or attributes relating to ethical practice in research (Davis et al., 2022). In addition, the international collaborative system on research involving human objects should be well-implemented to protect participants from being exploited (Rachmawaty, 2017). To protect participants and to conduct ethical research, researchers need to be mindful of differing international ethical requirements when applying for research approvals.

When considering collaborative research projects with researchers and post-graduate students from Australia and Indonesia, navigating the differences in ethical approval processes needs to be negotiated so that all factors are considered. These include the ethical principles of respect for autonomy, beneficence, nonmaleficence, and justice (Varkey, 2021). In nursing research, ethical principles are implemented to protect vulnerable groups and study participants from any potential harmful effects from the study that is being conducted, and to maintain the fullest respect, dignity and privacy of participants involved in research projects (Rashid, 2022). When applying these principles, it is important to understand that differences in ethical processes across countries such as Australia and Indonesia may exist and requires further exploration. Hence, the aim of this paper is to describe and discuss different ethical approval processes experienced by researchers and post-graduate students in different locations in urban, sub-urban and rural locations in Indonesia conducted between 2014 and 2021 which all had an Australian university overseeing the projects. Understanding the differences in processes may assist future researchers and post-graduate students to navigate the different ethical approval systems, particularly within Indonesia.

Materials and Methods

This paper applies a collective case-study methodology to provide a reflexive account of the experiences of three nurse researchers in applying for ethical clearances for their nursing projects. A collective case-study methodology aims to gain a deeper understanding of similar cases allowing for a wider and deeper understanding of a phenomena (Jones and Lyons, 2004). According to Gangeness and Yurkovich (2006), case study research provides nurses with a holistic and appropriate form of inquiry that is suitable for a variety of settings, thus making this methodology appropriate for this review paper. A descriptive method was utilized within this case-study, which, according to Yin (2003), allows for a description of the phenomena within their context. A purposive sample of research projects was selected based on the lead Australian researcher of this study being the common denominator in all three independent projects. Each of the researchers in the three projects were approached via email by the lead researcher of this study inviting them to voluntarily participate. The three researchers agreed to participate.

The three different nursing research projects were conducted in Jakarta, Surabaya and Bandung in Indonesia by the authors of this paper whose experiences of managing ethical clearances in Indonesia are included in this review. The researchers involved in the projects included academics, researchers, and research higher degree post-graduate students (PhD candidates). The ethical research processes were reviewed for the three research sites that were conducted in urban, sub-urban and rural Indonesian settings between 2014 and 2021 by the academic, researchers and post-graduate students involved in the research projects. Each of the projects research methodologies and methods were reviewed and documented. This included reviewing the methods chapters of two theses which contained in-depth detail on the ethical application processes and one research project documentation. The ethics application processes were all reviewed. All documents were assessed for

Table 1. Ethical approval processes in three sites in Indonesia

	Project 1 Surabaya (2014-2016)	Project 2 Bandung & Batam (2018-2020)	Project 3 Jakarta (2019-2021)
Study type	Phenomenology	Phenomenology	Case Study
Demographic location	Urban	Rural Urban	Sub-urban Urban x 2
Number of data collection sites requiring approval	1	2	3
Data collection method	1. Interviews 2. Focus group discussions 3. Field notes observations	1. In-depth interviews	1. Interviews 2. Focus group discussion 3. Field note observations
Ethics Committee approvals	An Australian University Social and Behavioural Research Ethics Committee An Indonesian University Research Ethics Commission, Institute for Research and Community Service	An Australian University Social and Behavioural Research Ethics Committee	An Australian University Social and Behavioural Research Ethics Committee Hospital Research Ethics Committee
Additional approvals required	Site 1 - yes Site 2 - yes Site 3 – yes	Site 1 - Yes Site 2 - Yes	Site 1 - Yes Site 2 - Yes Site 3 – Yes
Payment required	Yes	No	Site 1 – No Site 2 – Yes Site 3 – Yes
Total length of time to gain final ethical approval	2 months	4 months	6 months

similarities, differences and challenges faced during the ethical application and approval processes by the academic. Themes were identified by coding categories and concepts based on reading and re-reading of the data. Member checking was conducted with all the research team members.

All three projects were overseen by an Australian university academic/researcher, which meant that the integrity of the projects adhered to strict guidelines. These guidelines included assessing all projects for the four specific categories of physical harm, psychological harm, social harm and economic harm and which were closely reviewed before permission to conduct the research could occur (National Health Medical Research Council (NHMRC), 2022). All three applications were submitted to the Australian university research ethic committee.

The Australian HREC panel, which met monthly, comprised of a variety of experts from various fields (The Flinders University of South Australia and Flinders Medical Centre, 2011). The process involved review of all the applications and issues of concern were raised with conditional approval being granted until those issues were addressed. The Australian HREC required any additional REC approvals and other permissions to be provided in English for review before the final permission for the projects was granted. This meant translations were required from Bahasa to English and had the approved translations certified.

Results

The research approaches of the three studies varied from phenomenology to case studies. Data sources included semi-structured and in-depth interviews with experts in their field, consumers of healthcare and focus group discussions with healthcare professionals and consumers of healthcare (see Table 1). Additionally, field notes were recorded at some sites. Four themes were identified by coding categories and concepts based on reading and re-reading of the data. These were timeframes for approval, additional permission requirements, payment of fees and transparency and bureaucracy of the application procedures. Each of the three projects is described below and includes the project details, and total timeframe for each application.

Project 1

Project 1 was a phenomenological study in urban and sub-urban Surabaya that involved three sites for data collection. This project aimed to identify the specific health needs of women and their families living in a coastal area in Surabaya. This study examined statistical data, health records, focus group discussions, individual in-depth interviews, and field note

observations. The participants of this study were mothers, community leaders, healthcare providers, including doctors, midwives, and nurses, as well as Ministry of Health officers. Apart from the Australian university HREC approval, an additional Indonesian university REC approval was required before data collection could proceed. The result of the ethical review process in Indonesia was a full board classification. This process involved submission of an ethical protocol followed by the researchers presenting the research proposal to a panel of three research ethics reviewers who required further discussion involving questions, clarifications, input and suggestions for improvement of the proposal. Following this discussion, the original proposal was revised and, once the three reviewers agreed, a new ethical certificate was issued by the Indonesian university institution. Additional site approvals were also required for this project from the Ministry of Health, Surabaya. No payments were required for administration of the additional approvals by any of the three sites. Once all the permissions were received in writing, they were translated into English before submission to the Australia University HREC for final approval of the project. Once approved, the project commenced. The whole process for the ethics approval took two months.

Project 2

Project 2 was a phenomenological study exploring women's experiences in the use of Complementary and Alternative Medicine for Breast Cancer management. Data were sourced from in-depth interviews with women with breast cancer in two different sites. The first site was a cancer support group in Bandung, West Java, and the second was a cancer support group located in Batam, Kepulauan Riau. There was no REC approval required at either of the sites; however, additional permissions were required. Site 1 required a permission letter from the chairperson of the support group who did not have any understanding of ethical processes. This meant the researcher was required to meet with the chairperson and explain in detail all aspects of ethical research processes and responsibilities. Similarly at site 2, permission was required from the chairperson of the support group. At this site the chairperson was familiar with ethical processes and a permission letter was provided. There were no costs required in the process of obtaining the permission letter from both sites. The official permission letters were submitted to the Australian HREC following translation into English and final approval to commence the project was given. The whole process for the ethics approval took four months.

Project 3

Project 3 was a single embedded multiple unit case study in urban and sub-urban Jakarta. This study involved adult patients with Type 2 Diabetes Mellitus (T2DM) who attended outpatients units in a primary healthcare service (Site 1) (Ind. Puskesmas), a regional hospital (Site 2), and a top referral national hospital (Site 3). Medical doctors, nurses, and dietitians who worked with the patient participants were also included in this study. Additional approvals were required from the three data collection sites for the interviews, observations, focus group discussions and field notes. Site 1 did not have a specific REC but did require permission letters/correspondence from the Head of the Provincial Health Office, Head of Home Affairs Office and the Head of Community Health Care Centre. Site 2 and Site 3 required additional Indonesian REC approval. Site 2 required the hospital ethics committee to approve the project, which also involved permission letters from the Head of the Provincial Health Office, the hospital director, and the hospital research and training department. Site 3 required Hospital and Faculty of Medicine REC approval, which involved permission letters from the hospital director, Head of Internal Medicine Department, and Head of Endocrine and Diabetes Division. The researcher was required to pay an administration fee to all three sites; however, site 1 waived the fee due to the researcher's affiliation with the Provincial Health Office. Once all the written approvals, which were translated into English, were received they were submitted to the Australian HREC for final approval and the project commenced. The ethics review process for this research protocol posed minimal risks to participants, involving data collection through non-invasive methods and was reviewed as accelerated. The whole process for the ethics approval and permission process to enter the field took six months.

Discussions

There were a number of issues identified across all three research site locations in the urban, sub-urban and rural areas. These ranged from differing time periods for the ethics approval processes, differing additional permission approvals, inconsistency in payment of administration fees, issues of transparency during the processes of obtaining clearances, and bureaucratization of the processes.

Timeframes for approval

The ethics approval process commenced with applications presented in the three different study locations in Indonesia. Once these approvals were gained, the international university in Australia HREC reviewed and approved the projects. This highlights the hierarchy of approval and demonstrates the potential for power imbalance where each country has their own approach to research ethics, having their own focused priorities and operational norms of ethical principles (Chiumento, Rahman and Frith, 2020). These differences impacted on the time period to gain ethics approval. Approvals varied greatly between the three projects. The minimum timeframe was two months with the longest timeframe being six months. The time taken varied due to differences in local requirements, availability of ethics committee members, availability of meeting times for involved staff, complicated administration and bureaucracy systems and the impact of the COVID 19 pandemic.

Delays such as these experienced in all three projects are not uncommon. Lengthy regulatory and ethical review delays from the commencement of a project to the start of the actual research data collection in developing countries have been reported in many studies, resulting in creating obstacles for the research projects (Alemayehu, Mitchell and Nikles, 2018). Overcoming barriers such as time delays in gaining ethical approval is vital so that future research projects are not unnecessarily delayed as delays could impact on improvements in health outcomes for patients (Ichsan et al., 2018). Additionally, researchers need to allocate appropriate timelines for research projects taking into consideration funder requirements, institution requirements and site-specific requirements.

Additional permission requirements

Gaining permissions from different agencies associated with the research projects varied. Some agencies required written approval from senior management officials who were familiar with ethical principles whilst other centers were unfamiliar with ethical principles. This required the researchers to meet with officials, who acted as the gatekeeper, to personally explain the research and processes. Gatekeepers are seen as an integral part of the ethical process as these decision-makers share a desire to protect research participants from harm (Kay, 2019). Additionally, gatekeepers hold the power to approve or deny access to the research participants, access to research sites and be concerned about the researchers being scrupulous in adhering to ethical principles (Clark, 2011; Christian et al., 2022) . As gatekeepers are often the vital link for successful research outcomes, positive relationships between the gatekeeper and the researcher are essential (Kay, 2019; Koirala, Amgai and Davidson, 2020; Thoft, Ward and Youell, 2021).

The development of trusting relationships takes time and patience and may present additional challenges to undertaking a research project. For researchers seeking additional approval permissions to access data collection sites, this can cause additional delays in the application processes. The gatekeepers, who may constitute different types, including the person who could provide immediate approval, the person who re-directed the request to others, the person did not know if they could approve the application, or one who did not respond at all to the request, need to be identified and contacted, which can tedious, time-consuming and obstructionist (Christian et al., 2022). According to Susulo et al. (2014) , differing roles in the healthcare field can result in differing ethical views. These differing roles can also impact on gatekeeping outcomes and need to be considered. Once the gatekeeper has been contacted, trusted working relationships need to be developed. These additional steps created additional burdens for the researchers involved in the three Indonesian projects. To mitigate these types of delays for future research projects it is suggested that ongoing education is required at all healthcare facility levels regarding research ethics procedures and processes.

Payment of fees

Inconsistency in payment fees was seen between all three projects, questioning the bureaucracy of the different locations. There was no cost required from applicants by the Australian university HREC. However, a number of the sites in one of the projects in Indonesia required payment before the ethics application would be assessed and permission granted. Payment of fees for services (administration), is viewed as one way to improve service certainty and expedite application processes (Taufik et al., 2021). However, there was no consistency in fee requirements across the three Indonesian research project sites. Costs varied for one of the projects from 500,000 to 1.5m rupiah (AU $ 50-150) for one of the projects where fees were required for the three different data collection sites. According to Fakultas Kedokteran Universitas Indonesia-Rumah Sakit Cipta Mangunkusumo K E P K User Guide (2023), the variation in fees was dependent on whether the research was conducted by foreign researchers or was a sponsored research project, such as in the case of ethics approval fees by the Indonesian national referral hospital for one of the projects. The added burden of

administration payments contributed to the delay to this particular project as additional rules and guidelines were required to be followed.

Other fees were also paid in some of the research projects. Participation incentive fees were provided to some participants in the projects which ranged from Rp50,000 to Rp 200,000 (AU$5 -AU$20). This was in line with other similar studies in Indonesia (Linawati et al., 2022). Although the practice of participation fees is widespread across the globe, it remains ethically contentious (Pollacsek, Boardman and McCann, 2017; Largent et al., 2022). However, according to Pollacsek, Boardman and McCann (2017), providing a payment as an incentive is not considered unethical as a payment is considered an offer rather than a threat. It is vital, however, that participants are provided with informed consent so they are aware of what they are agreeing to, being paid for and that the fees are equitable. According to Largent et al. (2022), concerns about payments cited in other studies include that participation fees might unduly influence the participants or lead to coercion, undermine participant informed consent, or result in the disproportionate enrolment of low-income or otherwise disenfranchised individuals. However, their research, which was conducted in a developed country, found that incentives did not impact unduly on participant recruitment.

According to Pollacsek, Boardman and McCann (2017), when conducting research with vulnerable populations, those who are socially or economically disadvantaged, the amount of payment suggested as being appropriate can be guided by advice from the local community. LeBarron et al. (2015), also recommend that researchers in low-income country settings consult with local collaborators and mentors about being culturally sensitive as to appropriate ways to compensate participants for their time. All three project researchers liaised with key personnel in their specific research locations. As a result, participants in some of the studies were provided with a participation fee, the amount of which was determined during the consultation. This was regarded as being acceptable to all parties involved as it was viewed that, in Indonesia, a low-income country, providing participants with funds to assist with travel or food is a cultural expectation rather than an incentive expectation.

Transparency and bureaucratization of the application processes

There were issues with transparency and bureaucracy in the research ethics application processes leading to additional steps required by the applicants that were not anticipated. These additional steps resulted in time-consuming hurdles for the applicants, delaying the approvals and commencement of the projects. For instance, one of the project applications required the additional steps of the researcher following up directly with the person-in-charge/administrator both by telephone and in person. Another of the projects required the researchers to personally present the proposed project to a panel of the research ethics committee. Although there were guidelines for the HRECs applications, there was ambiguity in requirements, resulting in tensions and challenges.

According to some researchers, ethics approvals can lack transparency, which can be especially challenging for researchers in developing countries who face issues with differences in culture, security, society structures and norms that are different to developed countries. Further, according to Brown, Spiro and Quinton, there can be a disconnect between researchers and ethics committees in relation to bureaucracy and formality were ethical regulations substantially increase the time and effort required by researchers to meet the administrative demands. Additionally, there can also be a disconnect between research site approvals and researchers with the navigation of bureaucratic requirements. For example, the researchers of the three projects had to be well-informed and familiar with the administrative procedures and which departments/government authorities were required to be approached for providing permission to conduct research in their specific community areas. There was no consistent approach across the three different projects.

According to Koirala, Amagai and Davidson (2020), researchers need to use professional and organizational networks from a broad range and build a good rapport so that access to systems during the research projects is achievable. This may include pre-planning to identify the key contacts, use of strategic connections, dedication and some luck (Koirala, Amgai and Davidson, 2020). Additionally, use of formal (such as email requests) and informal (such as online social networks) systems in developing countries to navigate the bureaucracy can help in the process (Koirala, Amgai and Davidson, 2020). Furthermore, LeBaron et al. (2015), report that the importance of advanced planning when conducting research in developing countries cannot be underestimated. However, the impact of unforeseen events such as the COVID 19 pandemic, cannot be planned for. Hence, ensuring transparency of ethical approvals and understanding complex bureaucratic systems is vital in the initial instance when conducting research in developing countries.

Study strengths and limitations

This study contributes to the gaps in existing knowledge regarding ethics application processes in developing countries such as Indonesia. Notably, this study adds to the existing literature by exploring the experiences of researchers and post-graduate research higher degree students base in Indonesia in the Asia-Pacific region highlighting the differences in processes in three different projects within the same developing country.

A limitation of this study is the difference in timeframes between the three projects applications for ethics approval. The time period for when the research projects were conducted varied from three to eight years ago. During this time, changes have occurred in the Asia-Pacific region with the development of WHO March 2022 Standard Operating Procedures (SOP) for the ethics review committee (World Health Organization (WHO) South-East Asia, 2022). These SOPs may assist in future research ethics applications in centers unfamiliar with ethical approval processes which, in turn, may shorten the ethical approval timeframe for research projects.

Conclusion

Symptoms commonly occur as clusters rather than as a single symptom. Identifying symptom clusters is important in terms of maintaining patient's health-related quality of life. The Indonesian version of the CKD–SBI was demonstrated to be a valid and reliable instrument to identify symptom clusters among patients with hemodialysis in Indonesia. The Indonesian version of the CKD-SBI was shown to be suitable for specific characteristics and can be used in clinical settings in Indonesia to identify symptom burden and symptom clusters among patients with hemodialysis. For further study, research about symptom management among patients with hemodialysis can be the main focus.

Conflict of interest

The authors declare that there is no conflict of interest.

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