KNOWLEDGE OF RESEARCH ETHICS GUIDELINES IN DARLING DOWNS HEALTH CLINICAL STAFF

A Thesis submitted by

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For the award of

Master of Professional Studies by Research

2019

Abstract

Health care practitioners are increasingly expected to engage in research to enhance patient outcomes and ensure evidence-based care. To conduct valid research, an investigator requires academic skills, knowledge of the behaviours expected of the research profession, and knowledge of the guidelines that govern the ethical conduct of research. This work-based project investigated the knowledge of research ethics guidelines among clinical staff in a public health service. The study utilised an objective measure to evaluate and quantify the level of knowledge about research ethics guidelines of health care practitioners employed within a public health service in regional Queensland.

A descriptive, cross sectional prospective research design was used. The setting was the Darling Downs Hospital and Health Service; a public health service in south-east Queensland which serves a population of around 280,000 people across 90,000 square kilometres, through services provided at 29 facilities including hospitals, outpatient clinics, multipurpose health centres and aged care facilities. The working population (N = 3,726) consisted of all clinical staff employed by the Hospital and Health Service under the Medical Officers, Health Professional and Dental Officers, and Nursing and Midwifery awards. A custom questionnaire was utilised to measure: knowledge of research ethics guidelines as described in the National Statement; confidence in knowledge about research ethics; interest in conducting research in the future; and interest in attending training in research ethics, along with demographic variables. Knowledge of research ethics guidelines was measured by posing 5 multi-option questions (choose all that apply) across research-specific topics. Confidence about knowledge of four research-specific topics was measured on Likert-type scales where respondents responded to a statement (I am confident I understand the requirements for) on a 5-point scale (Strongly Disagree – Strongly Agree). Interest in conducting research was measured on a single 5-point Likert-type scale and interest in attending research ethics training was measured as a dichotomous (yes/no) response. Participants completed an anonymous web-based survey between November 2018 and February 2019. An 11.6% response rate provided a final sample size of n = 432 consisting of 85% females with a median age of 46 years (range 20-74 years). Overall,

demonstratable knowledge of research ethics guidelines was low-to-medium; with no participant able to correctly answer all 5 knowledge questions, and 27% failing to correctly answer any of the knowledge questions. Individuals' confidence in their knowledge of research ethics guidelines was also measured and compared to actual (demonstrated) knowledge. The proportion of respondents believing they understood a topic was higher than the proportion who could demonstrate knowledge about the topic, across all topics. There was a significant relationship between demonstratable knowledge and research experience, however confidence was not related to either demonstratable research ethics knowledge or research experience.

Although knowledge levels within this sample are comparable to previous findings, responses to additional questions suggest that respondents do not know the whereabouts of the pertinent information, and would therefore struggle to source the information on their own should that be required. Overconfidence also replicated previous findings. In this sample, at least part of the explanation for overconfidence may lie in the similarity of the clinical and research terminology, thus leading clinicians to think they know about a research topic because it has the same name as a clinical topic.

Despite less than half of respondents expressing interest in conducting research in the future, interest in attending training was extremely high. This suggests that many of those who were ambivalent about conducting research may nevertheless be interested in attending training. Notwithstanding high interest in training, comments indicated that organising time away from clinical practice to attend training could be a barrier to attendance. A number of those respondents not interested in research (and subsequently not interested in research ethics training) expressed a concern that mandatory indiscriminate research ethics training would add to the perceived burden of unnecessary training imposed upon already time poor staff.

A number of demographic variables were found to have a relationship with the main variables of interest. Relationships were found between professional stream (i.e. Allied Health, Medicine, and Nursing and Midwifery) and knowledge ($p = .005$), confidence ($p < .001$) and interest in research ($p < .001$). Those respondents with a research-specific tertiary qualification (i.e., a Higher Degree by Research qualification) demonstrated higher levels of knowledge ($p < .001$), confidence ($p = .001$), and interest in conducting research in the future ($p = .001$). Generalisability is limited by the non-representativeness of the sample. This may be particularly so in the

Medical stream where the high proportion of adjunct appointments in this group (43% compared to an estimated 15% within the working population) may be indicative of recruitment of a non-representative sample biased toward research interest and activity.

This research offers an initial contribution to the area of quantifying knowledge of research ethics guidelines in the Australian context, and amongst a population of health care practitioners in a regional public health service. The findings indicate further education is warranted, although this should be focused on those clinicians intending to conduct research, rather than mandated for all staff. A report of findings will be prepared for the Executive of the Darling Downs Hospital and Health Service to inform funding forecasting for future training.

Certification of Thesis

This Thesis is entirely the work of Donna Rouse except where otherwise acknowledged. The work is original and has not previously been submitted for any other award.

Principal Supervisor: Dr. Lee Fergusson

Associate Supervisor: Dr. Anna Tynan

Student and supervisor signatures of endorsement are held at the University.

Acknowledgements

It is appropriate I acknowledge my principal supervisor Dr Lee Fergusson, for his role in the completion of the MPSR and this thesis.

It is with gratitude that I acknowledge the input and guidance of my associate supervisor Dr Anna Tynan, without whom I would neither have started nor completed the course. Thank you Anna.

My colleague Dr Maxine O'Brien deserves acknowledgement for her forbearance, empathy and encouragement. Thank you Maxine.

I would also like to acknowledge the staff at Darling Downs Health; those who assisted with recruitment procedures and those who participated in the study.

This research has been supported by an Australian Government Research Training Program Scholarship.

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Abbreviations

DDHHS: Darling Downs Hospital and Health Service

HREC: Human Research Ethics Committee

U.S.: United States

HHS: Hospital and Health Service

ORI: (US) Office of Research Integrity

the Code: Australian Code for the Responsible Conduct of Research

NHMRC: National Health and Medical Research Council

FFP: Falsification and fabrication of data and plagiarism

National Statement: the Australian National Statement on Ethical Conduct in Human Research

GCRP: Good clinical research practice

RCR: Responsible conduct of research

MPSR: Master of Professional Studies by Research

WBHD: Work-based higher degree

Chapter 1: Introduction

The project described in this thesis was undertaken in response to questions arising in the workplace. The thesis provides a background to the research; a thorough exposition of how the research project was designed and undertaken; what the outcomes were and how they addressed the original questions. Chapter 1 provides the background and context for the study and outlines the format of the rest of the thesis. Section 1.1 of this chapter provides the background, followed by the context in section 1.2. The purpose of the study is explained in section 1.3 and the significance, scope and definitions are explained in section 1.4. Finally, an overview of the remaining chapters of the thesis is provided in section 1.5.

1.1 BACKGROUND

Health care practitioners are increasingly expected to employ evidence-based practice and participate in research within their clinical roles (Australian Medical Council, 2012; Queensland Industrial Relations Commission, 2016). This requires the ability to critically appraise the research of others, to partner in projects being led by others, and ideally, to conduct original research. Health care professionals within the Darling Downs Hospital and Health Service (DDHHS; the public health sector in the Darling Downs region of south-east Queensland) are not exempt from this requirement.

To conduct robust and useful research, an investigator requires not only certain academic skills (such as the ability to conduct a literature search and review, write a protocol, select a suitable methodology, conduct interviews, etc.) but also a working knowledge of the rules and guidelines that govern the conduct of research in their location (i.e. their state, country and organisation). These rules and guidelines state how researchers should conduct ethical and valid research in order to, among other things, demonstrate respect for respondents and ensure their protection.

Several years' experience by this author in the research support department of a public health service has provided anecdotal and observational evidence which suggests that clinicians as a group do not have a clear understanding of the guidelines

for the ethical conduct of research, as they apply to healthcare research conducted within DDHHS. Specifically, information addressing data access, storage and confidentiality; recruitment from patient and staff populations; provision of participant information; requirements for obtaining informed consent; and requirements for monitoring and reporting of studies, is noticeably absent or incomplete in many research protocols prepared by clinicians and submitted to the Human Research Ethics Committee (HREC) of the DDHHS. In such a population, whose primary training and core business is the prevention and treatment of disease, it is understandable that knowledge of research ethics may be rudimentary or insufficient. Recognition of this by clinicians themselves often appears to prompt help-seeking behaviours in the design stages of a study, as witnessed by the researcher within the organisation. Whilst some clinicians are aware of their gaps in knowledge and seek support from internal and external research support services, others are referred for assistance when they present scientifically or ethically flawed study proposals to the DDHHS HREC for review. It is often the job of the research support team to assist those clinicians whose proposals fail to meet HREC standards, to correct the deficits in the study design.

Although the DDHHS has provided non-compulsory research education sessions to staff interested in research, these have generally been poorly attended, despite targeting topics for which assistance was most frequently sought in research consultations. Different days and times were trialled, to improve access, and external speakers engaged to peak interest, however attendance rates have fallen sharply across the two years of provision of monthly education sessions. In 2017 the research support team moved to a model of provision where education sessions were provided at the request of teams and individuals, along with brief presentations at new staff orientation days. Nevertheless, inappropriate and incomplete protocols continue to be presented to the HREC as part of the ethical review application procedure.

The research support team is continually seeking ways to enhance staff knowledge of research methods, including ethical research practices and standards. While considering what modalities and content might be effective in engaging clinicians, I (the researcher) have been led to consider: how much do clinicians actually know about research ethics guidelines; does overconfidence hinder help-seeking; what proportion is actually interested in conducting research; and is there, in fact, any appetite for attending research ethics training? These questions form the basis of the research project.

1.2 CONTEXT

The work-based project which was undertaken and documented by this thesis was an evaluation of the knowledge of research ethics among clinical staff in the DDHHS. This project was nested within the larger Master of Professional Studies by Research degree (MPSR) undertaken by the author at the University of Southern Queensland.

Traditional post-graduate degrees have focused on producing academics and professional researchers, although there is little evidence to support the assumption that this is the pathway chosen by the majority of doctoral graduates (Costley & Lester, 2012). In contrast, a professional doctorate allows specialisation or professional development within an occupation, as opposed to the traditional academic focus of the PhD. However, an emergent learner population in the past decade has been the mid- to late-career professional; a group already possessing substantial professional experience, but needing to situate their learning within the work environment.

The failure of traditional higher degrees to meet the needs of the mid-career professional and the modern work context (Fergusson, Allred, & Dux, 2018) has been a driving factor in the development of the work-based higher degree (WBHD) (Costley & Lester, 2012). WBHDs offer professionals with expertise in their fields of practice, the opportunity to hone professional skills whilst remaining within the work force. Additionally, whilst facilitating personal and professional growth, they also provide the opportunity to address real-world issues relevant to the workplace and contribute to the broader community of practice (Costley & Abukari, 2015; Costley & Lester, 2012).

Thus the WBHD produces positive benefits for the learner, the workplace and the profession or community of practice (Costley & Lester, 2012; Fergusson et al., 2018), what Fergusson has termed a ‘triple dividend’ (Fergusson et al.). Others have articulated benefits as accruing to the learner, their work (encompassing both the organisation and the profession) and the university which supports the WBHD (Costley & Abukari, 2015), although it is not clear whether this goes beyond the usual benefits which accrue to universities upon completion of a higher degree candidate.

Through structured reflective practice the learner identifies target areas for personal and professional growth, and develops learning objectives based on these (Fergusson et al., 2018). Learning objectives are addressed through the undertaking of

a work-based project, which addresses an identified need or issue relating to the work place (Fergusson et al.). The work-based project results in a tangible outcome or 'artefact' of benefit to the organisation (Fergusson et al.). Personal and professional benefits accrue to the learner which enhance their competence, confidence and standing within the workplace (Costley & Abukari, 2015).

The MPSR is offered within the Professional Studies program of the University of Southern Queensland. The author has worked on the periphery of research for over ten years; initially in casual research assistant roles, through support of academic researchers, to latterly providing education and support to clinicians undertaking research in a public health service. Throughout this time, I have provided support to researchers in the conduct their own projects. The working questions motivating this study, and the work-based MPSR program, provided the opportunity to put my theoretical knowledge into practice within an academic framework and develop those skills which would contribute to my professional practice in the area of research support. My learning objectives for the program were therefore largely attached to the development of research skills, and the learning outcomes were framed around activities related to the design, conduct and reporting of the research. The six objectives listed below each addressed multiple learning areas.

1. Systematised information gathering
2. Analytical skills
3. Objective judgement
4. Problem solving
5. Creativity & innovation
6. Critical judgement

Managing all aspects of a research project, from inception to dissemination of results, provided the opportunity to practice and develop those skills about which I had previously only a theoretical knowledge. A summary of how these learning objectives were met is provided in section 5.10.

1.3 PURPOSES

The work-based project had two main purposes. Firstly, to address an identified issue within the organisation: the requirement to clarify staff knowledge in an area where they are required to operate but anecdotal evidence suggests an unacceptable level of knowledge (i.e., research ethics). Subsumed within this purpose is the

requirement to determine staff confidence in their knowledge, and their interest in research and research ethics training, and to gather information which may inform the development of an education package for use within the organisation. The outcomes of the research would contribute to the required artefact: a report to the Executive about staff levels of knowledge and recommendations for future training.

A second purpose of undertaking the work-based project is the upskilling of the researcher. The MPSR program provides an opportunity for personal and professional development, particularly upskilling for my role. Working in a research support context provides exposure to a broad range of needs, some of which I am not able to respond to due to my own lack of research experience. The research component of the MPSR provided the opportunity to address this deficit.

1.4 SIGNIFICANCE, SCOPE AND DEFINITIONS

The current literature on research knowledge has several characteristics which limit application of findings to the broader research community, and to the health care community in particular. Firstly, it is predominantly based on research undertaken with academic and post-graduate participants (i.e., researchers rather than clinicians), and largely consists of research conducted outside Australia. Public health services are a major source of research into health and medical issues (Clinical Trials Jurisdictional Working Group, 2016-2017), yet clinicians represent an under-investigated population. Clinician-led research differs in two major aspects from academic-led research. Academic research is undertaken within an environment specifically structured to support and promote the research endeavour, with quarantined time, administrative supports, and targeted resource allocation all supporting the researcher. By comparison, the core business of clinicians is patient care. It is only in the last two decades that strategic support for clinician-led research has begun to gain traction. Many clinician-researchers therefore may be endeavouring to undertake research with limited or no quarantined research time, managerial support, or targeted resource allocation. Indeed, in rural areas, even when time and resources are available, issues such as sourcing backfill for clinical roles can still pose an insurmountable barrier (Pain, Plummer, Pighills & Harvey, 2015). Topic choice is also influenced by context. Within the academic realm, career advancement is often predicated upon publication of research findings (Schimanski & Alperin, 2018), and research academics in particular may be required to fund their positions through rolling acquisition of

research grants. Choice of research topic for academic researchers may therefore be influenced by funding body decisions about the importance and value of a particular research topic. Clinician-led research, by comparison, tends to address topics of interest and value to the clinician in the clinical setting – topics focused on improving patient outcomes (Fradgley et al., 2019).

The present study utilised a population of health care clinicians, within a public health service. Whilst some of the staff within the health service hold adjunct appointments with universities, their primary roles remain clinical. Within the DDHHS context, adjunct appointments are teaching rather than research based and as such pertain to the provision of teaching and supervision to the various medical, nursing and allied health students on placement within the clinical sites across the health district.

The literature is also focused almost exclusively on professional integrity and ethical decision making rather than gauging the level of knowledge of the legislation which guides ethical conduct of research. The current study adds insight into the level of research ethics guidelines knowledge of health care professionals. This should provide a foundation for investigation into the conduct of research; complementary to but separate from the investigation of professional integrity and ethical decision making which currently dominates the research ethics research literature.

Self-confidence in knowledge of research ethics guidelines was also measured, and its relationship to knowledge investigated. Some mention has been made of this in the literature, but the relationship has not been well articulated.

Lastly, the current study is located within Australia and focuses on the application of Australian guidelines, which differ from those of the United States (U.S.) where the majority of the research is undertaken, and other international sites which predominantly follow the lead of the U.S. and have adopted its definitions for research related terminology.

The study investigated the level of knowledge of research ethics. Causal reasons for knowledge levels was not investigated, as this is likely to be historical and unable to be addressed within the Hospital and Health Service (HHS) training and education framework. Nor was research capacity and capability investigated, as these pertain to

research skills and culture, which are already being addressed (particularly within the Allied Health professions) by government funded initiatives.

For the purposes of this study, the term 'research ethics' was defined as a set of pre-determined guidelines which promote the protection of the rights and dignity of participants in human research activities. The guidelines underpinning research ethics were those elucidated in the Australian National Statement on Ethical Conduct in Human Research (the National Statement; *National statement on ethical conduct in human research 2007*, Updated 2018).

All staff within DDHHS (Queensland) employed under the Health Practitioners and Dental Officers, Medical and Nursing and Midwifery awards were invited to participate. The Health Practitioner and Dental Officers award covers a broad range of health care professions including Allied Health and some technical professions. A full list of these professions is provided in Appendix A. To enhance readability, and to distinguish them from the Medical and Nursing and Midwifery groups, and without diminishing the role of all other services involved, this group will be collectively referred to hereafter as 'Allied Health' professionals. This total population was estimated to be approximately 3,730 health care clinicians.

1.5 THESIS OUTLINE

The remainder of this thesis provides a detailed narrative of how the research project to address the above issues was designed and implemented. Chapter 2 begins with a review of the literature on research ethics, including discussion of the three factors which make up the concept of research ethics within the international literature: 1) research skills; 2) professional integrity; and 3) research ethics. The literature is summarised, and then research aims proposed and research questions formulated.

Chapter 3 describes the methodology adopted to address the aims of the study. Full details are provided of the methods employed including: the research paradigm and study design; the design and administration of the instrument; and the participants, including population, sampling, recruitment and participant characteristics. Chapter 4 provides the results of the analyses which are then discussed in detail in Chapter 5. Chapter 5 also includes a brief discussion of the limitations of the study and suggestions for future directions. Finally, the outcomes for the learning objectives associated with the MPSR program are summarised.

The Appendices contain extra material referred to within the body of the work, and which may be of interest to the reader, including a copy of the questionnaire used for the study.

Chapter 2: Literature Review

2.1 INTRODUCTION

This chapter introduces a conceptual model of the requirements for conducting quality research and situate the knowledge of research ethics guidelines within that model (section 2.2). The chapter then presents a review of the literature around the three aspects of the model: research skills (section 2.3); research integrity (section 2.4); and research ethics (section 2.5). In section 2.4 the three main perspectives on research integrity are discussed and explored and compared to the Australian perspective. Research exploring factors related to research integrity is also discussed. Two perspectives on research ethics are reviewed in detail in section 2.5, and the Australian perspective discussed and compared to the international perspectives. Evidence of factors relating to knowledge of research ethics, and in particular clinicians' knowledge, is examined. The discussion is summarised in section 2.6 and implications for research highlighted. A rationale for the present study is presented in section 2.7, the significance of the research is highlighted in section 2.8, the purpose reiterated in section 2.9, and finally the research questions guiding the present study are formulated in section 2.10.

2.2 A CONCEPTUAL MODEL OF RESEARCH ETHICS

Healthcare professionals are increasingly expected to engage in evidence-based practice, undertake quality assurance activities (such as clinical audit and service evaluation) and conduct research as a part of their roles (*Allied Health clinical governance framework in Queensland Health*, 2015; Medical Board of Australia, 2014). Indeed, there is some evidence that trainees themselves recognise the importance of research and evidence-based practice to the role of the effective clinician (Harding, Porter, Horne-Thompson, Donley, & Taylor, 2014; Rosenkranz, Wang, & Hu, 2015). Evidence based practice requires clinicians to make clinical decisions based in part on a knowledge of the current available evidence. This in turn, requires the capacity to understand the mechanisms of research and assess the value of research outputs. Whilst not strictly research, findings from in-house quality activities such as

clinical audit, service evaluation and service development (henceforth: quality activities) have the potential to impact on clinical practice, and should therefore be conducted with the same level of scientific rigor as research (Edwards, 2009). While Queensland Health mandates annual service-wide quality assurance audits, ad hoc clinician-led quality activities provide ongoing improvement to clinical practice which impact directly on level of care provided to consumers. The skills required by a clinician to conduct quality activities or engage with research to inform evidence-based practice are those primary skills on which more advanced research skills are built (Pighills, Plummer, Harvey, & Pain, 2013). Research activities allow clinicians in all professions to stay abreast of emerging trends in care, contribute to the knowledge base about their profession and provide evidence-based care options in the clinical setting. Moreover, engagement in research facilitates personal as well as professional growth for clinicians and opens the way for interaction with content experts in chosen fields (Bonilla-Velez, Small, Urrutia, & Lombek, 2017).

Within DDHHS (the public health service of the Queensland Darling Downs region) the conduct of quality activities and research is included in various professional standards (e.g., Australian Medical Council, 2012; Nursing and Midwifery Board of Australia, 2018); at numerous levels of the various state awards under which staff are employed (*Health practitioners and dental officers (Queensland Health) award – State 2015*; *Medical Officers (Queensland Health) Award – State 2015*; *Nurses and Midwives (Queensland Health) Award – State 2015*); within the DDHHS organisational strategy (Darling Downs Hospital and Health Service, 2017); and may be included in individual role descriptions. Indeed, the Queensland Government advocates a health care system underpinned by research, where research is embedded into the key performance indicators of public health services (*Queensland advancing health research 2026: Healthier Queenslanders through research-informed care*, 2017). In line with this state-wide goal, DDHHS has incorporated a commitment to research in regional health care into its strategic plan (Darling Downs Hospital and Health Service, 2017). This necessitates not only collaboration with partner organisations on research projects pertinent to the Darling Downs population, but also enhancing the research capability and capacity of the DDHHS workforce.

To design and conduct scientifically and ethically robust research, an investigator requires skill and knowledge across three domains (Ingham-Broomfield, 2017; White, Satterfield, & Blackard, 2017). Firstly, a set of skills in research specific

activities. Secondly, knowledge of and adherence to the professional standards expected from the scientific research community. And thirdly, knowledge of and compliance with the ethical guidelines underpinning the conduct of research within the researcher's geographic location. Research skills, professional integrity and knowledge of research ethics are gleaned through both research experience and formal learning. Their acquisition is however, moderated by individual interest in research. Their application to the design and conduct of research is in turn moderated by demographic and personal factors such as personality type and language proficiency. This conceptual model of the acquisition and application of skills and knowledge required for the successful conduct of research is illustrated in Figure 2.1 and will be further expounded in the following sections.

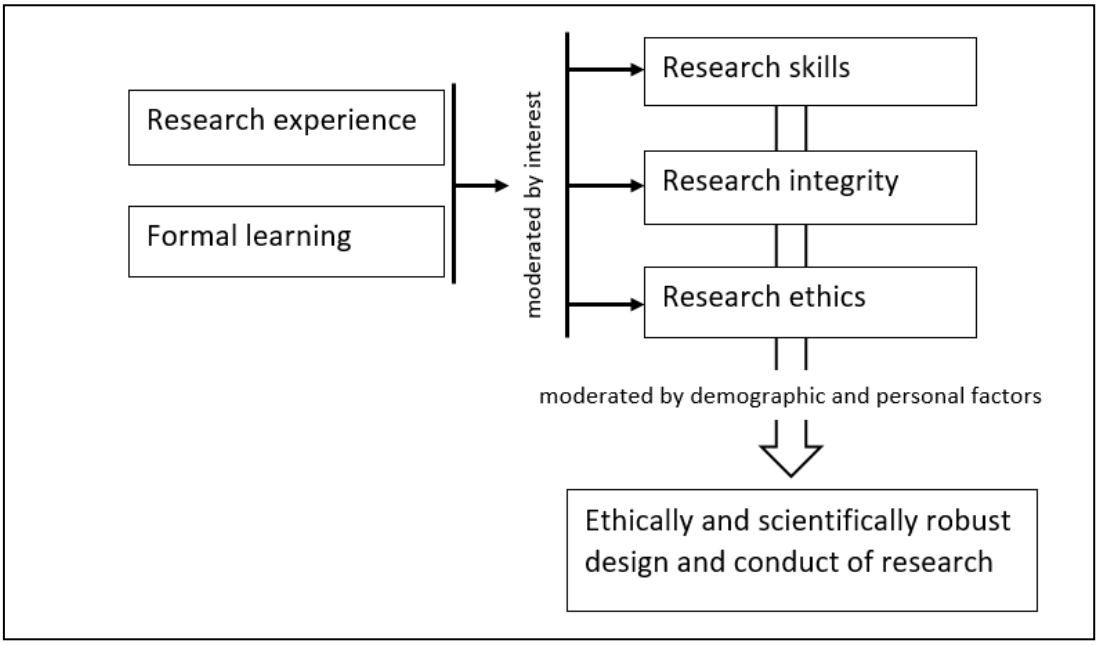

Figure 2.1. Conceptual model of skills and knowledge required to conduct ethically and scientifically robust research.

2.3 RESEARCH SKILLS

It is generally acknowledged that the conduct of research requires certain academic and investigative skills. Several studies have sought to categorise and quantify these skills, often with a view to providing a baseline for subsequent education and resource allocation. One of the earliest tools developed to categorise and measure research skills in health professionals is the Research Spider which assesses research skills across ten aspects of the research process (see Table 2.1) (Smith, Wright, Morgan, Dunleavey, & Moore, 2002). The resultant star-plot illustrates

research experience from ‘none’ to ‘very experienced’, across the ten identified skills. Some authors have extrapolated these findings to represent research capability of participant groups (e.g. Mullan, Weston, Rich, & McLennan, 2014), although self-reported experience and actual capability may not be interchangeable concepts (Wenke, Mickan, & Bisset, 2017a). The tool has had substantial uptake since its development and has been adapted to collect additional data on research interest and confidence across the specified areas (e.g., Finch, Cornwell, Ward, & McPhail, 2013) with the subsequent interest and confidence plots being mapped onto the original star-plot.

More recently, the Research Culture and Capability tool was developed to assess organisational research culture and individual researcher skills (Holden, Pager, Golenko, & Ware, 2012). It identified 15 skills which can be quantified to measure research capability of an individual, with self-reported experience again being taken as a measure of capability. These include the 10 skills identified by the Research Spider, with the addition of several procedural steps as well as the translation of research into practice and mentoring of less experienced researchers (refer Table 2.1). Once again, other researchers have adapted or modified this tool for their own purposes (e.g. Pighills et al., 2013).

Finally, other tools exist which, while not specifically designed to measure research skills, include some aspect of skills assessment in their overall design (e.g. the Edmonton Research Orientation Scale; Pain, Hagler, & Warren, 1996). While different tools categorise them in different ways, the consensus is that skills required to conduct research include the ability to: find and review relevant literature; identify the appropriate methodology and write a research protocol; submit an ethics application; collect, manage and analyse data; and systematically and coherently communicate the results to peers.

Recent studies among Australian Allied Health practitioners and Nurses have identified a self-perceived lack of research skills as being a barrier to undertaking research in between 40% and 55% of respondents (Borkowski, McKinstry, Cotchett, Williams, & Haines, 2016; Friesen & Comino, 2016; Wenke et al., 2017a). These studies demonstrate that irrespective of the amount of exposure, a lack of interest will prevent clinicians participating in research. Lack of interest was cited as a barrier to research involvement in between 8% and 28% of respondents.

Table 2.1

Comparison of research skills identified by two research capability measures

Research Spider*	Research Capability and Culture Tool**
Generating research ideas	
Finding relevant literature	Finds relevant literature
Critically appraising the literature	Critically reviews the literature
	Uses a computer referencing system (i.e. referencing software)
Writing a research protocol	Writes a research protocol
Applying for research funding	Secures research funding
Using quantitative research methods	
Using qualitative research methods	
	Designs questionnaires
	Submits an ethics application
	Collects data e.g. surveys, interviews
	Uses computer data management systems
Analysing and interpreting results	Analyses qualitative research data
	Analyses quantitative research data
Writing and presenting a research report	Writes a research report
Publishing research	Writes for publication in peer reviewed journals
	Integrates research findings into practice;
	Provides advice to less experienced researchers

Note. *Adapted from Smith et al., 2002. **Adapted from Holden et al., 2012.

Alongside the skills needed to correctly design, conduct and report scientifically robust research, is the requirement for a working knowledge of the rules and guidelines that govern the conduct of research in the researcher's field of expertise and their geographical location (i.e., their country, state and organisation). This is covered by the knowledge of the professional standards for scientists as well as the knowledge of research guidelines. We look first at the knowledge of professional standards and its application, also known as research integrity.

2.4 RESEARCH INTEGRITY

Research integrity is an abstract construct which has proven difficult to define (Helton-Fauth et al., 2003). Indeed, one researcher declared the study of research ethics and integrity 'incoherent' with subject matter encompassing "…ageless moral truths and recent arbitrary conventions; minute details of particular actions and the broad

sweep of public policy; life-and-death issues and matters just the other side of simple etiquette" (Pimple, 2002, p. 191). This ambiguity is reflected in the literature, where research integrity is approached from three distinct perspectives: professional integrity; ethical decision making; and imperatives. All three perspectives will be discussed below to provide a comprehensive introduction of the concept.

2.4.1 Research integrity as professional integrity

Nicholas Steneck, a consultant to the U.S. Federal Office of Research Integrity (ORI) and a leading authority in the field, offered an early definition of research integrity as "… possessing and steadfastly adhering to high moral principles and professional standards, as outlined by professional organizations, research institutions and, when relevant, the government and public" (Steneck, 2006, p. 55). Antes, English, Baldwin and DuBois (2017) further elucidated Steneck's definition by clarifying the principles and standards as deriving from regulations, norms and ideals.

In the context of professional integrity, regulations are defined as those rules enshrined in law, the violation of which attract penalties under the criminal code. This may cover such areas as human and animal protection, falsification and fabrication of data, and plagiarism (Antes et al., 2016). (In the US, these last three items form the definition of research misconduct, which has direct legal consequences.) Given their legislative underpinnings and subsequent judicial consequences, these rules are given substantial weight and wilful breaches are termed 'research misconduct' (Resnik, 2015).

Scientific norms are those behaviours and attitudes deemed appropriate and desirable for persons claiming membership of the scientific community. They include aspects of authorship practices, transparency in reporting methodologies and results, peer review processes and data management practices (Antes et al., 2017). These norms may be formalised, for example in institutional policies or professional codes of practice but may equally remain unwritten. Violations are termed 'questionable research practices' and while they may attract professional or institutional censure, they are not usually such that they are prosecutable under law.

Lastly there are informal, professional ideals which span such areas as membership of professional associations, building community goodwill, collegiality and mentoring. Although non-compliance does not usually attract formal consequences, it is likely to result in personal or career ramifications as a result of a

decline in professional standing amongst peers (Antes et al., 2017). Although failure to comply with professional ideals may not directly impact on research participants or outcomes, it may have an indirect impact on society through reduced peer collaboration and declines in community trust in researchers generally.

Questionable research practices are by definition considered less serious than research misconduct (Resnik, 2015) based on the commonly held belief that they have no impact on the integrity of the research process (Antes et al., 2017). However, Steneck (2006) makes a convincing argument for at least some questionable research practices having the potential to impact individuals and society at least as much as acts of serious misconduct, and concludes the adherence to scientific norms is therefore as important as adherence to legislated regulations. For example, claiming the work of another as original does not of itself corrupt research outcomes or cause harm to society, however it constitutes plagiarism and is classified as research misconduct, attracting legal prosecution. By comparison, allowing a financial bias to influence research design, participant selection and/or reporting may cause significant public harm if decisions are made on the release of a product based on the findings. Bias, and failing to declare conflicts however, are only categorised as questionable research practices in the U.S. (and subsequently in the majority of the international research ethics literature), attracting institutional censure, but not legal consequences. Other authors have advocated for a broader definition of research misconduct which encompasses questionable research practices (Breen, 2016; Zimmerman & Wallace, 2013) acknowledging potential serious outcomes and noting characteristics such as honesty and social responsibility are as vital to the pursuit of science as integrity in data management and reporting (DuBois et al., 2016b; Sacco, Bruton, & Brown, 2018). Moreover, there is emerging evidence that researchers are more likely to engage in questionable research practices if they believe them to be ethically defensible or normative (Sacco et al., 2018). Acknowledging that questionable research practices are potentially as harmful as research misconduct and applying penalties commensurate to their potential impact, may therefore inhibit some researchers from engaging in some questionable research practices. Notwithstanding definitions that draw a distinction between research misconduct and questionable research practices, both terms are frequently used generically to refer to failures of researchers to act with professional integrity (e.g., Rajah-Kanagasabai & Roberts, 2015).

Failures of research integrity may be evidenced in the public arena via retracted publications and public prosecutions (e.g., Crime and Corruption Commission, 2017; George, 2016). Whilst bringing research misconduct to the attention of the broader public, these remonstrations fail to illustrate the less visible outcomes of research misconduct such as implementation of non-beneficial practices, wasted resources, and subsequent public distrust in the research process (Fang, Steen, & Casadevall, 2012; Stern, Casadevall, Steen, & Fang, 2014). Notwithstanding ambiguities in definitions, failures in research integrity are broadly acknowledged as an ongoing issue within the scientific community, and their continued perpetration is noted as a matter of collective concern (Breen, 2016; Coughlin, Barker, & Dawson, 2012; Fanelli, 2012; Farthing, 2014; Mijaljica, 2014).

2.4.2 Research integrity as ethical decision making

A large part of the effort to promote research integrity – and consequently reduce research misconduct – has occurred through the introduction of education in the responsible conduct of research (RCR), predominantly in and by universities, and targeting research academics and students. In 2000, the ORI identified nine core areas for instruction in RCR, from which we may infer nine principles required for the responsible conduct of research. The ORI areas are (1) data management practices; (2) mentor and trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative research; (6) human subject protection; (7) the welfare of laboratory animals; (8) research misconduct; and (9) conflict of interest and commitment (Steneck, 2004 - Revised 2007). These nine principles continue to provide the basis for understanding professional integrity and defining RCR in the U.S.

Steneck (2006) posited that the responsible conduct of research requires the capacity to operate from two perspectives: the application of professional standards to the research context (i.e. research integrity, as previously described), as well as the ability to make moral decisions when faced with ambiguous situations in the research setting. This second aspect Steneck termed research ethics, because it concerned making ethical decisions about research. His concept is presented diagrammatically in Figure 2.2. Basically, he proposed that RCR requires a knowledge and application of professional standards (research integrity) through the exercise of moral principles (i.e. ethical decision making) in any given situation. His definitions of research integrity,

research ethics and subsequently the responsible conduct of research within this framework, form the basis for much of the content of RCR courses; comprising procedural knowledge, instruction in professional standards, as well as the development of higher order thinking skills that support ethical decision making. Unfortunately, due to the close association of research ethics, research integrity and the responsible conduct of research, the three terms are often used interchangeably by academics and researchers alike (e.g., Fisher, Fried, Goodman, & Germano, 2009; Ingham, 2003; Komic, Marusic, & Marusic, 2015; Mumford, Steele, & Watts, 2015; Torrence et al., 2017; Watts et al., 2017).

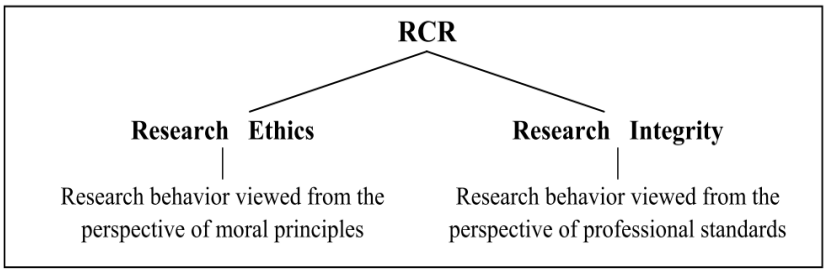

Figure 2.2. Research ethics and research integrity in RCR (Source: Steneck, 2006, p. 56.).

As a consequence, content and delivery of RCR courses varies greatly (Antes et al., 2009; DiLorenzo, Becker-Fiegeles, & Gibelman, 2014; DuBois, Schilling, Heitman, Steneck, & Kon, 2010; Mijaljica, 2014; Minifie et al., 2011; Phillips, Nestor, Beach, & Heitman, 2017; Watts et al., 2017); encompassing not only procedural information and knowledge of professional standards, but training in higher order thinking and ethical decision making skills. Subsequently, effectiveness of training is measured not only in terms of knowledge acquisition, but also of researcher capacity to make ethical decisions. Research integrity may therefore be operationalised in the literature as knowledge of RCR principles, as well as the ability to make ethical decisions in the research context. Notably, ethical decision-making measures are widely applied in studies of research integrity (Antes et al., 2016; Antes et al., 2017; DuBois et al., 2016b; Mumford et al., 2006; Taylor et al., 2012; Wester, Willse, & Davis, 2008). That ethical decision making is requisite for professional integrity is a reasonable assumption. That the two terms are interchangeable is far more open to debate.

2.4.3 Research integrity as defined by imperatives

Another way of defining research integrity is by the focus of its imperatives. Gefenas (2006) differentiated between research integrity and research ethics based on spheres of application and influence. 'Research integrity' is applied to inward looking relationships: those of the researcher with the research community and data. This encompasses the ORI's RCR domains of data management practices; publication practices and responsible authorship; peer review; collaborative research; mentor and trainee responsibilities; research misconduct; and conflict of interest and commitment. 'Research ethics' is applied to outward looking relationships: that is those of the researcher with participants and the environment. In the case of the ORI domains this encompasses human subject protection and the welfare of laboratory animals.

Gefenas (2006) identified the difficulties of cleanly dividing internal and external relationships when some actions will have a bearing on both domains. For example, conflict of interest is largely a matter of research integrity in so far as it may have ramifications for data collection and reporting. However, in so far as it may impact on participant recruitment and safety it is also a matter of research ethics. Notwithstanding the grey areas, the concerns listed in the ORI RCR domains are predominantly those which fall into the 'internal' relationships of research integrity – those of the researcher with the research community and data. The exceptions are the 'Protection of humans' and 'Welfare of laboratory animals' domains. As they stand, these domains provide little in the way of substantive guidance, however their inclusion is not inappropriate in a statement on responsible conduct of research.

The three perspectives from the preceding discussion may be synthesized into a new definition of research integrity for the international context:

> The adherence to legal regulations, scientific norms and professional ideals, both formal and informal, which govern explicitly and implicitly the behaviour of researchers, as expressed through ethical decisions made about research situations.

A caveat must be added, however that some writers would disagree on whether the domains covered should include participants and the environment or be limited to the research community and research data.

2.4.4 Research integrity in Australia

Research integrity is underwritten in Australia by the Australian Code for the Responsible Conduct of Research (the 'Code'; Australian Research Council & Universities Australia, 2018) which provides principles, responsibilities and expectations for individuals and institutions undertaking research. Its eight principles address the integrity of the researcher and institution and are expanded in 29 subsequent responsibilities for individuals and organisations. Further expansive guidance is provided in subsequent guides released by the National Health and Medical Research Council (NHMRC) which support the application of the Code. (See for example "Authorship: A guide supporting the *Australian Code for the Responsible Conduct of Research"* and "Management of Data and Information in Research: A guide supporting the *Australian Code for the Responsible Conduct of Research*"; both recently released by the NHMRC and available from their website; [National Health and Medical Research Council, n.d.]). Failures to comply with the principles and responsibilities of the Code are designated as breaches, with the term 'research misconduct' only applied to 'a serious breach of the Code which is also intentional or reckless or negligent' (Australian Research Council & Universities Australia, 2018, p. 5). Compliance with the Code is mandatory for those researchers, research projects and institutions funded by the NHMRC or Australian Research Council. Whilst compliance with the Code is not mandated for other researchers or organisations, institutions may and do adopt the Code for their own use. (Queensland Health is one such organisation which has elected to adopt the Code for the guidance of researchers wishing to conduct research in its institutions or under its auspices.)

Consistent with Gefenas's (2006) definition of research integrity in terms of internal issues, Gorman (2011) identifies the focus of the Australian Code as being on the interests and obligations of the hosting institution, and the obligations of the researcher to the institution (and potentially the funding body). This includes issues pertaining to publication and authorship, academic integrity, financial accountability of the researcher and institution, as well as legal matters pertaining to contracts and insurance (Gorman). Within the Australian context, the identified issues come under the umbrella term of 'research governance', and are consistent with earlier definitions of research integrity as pertaining to behaviours illustrative of professional standards (e.g., Steneck, 2006).

Table 2.2 illustrates the similarities and differences between the ORI domains and the Australian Code. Most of the ideals are represented within both frameworks and the majority of apparent differences may be reconciled. For instance, the U.S. *ORI Falsification, Fabricating and Plagiarism* domain (collectively known as FFP and constituting research misconduct) is represented by several of the principles within the Australian Code. Principle 1 (P1) *Honesty,* encompasses the honest presentation of research results; and *P3 Transparency* includes the accurate sharing of data and findings. While not making the requirement explicit, both of these imperatives cover the requirements for (avoidance of) data falsification and fabrication. Similarly, *P4 Fairness,* incorporates the requirement to appropriately acknowledge the work of others; thereby disallowing plagiarism. Further, while *P4* mandates the principle of fair treatment of one's peers, *Responsibilities 25* and *28* (not illustrated in Table 2.2) state quite explicitly requirements for honesty in designation of authorship and the need for providing accurate, fair and timely peer review. Whilst not explicated in either the Principles or Responsibilities of the Code, the principle of promotion of responsible research practices (P8) would encompass the ORI mandate for professional behaviours in collaborative endeavours. Thus, the only substantive difference appears to be the lack of comparable ORI domains for the Code's recognition of Indigenous persons (P6) and accountability (P7). In so saying, it is not implausible that engagement with and inclusion of indigenous groups in research design is not assumed in the ORI *Protection of Humans* domain. One could equally assume it to be implicit in *P5 Respect* of the Code. It is, in fact only in the latest 2018 iteration of the Code that such requirements have been given such clear expression.

In its intent to provide a set of professional standards which "characterise an honest, ethical and conscientious research culture" through adherence to a set of professional standards, (Australian Research Council & Universities Australia, 2018, p. 1) the Code is consistent with the ORI requirement for adherence to professional, organisational, and potentially national standards of behaviour. That the application of these standards to research situations would require higher order thinking as described in the ethical decision-making processes parsed out of the research integrity concept is a reasonable assumption. Thus, the Australian definition of research integrity is not

Table 2.2

Comparison of ORI RCR domains with NHMRC Principles of responsible conduct of research

The Australian Code for the Responsible Conduct of Research*	US ORI Responsible Conduct of Research Domains**
	Research misconduct: Falsification, fabrication of data and plagiarism (FFP)
P1 Honesty in the development, undertaking and reporting of research	
P2 Rigour in the development, undertaking and reporting or research *(avoidance of bias, use of robust methodology)*	
P3 Transparency in declaring interests and reporting research methodology, data and findings *(sharing and communication of data and findings)*	Conflicts of interest
	Data management practices (ownership, collection, protection, sharing)
P4 Fairness in treatment of others *(respect and credit of fellow researchers)*	Publication practices and responsible authorship
	Peer review (meeting deadlines, assessing quality, judging importance, preserving confidentiality)
P5 Respect for participants, animals and wider community *(including vulnerable groups)*	The protection of humans
	The welfare of laboratory animals
P6 Recognition of the right of Aboriginal and Torres Strait Islander peoples to be engaged in research that affects or is of particular importance to them *(recognition, engagement and reporting)*	
P7 Accountability for the development, undertaking and reporting of research *(compliance, stewardship of resources, social responsibility)*	
P8 Promotion of responsible research practices *(fostering a positive research culture)*	Mentor and trainee responsibilities
	Collaborative research

Note. *National Health and Medical Research Council, 2018. **Steneck, 2004 – Revised 2007.

inconsistent with the international definition which consists in professional integrity and ethical decision-making capacity.

2.4.5 Factors related to research integrity

For around two decades, academics have been applying themselves to the development of effective methods for teaching the responsible conduct of research. The most recent reviews confirm that while much remains to be done, the effectiveness of RCR courses is improving (Todd et al., 2017a; Watts et al., 2017). There is ample evidence derived from course evaluations which indicates that, with allowance made for variables such as trainer characteristics, content, format and medium, the responsible conduct of research – both theoretical and applied – can be effectively taught and learned (Antes et al., 2016; DuBois et al., 2016b; McCormack & Garvan, 2014; Mulhearn et al., 2017; Ramalingam, Bhuvaneswari, & Sankaran, 2014; Todd et al., 2017b; Torrence et al., 2017; Watts et al., 2017)

There is a growing body of research too around what factors are associated with ethical decision-making by scientists in research contexts. It has been well documented that ethical decision-making scores are positively correlated with the level of knowledge of RCR (e.g., Antes et al., 2016). This supports the intuitive supposition that the individual does require some knowledge of regulations to be able to comply with them. However, research consistently fails to demonstrate any correlation between the amount of instruction received in RCR and either the level of RCR knowledge or ethical decision-making scores (Antes et al., 2016; Antes et al., 2017; Antes et al., 2010; DuBois, Chibnall, & Gibbs, 2016a). This would seem to suggest that it is not simply the volume of teaching one has received that determines whether one is willing or able to make ethical decisions. Irrespective of the hours of tuition received, there appear to be other factors influencing the willingness and/or ability to act with integrity.

Negative personality traits such as impulsivity, compliance disengagement, moral disengagement and narcissism have been shown to predict lower ethical decision-making scores (Antes et al., 2016; DuBois et al., 2016a; DuBois et al., 2016b; Mumford et al., 2006). Additionally, Machiavellianism has been positively associated with self-reported research misbehaviour (Tijdink et al., 2016). Moreover, research suggests course participants are less likely to demonstrate a change in ethical decision making if the course content contradicts their past knowledge or experience (McGee,

Almquist, Keller, & Jacobsen, 2008). In the U.S., research among academics has shown demographic factors such as nation of origin (i.e. U.S. or otherwise) and having English as a first language (in a test administered in English) to be predictors of ethical decision-making scores (Antes et al., 2016; Antes et al., 2017; DuBois et al., 2016a). For example, researchers who were born in the U.S., or highly acculturated to the U.S., had greater knowledge of regulations, were more accurate in their assessment of the severity of breaches, and scored higher on ethical decision-making measures.

Lastly, exposure to unethical research practices in the work environment has been demonstrated to be negatively related to ethical decision making of post-doctoral students (Fisher et al., 2009; Mumford et al., 2009).

It can therefore be concluded from the accumulating evidence that knowledge of RCR practices, and the possession of metacognitive strategies for working through complex ethical issues, is not of itself sufficient to guarantee research integrity. There are clearly moderating factors at work within the environment and the individual that allow, or compel, researchers to behave in ways contrary to the regulations, norms and ideals espoused by the research community.

2.5 RESEARCH ETHICS

2.5.1 Research ethics

Research Ethics in the international context (largely influenced by the U.S. model) is another ambiguous concept (Pimple, 2002). Presently, it falls roughly into two types: research ethics as the application of moral principles to research situations; and research ethics as a set of ideals or standards which ensure the protection of human (and animal) subjects in the conduct of research. The first definition of research ethics as the application of moral principles to research situations contributes to Steneck's (2006) definition of RCR, discussed previously. This definition of research ethics has been referred to as 'procedural research ethics' with the emphasis on the capacity of the researcher to apply moral principles to challenging situations arising in the research context (DuBois et al., 2016b). The alternative definition of research ethics describes a set of guidelines for ethical research design and conduct, and while it is not the prevailing definition in the international literature, it has sound foundations and well-established support.

2.5.2 Research ethics as ethical guidelines

Emanuel, Wendler, and Grady (2000) examined the foundations of modern research ethics based on seminal documents such as the Nuremberg Code, Declaration of Helsinki, CIOMS International Ethical Guidelines for Health-related Research Involving Humans, and the Belmont Report; all of which have contributed to the modern ideal of research as a scientific pursuit guided by high ethical standards (Artal & Rubenfeld, 2017). From their review of these and other documents (including the Australian National Statement on Ethical Conduct in Human Research), Emanuel et al. extracted and detailed seven requirements for ethical research in the clinical context. These were: social or scientific value; scientific validity; fair subject selection; favourable risk/benefit ratio; independent review; informed consent; and respect for participants (encompassing data confidentiality). These principles covered the range of activities inherent in a research study and were intended to provide comprehensive guidance to researchers and reviewers alike on aspects requiring consideration in the design and review of a research proposal.

Resnik (2008) later expanded the Emanuel et al. (2000) list to explicitly include: risk minimisation; protection for confidentiality and privacy; protection of vulnerable subjects; and data and safety monitoring. Although Resnik wrote from the perspective of Environmental Health research, his additional categories are no less relevant within the clinical research context.

Bernabe, van Thiel, and van Delden (2016) later conducted a conceptual analysis of five of the major documents which have contributed to the research ethics landscape. Their bottom-up analysis identified 12 themes or ‘clusters’ for all of the imperatives within the documents. In addition to the principles previously identified by Emanuel et al. (2000) and Resnik (2008), Bernabe et al. included research collaboration, publication and registration, regulatory sanctions and basic principles. Table 2.3 provides a comparison of the three reviews. The extraction of additional principles by Bernabe et al. may be explained by the nature of the reviews.

Table 2.3

Comparison of research ethics requirements from three reviews

Emanuel et al.*	Resnik**	Bernabe et al.***
7 requirements	10 requirements	12 clusters
Favourable risk/benefit ratio	Risk minimisation; Benefit/risk justification;	Favourable benefit/risk ratio; Justified research on the vulnerable population.
Informed consent	Informed consent;	Informed consent;
Respect for potential and enrolled subjects	Protection for confidentiality & privacy; Protection of vulnerable subjects;	Respect for participants;
Fair subject selection	Equitable subject selection;	Fair participant selection;
Social or scientific value	Social value;	Social value;
Scientific validity	Scientific validity;	Scientific validity;
Independent review (of study)	Independent review (of research) Data and safety monitoring;	Independent review; Research collaboration; Publication and registration; Regulatory sanctions; Basic principles – includes respect, beneficence, justice along with 6 other principles minimising harm to the environment and distinction between therapy and research.

Note. Sources: *Emanuel et al., 2000; **Resnik, 2008; ***Bernabe et al., 2016.

Whilst Emanuel et al. (2000) and Resnick (2008) set out to provide a composite list of properties underpinning ethical research, drawn from internationally recognised guidelines, Bernabe et al. (2016) endeavoured to extract all themes and statements about the ethical conduct of research ('imperatives') from the guidelines and determine their consensus across the documents. Emanuel et al. and Resnik therefore were at liberty to omit those items not deemed essential to ethical research; Bernabe et al. were obliged to include all imperatives from all documents. If we return to the Gefenas (2006) model which defined research ethics as pertaining to the protection of participants and the environment, we can see that three of the four items added by Bernabe et al. (research collaboration, publication and registration, and regulatory sanctions) pertain to the relationship of the researcher with the research community. In other words, and according to Gefenas, they are matters of research integrity rather than research ethics. Items in the Bernabe et al. Basic Principles category were drawn from a range of sections (such as preambles) and may therefore represent introductory and general statements, or broader statements on professional behaviour. While statements on professional integrity are not inappropriate within a document which discusses research ethics, they may not necessarily be extracted when seeking to identify principles underlying the ethical conduct of research. Hence their omission from the Emanuel et al. and Resnik lists. Lastly, one item appearing in the Resnik list (Data Safety and Monitoring) is definable as research integrity in so far as it pertains to the verifiability of research data (Gorman, 2011). However, in so far as it relates to ensuring participant confidentiality it could also be categorised as representing an external relationship (Gorman). As Gefenas pointed out, there are grey areas and overlaps; data safety may be one of those areas – or simply a divergence of opinion. For the most part however, there is solid consensus on at least seven core requirements for ethical research, comprising the protection of participants and their rights.

2.5.3 Research ethics in Australia

The major point of difference between the U.S. and Australian models of research oversight is the clear distinction in Australia between research integrity and research ethics; with both areas being governed by separate but complementary guidelines.

In Australia, guidelines for the ethical conduct of research are largely contained in the National Statement on Ethical Conduct in Human Research (*National statement*

on ethical conduct in human research 2007, Updated 2018). The National Statement endeavours to identify issues of ethical concern which may arise when humans are involved as participants in research, and to provide guidance to the researcher to address the concerns in the design stages. It is also intended to be a tool for members of Human Research Ethics Committees (the main means of ethical review of research within Australia) to guide review of research applications. The National Statement highlights issues in relation to the design, review and conduct of research and articulates how the values of research merit and integrity, justice, beneficence, and respect can be applied to ensure the protection of the rights and dignity of participants. The subject matter and intent of the National Statement is well matched to Gefenas's (2006) identification of research ethics as pertaining to the rights and welfare of research participants (Gorman, 2011).

The National Statement recently underwent a major review and restructure. Figure 2.3 provides an overview of the content of the current National Statement. Each section within each chapter provides a discussion of the ethical issues pertinent to the topic, followed by comprehensive guidelines on how the issues may be addressed. The current version (2018) runs to 99 pages excluding glossary and index. While not all information pertains to all studies (e.g. genomic research, use of databases, etc.) there is nevertheless, substantial, specific guidance for researchers on the majority of research processes, particularly with respect to participant engagement. It should also be noted that while the National Statement comprises the major body of guidelines for conducting research within Australia, it is not exhaustive. It is supplemented by nationally applicable documents providing more detailed guidance for specific topics. For example, research conducted with Australian Indigenous populations (*Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders*, 2018) and the conduct of clinical trials (National Health and Medical Research Council, 2018). Within each state further legislation such as state privacy laws will apply; and within organisations further interpretations of the National Statement, along with internal policies, procedures and governance mechanisms may also apply. However, broadly speaking and as a starting point, adherence to the requirements of the National Statement is the minimum requirement for the conduct of ethical research within Australia. Compliance with other legislation is dictated by the nature of the research being proposed.

Although external compliance with rules does not necessarily reflect ethical decisions nor equate to ethical behaviour (Gorman, 2011), it is the vehicle by which researchers may (or indeed; must) demonstrate the meeting of ethical obligations in relation to the respect and protection of persons in the research context (DuBois et al., 2016a). Consequently, compliance with legislated guidelines is currently the best way in which society can be assured of the protection of its members who choose to participate in research.

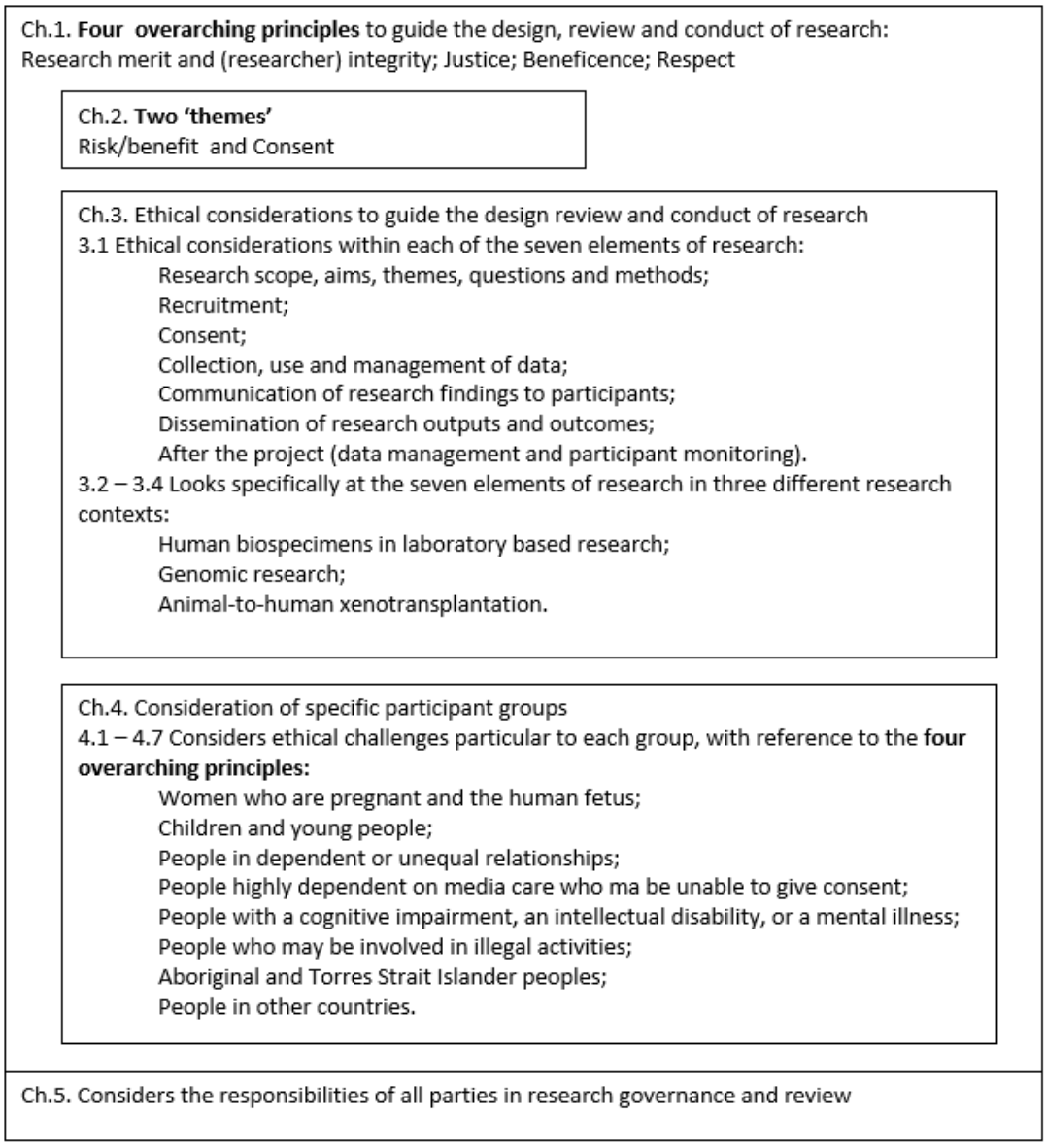

Figure 2.3 Overview of the structure and content of the Australian National Statement on the Ethical Conduct of Human Research.

2.5.4 Factors related to knowledge of research ethics

As previously discussed, research ethics and research integrity are intertwined within the U.S. model of research governance, and subsequently in their teaching models. Additionally, the definition of research ethics in the U.S. can be unclear; encompassing ethical decision-making processes, guidelines for ethical research, or both. It is very difficult therefore to disentangle findings specifically about levels of research ethics knowledge from studies evaluating RCR. Countries where the model is different – where, as in Australia, there is a clear distinction between professional behaviour and ethical guidelines - provide some support for the supposition that knowledge of research ethics guidelines can be learned in a formal setting. For example, a study assessing the effectiveness of a course aimed at improving knowledge of national research ethics guidelines in Nigeria, demonstrated significant gains were made and maintained for up to one month post training, in participating research academics (Ajuwon & Kass, 2008). There appears to be negligible research specifically investigating personal, environmental or contextual factors which may influence the application of research ethics knowledge to the design and conduct of research (i.e., in the literature search conducted for this review, no studies were located). This may be attributable to the subsuming of knowledge of guidelines for ethical research into the broader RCR field of study. As discussed previously, there is ample evidence for internal and external factors affecting researcher compliance with professional standards (research integrity). It would not seem unreasonable to assume a range of factors could potentially influence researcher compliance with rules for the ethical conduct of research.

2.5.5 Clinicians' knowledge of research ethics

Research specifically determining base levels of knowledge about research ethics guidelines is also sparse in the international literature. This may be attributable to the ambiguity of the definition and subsequent obscurity of what is being assessed (i.e., knowledge of ethical guidelines, professional standards, etc.). For example, in a review of the research ethics curricula in seven Southern European university medical schools, the term 'research ethics' was found to be used by universities to convey both research integrity and responsible conduct of research (Mijaljica, 2014). Papers discussing research ethics in the international context often display the same ambiguous use of terminology (e.g., Ateudjieu, Hurst, Yakum, & Tangwa, 2019;

Ramalingam et al., 2014; Taylor et al., 2012). Notwithstanding, there is a small body of research investigating knowledge of research ethics guidelines.

Babl and Sharwood (2008) investigated knowledge of good clinical research practice (GCRP) in staff and students at a major hospital-affiliated research institute in Australia. GCRP is an international ethical and scientific quality standard for the design, conduct, recording and reporting of clinical trials involving human participants. It was adopted by the Australian Therapeutic Goods Administration to provide guidance specific to clinical trials, however its principles are equally applicable to a broad range of human subject research (Therapeutic Goods Administration, 2016). Babl and Sharwood's investigation of GCRP can therefore be understood as an examination of research ethics knowledge in a clinical trials context. Participants in their investigation were academic researchers, research students, and clinicians who held joint appointments with a university and a hospital. The research utilised a custom tool with objective and subjective measures of research ethics knowledge (i.e. measures of knowledge and confidence). The study found that despite 39% of participants claiming to understand the nature of a Serious Adverse Event (harm accruing to a participant in a clinical trial) and its reporting requirements, and 62% claiming to understand the requirements for storing confidential data, only 16% of participants were able to demonstrate their knowledge through provision of detailed information for each item. Self-confidence notwithstanding, the results indicate that in a research focused setting, demonstrable knowledge of two basic tenets of ethical research was very low.

Weston et al. (2016) also investigated knowledge of research ethics principles in an Australian population. Participants included academics, clinicians with adjunct appointments and medical students, from two Australian university medical schools. Weston et al. employed an objective measure of research ethics knowledge adapted from the Babl and Sharwood (2008) tool. Four multi-option questions, providing a variety of correct and incorrect responses to each question (i.e., choose all that apply) evaluated knowledge of consent, participant information, and confidentiality requirements. Overall, 44% of respondents correctly identified when participant information ought to be provided, and knowledge of the requirement for consent was correctly demonstrated by 27% of participants. Overall results were not reported for the question of when data from patient medical records may be used in research, however a significantly smaller proportion of clinicians (47%) than academics (68%)

or students (66%) responded correctly. Given that all participant groups have the potential to conduct research in their roles, (and clinicians and academics have the additional potential to supervise students in research) the results are not encouraging, although they are somewhat better than the earlier results from Babl and Sharwood. The improvement in results may be attributable to the growing interest in research ethics education in the intervening eight years (see Davidson & Babl, 2010; Fernandes, 2017; Mahmud & Bretag, 2014; Waller, Barr, Taylor, & Wijburg, 2016).

Finally, one U.S. study looked at compliance with research ethics guidelines among a non-academic population of primary health care clinicians whose general practices were involved in clinical research. While results indicated clinicians conducted clinical research within their practices to benefit both the practice and the patients, it was also evident that there were significant departures from legislated research ethics guidelines; although whether this was deliberate (to further patient and clinician interests) or through lack of knowledge of the guidelines, was not elucidated (Cook & Hoas, 2014).

2.6 SUMMARY AND IMPLICATIONS

In summary, this literature review has shown that while skills and knowledge necessary for the conduct of ethically sound and scientifically robust research may be acquired through formal and informal learning, their application is not thereby guaranteed.

Firstly, the academic skills required for research (e.g., literature searching, data analysis, academic writing, etc.) have been investigated and listed, and their application shown to be dependent upon, amongst other things, confidence and interest. Secondly, it is evident that the meaning of research integrity is essentially the same across the Australian and international contexts. It refers to the understanding and application of professional standards and applies to the relationship of the researcher to the research community and the data. Professional standards may be learned by formal teaching or informally in the work environment and their application is influenced by personal and social factors. Thirdly, while research ethics may refer to the application of moral reasoning to ethical dilemmas within the research context (as in the dominant U.S. conceptualisation), it may also refer to adherence to a set of guidelines for the design and conduct of ethically responsible research which protects the rights of participants. This latter is the Australian application of the term. The

former term provides the basis of ethical decision making, a construct integral to the dominant RCR model. Its application has shown to be strongly influenced by personal factors.

Whilst there is a significant body of research around professional integrity and ethical decision making, there is only minimal research investigating researchers' knowledge of ethical guidelines for the conduct of research. A thorough investigation of the reasons for this is beyond the scope of this discussion, however two possibilities bear mentioning. One possibility is the ORI focus on integrity in its offensive against research misconduct. A second and related possibility is that international model of RCR (strongly influenced by the U.S.) focuses on professional integrity and ethical decision making (refer to the Steneck [2006] model discussed earlier and illustrated in Figure 2.2). Based on the discussion in this literature review it is possible to re-frame the Steneck (2006) RCR model discussed earlier, into a model which incorporates the original concepts of professional integrity and ethical decision making, along with the Emanuel et al. (2000) and Resnik (2008) definition of research ethics. This is presented diagrammatically by three overlapping circles (Figure 2.4). The term professional integrity stands as discussed; the term 'research ethics' is replaced by the more definitive term 'ethical decision making'. The 'research ethics' circle now represents the knowledge and application of a set of guidelines for ethical conduct of research. Although the three concepts have overlaps where content may be pertinent to, or categorised under two or three of the concepts, they are predominantly separate domains having large proportions of discrete content which may be taught and evaluated distinctly from one-another.

The current research investigates the domain which has largely been neglected in the literature: knowledge of the guidelines for ethical research. Whilst evidence from the other domains has indicated that knowledge alone is not sufficient to guarantee the rules will be applied, it is undeniably necessary as a starting point.

Figure 2.4. Relationship between professional integrity, ethical decision making and research ethics.

2.7 RATIONALE

Responsibility R4 of the Australian Code for the Responsible Conduct of Research notes that the onus is on institutions to provide adequate training for staff who are engaging in research (Australian Research Council & Universities Australia, 2018, p. 3). Whilst DDHHS has in the past provided non-mandatory research education training sessions to staff interested in research, these have been poorly attended overall. In contrast, there is a small but consistent body of evidence suggesting that not all staff intending to conduct research will have sufficient knowledge of research ethics to ensure they are meeting national, state and organisational requirements (Babl & Sharwood, 2008; Weston et al., 2016). The onus then, is on the organisation to provide research ethics training corresponding to the expectation of research to be conducted. However, in any publicly-funded organisation there is a high expectation and requirement for accountability of resource use. Thus, before a large-scale research ethics education initiative can be considered, evidence of the need for such an initiative must first be gathered.

When the distinction is made between research integrity and research ethics, and a further clarification of the meaning of research ethics is made (i.e., that it pertains to the knowledge of a predetermined set of guidelines for the ethical conduct of research), it would appear that most prior research has been on research integrity – the professional behaviour of researchers – or ethical decision making. The present study

is concerned with research ethics – the guidelines laying out the protection of the rights and safety of research participants. Specifically, it is concerned with investigating clinician knowledge of the guidelines around the ethical conduct of research.

2.8 SIGNIFICANCE

The information derived from the study will inform organisational policy on clinician training in the area of research, specifically the knowledge of research ethics as described by the National Statement (*National statement on ethical conduct in human research 2007*, Updated 2018). Currently there is an understandable focus on developing clinical skills, with scarce financial resources being prioritised to those areas deemed to have a direct bearing on clinical practice. However, with the increasing expectation that clinicians will conduct research of significance to the health service and its consumers (Darling Downs Hospital and Health Service, 2017), it is imperative that the development of skills and knowledge in the area of research be actively supported by the organisation and built into education budgets. In addition to the financial constraints faced by any large organisation when allocating funding, publicly funded bodies such as public health services, have a particular responsibility to ensure the expenditure of public monies is based on well-founded evidence. The results of this study will provide an evidence base for the application of funding toward research education.

More broadly, the area of knowledge of research ethics guidelines has hitherto been under-researched in both the Australian and international arenas. Knowledge of professional standards expected of scientists; how and under what circumstances such knowledge is acquired; and the factors affecting the disposition of the individual to act on said standards, have all been, and continue to be thoroughly investigated. Equally, what factors constitute a capacity to make ethical decisions; whether and how such methods may be learned, and what factors impede their application are also the subject of much research. If the responsible conduct of research is seen as consisting of three domains – professional integrity, ethical decision making and knowledge of research ethics – rather than the two previously proposed (i.e., professional integrity and ethical decision making) then addressing any deficits in knowledge of research ethics guidelines is as vital for the improvement of research integrity as increasing professional integrity and ethical decision making capability. The first step is to determine what researchers know about research ethics guidelines. This study makes

an initial contribution to this area of research by examining the knowledge of research ethics guidelines within a distinct sub-population of researchers – that is; health care professionals in a public health service.

2.9 PURPOSE

This study will utilise an objective measure to evaluate and quantify the level of knowledge about research ethics guidelines of health care practitioners employed within a public health service in regional Queensland. This will provide baseline data to inform internal decisions on resource allocation to staff education in the area of research training. The research will also investigate the relationship between knowledge and confidence in understanding research ethics guidelines. This will be achieved by use of a subjective measure of confidence. This information will inform the decision about whether subsequent training should be mandatory or voluntary. Finally, the research will add to the broader body of knowledge by providing data on research ethics knowledge across the full spectrum of health care professions (i.e., Allied Health, Nursing and Midwifery and Medical), in a health practitioner population and within a regional Australian setting.

2.10 RESEARCH QUESTIONS

The study primarily aims to provide a baseline measure of clinician knowledge of research ethics guidelines, specifically for the purpose of informing future decisions about the provision of staff training within the organisation.

To inform these later decisions on training, it is also necessary to collect information about confidence in research ethics knowledge and interest in conducting research. Confidence in knowledge levels is relevant if subsequent provision of training is optional rather than mandatory. If staff believe they have an adequate knowledge of research ethics guidelines, they may be less likely to attend an optional education session, especially if they are required to take time out from essential clinical practice to do so. However, if objective measures of knowledge demonstrate a level of knowledge well below confidence levels, it may be worth considering making training mandatory for those staff whose role includes the conduct of research, to ensure attendance. An early investigation of knowledge of GCRP (Babl & Sharwood, 2008)

found that academics, students and clinicians believed themselves more proficient in GCRP than was able to be demonstrated in corresponding objective measures.

Basic demographic data will be collected to determine whether any personal characteristics are related to levels of knowledge, confidence or interest. Despite literature on the impact of personal characteristics on ethical decision making the decision to include only those limited demographic variables collected in this study was taken based on the premise that clinicians are time poor and not necessarily interested in engaging with a subject which is considered by some to be extraneous to clinical practice (Borkowski, McKinstry, & Cotchett, 2017; Harding et al., 2014). Studies evaluating the impact of personality traits on the conduct of research can entail a barrage of questionnaires, taking up to 75 minutes to complete (Antes et al., 2016). Once again, the requirement to provide a quick questionnaire constrained the decision on what variables should be included.

The study investigated some personal factors around opportunities to learn (i.e. highest level of education, first language, location of degree) to gain some insight into the nature of whether these factors influence levels of research ethics knowledge. Additionally, certain factors previously associated with research experience will be included to determine whether and to what degree past engagement with research influences knowledge of research ethics guidelines.

Interest in conducting research and attending research ethics training is likely to impact attendance and engagement at subsequent training sessions. A basic measure of interest and willingness will be included to aid in determining whether and in what format training should be provided.

With the preceding considerations in mind, the research questions for the present study were framed as follows:

RQ1: What is the level of knowledge of research ethics guidelines amongst staff employed in health care roles within Darling Downs Health?

RQ1a: How confident are staff in their knowledge of research ethics guidelines?

RQ2: What is the level of interest in conducting research?

RQ2a: What is the level of interest in attending research ethics guideline training?

RQ3: What characteristics of the respondents are associated with variations in knowledge, confidence and interest?

Chapter 3: Research Design

3.1 INTRODUCTION

This chapter provides detail of the research design and methods used to achieve the aims and objectives stated in section 1.3 of Chapter 1. Section 3.2 of this chapter discusses the research paradigm underpinning the formulation of the research questions and the study design. It then provides a rationale for, and description of the study design. Details of the respondents are provided in section 3.3 including the population, the sample size, sampling and recruitment strategies. The development of the instrument is described in section 3.4. Section 3.5 provides a timeline for the study and details of the procedures. An outline of analyses is included in section 3.6 and ethical considerations discussed in section 3.7.

3.2 METHODOLOGY AND RESEARCH DESIGN

3.2.1 Research paradigm and method

The research questions seek to measure and quantify levels of knowledge, confidence and interest. Such questions may be addressed from a Post-positivist paradigm, which assumes that knowledge is objective, quantifiable and generalisable (MacKenzie & Knipe, 2006). This paradigm however does not allow for the understanding that some truth is socially constructed, a view with which the researcher agrees. The Pragmatist paradigm offers an inclusive alternative. It allows that truth may be objective or subjective and knowledge may be measurable or phenomenological. As such, Pragmatism does not oblige the use of one methodology over another, but contends that good research methods are dictated by the research question (MacKenzie & Knipe). The Pragmatic paradigm was thus adopted for this study.

The aim of the research was to provide a summary measure of knowledge of research ethics guidelines on which to base future decisions about the provision of education in research ethics to staff within the organisation. This intended use of the findings was a major factor in the decision to utilise a quantitative research method of enquiry rather than a qualitative method.

Further, the need for brevity was paramount in the research design. Whilst qualitative data would have provided an understanding of the complex issues around the knowledge, understanding and application of research ethics guidelines, a study incorporating qualitative methods would have exponentially increased the level of engagement required by respondents. A quantitative design allowed for the collection of maximum data in minimum time – a salient point when seeking to engage a time-poor and disengaged population. It was strongly felt that the completion of a 10-minute survey would have greater buy-in in a population with apparent low research interest than interviews or focus groups (a conclusion based on experience in the workplace from which the sample was drawn).

3.2.2 Research design

The present study sought to evaluate the level of participant knowledge of research ethics guidelines with the aim of producing a quantifiable outcome. This was achieved using a descriptive, cross-sectional, prospective study design.

A cross-sectional study design was most suited to answering the research questions as it provided a snapshot of the level of clinician knowledge at a given period of time. Additionally, cross-sectional designs have been used in research seeking to quantify levels of knowledge in similar populations (Babl & Sharwood, 2008; Weston et al., 2016). The study met the requirements for a descriptive design as the nature of the enquiry did not require manipulation or control of variables but was largely observational. Additionally, the study began with no pre-determined hypothesis, but set out to describe the phenomena under investigation (Leavy, 2017).

3.3 RESEARCH SETTING

The research was undertaken across the DDHHS district, a geographical area of some 90,000 square kilometres and employing more than 5000 staff, nearly three-quarters of whom are engaged in clinical roles. Toowoomba is the hub for the region's health services, providing a major referral hospital for the 21 outlying rural and remote facilities (*Darling Downs Hospital and Health Service annual report 2017-18*, 2018).

The challenges of providing healthcare in non-urban settings have been well documented and include lack of physical and human resources, limited referral options and the need for multiple skills (Orkin & Kelly, 2016). Clinicians are often isolated

from peers and supervision opportunities, and finding time to include non clinical activities such as research can be challenging (Pain et al., 2015).

3.4 PARTICIPANTS

3.4.1 The population

The population for the study was those staff within DDHHS who were likely to have the conduct of research in their employee role descriptions, professional role descriptions or employment awards. This included staff employed under the General Employees Award (*Hospital and health service general employees (Queensland Health) award - State 2015*), Nurses and Midwives State Award (*Nurses and Midwives (Queensland Health) Award – State 2015*), and Health Practitioners and Dental Officers Award (*Health practitioners and dental officers (Queensland Health) award – State 2015*). Whilst the award for medical practitioners (*Medical Officers (Queensland Health) Award – State 2015*) does not stipulate the conduct of research, the Australian Medical Council lists the ability to conduct and consume research in its Graduate Outcome Statements (Australian Medical Council, 2012) – the list of desirable attributes for medical graduates. Additionally, an internet search of the websites of the specialist medical colleges in Australia indicates that many Colleges include a research component in their qualification criteria for fellowship, or the capability to consume and conduct research in the professional capabilities of graduates. These factors, along with the experience of the researcher which indicates that medical officers are conducting research within the clinical setting, determined their inclusion in the population.

Excluded from the population were staff who were not employed under a health worker award (for example, maintenance and catering staff). Although the role description of these staff may not specifically exclude the conduct of research, a review of internal records yielded no evidence of their participation in research involving humans within the organisation (i.e. via Human Research Ethics applications or assistance sought through the in-house Research Support team), nor do their awards stipulate the conduct of research.

3.4.2 Sample size

All staff employed under the Health Professional and Dental Officer, Medical, and Nursing and Midwifery awards were invited to participate. According to a recent

Mandatory Obligatory Human Resource Indicator headcount (an internal organisational auditing program), this included a population of 3,726 eligible staff (Medical = 452, Health Professional = 546, Nursing and Midwifery = 2,728) at the initiation of the study. Given the size of the organisation however, it cannot be assumed that the population remained stable for the duration of the recruitment and survey period. For example, a private communication from a Nurse Educator in the organisation indicated that in the first five months of 2019 around 120 new nurses and midwives commenced employment with the organisation. It is not known how many staff in the other two clinical streams commenced, nor how many clinical staff left employment with the organisation in the same period. Therefore, although the population numbered 3,726 at the time the protocol was approved by the Human Research Ethics Committee, the actual population size at any given time across the study period was not known.

3.4.3 Sampling

It is generally acknowledged that the preferred sampling method for a quantitative methodology is probability sampling where every member of the population has an equal chance of being selected (Shaughnessy, Zechmeister, & Zechmeister, 2006, p. 138). This in turn produces a more representative sample and results which are generalisable to the broader population. However, random sampling necessitates a known population size where all individuals are accessible for recruitment (Shaughnessy et al.). In the present study, although the population size was generally known, it was not possible to guarantee all members of the population would be accessible for recruitment (see discussions of recruitment strategies for further explanation). Where the working population does not meet the requirements for random sampling, researchers may draw on non-probability sampling strategies (Shaughnessy et al.). While the results will lack the generalisability of data from randomly selected samples, they still may allow for the formulation of conservative inferences, particularly if a sufficiently large sample is obtained (Bouma, 1996). Due to the uncertainty of the reach of the recruitment strategies in the population under investigation, non-probability sampling was utilised for the current study. Specifically, the researcher employed a proportionally stratified quota sampling strategy to ensure the most representative sample possible under the circumstances.

Stratification can be a useful sampling strategy for describing sub-populations where there is likely to be substantial variance on a characteristic related to the main variable being investigated (Leavy, 2017). This was the case in the present study where the researcher hypothesised that the main variable (level of knowledge of research ethics guidelines) was likely to vary across the three professional streams (Medical, Allied Health, and Nursing and Midwifery) which make up sub-populations within the working population. Respondents employed in each of the three professional streams are likely to demonstrate notable differences in research ethics knowledge based on their experience of research in their pre-vocational training pathways. This is particularly so in the field of nursing where until the 1990s nurses came through the clinical training pathway and did not undertake academic training, thereby missing formal education in research which is included in some of the Bachelor of Nursing degrees available in Australia today. This remains true for the current Enrolled Nurse (EN) position which requires a Diploma of Nursing (National Enrolled Nurses Association of Australia (ANMF-SIG)) focusing on clinical skills and not providing training in less practical skills, although some may offer research units as electives. (See for example, the Diploma of Nursing available through TAFE; TAFE Queensland, n.d. 1). Similarly, an Assistant in Nursing (AIN) qualification requires a Certificate III (TAFE Queensland, n.d. 2) which focuses on skills designed to provide practical patient support services to Enrolled and Registered Nurses.

The sub-populations are also likely to vary in level of knowledge due to notable differences in research uptake following graduation, due to professional requirements and expectations. For example, a search of the grey literature, including numerous specialist medical college web sites indicates most specialist medical college fellowships require the undertaking of research as part of the assessment process. This suggests most medical officers will have some work-based research experience.

Quota sampling is a non-probability sampling technique whereby recruitment is conducted from a convenience sample until a predetermined quota is reached (Leavy, 2017). Given the response rates of recent studies among Allied Health professionals in the Queensland public health service which have utilised management distribution of recruitment emails, of between 13% and 55% (Finch et al., 2013; Harvey, Plummer, Pighills, & Pain, 2013; Holden et al., 2012; Wenke et al., 2017a), an estimated 30% response rate for each of the sub-populations was considered

conservative. This had the potential to provide a final sample size of approximately 1,117.

It is acknowledged that convenience sampling has inherent self-selecting bias (Shaughnessy et al., 2006); in the present study this was likely to be a sample with a high representation of staff with an interest in research. Nevertheless, the use of proportionate stratified sampling was intended to provide some balance to the lack of random sampling; providing results which would be representative of the three separate streams, if not completely generalisable.

3.4.4 Recruitment

Several strategies were employed to recruit for this study. Reasons for multiple recruitment methods and explanations of the sampling frames are discussed below.

The initial recruitment drive was conducted via staff email. The sampling frame was all staff employed in the Nursing, Allied Health or Medical streams, who had registered with the organisation's online education unit using a corporate email address. Registration with the education unit facilitates access to mandatory staff training. Unfortunately, this excluded staff who had registered with the unit using a personal email account (as these cannot be shared), and staff who had not registered with the unit at all. All automated responses that indicated the address was no longer active (i.e. the person had left the organisation) or the person would be on leave for the duration of the recruitment period, were deleted from the distribution list and not used in the subsequent round of recruitment emails.

Email distribution was further utilised by means of inclusion of an item in the twice-weekly corporate email newsletter which is distributed to all corporate email addresses. This allowed distribution to persons with corporate email addresses who had not registered with the education unit but was limited by the requirement for staff to actually utilise their corporate email accounts, a practice which, anecdotally, is not widespread throughout the organisation (Nursing Director, personal communication).

A second round of email distribution was undertaken in the middle of the recruitment period. As staff use of computers may vary across the week, this second mail-out was sent on a different day to the first mail-out. Prior to this second mail-out, a manual search of the corporate email system was made to include those staff in Allied Health, Nursing and Midwifery, and Medical professions who were not listed on the initial distribution list. Finally, contacts known personally to the researcher were

emailed once in the final two weeks and asked to distribute the invitation email to their contacts, with the intention of reaching specified teams and units within the organisation which may have been missed previously.

The second recruitment strategy was publicity via the corporate website. This provided for inclusion of a page in the scrolling screensavers on all corporate computers and a 'spotlight' (similar to a screensaver but displayed on the home screen of the corporate intranet website). The sampling frame was all staff with access to the organisation's intranet webpages. This second recruitment strategy had the potential to capture staff who do not necessarily read emails, but who utilised shared computers at common work-stations. However, anecdotal evidence suggests the nature of much clinical work does not necessarily allow a great deal of time spent at a computer terminal, even for work related purposes, thus potentially missing a large portion of the workforce. Nevertheless, this strategy was repeated in the final four weeks of the recruitment period.

A third recruitment strategy was utilised in an attempt to include those staff who do not frequently access the organisation's intranet or corporate email. This necessitated dissemination of information about the study through verbal channels: i.e. via Executive and Management roles; at presentations related to the researcher's role in the organisation (e.g. research education presentations); and via word of mouth. The sampling frame was indeterminate, consisting of line managers and their supervisees as well as meeting attendees.

Whilst no single recruitment strategy was deemed sufficient to reach the entire population, the combination of methods aimed to provide the broadest coverage possible. Recruitment was open for four months, from 1 October 2018 until 14 February 2019. This timeframe accommodated several factors. Firstly, it allowed for numerous recruitment strategies, particularly the verbal dissemination of information. Secondly, it allowed for the movement of staff in and out of the organisation. And finally, it took account of the end-of-year holiday period. Whilst this is often a quieter time for clinical staff, it is also a time when a large number of staff take annual leave. Extra time was therefore allowed to cover this period which may have seen a downturn in staff presence in the service.

3.5 INSTRUMENTS

A copy of the questionnaire used for this research is included as Appendix B. The customised questionnaire for this study was adapted from one originally developed by Babl and Sharwood (2008) and subsequently modified by Weston et al. (2016). Babl and Sharwood investigated knowledge of Good Clinical Research Practice (GCRP) while Weston et al. investigated knowledge of research ethics. GCRP is similar to research ethics but having a focus on the research ethics of clinical trials. This is evident in the content of the Babl and Sharwood questionnaire, where there is a question related to Serious Adverse Events and their reporting, which is dropped from the subsequent Weston questionnaire. Access to the original questionnaire used by Babl and Sharwood was not possible, so the Weston et al. adaptation was used as a basis for development of the questionnaire for the present study. Both studies were located in an Australian setting and with populations which included clinicians.

The present questionnaire consisted of five sections:

- Section 1: (questions 1-12) demographics including personal information, employment information, education history
- Section 2: (questions 13-23) research experience including conducting research, publications, ethics applications, membership of a Human Research Ethics Committee (HREC) and training in ethical conduct of research
- Section 3: (questions 24-27) confidence in knowledge of informed consent, requirements for data confidentiality, provision of participant information and triggers for ethical review
- Section 4: (questions 28-33) knowledge of ethical guidelines including use of patient medical records, provision of participant information, informed consent, data confidentiality and ethical review, as well as knowledge of guidelines applicable to the physical location (i.e. a public health service in Queensland, Australia)
- Section 5: (questions 34-36) interest in doing research and attending training in research ethics

The following section discusses the design of the questionnaire. Specifically, each section of the questionnaire is discussed in detail. Questions of validity and reliability are addressed within the section to which they pertain; for example, a Likert

scale is used for the confidence questions, so discussion of issues arising with Likert scales is confined to this section.

The final questionnaire was reviewed by two hospital-based research fellows who both have clinical backgrounds and experience working with clinician researchers in the hospital setting. A Human Research Ethics Coordinator provided a final review of the content of the research knowledge questions and a statistician provided review of the question format. The questionnaire was not piloted due to difficulties obtaining a valid sample outside of the intended study population.

3.5.1 Research experience

Weston et al. (2016) used 15 questions to explore research experience. For the present study three questions were omitted (reviewer for an HREC, having read the National Statement, and having read the Code) leaving 11 questions. The remaining were either used verbatim, or modified slightly to provide clarity. For example, one of the original questions asked, "Have you previously conducted any scientific research on humans?" It was felt this wording could subtly exclude those who had worked as research assistants, who may do a lot of the practical and administrative work involved in research such as writing ethics applications and amendments, recruiting and consenting participant and collecting and entering data – all valid research experiences even though the research assistant may not be considered to be conducting or directing the research. The question was therefore modified to read "Have you ever been involved in the conduct of scientific research on humans (excluding involvement as a participant)?" The question about having been a reviewer for an HREC was omitted as scientific review committees provide feedback on the robustness of the study design, whereas HREC committee members review a study with regard to its ethical standards – the respect and protection of human participants. Two questions used by both Babl and Sharwood (2008) and Weston et al. asked whether the respondent had read, at least in part, the National Statement and the Code. These questions were omitted from the present questionnaire as they appeared to be gauging respondents' awareness of the existence of the documents rather than any knowledge of their content. A question to ascertain respondents' awareness of the documents was added in the knowledge section.

Weston et al. (2016) asked several questions about volume (e.g., number of studies involved in, number of research publications, etc.) and provided arbitrary

categorical option responses. In an endeavour to elicit richer data, these response options were changed to an open response format. Unfortunately, technical difficulties with the online survey platform did not allow for restriction to numerical responses. Subsequently six out of the seven questions attracted a number of ambiguous responses which could not be coded numerically, so these questions were dropped from quantitative analysis. This left five questions to collect information about the respondents' research experience. Scale reliability could not be determined as the questions required dichotomous responses (Yes/No). The five responses were summed to provide a 'Total Experience' variable for further analysis. Possible scores for Total Experience ranged from 0 to 5.

3.5.2 Confidence

The questionnaire measured not only objective knowledge levels, but subjective levels of knowledge. This was done to provide insight into whether staff have a realistic understanding of their own level of knowledge in the area of research ethics guidelines. Previously, claims to understand research ethics requirements have been found to fall well below demonstrable levels of knowledge (Babl & Sharwood, 2008).

Subjective level of knowledge was operationalised as confidence and measured by four questions. Respondents rated their confidence on a Likert scale, consisting of four questions with anchors at (1) Strongly Disagree, (2) Disagree, (3) Neutral, (4) Agree, (5) Strongly Agree. Levels of confidence for each item were examined, and a total scale score was calculated and used for further analysis. Possible range of scores for 'Total Confidence' was 4 to 20.

Likert scales are an accepted method for measuring underlying phenomena by aggregating respondents' ratings of their strength of agreement with a number of statements. While debate remains about whether scale scores should be treated as interval or ordinal data, this study will follow the argument that aggregated rating scales may be analysed as interval data whereas individual Likert items must be treated as ordinal. Harpe (2015) argues that the aggregation of scores from a set of (ordinal) Likert-type items produces an interval measure variable; the subsequent score should thus be described and analysed as interval data. This does not excuse the researcher from ensuring statistical assumptions are met, and where they are not, recourse is made to suitable non-parametric tests (Boone & Boone, 2012). Caution should also be

exercised in ascribing meaning to numeric representations of adjectival data (Kuzon, Urbanchek, & McCabe, 1996; Sullivan & Artino, 2013).

There is general consensus that the number of points on the scale increases the level of detail able to be collected about the phenomena under investigation. For the purpose of the present study, fine distinctions between levels of confidence were not considered necessary, so a 5-point scale was adopted.

Respondents were asked to indicate the extent to which they agreed that they understood the requirements for: informed consent; data confidentiality; provision of participant information; and triggers for ethical review, when undertaking research with humans. The topics were chosen to correspond with the knowledge questions and thus facilitate comparison of levels of confidence and knowledge. Notably, they also reflect areas which are pertinent to clinicians conducting research within the author's institution. A Cronbach alpha of .88 demonstrated good internal consistency between items, and suggests the components are sufficiently intercorrelated to be measuring a single underlying variable (Sullivan & Artino, 2013). Item correlations are reported in Table 3.1.

Table 3.1

Inter-item correlation matrix for confidence scale questions

Item	24	25	26	27
24 Informed consent	-			
25 data confidentiality	.771	-		
26 Participant information	.671	.710	-	
27 Ethical review triggers	.522	.550	.726	-

Relationships between research confidence, research knowledge and research experience were explored as well as any relationships with demographic variables.

3.5.3 Research knowledge

Objective level of knowledge was measured by posing five questions about research ethics guidelines as they applied within the organisation. Although the National Statement is the foundation for research ethics guidelines, it provides for discretionary decision making in some areas (see, for example, NS s5.1.7 and 5.1.2).

The questions asked about: the use by clinicians of patient data for research purposes; the provision of information to participants; the requirements for participant

consent; identifiability of data; and the requirement for a submission to the Human Research Ethics Office. The questions were based on those used by Weston et al. (2016) with the addition of two new items. The original question about provision of participant information was used verbatim. The question asking under what circumstances a clinician may use information from patient files for research purposes was amended to include two response options which have been cited by clinicians within the author's organisation as reasons for not needing consent (i.e., when data is about a clinical procedure to which a patient has consented and when there is no foreseeable harm to the participant). The original question about the requirement for written consent was altered to ascertain knowledge around consenting generally. Two new questions were added to the questionnaire. These were identified by the researcher as topics about which clinicians have previously demonstrated confusion when conducting research within the organisation. The first asked about when data are considered non-identifiable. The second question asked when a project needed to be submitted to the HREC Chair. All questions were multiple choice (i.e., choose all items that apply) with questions being marked correct when all of the correct items and none of the incorrect ones had been selected. Responses to each question were compared using descriptive statistics. Responses on all five questions were summed to create a 'Total Knowledge' variable for use in further analysis. Potential Total Knowledge scores ranged from 0 to 5.

Lastly in the knowledge section, respondents were asked to list any national, state or organisational guidelines for research of which they were aware. This was done to determine whether respondents were in fact aware of any of the guiding documents, but particularly the National Statement and Code, without provoking social desirability bias in the response (Shaughnessy et al., 2006, p. 546).

3.5.4 Interest in conducting research

Respondents were asked to indicate their interest in conducting research in the future. Respondents rated their agreement with a positively framed statement on a Likert-type response scale with anchors at Strongly Agree, Agree, Neither Agree nor Disagree, Disagree and Strongly Disagree. Although it has been noted that the distance between items on the Likert scale cannot be said to be equivalent (Boone & Boone, 2012), this is not an issue for this question where the intention is only to determine

positive or negative intent toward research in the future. Responses were coded from 1 – Strongly Disagree to 5 – Strongly Agree.

Relationships between research interest and experience, confidence, knowledge, and interest in attending training were all explored, as was relationships with pertinent demographic variables.

3.5.5 Interest in research training

Respondents were asked if they were interested in attending training in research ethics in the future. The positive response options offered a range of time frames from 2 hours to one day duration for those respondents interested in attending, however these were collapsed into a single *Yes* category for analysis. Thus the 'Interest in Training' variable reported in the results refers to a dichotomous variable (Yes/No). The duration options were collected to inform the development of later educational intervention formats. A free text box was provided for respondents to indicate their reasons for not wishing to attend.

Lastly, a free text box was included and respondents invited to indicate the type of information, education, or training that they considered might be useful. This was not used in analysis of clinician knowledge, confidence, or interest, but was retained to inform later program development.

3.5.6 Demographic variables

Twelve questions were used to elicit data about personal and work characteristics of respondents. A question about native language (English or otherwise) was included, as was a question about the country in which qualifications were awarded, based on previous research which indicates an association between language proficiency and RCR scores (Antes et al., 2016; Antes et al., 2017; DuBois et al., 2016a).

Highest qualification received was collected across eight categories plus 'Other' and recoded into three categories for analysis. The rationale for collection of this variable was to determine whether the level of exposure to research inherent within each level of qualification was associated with any of the main variables (knowledge, confidence, interest in research, and interest in attending training). The recoding reduced the original categories down to three common levels of exposure to research, which could be applied across all of the levels of qualification: non-tertiary qualification (with no research-specific training), tertiary qualification with some

possible exposure to research concepts), and research higher degrees (where research training is the focus of the degree).

Principal place of work elicited 23 different locations, however this was recoded into two groups for further analysis. The three facilities in Toowoomba city were recoded as Toowoomba (the residential nursing home, the extended inpatient mental health service, and the Toowoomba Hospital). All other facilities were coded as Other. The Toowoomba Hospital is the major referral hospital for the DDHHS being the only secondary hospital in the region. As such, Toowoomba is the largest and most resourced site within the HHS. Data from this question was used to determine whether being situated outside of the main regional area is associated with knowledge, confidence, interest in research and interest in attending training.

3.6 PROCEDURE AND TIMELINE

A web-based format was utilised for the study for several reasons. Firstly, it is a cost-effective method of providing access to a large number of participants across a broad geographic area. The working population was around 3,700 staff, spread across 29 facilities over some 90,000 square kilometres (Darling Downs Hospital and Health Service, 2017). Engagement with staff on a personal or individual level, or through the requirement to physically return a survey was impractical under these conditions, and likely to limit the capacity of staff in outlying areas to participate in the study.

Secondly, the web-based format allowed for anonymity of respondents. Although research ethics guidelines is not a sensitive topic, the researcher acknowledges that an apparent lack of knowledge, or discovering one knows less than one thought, may cause some embarrassment in respondents, therefore it was felt that the ability to maintain anonymity for the survey was a significant factor in choice of delivery.

Lastly, the web-based format is easy for respondents to use, only requiring access to a computer with internet capability, which is provided in all workplaces, and incurring no cost or effort to ‘return’ the completed questionnaire to the researcher.

Data were collected via a one-time, anonymous, online questionnaire hosted on the University of Southern Queensland’s LimeSurvey platform. LimeSurvey holds data on secure servers in the nominated hosting country (in this case Australia) and data can be exported in several standard formats (e.g., Excel, SPSS, etc.).

Respondents were able to leave the survey and return to it at a later time if they wished. No measures were taken to prevent respondents completing multiple versions of the questionnaire as this seemed a highly unlikely occurrence since multiple completions would be time consuming and of no benefit to the respondent. Data were downloaded and entered into SPSS for cleaning and analysis.

3.7 ANALYSIS

Scores for knowledge, confidence, interest in conducting research and interest in attending training were analysed and compared across levels of demographic variables. Quantitative data were analysed using descriptive and inferential statistics including mean, median, frequencies and range of data as appropriate.

Inferential statistics, with a level of confidence set at $p \leq 0.05$, were used to explore relationships between variables. Ordinal, nominal and categorical data, which by definition do not meet the assumptions required for parametric tests, were analysed using nonparametric tests. The Total Confidence variable was treated as interval data (as per Harpe, 2015), however it was not normally distributed and thus required use of non-parametric tests for analysis. Total Experience and Total Knowledge were both ordinal variables, demographic variables were a mixture of categorical, (e.g. sex) ordinal (e.g., age) and nominal (e.g., highest qualification).

Kruskal-Wallis tests were used to explore difference between categorical variables on ordinal scores (e.g., comparison of three streams on knowledge scores). To subsequently determine which groups differed significantly, post-hoc Mann-Whitney U tests provide pair-wise comparisons, with Bonferroni adjustments which utilise a more stringent alpha level to control for type 1 error (Pallant, 2016, p. 240). A Jonckheere-Terpstra test for ordered alternatives was used to test for significant relationships between two or more groups on ordinal variables (e.g. age and confidence scores). Chi-Square test for independence explored relationships between two or more categorical variables. Fisher's exact probability statistics were reported when 2x2 tests violated the expected frequency (minimum frequency 10 per cell) (Pallant, p.218). Effect sizes are reported where appropriate with Cramer's V reported for larger than 2x2 Chi-square associations, which considers the degrees of freedom.

Quantitative data were analysed using IBM SPSS version 25.

Deductive thematic analysis was undertaken on the qualitative data. Responses were printed and coded by hand, with content being categorised into themes which were identified within the data (Bennett, Barrett, & Helmich, 2019).

3.8 ETHICAL CONSIDERATIONS

No ethical issues were identified in relation to the study. Participation was voluntary and anonymous, with respondents able to withdraw at any time. The topic was not around sensitive issues, as identified by the National Statement, nor did it target vulnerable groups. Data shared with external collaborators (i.e., student supervisors) was non-identifiable.

Ethical approval for the study was obtained from the Human Research Ethics Committees of Darling Downs Hospital and Health Service (approval number LNR/QTDD/43455) and the University of Southern Queensland (H18REA233). Governance approval was obtained from the DDHHS for the conduct of the study at the Darling Downs site (SSA/QTDD/43455). Governance approval included authorisation to utilises staff emails for recruitment, as the researcher is a member of the organisation and the study supports the monitoring and improvement of services within the organisation.

Chapter 4: Results

The primary aim of this research was to benchmark knowledge levels of research ethics guidelines in a population of health care professionals in a Queensland public health service. Secondary aims were: to determine how confident this population of clinicians was in its knowledge, and compare this to demonstrable knowledge; to determine the level of interest in this population in conducting research in the future and the level of interest in attending research ethics training, and lastly to determine whether any demographic variables were related to knowledge, confidence and interest within this population. Chapter 4 begins with a description of the respondents and in Section 4.1 followed by a summary of the questions used to create the research experience variable in Section 4.2. Results are then reported for all main variables of interest: section 4.3 Research Knowledge, and relationships with demographic variables; section 4.4 Confidence and relationships with demographic variables, confidence and knowledge, and confidence, knowledge and experience; Section 4.5 interest in conducting research and attending training, relationships with demographic variables, and comments about training.

4.1 PARTICIPANTS

The online survey site received 666 hits, however 77 individuals did not progress to the survey from the participant information page, and three individuals left the first page of the survey without entering any information. Twenty-three individuals withdrew after completing the demographic questions, and another 12 after completing the section on research experience. Of the 551 remaining respondents, 17 were judged ineligible based on location (Q11) and employment stream (Q8) and were removed from the data set. This left 534 complete sets of data for analysis of staff confidence in their knowledge of research ethics. However, 102 respondents did not go on to attempt the knowledge questions, meaning only 432 complete data sets were available for investigation of levels of staff knowledge, relationships between confidence and knowledge, and relationships between knowledge and demographic factors. To further reduce the possibility of an individual completing more than one version of the questionnaire, this smaller data set was used for all analysis and reporting, thus

ensuring the integrity of the data. The final sample therefore consisted of 432 respondents with complete responses across the main variables of interest (knowledge, confidence, and interest); a response rate of 11.6%.

The highest proportion of respondents was from the Nursing and Midwifery stream. Nurses and Midwives make up the largest proportion of clinical staff employed by Darling Downs Health at around 73%. Allied Health makes up around 15% of the clinical staff population, and were therefore over-represented within the sample (see Table 4.1). The Medical stream was slightly under-represented in the sample at 9%. Full time employees made up the greatest proportion of respondents, around 50% across all streams. This is slightly higher than the proportion of clinical staff employed in full time positions within the organisation (40%). Subsequently, part time workers were under-represented by around the same proportion. Ages ranged from 20 to 74 years with a median age of 46 years. Females predominated across the sample (85% overall), closely replicating the gender make-up of clinical staff within the organisation (females = 82%). The highest proportion of respondents held a non-research tertiary qualification (80% overall), with the majority of respondents having gained all of their qualifications entirely within Australia (90%), and having English as their first language. Sixty-three percent of respondents were primarily located in Toowoomba; this is consistent with the proportion of the population located there (65%). Frequencies for demographic variables are presented in Table 4.2.

Table 4.1

Proportion of each professional stream in workplace and study sample

	Medical	Allied Health	Nursing & Midwifery
Workforce	12%	15%	73%
Sample	9%	26%	65%

Table 4.2

Demographic characteristics of study respondents

Type of employment		
Part time	180	41.7
Full time	219	50.7
Casual	21	4.9
More than one role	12	2.8
Age in years, range (mean, median)	20-74	45.2, 46
Gender		
Female	357	84.6

Male	65	15.4
Native language		
English as first language	395	91.9
English not first language	35	8.1
Highest qualification received		
Non-tertiary	55	12.9
Tertiary-non research	344	80.4
Tertiary-research	29	6.8
Where qualified		
Qualifications awarded in Australia only	390	92.4
Qualifications awarded in Australia and overseas	24	5.7
Qualifications awarded overseas only	8	1.9
Stream		
Allied Health	113	26.2
Medical	37	8.6
Nursing & Midwifery	282	65.2
Work location		
Located in Toowoomba	274	63.4
Located in Other	154	35.6
Adjunct appointment with a university		
Yes	26	6.0
No	406	94.0

Note. n = 432. % = valid percent. Results are presented as n and % unless otherwise stated.

4.2 RESEARCH EXPERIENCE

Research experience was measured across eight questions. Questions asking the number of ethics applications, number research projects involved in, and type and duration of research training, included responses which were too ambiguous to code, so the results are not reported in the frequencies table, nor included in further analysis. Frequencies were run to provide response rates of correct answers to the remaining questions, and a Total Experience score was created for further analysis. Total Experience is the sum of correct responses to questions 13, 17, 19, 21 and 22 (i.e. questions listed in Table 4.3).

4.2.1 Individual questions

Approximately one-quarter of respondents (26.9%) claimed to have been involved in the conduct of research and slightly less had been involved in the completion of a human research ethics application (20.6%) or attended research ethics

training (`17.4%). Less than 10% had ever published in a peer reviewed journal or sat on an ethics committee. See Table 4.3 for a full list of exact frequencies.

Table 4.3

Response frequencies to research experience questions

Question	*n*	%
Have you ever been involved in the conduct of scientific research on humans?	116	26.9
Have you ever published or co-authored any papers from a human research project in a peer reviewed journal?	42	9.7
Have you ever completed or assisted in the completion of an ethics application for research with humans?	89	20.6
Are you or have you ever been a member of a Human Research Ethics Committee (HREC)?	15	3.5
Have you ever received training in the ethical conduct of human research?	75	17.4

Note. $n = 432$.

4.3 KNOWLEDGE OF RESEARCH ETHICS GUIDELINES

Knowledge of research ethics guidelines was measured on five questions covering four topic areas: data confidentiality, provision of participant information, informed consent, and ethical review. Frequencies were run to provide response rates for correct answers, and a Total Knowledge score was calculated for further analysis.

Respondents were asked five questions and required to select all correct responses, and no incorrect ones, from a list of response options for each question. The proportion of respondents answering each question correctly ranged from 3.5% for ethical review requirements, to 42.4% for provision of participant information. Table 4.4 shows frequencies for all knowledge questions.

No single respondent answered all five questions correctly; while 27% of respondents failed to answer any questions correctly (see Table 4.5).

Table 4.4

Correct response frequencies for research ethics knowledge questions

Item	Correct response	
	n	%
When can a health care professional use information from the medical records of his/her patients for a research study?	117	41.0
When is it necessary to provide participant information (either written or verbal)?	183	42.2
Which of the following statements about participant consent is correct?	73	16.9
Which of the following types of data meet the criteria for non-identifiable data?	119	27.5
Which of the following examples, when conducted within DDHHS, requires submission to the Human Research Ethics (HREC) office?	15	3.5

Note. *n* = 432.

Table 4.5

Number of research ethics knowledge questions answered correctly

Number of questions correct	*n*	%
0	117	27.1
1	144	33.3
2	101	23.4
3	59	13.7
4	11	2.5
5	0	0.0

Note. *n* = 432.

A final knowledge question asked respondents to name any documents or policies governing the conduct of research across the national, state or organisational levels of which they were aware. Seventy-eight respondents (18%) provided comments. A small number (*n* = 16) of respondents were able to demonstrate they were aware of a range of legislation and mandatory guidelines by making reference to the National Statement, the Code, and other legislation (e.g., “the Information Privacy Act”); if not by the correct title, then at least in a way that made it obvious to which

document or legislation they were referring (e.g., “there is a National Statement”). A very few (n = 3) respondents referred specifically to professional standards (e.g., “Nurses codes of conduct”, “APS ethical guidelines”).

Respondents also referred to non-mandatory documents such as templates and toolkits, as well as actual ethics application forms, and some indicated an awareness of the existence of legislation and policy but did not know what or where (e.g., “HREC guidelines and policy”, n = 6). A small number (n = 6) were aware of the organisation having policies and procedures, but not able to articulate them (e.g., “DDHHS has a document”). Nearly half of respondents (n = 37) plainly stated they did not know what the documents were or where they were located (e.g., “Don’t know”; “None I’m aware of”). Most of this last group were respondents who indicated they had not been involved in research. Five respondents who indicated they had been involved in the conduct of research indicated they did not know or were not aware of any documents. About one-fifth of respondents (n = 16) referred to organisations, departments and HRECs rather than specific documents or legislation (e.g., “NHMRC”; “WHO”; “Uni HREC”).

4.3.1 Knowledge and demographic variables

A Kruskal-Wallis test revealed a statistically significant difference in Total Knowledge scores between the three Streams (Gp1, n = 113: Allied Health, Gp2, n = 37: Medical, Gp3, n = 282: Nursing & Midwifery), X^2 (2, n = 432) = 10.716, p = .005. Nursing and Midwifery scored significantly lower than both Allied Health (p = .034, 2-sided) and Medical (p = .037, two-tailed). Although Medical was the top scoring stream, the difference between it and Allied Health was not significant (p = .413, two-tailed).

A Kruskal-Wallis test revealed a significant difference in knowledge levels across the three categories of Highest Qualification Received (Gp1, n = 55: non-tertiary, Gp2, n = 344: tertiary non-research, Gp3, n = 29: tertiary research), X^2 (2, n = 428) = 26.012, p < .001. Pair-wise comparisons with Bonferroni corrections showed significant differences between all three categories. Holders of tertiary research qualifications had significantly higher levels of knowledge than holders of either tertiary non-research (p = .003) or non-tertiary qualifications (p < .001), and holders of tertiary non-research qualifications had significantly higher level of knowledge than holders of non-tertiary qualifications (p = .001).

Kruskal-Wallis tests showed no significant difference in knowledge levels across the categories of Type of Employment (p = .828), Gender (p = .710), Country Qualified (p = .202), or Age (p = .247).

Mann-Whitney U tests showed no significant difference in knowledge levels between categories of Native Language (p = .429), Location (p = .834), and holding an Adjunct Appointment (p = .136).

4.4 CONFIDENCE

4.4.1 Individual questions

Respondents were asked to indicate their level of agreement with a series of statements expressing confidence across five topics of research ethics knowledge. Response options were on five points from Strongly Agree to Strongly Disagree, however, for analysis, the five categories were collapsed to three; Agree, Neutral, Disagree. Frequencies were run to provide response rates of correct answers, and a total confidence score was created for further analysis.

Confidence was highest for the consent item (82% agreement and 7% disagreement). Confidence was also relatively high for data confidentiality, with around three-quarters of respondents (76.1%) agreeing that they understood all the requirements. Respondents demonstrated moderate levels of confidence in provision of participant information. Almost two-thirds of all respondents (59.5%) agreed they were confident in their knowledge of the subject. Respondents were least confident about their knowledge of the requirements for ethical review with only one-third of respondents indicating they agreed, while a similar proportion disagreed. All frequencies are displayed in Table 4.6.

Table 4.6

Response frequencies for confidence questions

Item	Response	*n*	%
I am confident that I understand the requirements for informed consent.	Agree	354	81.9
	Neutral	41	9.5
	Disagree	37	8.6
I am confident that I understand the requirements for data confidentiality.	Agree	329	76.1
	Neutral	60	13.9
	Disagree	43	10.0

I am confident I understand the requirements for the provision of participant information.	Agree	257	59.5
	Neutral	96	22.2
	Disagree	79	18.3
I am confident I understand the triggers for ethical review of research.	Agree	141	32.6
	Neutral	114	33.3
	Disagree	147	34.1

Note. n = 432.

4.4.2 Confidence and demographic variables

Total Confidence scores were obtained by aggregating the scores on the individual confidence items. A Kruskal-Wallis test revealed a significant difference in confidence levels across the three Streams (Gp1, n = 113: Allied Health, Gp2, n = 37: Medical, Gp3, n = 282: Nursing & Midwifery), X^2 (2, n = 432) = 17.241, p < .001. Nursing and Midwifery scored highest and Allied Health the lowest. A pair-wise comparison with Bonferroni corrections showed the difference between Nursing and Midwifery and Allied Health was significant (p < .001, two-tailed). The Medical Stream did not differ from either Nursing and Midwifery (p = .623, two-tailed) or Allied Health (p = .625, two-tailed) on Total Confidence scores.

A Kruskal-Wallis test revealed a significant difference in confidence levels across the three categories of Highest Qualification Received (Gp1, n = 55: non-tertiary, Gp2, n = 344: tertiary non-research, Gp3, n = 29: tertiary research), X^2 (2, n = 428) = 13.692, p = .001. A pair-wise comparison with Bonferroni corrections showed confidence levels of respondents who had obtained a tertiary research qualification to be significantly higher than confidence levels of respondents who had obtained a tertiary non-research qualification (p = .003, two-tailed). There was no significant difference between confidence levels of respondents holding tertiary research qualifications and respondents holding non-tertiary qualifications (p = .141). Nor was the difference between respondents holding non-tertiary qualifications and tertiary non-research qualifications significant (p = .375).

Kruskal-Wallis tests showed no significant difference in confidence levels across the different categories of Type of Employment (p = .272), Gender (p = .320) or Country Qualified (p = .667). Mann-Whitney U tests showed no significant difference in confidence levels between categories of Native Language (p = .419),

Location (p = .650) and holding an Adjunct Appointment (p = .716). A Jonckheere-Terpstra test for ordered alternatives found no significant association between Age and Total Confidence score, TJT = 43640.50, z = .1.564, p = .118.

4.4.3 Confidence and knowledge

The knowledge and confidence questions were structured to provide an opportunity to compare the proportion of respondents who agreed with the statement that they understood the requirements around a subject with the proportion of respondents who were able to demonstrate their knowledge on the subject. The collapsed response categories (Agree, Neutral and Disagree) for the confidence questions were used for comparison with correct response rates for corresponding knowledge questions. Proportions of respondents agreeing for each confidence item are shown in Table 4.7. Alongside these data are the proportions of respondents demonstrating a correct response on each knowledge item. Table 4.7 shows that there are no topics on which respondents were able to demonstrate a level of knowledge commensurate with their level of confidence.

Table 4.7

Comparison of confidence with knowledge on corresponding questions

Topic	Confidence % Agree	Knowledge % Correct
Consent	82.0	16.9
Participant information	59.5	42.4
Data confidentiality /patient data	76.1	41.0
Data confidentiality /de-identified data	76.1	27.5
Ethical review	34.1	3.5

Note. n = 432.

4.4.4 Confidence, knowledge and experience

The relationship between research experience, confidence, and knowledge (as measured by the Total Experience, Total Confidence and Total Knowledge scores respectively) was investigated using a Spearman Rank Order Correlation (rho). No relationship was found between confidence and either knowledge or experience (Table 4.8). A small positive relationship was found between experience and knowledge, with higher levels of experience associated with higher levels of knowledge.

Table 4.8

Correlations between measures of experience, confidence, and knowledge

	Total Experience	Total Confidence	Total Knowledge
Total Experience	-		
Total Confidence	.085	-	
Total Knowledge	.220**	.070	-

Note. $n = 432$. ** $p < .001$ (two-tailed).

4.5 INTEREST IN FUTURE RESEARCH AND TRAINING

4.5.1 Interest in conducting research in the future

Respondents indicated their agreement with the statement that they were interested in conducting research in the future. Less than half of all respondents (42%) expressed a definite interest (Agree) in conducting research in the future (see Table 4.9). About half as many (22%) expressed a definite disinclination to engage in research in the future (Disagree), while around one-third (36%) were ambivalent.

Table 4.9

Interest in conducting research in the future by professional stream.

Response	Allied Health	Medical	Nursing & Midwifery	All
Disagree	16 (14.8)	6 (16.7)	70 (25.9)	92 (22.0)
Neutral	31 (28.7)	7 (19.4)	112 (41.5)	150 (36.0)
Agree	61 (56.5)	23 (63.9)	88 (32.6)	174 (42.0)

Note. Allied Health, $n = 108$. Medical, $n = 36$. Nursing and Midwifery, $n = 270$. All, $n = 414$. Data are presented as *n* (%).

4.5.2 Interest in conducting research and demographic variables

Interest in Conducting Research in the future was greatest among Medical stream respondents with nearly two-thirds (63.9%) expressing a definite interest and only 16.7% expressing a definite disinterest (Table 4.9). Nursing and Midwifery had the lowest interest rates in future research overall, with the lowest interest rate (32.5%) and the highest disinterest rate (23.0%). It also had the highest rate of ambivalence (41.5%). A Chi-square test for independence indicated a small but significant association between Interest in Conducting Research in the future and Stream, X^2 (4, $n = 414$) = 26.71, $p < .001$, Cramer's V = .18. A significantly greater proportion of the

Allied Health and Medical streams were interested in research than Nursing and Midwifery and significantly fewer Allied Health and Medical were disinterested than Nursing and Midwifery.

Small but significant associations were found between research interest and holding an Adjunct Appointment X^2 (2, n = 412) = 6.49, p = .039, Cramer's V = .21; Location X^2 (2, n = 410) = 6.634, p = .036, Cramer's V = .13; and Highest Qualification Received X^2 (4, n = 410) = 19.03, p = .001, Cramer's V = .15. Those holding a research higher degree, having an adjunct appointment with a university, or located in Toowoomba were more interested in conducting research in the future.

A Kruskal-Wallis test revealed a statistically significant association between Interest in Conducting Research and Age (Gp1, n = 92: Disagree, Gp2, n = 147: Neutral, Gp3, n = 171: Agree), X^2 (2, n = 410) = 7.591, p = .022. Those who were interested in attending training had a lower median age than those who were not interested in attending training.

Chi-square tests for independence indicated no significant association between research interest and Gender, Employment Type and Native Language, as shown in Table 4.10. There was a significant association between interest in conducting research in the future and Highest Qualification Received.

Table 4.10

Chi-square values applied to interest in conducting research in the future and demographic variables

Variable	*n*	Chi-square	DF*	*p* (two-tailed)
Employment type	385	4.26	2	.119
Highest qualification received	410	19.03	4	.001
Location	410	6.63	2	.036
Native language	172	2.70	2	.355
Gender	404	2.60	2	.273
Adjunct	412	6.49	2	.039

A Kruskal-Wallis test revealed a statistically significant association between Interest in Conducting Research and research experience (Gp1, n = 92: Disagree, Gp2, n =150: Neutral, Gp3, n = 172: Agree), X^2 (2, n = 414) = 24.651, p < .001. Pair-wise comparisons with Bonferroni corrections showed significant differences between the

disagree and agree categories ($p < .001$) and the neutral and agree categories ($p < .001$). There was no difference between the disagree and neutral categories ($p = .539$). Those with greater experience were more interested in conducting research in the future.

4.5.3 Interest in attending training

Respondents were asked whether they would attend a research ethics training course. Overall, interest in attending training was high with 83.5% of all respondents stating they would be interested in attending training in research ethics.

4.5.4 Interest in attending training and demographic variables

All streams had greater than three quarters of respondents willing to attend training (see Table 4.11) with only eight percentage points between highest (Allied Health) and lowest (Medical). A Chi-square test for independence indicated no significant difference in Interest in Attending Training across Streams, X^2 (2, $n = 418$) = 1.47, $p = .479$.

Table 4.11

Interest in attending research ethics training by professional stream

Response	Allied Health	Medical	Nursing & Midwifery	All
Number of respondents	108	36	270	418
Yes *n* (%)	94 (86.2)	28 (77.8)	227 (83.2)	349 (83.5)
No *n* (%)	15 (13.8)	8 (22.2)	46 (16.8)	69 (16.5)

A Mann-Whitney U test indicated a small but significant association between Interest in Attending Training and Age, Yes (*Mdn* = 45 years, $n = 346$), No (*Mdn* = 52 years, $n = 68$), $U = 13834.00$, $z = 2.296$, $p = .022$, $r = 0.110$. Respondents who were interested in training had a lower median age than those not interested in attending.

There was no association between Interest in Attending Training and any other of the demographic variables. Results of Chi-square and Fisher's Exact test (Adjunct x Interest in Training) are presented in Table 4.12.

Relationships between research experience and interest in attending training could not be determined due to a violation of assumptions for the Chi-square test (i.e. greater than 25% of cells with expected counts less than 5; Pallant, 2016, p. 218).

Table 4.12

Results of tests for association for demographic variables and interest in attending training

Variable	*n*	Chi-square	DF*	*p* (2-sided)
Discipline most recently qualified	404	2.60	2	.273
Employment type	388	.273	1	.602
Highest qualification received	414	4.78	2	.091
Location	414	1.65	1	.199
Native language	417	.122	1	.727
Gender	408	.089	1	.765
Adjunct	416			.053

Note. *DF, degrees of freedom.

4.5.5 Comments about attending training

Respondents were given the opportunity to provide a comment on attendance at training; 89 respondents (21%) provided comments which are summarised here. Around one-quarter of comments (26%) were from respondents who stated they were not interested in attending training because they were not interested in research or research ethics. Nineteen percent stated that research and/or research training was irrelevant to their current role. A mixture of respondents (15%) both interested and not interested in attending training cited difficulties in obtaining time away from clinical duties as impacting on ability to attend. Some respondents (11%) felt that training was of most value when staff were engaged in research.

A small proportion of respondents viewed research as an extra-curricular activity for which they did not have time or were close to retirement and were therefore not interested (7% each). The remainder of the responses were unclassified, relating to topics as varied as why the person was interested in training (e.g. “undertaking a PhD”), their general interest in ethics, or comments on the duration of training sessions (28%). Note that percentages do not sum to 100 as some respondents’ comments were relevant to more than one category.

Chapter 5: Discussion and Conclusions

5.1 INTRODUCTION

This study examined the level of knowledge of research ethics guidelines in a population of clinicians in a regional Australian public health setting. Previous research has examined research behaviour from the perspectives of professional integrity and ethical decision making. There has been little research to date on the knowledge of researchers about the guidelines for the design and conduct of ethical research. Furthermore, the majority of prior research has utilised academic populations.

This research addressed the question of knowledge of research ethics guidelines, as expressed in the Australian National Statement of Ethical Conduct of Human Research (2007, updated 2018). Additional questions were asked about the level of confidence clinicians had in their own knowledge, their interest in conducting research in the future and their interest in attending research ethics training. Relationships were explored between knowledge, confidence, interest and professional and work characteristics.

In Chapter 5 the results are discussed and interpreted in light of both the literature and the organisation in which the research is situated. The discussion begins by noting the limitations of the study in section 5.2. The results are then discussed in reference to the research questions: Section 5.3 What is the level of staff knowledge of research ethics guidelines; Section 5.4 What is their level of confidence; Section 5.5 What is the level of interest in conducting research in the future; Section 56. Interest in attending training; and Section 5.7 is there any relationship with these levels and demographic variables? The relevance of these findings to the workplace are discussed in Section 5.8, and Section 5.9 looks briefly at suggestions for future research to build on the present study. The discussion concludes with a summary of outcomes related to the Learning Outcomes of the MPSR program, in Section 5.10.

5.2 LIMITATIONS

Before proceeding to a discussion of the findings, there are certain limitations to the study which should be noted, and their subsequent impacts acknowledged. These limitations are largely a result of the recruitment methods, which in turn were dictated by the nature of the population and confidentiality requirements of the organisation.

Firstly, due to the difficulties of contacting such a large and diverse population, there was no guarantee that all eligible employees would hear about the study, therefore a genuinely random sample could not be obtained. This was confounded by the time constraints of this population: clinicians in public health services are generally acknowledged to be time poor and their engagement with a topic which they may potentially view as irrelevant could not be guaranteed. This limited the type of analyses suitable for the data and the comparability between the professional streams. Comparability may also have been impacted by the substantial variation between the response rate from the professional streams; from 9% for Medical through to 65% for Nursing and Midwifery. Additionally, the response rates are not truly representative of the population from which the sample is drawn; the Allied Health stream was overrepresented, and the other streams underrepresented in the study sample. Therefore, where comparisons are made and conclusions drawn, these are to be viewed with a measure of caution. Additionally, the low response rate by the medical stream further limited the analysis available for some demographic variables, (i.e. through violation of expected cell counts for Chi-square tests).

Finally, the low engagement of medical officers proved a limitation in the present study, and it is uncertain whether the respondents in the medical stream may be considered representative. For example, around 43% of the medical officers within the sample held adjunct appointments. While there are no formal statistics, an informal estimate of the number of medical officers within the organisation holding adjunct (teaching) appointments with local universities is around 15%. Furthermore, in a discussion with the head of a medical department during the recruitment phase, the incumbent offered the opinion that unless medical officers perceived an item to be directly applicable to their practice they would “not even open the email”. Given the subsequently high knowledge, confidence and interest in research, as well as high adjunct levels of this group, it is highly likely that predominantly only those medical officers interested in research have responded to the recruitment publicity.

With these cautions in mind, the results are discussed below.

5.3 KNOWLEDGE

RQ1: What is the level of knowledge of research ethics guidelines amongst staff employed in health care roles within Darling Downs Health?

Overall, knowledge of research ethics guidelines was low to moderate in this sample of clinicians. No single knowledge question was answered correctly by more than 42% of respondents. Additionally, no individual respondent was able to correctly answer all five knowledge questions, and 27% of respondents failed to answer any of the questions correctly, although this is directly proportionate to 27% of the sample indicating they had never been involved in conducting research. Heitman, Olsen, Anestidou, & Bulger, (2007) suggest the adoption of the academic pass level of 80% to indicate an adequate level of knowledge. Using this standard, only 3% of respondents would have received a pass mark, despite 17% of respondents having undertaken some type of research training. Even at the very conservative level of a 60% pass mark, only 14% of respondents would have been successful.

Although low, knowledge rates for this sample of clinicians are comparable to previous results. Weston et al. (2016) found 47% of clinicians were able to correctly answer a question about the use of data from patient files. Within the present sample, correct responses were achieved by slightly fewer (41%) respondents for a similar question. Forty-four percent of respondents in the Weston et al. sample were able to correctly answer a question about provision of information to respondents, compared to 42% of the current sample. Note however, that for this question, the comparison is with the total sample from the Weston et al. study including clinicians, students and academics, not just the clinician sub-set. Greater variation is evident when results are compared for the question about consenting, where the correct response rate for the present study was about half that of the Weston et al. study (17% and 36% respectively).

Although Babl and Sharwood's (2008) earlier study did not report all results, they noted correct response rates for two knowledge questions substantially lower than those reported by Weston et al. (2016) (i.e., 16%). This may be an artefact of the question format adopted by Babl and Sharwood, who asked respondents to list all factors associated with a certain item, rather than providing a selection of items from which to choose correct options. Alternatively, it may illustrate the variation in

knowledge across research ethics topics and populations, or across time. In the present study, two questions had correct response rates of around 40% (described above). However, questions about data identifiability and informed consent were correctly answered less often (28% and 17% respectively), and requirement for ethical review was answered correctly by only 4% of respondents. Although these correct response rates demonstrate a wide spread, they are not inconsistent with past findings which range from 17% to 44% (Babl & Sharwood; Weston et al.).

Respondents from the Nursing and Midwifery streams had significantly lower knowledge scores than both Medical and Allied Health stream respondents. In discussing the lack of research knowledge among Australian nurses, Chapman, Duggan, and Combs (2011) highlight the lack of research exposure in the (Australian) preservice training pathway, notably the now obsolete hospital-based program. This has been addressed to some extent in Australia by the change to a tertiary pathway in 1993 for registered nurses, however Assistant in Nursing (AIN), Enrolled Nurse (EN), and Endorsed Enrolled nurse (EEN) qualifications continue to be non-tertiary and focused on practical rather than academic skills. Furthermore, Highest Qualification Received was also significantly associated with knowledge: knowledge was highest for respondents who held research higher degrees and lowest for respondents with non-tertiary qualifications. Nevertheless, holding a non-tertiary qualification accounts for only 18% of the current Nursing and Midwifery sample. It is possible that even within the tertiary pathway, there is less of a focus on research in Nursing and Midwifery degrees than in Allied Health or Medical degrees. A brief review of course content from the 30 Australian universities offering Bachelor of Nursing degrees (or equivalent) showed 25 of the courses included at least one unit covering evidence-based care and or research. Some of these included an investigation of research methods, such as the 'Evidence-based nursing practice' unit offered by Murdoch University. Its course description is typical of those describing evidence-based care units; an extract of which states:

> This unit introduces students to the concept of evidence-based practice and its application to health and clinical care, as well as the research process and the principles of qualitative and quantitative methodologies (Murdoch University, n.d.).

Thirteen of the units reviewed specified research content – for example the unit entitled 'Research for Nursing and Midwifery' at Western Sydney University. With a few

exceptions however, the intention appears to be to enable students to become confident users, rather than producers, of research. (See Appendix C for a list of courses and universities reviewed.) A similar brief review was undertaken of a representative number of randomly selected Allied Health degrees offered at 14 Australian universities. Due to the number of professions included in the Allied Health Stream and the number of courses available for each profession, a full review would constitute a major undertaking and was therefore beyond the scope of this discussion. Fourteen courses covering nine Allied Health professions were included (see the table in Appendix D for details of universities and courses). All courses contained at least one specified research methods unit, although in one degree this was optional. Five courses had multiple units, with one course (Bachelor of Psychology Honours through Deakin University) having four research units within the undergraduate degree. In addition, a number of professions require further study (i.e., Honours or Masters) and in the six degrees reviewed which included honours, this involved the conduct of a research project. It may be therefore that the requirement for an honours year, at least in some Allied Health degrees, is a contributing factor to a greater knowledge about research. Undoubtedly, the skills and knowledge required to design and conduct a research project, albeit a small one, are additional to those required to critique and apply the research findings of others. No comparison is provided with preservice medical degrees as these were difficult to review: course content often being unavailable on university web pages.

The proportion of respondents responding to the request to list governing documents and legislation was relatively small; only 18% of the total sample (n = 78). Only around one-fifth of these responses referred to the National Statement, the Code or other relevant legislation such as privacy laws and organisational policy, either by title or in such a way as to be obvious which document was being referred to. This represents only a very small proportion of the overall sample (i.e. 4% of the total sample). A further minority indicated they were aware of the existence of some type of guidelines or legislation, however they did not know what they were or where they might be located. The remaining responses highlighted the confusion around research ethics in general, and knowledge of the guidelines in particular. Respondents referred to organisations such as the World Health Organisation and departments such as university HRECs. While the entities cited are involved in research in some way, they also have other functions and their mention therefore does not necessarily indicate an

awareness of the particular guideline or legislation provided by the organisations and associated with research ethics. In fact, some of the cited organisations do not produce any research ethics guidelines. In any case, their mention does not indicate an awareness of the National Statement which underpins the ethical conduct of research within Australia.

Questions used for the present study represented common scenarios facing clinicians who undertake research in a public hospital setting. Understanding when patient data may be used for research, what makes data non-identifiable, when and how information should be provided to respondents, when and how consent must be obtained, and the requirements for ethical review, are all salient issues for clinicians whose jobs potentially include the conduct of research. That levels of knowledge about the requirements in these areas range from almost non-existent to only moderate should raise concerns for those with a vested interest in ensuring research is conducted in an ethical manner. That so few respondents were able to identify even one document pertinent to research ethics does not bode well for the ability of clinician researchers to find their own way forward in this challenging area.

5.4 CONFIDENCE

RQ1a How confident are staff in their knowledge of research ethics guidelines?

Overall, respondents expressed a moderate to high level of confidence in their knowledge of research ethics, with over three-quarters of respondents agreeing they understood the requirements for both informed consent and data confidentiality, and more than half agreeing they understood the requirements for provision of participant information. These rates are comparable to findings in previous studies. Babl and Sharwood (2008) examined confidence levels in three groups of respondents including clinicians with joint appointments at a research centre and hospital. They found the proportion of staff confident in their knowledge of the requirements across four topic areas ranged from 47 to 71%; not entirely dissimilar to our present result where proportions range from 34 to 82% across four topics.

Confidence, in the context of this study however, only acquires real relevance when viewed alongside demonstrable knowledge. When comparisons are made between levels of confidence and levels of knowledge across each of the topics, confidence levels are not matched by knowledge; that is, there are no topics on which

respondents were able to demonstrate a level of knowledge proportionate with their level of confidence. The largest disparity was on the topic of consent, with 65 percentage-points between the proportion of respondents who stated they understood the requirements for consent and the proportion who correctly answered the corresponding knowledge question. The smallest discrepancy was regarding provision of participant information, where there was a 17 percentage-point difference. The comparison of frequencies supports the statistical analysis, demonstrating no relationship between knowledge and confidence in this sample.

Levels of confidence varied across the professional streams with a significant difference between the highest (Nursing and Midwifery) and lowest (Allied Health). The lower Allied Health confidence level is consistent with findings in previous studies which show that Allied Health professionals perceive their research skills to be lower than that of their peers (Borkowski et al., 2016), and lack confidence in research tasks (Finch et al., 2013; Harvey et al., 2013). It is not unreasonable to extrapolate a lack of confidence in skills required to conduct robust research, to a lack of confidence in knowledge about how to design and conduct ethical research. Both may be, at least partially, attributable to a lack of research exposure in the current Allied Health training pathway (Borkowski et al., 2016).

The comparatively high rate of confidence of nurses, especially when compared to their low knowledge score, is an interesting finding. Further focused investigation is required to tease out the factors behind this.

Levels of confidence also varied according to the highest qualification received. Confidence levels of respondents who had obtained a research higher degree were significantly higher than confidence levels of respondents who had obtained a non-research tertiary qualification, while respondents with non-tertiary qualifications (the middle scoring group) did not differ significantly from either group. This outcome may be attributable to the exposure to research and research ethics teaching received at each of the three levels of qualification. By definition, those respondents holding a research higher degree have gained more exposure to research, perhaps leading them to feel greater confidence in their knowledge of research ethics guidelines. The respondents who were tertiary qualified, but had not undertaken a research specific degree, may well have had some exposure to research teaching, as many undergraduate degrees and post graduate courses contain an element of research or a small research project (e.g., an honours year or a medical college fellowship). These respondents may

therefore be cognizant of research practices and terminology, to the degree that they are aware of gaps in their knowledge and therefore recognise their lack of comprehensive knowledge. The non-tertiary qualified group may be assumed to have received little or no research exposure in their training and may simply not realise their lack of knowledge about the subject.

The setting of the study may provide an alternative explanation for the high levels of confidence on subjects about which respondents were demonstrably not knowledgeable. Discrepancies between knowledge and confidence on the topics of provision of participant information, obtaining consent, and data confidentiality may be due to these subjects having corresponding clinical activities: i.e., providing information and obtaining consent for clinical procedures, and maintaining data confidentiality within the clinical setting. Knowledge of a similar topic, or a topic with a similar name, may be a cause of confusion among clinicians who do not understand the distinctions between clinical and research practices. This argument is strengthened by qualitative comments which indicate staff may not be aware that research ethics is any different from clinical or professional ethics. For example, one respondent who was not interested in attending research ethics training stated: “We already have to do mandatory training online regarding ethics.” This is correct, however, mandatory training to which the respondent refers is ethics, integrity and accountability, which encompasses ethical decision making and accountability in the public sector. This module does not include any information about research ethics. This confusion would be compounded by low levels of research ethics education received in pre-service training. It is notable that comparatively fewer respondents were confident in their knowledge of ethical review requirements, an activity which does not have a clinical counterpart.

Interestingly, confidence was not related to research experience as measured by the four research activities making up the Total Experience score, contrary to previous findings (Black et al., 2013; Rosenkranz et al., 2015). Therefore, while experience may increase knowledge, in this sample at least, it is not related to confidence. It is possible that this result is due to the unexpected and unexplained high level of confidence in the Nursing and Midwifery stream. It is possible that understanding that result may shed light upon why, in this sample, confidence was not related to either experience or knowledge.

5.5 INTEREST IN RESEARCH IN THE FUTURE

RQ2: What is the level of interest in conducting research?

Overall interest in conducting research in the future was moderate, with 42% of respondents agreeing they were interested and a further one-third being undecided. Only about one-fifth of respondents was definitely opposed to the idea. Interest was more likely if individuals had an adjunct appointment, held a research higher degree, or were working in Toowoomba. Relatively younger respondents were also more likely to be interested in conducting research. The Nursing and Midwifery stream was significantly less interested in conducting research than the other streams.

The lower level of interest in research demonstrated by the Nursing and Midwifery stream is not an unexpected outcome in this sample. This finding corroborates results from previous studies in similar populations which found that nurses were less interested in research overall (Marshall et al., 2016) and less inclined to instigate their own research (Paget, Lilischkis, Morrow, & Caldwell, 2014) than were either Medical and Allied Health streams.

Further, the researcher works in a research support service within the organisation from which the sample is derived and has personal experience of lack of research activity among the Nursing and Midwifery stream. For example, a record of consultations is maintained by the service, along with the streams to which consultative services are provided. For the 18 quarters for which data have been collected, Nursing and Midwifery has had the lowest number of consultations for 15 quarters, despite comprising the largest professional stream within the HHS. This is somewhat in contrast to the enthusiasm often demonstrated by nursing staff who attend education sessions and express an intention to undertake subsequent research. Apparently initial interest and enthusiasm are not necessarily translated into actual research activity. This is consistent with findings from a study utilising a nurse-only sample in a large international hospital. Although half of respondents expressed an interest in undertaking research, only a ‘very few’ were concurrently engaged in research activities (Akerjordet, Lode, & Severinsson, 2012). Barriers to research uptake in all health professions have been well documented and include lack of time, knowledge, support, acknowledgement, along with competing priorities (Borkowski et al., 2017; Friesen & Comino, 2016; Marshall et al., 2016; Paget, Caldwell, Murphy, Lilischkis, & Morrow, 2017). It has been proposed that nurses face some additional

barriers peculiar to their profession. Segrott, Green, and McIvor (2006) suggest that the historic context of nursing may play a major role in the slow uptake of research by this group. Although it is now around 25 years since the changeover to the tertiary training model in Australia, nursing has a tradition of being an applied, patient-centred profession. Historically, the role of nursing has been framed as the provision of care in the health context (Polifroni & Welch, 1999). Altruistic factors - the opportunity to help, to provide care and assistance - remain significant motivators for people choosing to enter the nursing profession within Western countries (Eley, Eley, & Rogers-Clark, 2010; Straughair, 2012; Wilkes, Cowin, & Johnson, 2015). The conduct of research is not intuitively concordant with the provision of care to the ill and is therefore not likely to be a key attraction for those taking up nursing. Whilst the understanding of the role of research in patient care can be addressed in both pre-service training and subsequent in-service professional development, it is likely that by its nature, nursing will continue to attract individuals high in empathy and altruism (Eley, Eley, Bertello, & Rogers-Clark, 2012), whose focus is on practical care rather than research. Simply mandating the conduct of research in awards and roles is not going to override what appears to be a strong cultural association of practical activity with the role of nursing.

The higher interest in research among the Allied Health stream is not surprising either. Although they face barriers common to all health professions when contemplating undertaking research in the public health system (Borkowski et al., 2017; Friesen & Comino, 2016; Marshall et al., 2016; Paget et al., 2014), Allied Health professionals are more inclined to recognise the intrinsic rewards of research and become involved to develop skills, enhance career opportunities, increase job satisfaction, and contribute to the evidence base for practice (Borkowski et al., 2017; Borkowski et al., 2016; Pager, Holden, & Golenko, 2012). Allied Health professionals are also apt to perceive research as being part of their role (Borkowski et al., 2016). This may be reflective of the relative newness of the Allied Health professions, and their focus on building a scientific evidence base for practice. Beginning in the early part of this century, Allied Health professional bodies in Australia have demonstrated a sustained commitment to building research capacity among clinicians through strategies such as funding of Allied Health research positions embedded within local public health services (Harvey et al., 2013; Wenke et al., 2017a; Williams et al., 2015). The organisation in which the current research is situated employed an Allied Health Research Fellow for five years from 2010 until the role was expanded to include all

professions in 2015. Furthermore, the records of the organisation's research support service confirm that Allied Health professionals are actively engaged in research: for the 18 quarters for which records have been kept, Allied Health staff have consistently been the highest service users of research support services within the health service. This anecdotal and localised evidence is supported by research confirming clinicians across a range of Allied Health professions consistently express interest in conducting research (Finch et al., 2013; Harvey et al., 2013; Pighills et al., 2013; Wenke et al., 2017a).

Neither is it entirely unexpected to have a high level of interest in research expressed by the Medical stream respondents. Modern medicine is predicated on evidenced based practice, with the expectation and requirement for practitioners in any specialty to maintain currency through research consumption (Bonilla-Velez et al., 2017). Furthermore, involvement in research from undergraduate years onward is now almost considered mandatory for career advancement, and numerous specialist colleges include research components in their qualification process (Bennett, 2016). Additionally, 43% of Medical stream respondents held an adjunct appointment with a university; a characteristic associated with interest in conducting research in the future. In the context of the organisation in which the study was conducted, holding an adjunct appointment comes with certain privileges, such as research support from the university, including access to a statistician. In comparison, only 4% and 2% of Allied Health and Nursing and Midwifery stream respondents respectively held adjunct appointments. Lack of access to research support has been consistently noted as a barrier to undertaking research in Allied Health populations (Pain et al., 2015). It does not seem unreasonable to extrapolate this to other clinical populations, nor to assume its absence will be a factor in an interest in undertaking research. Additionally, appointment to an adjunct position often entails the requirement for academic outputs, viz. research publications. It is highly likely that the association between having an adjunct appointment and an interest in conducting research is based in the requirement to generate research outputs. As discussed in the preceding Limitations section, the representativeness of the Medical stream respondents is questionable. Therefore, despite the higher level of interest being explainable by extraneous factors, it is feasible that the explanation for the level of interest in this particular case, lies in the biased nature of group.

Another commonly identified barrier to conducting research is location outside of a major urban or regional centre. Rurality can compound issues of quarantining research time or backfilling positions to allow for research activities to occur (Cooke, 2005; Pain et al., 2015). Respondents in the present study were more likely to indicate an interest in conducting research if they were located within Toowoomba (a city of some 105,000 residents; http://www.tr.qld.gov.au/our-region/living-here/our-towns) rather than any of the outlying rural locations. As discussed previously, this may be attributable to time issues, or perceived lack of supports. Although the organisation in which the research is situated offers research support to all staff via face to face or electronic means, physical distance can lead to a sense of dislocation (Isaac, Pit, & McLachlan, 2018).

Numerous studies have confirmed that the more an individual engages in research the more confident and skilled they become, and the more likely they are to engage with research in the future (Harding, Stephens, Taylor, Chu, & Wilby, 2010; Mullan et al., 2014; Rosenkranz et al., 2015). It is not surprising then that respondents who indicated greater research experience were also more interested in conducting research in the future, as were respondents who held a Higher Degree by Research (HDR), which is itself a source of research experience. Whilst this confirms previous findings, it does not provide any insight into how to engage non-interested staff in the research process in the first instance, thus providing the opportunity to further pique their interest.

5.6 INTEREST IN ATTENDING TRAINING

RQ2a: What is the level of interest in attending training in research ethics guidelines?

Interest in attending research ethics training was surprisingly high; well over three-quarters of respondents expressed interest in attending training (84%), twice the proportion that was interested in conducting research. However, the proportion of those interested in attending training was not dissimilar to the combined interested and neutral groups for conducting research (78%). It is possible that attending a training program might encourage some of the 33% of respondents who were ambivalent about conducting research in the future into a more positive attitude toward conducting research. The difficulty may be facilitating staff to attend, despite an expression of willingness. Comments provided by respondents indicated that training was seen as

most valuable at the time when research was being undertaken; therefore encouraging staff to attend training simply to improve knowledge as a prelude to contemplating research may prove difficult. Additionally, a number of respondents noted the difficulty of finding time away from clinical requirements to attend training. These comments are consistent with findings from the literature (Borkowski et al., 2017) as well as the experience of the researcher within the organisation.

Interest in attending training, like interest in conducting research, was related to age: a higher mean age was associated with lower interest in conducting research or attending training. Some light can be shed on this by the comments. A number of respondents who indicated they were not interested in training noted that they were approaching retirement, and therefore not interested in undertaking research, and by extension, learning about the regulations around it. It is possible that for many staff, as retirement looms, they are not interested in taking on new initiatives or upskilling.

Given the association of Stream with interest in research, particularly the low interest of the Nursing and Midwifery stream, it was interesting that no corresponding association for interest in attending training was observed. In fact, all streams were similar in their level of interest in attending training.

5.7 DEMOGRAPHIC FACTORS

RQ3: What characteristics of the respondents are associated with variations in knowledge, confidence and interest?

A number of personal and professional characteristics were related to the main variables of interest (i.e., knowledge, confidence and interest in research and training).

Professional stream (Allied Health, Medical, Nursing and Midwifery), was associated with level of research ethics knowledge, confidence, and interest in future research. Nursing and Midwifery was significantly higher in confidence but lower in knowledge and interest in conducting research. The Medical stream was significantly higher in knowledge and interest in conducting research. Caution should be used in extrapolating to the broader DDHHS clinical staff population due to the low proportion of medical stream respondents – only 9%, whereas medical officers make up around 12% of the clinical workforce – and the possible inclusion of predominantly research interested staff in this group.

The highest level of qualification received was associated with three of the main variables of interest. Having obtained a research-specific tertiary qualification in

particular was associated with higher levels of both knowledge and confidence, and greater interest in conducting research in the future. This corroborates previous findings that indicate involvement in research itself is both a predictor and outcome of research engagement (Finch et al., 2013; Harvey, Plummer, Nielsen, Adams, & Pain, 2016) and increases research self-efficacy (Black et al., 2013; Chapman et al., 2015). Likewise, research experience was positively associated with both knowledge and research interest, confirming previous research.

Being located in Toowoomba and holding an adjunct appointment were both associated with greater interest in conducting research in the future, as previously discussed.

Interestingly, age was associated with interest in conducting research in the future and attending training, but not knowledge or confidence. It is likely the explanation is found in the free text comments associated with the training question where a number of respondents expressed a reluctance to become involved in research as they neared retirement.

This study found no relationship between English as a second language and knowledge of research ethics, confidence, interest in conducting research or interest in attending training. Additionally, this study found no relationship between the country in which qualifications were received and the main variables, despite the variation in research legislation between countries, and previous research which has indicated a difference (Heitman et al., 2007). There is no reason to consider this result is not correct, at least for this sample, given that the proportion of the sample having English as a second language is equivalent to the proportion within the population of clinical staff within the organisation (HR Business Intelligence, 2019, p. 7).

No association was found between either employment type or gender and the main variables of interest. This is interesting considering 42% of the sample are employed part-time. It is, however, good news for an organisation with a high rate of part-time staff (51%) that this does not affect their interest in engaging in research. Also encouraging is the lack of association between gender and both knowledge and interest, although this may be due to the large proportion of the sample being female (83%). However, the gender break-down in the sample is concordant with the population from which it is drawn where females predominate in both the Allied Health and Nursing and Midwifery populations (79% and 90% respectively). It is

likely therefore that this finding is generalisable to the organisation's general clinician population.

5.8 APPLICATION TO THE WORKPLACE

This study investigated the knowledge of research ethics guidelines in a population of health care professionals within a public health service in regional Australia. It extends the current understanding of researcher knowledge to include knowledge of research ethics guidelines; specifically, guidelines pertinent to the Australian research landscape. Knowledge was found to be low, although comparable with previous findings in similar populations, and there was some evidence that clinicians could face significant challenges if left to address this deficit on their own. Additionally, disproportionality high confidence levels suggest clinicians may be unaware of their lack of knowledge. These findings support the need for the provision of education to staff about the requirements for ethical conduct of research in the healthcare context.

This research did not explicitly investigate the reasons behind the level of research ethics knowledge being what it was in this population. It is feasible however that lack of teaching on research ethics in preservice training is a primary underlying factor. This is understandable in a non-research degree where the focus is on teaching clinical skills. However, Australia aspires to be a nation which leads the world in research (Australian Research Council, 2015), including health research (*NHMRC's Research Quality Strategy*, 2019). Development of a research capable health workforce necessitates inclusion of an applied research component into all clinical degrees. There is clear evidence that exposure to research nurtures confidence and future intention (Black et al., 2013; Rosenkranz et al., 2015; Smith et al., 2016). While not diminishing the value of current courses which develop skills for the implementation of evidence-based practice, these rudimentary skills must be built upon with knowledge which allows the graduate to understand the constituents of ethically sound as well as scientifically robust research, and subsequently to move into the workplace confident and competent to engage in the research process. Be that as it may, considerations of curriculum content are beyond the scope of this thesis. Moreover, they are beyond the reach of the organisation in which this research is embedded. Therefore, while changes to preservice curriculum are a valid consideration for the future of health care research in general, of more practical concern are the

initiatives which may be implemented by the organisation to address the apparent knowledge deficit of its current workforce. We now turn to a consideration of these.

Firstly, the role of mentors for modelling and teaching ethical research cannot be discounted, and there is substantial evidence to indicate that research mentoring in a public health setting builds research knowledge and confidence in clinical staff (Chapman et al., 2011; Joubert & Hocking, 2015; Wenke et al., 2017b; Williams et al., 2015). Mentoring of individuals and teams is a resource intensive undertaking and whilst undeniably effective and attractive, cannot be supported without an evidence base of need and a critical mass of research activity within the organisation to validate the allocation of substantial resources. Whilst a case may be built for this over time, it is unlikely that it will be available in the immediate future to address staff education needs. A related strategy is that of clerkship, where a beginning researcher is placed on a project being led by experienced researchers. The beginning researcher can then learn from observation, participation and enquiry, about various aspects of research including research ethics. Whilst this strategy has substantial potential in larger organisations with an established research community, smaller, less resourced, and research emergent organisations such as DDHHS, may not be able to provide sufficient experienced researchers or research projects to make this viable.

As the provision of education to staff around research is one of the Key Performance Indicators of the research support team within the organisation, this is a more practical goal to address. The challenge is to develop an education package and find the right time and mode of delivery, to ensure it is targeting the right audience and not imposing an unnecessary burden on other (i.e., non-interested) staff.

Several points warrant consideration in relation to the provision of research ethics education within the organisation in which the researcher is employed: to whom should the information be provided; how and when should it be supplied; and of what should it consist? Provision of research ethics training to all staff is both unnecessary and burdensome. Irrespective of professional responsibility, experience shows that not all clinicians will conduct research, and those who do so will undertake it at varied stages of their clinical career. To impose irrelevant (or what may be perceived as irrelevant) training on disinterested staff is unlikely to encourage attendance, attention, or retention. It is far more judicious to expend the limited resources available within the organisation to target those staff who are contemplating the imminent conduct of research and to whom, therefore, the information is most relevant. Furthermore, the

prospect of additional irrelevant training was not popular with respondents, as illustrated by the comment; “There is too much training of limited value now. Please do not add more.” Informally and anecdotally, this is a common complaint within the organisation, where numerous training modules must be completed, whether online or in person, on a regular basis. A number of the topics are perceived to be of little practical application to those obliged to complete them, and are therefore considered an imposition on time-poor staff. Understandably, having to sit through training on research ethics, when the staff has no intention to engage in research and no interest in the content, as well as a pressing clinical schedule, is not going to promote engagement or knowledge retention. Additionally, a number of respondents noted that they thought training would be most effective if provided when research was being undertaken, as the following respondent comment illustrates:

> “If I were to be getting involved in research in the foreseeable future I would attend a training course. If I had no plans / opportunities for research anytime soon, I would be reluctant to enrol for a course at that point in time (I would likely forget relevant information and have to refresh it anyway by the time I actually started any research).”

The most practical solution is to provide research ethics training to staff if and when they are undertaking research. This raises the question of how such staff might be identified and targeted.

Ideally, staff should be exposed to research ethics training as early as possible in the research design process, increasing the likelihood of a study design incorporating ethical principles. This has the bonus for staff of potentially reducing the time required to obtain ethical approval, as most delays are related to requests by the reviewers for clarification of information in the application or requests for amendments to the protocol to enhance compliance with the National Statement. Unfortunately, there is currently no mechanism to identify staff intending to conduct research prior to submission of an ethics application.

Presently, all submissions for ethical review within the organisation (indeed, within the state-wide public health service) must be submitted via an online ethical review management platform (ERM; Infonetica, 2019). Potentially, it may be possible to link the validation of an ERM account with the requirement to complete an online research ethics course for users identifying with the organisation. While this method has the advantage of potentially identifying all organisation staff intending to conduct

research for the first time, it has two major disadvantages. ERM is utilised by public health service providers in two Australian states so there may be technical issues related to identifying and quarantining a very small subset of users. Moreover, this is not a decision which can be implemented by the organisation, but would require further discussions with the appropriate Queensland Government department which administers the ERM platform, and development of a suitable method of identification from their end. Furthermore, this method would only identify new ERM users, and not staff who already hold accounts.

Another option is for staff who submit an application to the HREC for review, and fail to address significant ethical principles, to be required to undertake a training module prior to resubmission of that project. While this method has the advantage of targeting clinicians who demonstrate a need for training, situating training within the ethical review process may have the disadvantage of adding to the already widely held opinion among clinicians within the organisation that ethical review is unnecessarily onerous. Unfortunately, for researchers who wish to have scientifically or ethically unsound research approved, the review process can prove to be onerous. Persistent resubmission of an unethical research protocol is tiresome for all concerned. Therefore as an adjunct to either elective completion of research ethics training or early training for all, mandatory training for identified staff may be appropriate, despite any potential negative associations arising from embedding it within the ethical review process.

Another alternative is the attendance of the researcher at a subsequent meeting of the HREC where salient ethical points may be discussed, and education provide in a more open and engaging format.

It is likely that the most effective approach is a combination of the above. The research support team already attends orientation days for nurses and midwives, and some medical officer orientations. On these occasions, they provide a brief presentation (20-30 minutes) which highlights the existence of the team and its role; the difference between quality assurance and research (an ongoing difficulty for clinical staff); and the requirement for ethical review of research projects. The intention of these presentations is to flag the need for guidance in the future when research is being contemplated. If some type of mandatory research ethics training is introduced, orientation presentations may provide a medium to draw attention to the requirement of training prior to submission of an application to the HREC for review. Thus, all staff are made aware of the requirement for training at the brief, mandatory,

introductory presentation, but only those staff to whom it is relevant need follow up with actual training. This brings us to the question of whether the training itself should be mandatory or elective.

As discussed previously in this thesis, non-mandatory education sessions have been trailed within the organisation and have failed to attract sufficient attendees to justify their continuation, despite targeting identified high areas of enquiry. Non-mandatory learning modules have also been provided on the organisation's eLearning platform. However, uptake has only been around 50 hits per year for the past two years (C. Reynolds, personal communication, August 27, 2019). This equates to approximately one percent of the clinical workforce. Whether this is due to a lack of interest in the content matter or a lack of awareness of the modules, is unknown; but probably both factors are pertinent. The results of the present study suggest at least two other factors may contribute to limited uptake of elective training; staff overconfidence in research ethics knowledge and the pressures of clinical practice limiting time available for non-mandatory and non-clinical activities. These factors suggest clinicians will not necessarily identify their need for training, so a mandatory component may be justifiable for those wishing to enter the research arena.

Findings from the current study suggest that although interest in attending training was high, organising time away from clinical practice to attend training is a significant barrier. Delivery of educational material across the broad geographical footprint of the organisation, and the need for resources to be accessible on an ongoing and as-needs basis, suggests an online learning platform would be the most practical mode of delivery for the major teaching endeavours. This is particularly attractive as the organisation already hosts an eLearning platform which is accessible to all staff. Support is readily available to design and deliver material in a format appropriate for online delivery.

The content will need to align with the requirements for ethical research design and conduct as detailed in the National Statement and should therefore be based on that document. As the present study has highlighted some apparent confusion between clinical and research terminology, this should also be addressed (and has already been incorporated into the orientation presentations). If it is possible to link new ERM accounts with the requirement for training, this phase may be best addressed by a general introductory and overview module. Additional in-depth training addressing ethical considerations related to the seven elements of research, as detailed in the

National Statement, might then be provided in separate modules. While the additional modules could be elective, proof of completion might be required for researchers identified through the ethical review process as needing targeted assistance on a particular topic. It is the expectation of the organisation that all new training initiatives will be evaluated for effectiveness, therefore an evaluative aspect would be built into the design of all research ethics training introduced into the organisation.

In summary, a series of online training modules could be developed, targeting research active staff. New researchers could potentially be identified when creating an account for the ethical review management platform and an introductory mandatory module completed. The ethical review process would flag staff requiring further training in specific areas and they would be required to complete the appropriate module before resubmitting their project. Content would be based on the National Statement. In addition, access to training modules would continue to be available as an elective to all staff through the organisation's eLearning platform. Whether all, or any components of the above plan are feasible will require further liaison with the organisation's Information Technology department, education division, HREC office and the Health Innovation, Investment and Research Office which manages the ERM platform.

5.9 CONCLUSIONS AND DIRECTIONS FOR FUTURE RESEARCH

The conduct of research is mandated in the awards and professional responsibilities of the majority of clinical staff employed by public health services within Queensland. However, this research has demonstrated that in this particular sample of clinical staff, overall knowledge of research ethics guidelines was moderate at best. Responses to the survey item requesting identification of documents providing ethical guidelines, suggests clinicians may not have the knowledge to be able to locate the required information on research ethics if the need should arise. Confidence was disproportionately higher than knowledge in this sample, particularly for items where there is a corresponding clinical equivalent (e.g., participant/patient information). This suggests at least some clinician overconfidence may be attributable to the confusion of clinical and research terminology. The high rate of confidence of nurses is a result for which no explanation could be proffered in this instance, particularly in light of the low knowledge score for this group. Further research is required to tease out the factors underlying this disparity, particularly as it may have some bearing on the lack of

significant relationship between confidence and both knowledge and research experience in the broader sample. Further investigations of research knowledge conducted with staff from other Queensland Health service districts would contribute to the interpretation of findings from this study by demonstrating similarities and differences in samples and results. More broadly, populations beyond the Queensland public health services could be included such as: clinical staff and consultants at private hospitals; General Practitioners and general practice nurses; and private allied health clinics (including psychologists), from Queensland and other Australian states. This would contribute to a broad picture of clinician knowledge of research ethics guidelines in some of the many settings in which health research is conducted outside of the academic context.

The results of this research indicate a need for further education in research ethics guidelines for this population. Research training should target those clinicians who are conducting (or intending to conduct) research. Although it would be preferable to channel clinicians into training prior to the design stage of research, it may not be possible in the public health workplace. A second option is to utilise the research ethics review application procedure to flag those researchers who require further information on particular areas of research ethics, and mandate completion of appropriate modules as part of the response to further information process of the HREC.

It seems likely that the diverse historical backgrounds of the professional streams (Allied Health, Medical, and Nursing and Midwifery) play a significant role in the differences between the streams not only in research knowledge, but also in confidence, and interest in both research and research ethics training. Further comparative research is warranted to tease out these differences and to inform responses tailored to meet the needs and characteristics of the streams.

While the need for training is confirmed by the findings of this research, the viability of any of the suggested training options remains to be investigated. However, the value of research within the health care system is undeniable, and it is incumbent upon organisations hosting research to ensure their researchers are conducting scientifically robust and ethically responsible research. This can only occur as we continually monitor and improve our processes. Not only will this assist the DDHHS to meet its goals of delivering evidence-based healthcare and maintaining a commitment to innovation and research in rural and regional healthcare (Darling

Downs Hospital and Health Service, 2017), but it will facilitate compliance with the obligation of institutions to train staff in research ethics, as mandated in the Australian Code for the Conduct of Research.

5.10 LEARNING OBJECTIVES – OUTCOMES

5.10.1 Systematised information gathering and Problem solving

As expected, the requirement to conduct a thorough literature review in the course of researching the background for the thesis, provided an opportunity to develop "systematised information gathering" skills. I feel I have learned a substantial amount about gathering information in the area of literature searching (i.e., locating and identifying information, storage and management via dedicated software). Other opportunities to develop skills in this area presented themselves in the course of the MPSR program where it was necessary to obtain information about the course. This was more challenging as I was unable to identify a formal structure for organisation of the information by the university, and subsequently was unsure how to proceed. This highlights my "problem solving" learning objective, which I feel was not as successfully addressed. I entered the program with limited problem-solving skills (largely limited to seeking advice from peers and supervisors, and locating policy and procedure). I was not able to identify new ways of solving problems and largely adhered to familiar processes (often with unsatisfactory results). Problem solving within the context of providing recommendations arising from the results of the study was less challenging as I was able to consult experts and the literature.

5.10.2 Analytical skills, Critical judgement, and Objective judgement

Several aspects of the thesis provided the opportunity to develop "analytical skills" and "critical judgement". The nature of a thesis necessitates the inclusion of evidence throughout the body of the work, including justification for choice of research methods, interpretation of results and recommendations. Thus, while the literature review was the obvious, and most prolific area wherein critical review and synthesis of the literature was required, analysis and integration of the literature was necessitated (and is evident) throughout the thesis.

Interpretation of the data, in light of both the literature and the setting provided the opportunity to develop both analytical and "objective judgement" skills. The research was initially undertaken based on observations which suggested a low level

of research ethics knowledge among staff. While this was confirmed, some of the results challenged my preconceived ideas, particularly with regard to the subsequent recommendations to the organisation. Having to review my own expectations in light of outcomes offered an opportunity to develop and exercise "objective judgement". Despite being a small step forward, I feel this is a significant point as it has helped me to realise that apparently obvious solutions may prove impractical or unsuitable upon further investigation, and to realise the importance of remaining objective when assessing situations and exploring solutions in the workplace.

5.10.3 Creativity and innovation

Opportunities to develop "creativity and innovation" were not abundant within the program or the study. However, the insights into the conceptual model of research ethics (see Figures 2.1 and 2.4) were both creative and innovative to a small degree. My expectation is that there will be greater opportunity for creativity and innovation in the design of subsequent educational interventions for staff around research ethics, now that the need for such an intervention has been supported.

5.10.4 Conclusion

My overarching goal in undertaking the MPSR was to develop my research skills to enable me to better carry out my role of research support to staff within the organisation; a goal which has been unequivocally achieved. The design of the research study provided the opportunity to develop knowledge of research methods. Further, lessons learnt through the conduct of the study have further enhanced that knowledge, providing insight into the practical issues of study design. The process of conducting research with a challenging population, matching methodologies to contexts, balancing expectations with actual eventualities and maintaining momentum have given me a greater appreciation for the challenges faced by colleagues undertaking research in this environment.

Although it was not a pre-defined learning objective for this program, a secondary outcome of the MPSR has been the opportunity to develop a greater level of expertise within my area of interest; research ethics. This has opened up the possibility of numerous other areas of investigation which may benefit the organisation and myself professionally in the future, as well as potential career pathways previously not considered.

Chapter 6: References

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APPENDIX A
LIST OF PROFESSIONS

The following list is extracted from HEALTH PRACTITIONERS AND DENTAL OFFICERS (QUEENSLAND HEALTH) CERTIFIED AGREEMENT (No. 2) 2016, Schedule 1, pages 27 and 28. The agreement is available on the Queensland Government (Queensland Health) webpage: https://www.health.qld.gov.au/employment/conditions/awards-agreements/current. Not all of the professions listed are employed within the DDHHS.

Eligible disciplines and professions:

(a) Anaesthetic Technicians;

(b) Art Therapists;

(c) Audiologists;

(d) Biomedical Engineers and Technicians;

(e) Breast Imaging Radiographers;

(f) Cardiac Perfusionists;

(g) Chemists and/or Radio-Chemists;

(h) Child Guidance Therapists;

(i) Child Therapists;

(j) Clinical Measurement Scientists and Technicians;

(k) Dental Officers

(l) Dental Prosthetists;

(m) Dental Technicians;

(n) Dental Therapists;

(o) Dietitians/Nutritionists;

(p) Environmental Health Officers;

(q) Epidemiologists;

(r) Exercise Physiologists;

(s) Forensic Scientists and Technicians;

(t) Genetic Counsellors;

(u) Health Promotion Officers;

(v) Leisure Therapists;

(w) Medical Illustrators;

(x) Medical Laboratory Scientists and Technicians;

(y) Music Therapists;

(z) Neurophysiologists;

(aa) Neuropsychologists;

(bb) Nuclear Medicine Technologists;

(cc) Nutritionists;

(dd) Occupational Therapists;

(ee) Oral Health Therapists;

(ff) Orthoptists;

(gg) Orthotists, Prosthetists and Technicians;

(hh) Patient Safety Officers;

(ii) Pharmacists and Technicians;

(jj) Physicists, including Radiation Oncology Medical Physicists, Nuclear Medical Physicists, Radiology Medical Physicists, and Health Physicists;

(kk) Physiotherapists;

(ll) Podiatrists;

(mm) Psychologists including Clinical and Neuropsychologists;

(nn) Public Health Officers;

(oo) Radiation Therapists;

(pp) Radiographers/Medical Imaging Technologists;

(qq) Rehabilitation Engineers and Technicians;

(rr) Researchers, Clinical Trial Coordinators and Data Collection Officers; Scientists – Environmental Health;

(ss) Social Work Associates;

(tt) Social Workers;

(uu) Sonographers;

(vv) Speech Pathologists; and

(ww) Welfare Officers.

APPENDIX B

QUESTIONNAIRE

A: About you and your job

1. Are you employed

□part time

□full time

□casual

□in more than one role

2. Please indicate your gender

□Male

□Female

□Other/rather not say

3. Please provide your age

4. Please indicate your native language

□English

□Other (i.e. English as a second language)

5. What is the highest qualification you have obtained?

□High school matriculation (e.g. HSC)

□An undergraduate degree

□An Honours degree (research)

□An Honours degree (coursework only, no research)

□A Master's degree (research)

□A Master's degree (course work only, no research)

□A Doctorate

□A Medical degree e.g. MBBS

□Other, please specify

6. In what country/ies did you receive your qualification/s? Please list all qualifications and countries.

7. With regard to your most recent qualification, in what discipline area did you qualify?

□Allied Health, Dental, Pharmacy and Medical Imaging

□Medicine

□Nursing & Midwifery

□Other, please specify

8. Which stream are you employed under within the DDHHS?

□Health Professional

□Medical

□Nursing

□Midwifery

□Administrative

□Dental

□Professional

□Operational

□Technical

9. Please provide your current roles in the DDHHS.

10. Is the conduct of research included in your current DDHHS role descriptions?

□Yes

□No

□Not sure

11. In what location is your principal place of work? (e.g. Wondai, Toowoomba, etc.)

12. Do you hold an adjunct or honorary appointment with a university?

□No

□Yes

B. Your research experience

13. Have you ever been involved in the conduct of scientific research on humans (excluding involvement as a participant)?

□No □If No, please go to Question 17

□Yes

14. If yes, about how long (full time equivalent) do you estimate you have been involved in research?

15. In what area/s is the research in which you have been involved?

e.g. medical, social sciences, epidemiological

16. Altogether, approximately how many separate human research projects (involving human participants or using information about people) have you ever

been involved in at any level (e.g. as an investigator or research assistant) and on any subject?

17. Have you ever published or co-authored any papers from a human research project in a peer reviewed journal?

□No □If No, please go to Question 19

□Yes

18. If yes, how many human research publications have you published in peer reviewed journals?

19. Have you ever completed or assisted in the completion of an ethics application for research with humans?

□No □If No, please go to Question 21

□Yes

20. If Yes, how many ethics application for research with humans have you completed or assisted with?

21. Are you or have you ever been a member of a Human Research Ethics Committee (HREC)?

□No

□Yes

22. Have you ever received any training in the ethical conduct of human research?

□No □If No, please go to Question 24

□Yes

23. If yes, please describe the type and duration of research ethics training you have received e.g. 8 hours online, international education provider

C. Ethics requirements for undertaking research involving humans

Please indicate your agreement with the following statements:

	Strongly Agree	**Agree**	**Neither Agree nor Disagree**	**Disagree**	**Strongly Disagree**
24. I am confident that I understand the requirements for informed consent.					
25. I am confident that I understand the requirements for data confidentiality.					
26. I am confident that I understand the requirements for the provision of participant information.					
27. I am confident that I understand the triggers for ethical review for research.					

28. When can a health care professional use information from the medical records of his/her patients for a research study? Please tick AS MANY answers as required.

□when using the information would advance scientific knowledge

□when the patient has given specific consent for that research project

□when the data is about a clinical procedure to which the patient has consented

□when 7 years has passed after the last consultation with that patient

□when there is no foreseeable risk of harm to the patient

□don't know

29. When is it necessary to provide participant information (either written or verbal)? Please tick AS MANY answers as required.

□when a research participant is invited to complete an anonymous survey

□when a research participant is asked for access to his/her medical records

□when a research participant is invited to be part of a drug trial

□when a research participant is asked for health information that may identify them to others

□when a research participant is from a vulnerable group, such as a non-English speaking background

□don't know

30. Which of the following statements about participant consent are correct? Please tick AS MANY answers as required.

□Participants may need to be consented more than once if there are several phases of a study

□Participants may need to be consented more than once if aspects of the study change

□Participants must always be consented by the principal investigator or lead researcher

□Participants must never be consented by the principal investigator if he or she is also the treating clinician

□Participants may be consented by any member of the treating (clinical) team

□Participants must be consented by a member of the research team

31. Which of the following types of data meet the criteria for non-identifiable data? Please tick AS MANY answers as required.

□Data from which all identifiers have been permanently removed and by which no individual can be identified

□Data from which identifiers have been removed and replaced by a code, where the code is stored separately to allow for reidentification of individuals.

□Data that have never been labelled with individual identifiers and by which no individual can be identified

□Data from which identifiers have been removed, and only UR numbers are retained

□Don't know

32. Which of the following examples, when conducted within the DDHHS, requires a submission to the Human Research Ethics (HREC) office? Please tick AS MANY answers as required.

□Comparison of discharge times from ICU for patients treated under an updated DDHHS procedure, where findings are reported back to the team and may be presented at a state conference

□Use of non-identifiable data from the Queensland Cancer Registry to compare rates and outcomes of colon cancer in regional and remote locations across the state

□A systematic review of clinical trials comparing side effects of three major analgesics with results to be published in a peer reviewed journal

□A review of conformity by staff within the medical ward to hand hygiene guidelines, with findings reported back to the NUM and staff at subsequent team meetings

□Don't know

33. Please list any national, state or organisational documents or policies governing the conduct of research, of which you are aware.

D. Future training and education in human research ethics

34. Please indicate your agreement with the following statement:

	Strongly Agree	**Agree**	**Neither Agree nor Disagree**	**Disagree**	**Strongly Disagree**
I am interested in in doing research in the future.					

35. Would you attend research ethics training session?

□Yes – up to 2 hours duration

□Yes – up to half a day duration

□Yes - up to one day duration

□No - please give your main reasons for not wishing to attend:

36. Please indicate below the type of information, education or training about human research ethics that would be useful for you.

Thank you for your participation

APPENDIX C

AUSTRALIAN UNIVERSITY BACHELOR OF NURSING COURSES (OR EQUIVALENT) REVIEWED FOR INCLUSION OF A RESEARCH UNIT

Institution	Degree	Unit/Course	URL
University of Southern Queensland	Bachelor of Nursing	Evidence based Nursing Practice	https://www.usq.edu.au/course/synopses/2019/NUR2300.html
Charles Sturt University	Bachelor of Nursing	Professional nursing: Evidence-informed practice understanding research processes	http://www.csu.edu.au/handbook/handbook19/subjects/NRS328.html
Victoria University	Bachelor of Nursing	Working with evidence consumer (includes Ethical principles of research)	https://www.vu.edu.au/units/HNB3123
University of Sydney	Bachelor of Nursing (Advanced Studies)	Nursing Research	https://sydney.edu.au/courses/units-of-study/2020/nurs/nurs1007.html
Queensland University of Technology	Bachelor of Nursing	Inquiry in Clinical Practice	https://www.qut.edu.au/courses/bachelor-of-nursing

Griffith University	Bachelor of Nursing	Research in Nursing	https://courseprofile.secure.griffith.edu.au/student_section_loader.php?section=1&profileId=106472
Royal Melbourne Institute of Technology	Bachelor of Nursing	Health Care informatics and Research Critique	https://www.rmit.edu.au/study-with-us/levels-of-study/undergraduate-study/bachelor-degrees/bachelor-of-nursing-bp032/bp032p04ausbu
Western Sydney University	Bachelor of Nursing	Research for Nursing and Midwifery	http://handbook.westernsydney.edu.au/hbook/course.aspx?course=4691.3
University of Newcastle	Bachelor of Nursing	Nil listed	https://www.newcastle.edu.au/__data/assets/pdf_file/0005/230675/B_Nursing_PMQ_full_time_11725_2016-2019.pdf
Australian Catholic University	Bachelor of Nursing	Nil listed	https://courses.acu.edu.au/undergraduate/bachelor_of_nursing
University of Notre Dame	Bachelor of Nursing	Health Communications, Research & Informatics	https://www.notredame.edu.au/programs/fremantle/school-of-nursing-and-midwifery/undergraduate/bachelor-of-nursing

Edith Cowan University	Bachelor of Nursing	1. Evidence Based practice in Nursing and Midwifery 2. Research and Teaching in Clinical Practice	https://www.ecu.edu.au/degrees/courses/bachelor-of-science-nursing-studies
University of Adelaide	Bachelor of Nursing	Research methods and evidence based nursing	https://www.adelaide.edu.au/degree-finder/2020/bnurs_bnursing.html#df-acc-degree_structure_parent
University of Technology Sydney	Bachelor of Nursing	Evidence in Nursing	https://www.uts.edu.au/future-students/find-a-course/bachelor-nursing#course-overview
Charles Darwin University	Bachelor of Nursing	Evidence based health research and practice	https://www.cdu.edu.au/study/bachelor-nursing-bnrsg-2020#!course-structure
Deakin University	Bachelor of Nursing	Understanding research evidence	https://www.deakin.edu.au/course/bachelor-nursing
University of South Australia	Bachelor of Nursing	Research Methodologies	https://study.unisa.edu.au/degrees/bachelor-of-nursing
Curtin University	Bachelor of Science (Nursing)	Evidence informed health practice	http://handbook.curtin.edu.au/courses/31/319405.html

James Cook University	Bachelor of Nursing Science	Nil listed	https://www.jcu.edu.au/courses-and-study/international-courses/bachelor-of-nursing-science
La Trobe University	Bachelor of Nursing /BM	1. Research evidence in practice 2. Nursing and Midwifery research	https://www.latrobe.edu.au/courses/bachelor-of-nursing-bachelor-of-midwifery
University of Wollongong	Bachelor of Nursing	Evidence Based Practice	https://coursefinder.uow.edu.au/information/index.html?course=bachelor-of-nursing
Flinders University	Bachelor of Nursing	Clinical Governance and Practice Improvement	https://students.flinders.edu.au/my-course/course-rules/undergrad/bnursing/bngu
Swinburne University of Technology	Bachelor of Nursing	Nursing Research (requires a study)	https://www.swinburne.edu.au/study/course/bachelor-of-nursing/
University of Tas	Bachelor of Nursing	Improving health and nursing practice	http://www.utas.edu.au/courses/chm/courses/h3d-bachelor-of-nursing
University of Canberra	Bachelor of Nursing	Nil listed	https://www.canberra.edu.au/coursesandunits/course?course_cd=364JA&version_number=1&title=Bachelor-of-

			Nursing&location=BRUCE&rank=AAA&faculty=Faculty-of-Health&year=2020
University of New England	Bachelor of Nursing	Information and evidence in health and social care	https://my.une.edu.au/courses/2019/courses/BNURS/program-of-study-rule(a)(d).html
The University of Queensland	Bachelor of Nursing	Evidence based practice	https://my.uq.edu.au/programs-courses/program_list.html?acad_prog=2241
Murdoch University	Bachelor of Nursing	Evidence based nursing practice	https://www.murdoch.edu.au/study/courses/course-structure/nursing-(bnurs)
Monash University	Bachelor of Nursing	Nil listed	http://www.monash.edu/pubs/handbooks/courses/M2006.html
Federation University	Bachelor of Nursing	Introduction to research and evidence based practice	https://study.federation.edu.au/#/course/DHN5

Notes. 30 universities offering a BN or BSc (N) degree. 25 listed a course dealing with evidence based care or research. Note that some did not provide a link to their courses so could not be verified. 13 had research specific courses, although some of these appeared to have similar content to the evidence based care courses, and some of the evidence based care courses included research methodologies and research ethics (for example).

APPENDIX D

ALLIED HEALTH COURSES REVIEWED FOR INCLUSION OF A RESEARCH UNIT

Institution	**Degree**	**Unit name, *n* research/*n* total**	**URL**
Griffith University	Bachelor of Nutrition & Dietetics	Public health research methods 1/24	https://degrees.griffith.edu.au/Program/1355/Courses/Domestic#course-list
La Trobe University	Bachelor of Human Nutrition	Epidemiology and research skills for nutrition 1/24	https://www.latrobe.edu.au/courses/bachelor-of-human-nutrition
Australian Catholic University	Bachelor of Physiotherapy	Research and Evidence-based practice for physiotherapy 1/30 (4 year)	https://courses.acu.edu.au/undergraduate/bachelor_of_physiotherapy
Bond University	Bachelor of Exercise and Science	1/24 2 years	https://bond.edu.au/program/bachelor-exercise-and-sports-science
Central Queensland University	Bachelor of Social Work	Health research methods	https://handbook.cqu.edu.au/he/courses/view/cc48
Charles Darwin University	Bachelor of Social Work	1/28 Social research methods	https://www.cdu.edu.au/study/bachelor-social-work-wscwk1-2020#!course-structure
Deakin University	Bachelor of Psychological Science - Honours	1/28 Social research methods	https://www.deakin.edu.au/course/bachelor-psychology-honours?_ga=2.61627498.713980736.15

			67408304-641030984.1567127105&_gac=1.54127066.1567408304.CjwKCAjw-7LrBRB6EiwAhh1yX1o4Ll7Zi_yurj9lSaJfBroZBLhMY7HTXjnWVm-VFEu1uyn5H96DeRoCKWMQAvD_BwE
University of Western Australia	Bachelor of Psychological Science - Double Major	4/32 plus a 2-unit research project	https://www.uwa.edu.au/study/courses/psychology-double-major https://handbooks.uwa.edu.au/undergraduate/honoursdetails?code=hon-psych
Queensland University of Technology	Bachelor of Medical Imaging - Honours	Double degree 3/24, plus honours	https://www.qut.edu.au/courses/bachelor-of-medical-imaging-honours
Monash University	Bachelor of Radiography and Medical Imaging - Honours	Honours: 4 research units plus 2-unit research project	http://www.monash.edu/pubs/handbooks/courses/M3006.html

University of the Sunshine Coast	Bachelor of Occupational Therapy - Honours	3/30 including a 2-unit research project	https://www.usc.edu.au/learn/courses-and-programs/bachelor-degrees-undergraduate-programs/bachelor-of-occupational-therapy-honours#what-will-i-study
Western Sydney University	Bachelor of Podiatric Medicine	16 courses, one optional research	http://handbook.westernsydney.edu.au/hbook/course.aspx?course=4708.1
James Cook University	Bachelor of Pharmacy - Honours	2/22 including optional research pathway	https://my.une.edu.au/courses/courses/HBPH1/program-of-study.html
Flinders University	Bachelor of Speech Pathology	2/24 or (4 year) 32	https://students.flinders.edu.au/my-course/course-rules/undergrad/bspp#program-of-study