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### Academic guidance in medical student research: how well do supervisors and students understand the ethics of human research?

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## Academic guidance in medical student research: how well do supervisors and students understand the ethics of human research?

### Abstract

Research is increasingly recognised as a key component of medical curricula, offering a range of benefits including development of skills in evidence-based medicine. The literature indicates that experienced academic supervision or mentoring is important in any research activity and positively influences research output. The aim of this project was to investigate the human research ethics experiences and knowledge of three groups: medical students, and university academic staff and clinicians eligible to supervise medical student research projects; at two Australian universities. Training in research ethics was low amongst academic staff and clinicians eligible to supervise medical student research. Only two-thirds of academic staff (67.9 %) and students (65.7 %) and less than half of clinicians surveyed (47.1 %;  $p = 0.014$ ) indicated that specific patient consent was required for a doctor to include patient medical records within a research publication. There was limited awareness of requirements for participant information and consent forms amongst all groups. In the case of clinical trials, fewer clinicians (88.4 %) and students (83.3 %) than academics (100 %) indicated there was a requirement to obtain consent ( $p = 0.009$ ). Awareness of the ethics committee focus on respect was low across all groups. This project has identified significant gaps in human research ethics understanding among medical students, and university academic staff and clinicians. The incorporation of research within medical curricula provides the impetus for medical schools and their institutions to ensure that academic staff and clinicians who are eligible and qualified to supervise students' research projects are appropriately trained in human research ethics.

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# **Academic guidance in medical student research: how well do supervisors and students understand the ethics of human research?**

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Key words: research ethics, medical student, medical school, curriculum, ethics committee

Compliance with Ethical Standards

The authors declare that they have no conflicts of interest. The study was approved by two university ethics review committees. Participants were provided with participant information. Tacit consent was implied by completion of an anonymous survey. All data were collected anonymously.

## Abstract

Research is increasingly recognised as a key component of medical curricula, offering a range of benefits including development of skills in evidence-based medicine. The literature indicates that experienced academic supervision or mentoring is important in any research activity and positively influences research output.

The aim of this project was to investigate the human research ethics experiences and knowledge of three groups: medical students, and university academic staff and clinicians eligible to supervise medical student research projects; at two Australian universities.

Training in research ethics was low amongst academic staff and clinicians eligible to supervise medical student research. Only two-thirds of academic staff (67.9%) and students (65.7%) and less than half of clinicians surveyed (47.1%;  $p = 0.014$ ) indicated that specific patient consent was required for a doctor to include patient medical records within a research publication. There was limited awareness of requirements for participant information and consent forms amongst all groups. In the case of clinical trials, fewer clinicians (88.4%) and students (83.3%) than academics (100%) indicated there was a requirement to obtain consent ( $p = 0.009$ ). Awareness of the ethics committee focus on respect was low across all groups.

This project has identified significant gaps in human research ethics understanding among medical students, and university academic staff and clinicians. The incorporation of research within medical curricula provides the impetus for medical schools and their institutions to ensure that academic staff and clinicians who are eligible and qualified to supervise students' research projects are appropriately trained in human research ethics.

## Introduction

Research is increasingly recognised as a key component of medical undergraduate curricula with expectations that graduates will not only understand evidence-based medicine, critically appraise and apply the evidence, but also undertake independent inquiry (Irby 2011; Laidlaw et al. 2009; Schor et al. 2005). Medical students may conduct research as an elective experience, but there are now greater expectations for research to be a compulsory component of medical programs (Riley 2009, Rosenkranz et al. 2015), particularly as there are few opportunities or expectations for graduates to do research in the first few years of graduate practice and clinical training (Health Workforce Australia 2012). This is reflected in the emergence of graduate programs with the aim of producing clinician scientists (Dannefer et al. 2014), and recent revisions of accreditation criteria for medical schools. For example, the current graduate outcomes which graduates of all accredited Australian and New Zealand medical schools now must achieve specifically include students' ability to:

*1.5 Apply knowledge of common scientific methods to formulate relevant research*

*questions and select applicable study designs, and*

*1.6 Demonstrate a commitment to excellence, evidence based practice and the generation of new scientific knowledge*

(Australian Medical Council 2012).

The research activities which students undertake may be part of established research programs or as stand-alone projects (Black et al. 2013; Boyd and Wesemann 2009; Halpain et al. 2005; Houlden et al. 2004; Schor et al. 2005; O'Connor Grochowski et al. 2007; Rosenthal et al. 2009; Mullan et al. 2014), with many students being supervised by academic staff or clinicians associated with a medical school.

Students are more likely to obtain a satisfying research experience if their research mentors or supervisors are suitably qualified and experienced (Rosenkranz et al. 2015). Mentor/supervisor experience is essential in guiding students in developing appropriate research questions, designing research methodology, and analysing and interpreting study results, while also advising and directing students in the ethical conduct of research. However, many academic staff, clinician researchers, and research mentors have not received formal training in human research ethics (Babl and Sharwood 2008), which may result in poor advice to students in research activities such as recruitment, access to medical records, and maintaining privacy. Undertaking 'bad science' can negatively impact on the development of students' research integrity, create a negative opinion of ethics review committees, or result in unpublishable research findings (Rosenkranz et al. 2015).

The aim of this project was to investigate the human research ethics experiences of current medical students, and university academic staff and clinicians who supervise medical student research projects, at two Australian universities. The knowledge of these medical students, university academics and clinicians about human research ethics issues such as informed consent, appropriate use of patient medical records, and research participants' privacy was also investigated.

## **Methods**

### **Context and Participants**

Academic and clinical conjoint staff, and students from the medical programs at two Australian universities were invited to participate in this study. These medical schools were selected as examples of the diversity of medical school curricula in Australia and New Zealand, ranging from 6-year direct school leaver entry to 4-year graduate entry programs. While both medical schools in this study have compulsory community-based research course components and students are expected to achieve the same graduate outcomes, the students differ in their backgrounds and prior research experiences.

The medical course at University A (Univ. A) is a 4-year graduate-entry program in which research and critical analysis is embedded as a core theme throughout the entire course (Mullan et al. 2014). The capstone activity is a community-based research project undertaken in the senior years during a 12-month longitudinal integrated clerkship placement. All students are provided with qualified research supervision as they experience the continuum of research from developing a research question, applying for research ethics, data collection and analysis and final reporting and dissemination. Student publications and presentations have resulted from these research projects, and evidence of students' increased capacity in research has been demonstrated (Mullan et al. 2014).

University B (Univ. B) provides a 5-year direct school leaver entry medical program. While 40% of students have completed at least one year of university, a minority (<10%) are graduates from other courses, or have conducted research (<10%) prior to starting medical school. During the fourth year of the course, all students undertake a community-based research project in groups, supervised by an academic or conjoint, with formal instruction in research methods provided by dedicated teaching staff (Rosenkranz et al. 2015). Groups develop a research question and project plan, apply for ethical approval, collect and analyse data, and complete a report in the style of a journal publication, with many going on to present their research at academic conferences. A mixed methods study confirmed the potential of compulsory research projects to motivate students to do research later in their careers (Rosenkranz et al. 2015).

Both universities draw upon similar groups to supervise student research; they include staff who are employed as academics with responsibilities for teaching and research, or those who are appointed as conjoints (honorary academic positions), who work primarily as clinicians in affiliated teaching hospitals and community-based services. As there is considerable overlap between the activities and backgrounds of these groups, for the purposes of the study we defined “Academics” as participants with research qualifications and experience, such as doctorates, peer reviewed publications and grants. “Clinicians” may have a range of research qualifications and expertise. Those with research qualifications or equivalent experience are eligible to supervise medical student research alone, while those less qualified may provide support to medical students undertaking research, in collaboration with a research qualified academic staff member.

## **Survey**

A survey to assess participants’ research experience and responses to ethical issues in human research was adapted from a questionnaire developed by Babl and Sharwood (2008) to evaluate the research experience and knowledge of research ethics of staff, clinicians and research students prior to implementing a training intervention. Similar to Babl and Sharwood’s survey we included background questions about the participant’s research experience, training and awareness of key policies, adapted for our medical schools, but also included multiple choice questions based on common research ethics scenarios. A copy of the survey questions is available by contacting the authors. The scenarios covered issues of consent, participant information, focus of a research ethics committee, and researcher responsibility regarding privacy when a health issue is revealed during research. Scenarios were informed by national policy documents, research ethics guides (Australian Government [2007A,B]), the expertise of one author (CT), who is a former chair of the Australian Health Ethics Committee (Australian Government, 2015), and the experience of all authors in developing and coordinating student research programs and assessments at our respective medical schools.

## **Survey distribution and data collection**

To maximise response rates for this diverse group, we used university internal mail services to distribute the surveys to staff (university academics and clinicians) and students. Surveys were also distributed at teaching hospital Grand Rounds meetings (Univ. A), together with a pre-addressed envelope for the anonymous return of the survey. An online version of the survey in Survey Monkey<sup>TM</sup> was also used to increase response rate (Univ. B). Given the differences in timing of research skills teaching in the program, Univ. A students from all phases of the course were invited to participate, with forty percent of respondents being senior students who had already completed their research project. Univ. B medical students completed the survey prior to undertaking formal teaching on research ethics.. At Univ. B, surveys were distributed to students via university email using Survey Monkey<sup>TM</sup> as an online platform, or as paper-based surveys distributed to students during

lectures. After the first mailout, participants were requested to ignore reminders and other versions of the survey if they had already completed it.

A participant information sheet was provided to all participants and involvement in the study was anonymous and voluntary. This study was approved by the the human research ethics committees of both Univ. A (HE 11/438) and Univ. B (ID No 9737) and was performed in accordance with the ethical standards as laid down in the National Statement on Ethical Conduct in Human Research (2007 as at 2015) (NHMRC/ARC/UA) (Australian Government 2007) and the Declaration of Helsinki (World Medical Association Inc. 2015).

### **Data analysis**

Results are presented as numbers and percentages of respondents. Associations across respondent groups (i.e. medical students, clinicians and academic staff) were analysed using Chi squared and Fisher's exact tests. Individual group response observed rates were compared to expected rates based on entire cohort responses. Statistical analysis was conducted using Prism 6 for Windows (GraphPad Software, Tallahassee). Statistical significance was accepted when  $p < 0.05$ .

## **Results**

### **Respondents**

A total of 351 participants completed the survey (Table 1). Males predominated amongst the clinicians, while the converse was the case for academic staff and medical students. In general, academic staff had the most research experience of the three groups; most academic staff had previously completed an ethics application (83.9%), while only about half of the clinicians (52.6%) and 16% of the medical students had done so. The median duration of research experience, number of research projects and number of publications was highest for the academic staff. About one-third of the clinicians had no previous research experience and only one-quarter had at least 2 years research experience. In contrast, most academic staff had some research experience (88.7%) and over 60% had at least two years prior research experience.



Table 1: Demographics of survey participants

	Academic staff	Clinicians	Medical students
All participants N (%)	62 (17.7)	76 (21.7)	213 (60.7)
Univ. A (4-year graduate-entry) N	25	40	Years 1/2 n=45 Years 3/4 n=137
Univ. B (5-year high school matriculation-entry) N	37	36	Year 3 n=30 Year 4 n=1
Median age range (years)	40-49	40-49	25-29
Female N (%)	38 (61.3)	31 (40.8)	121 (56.8)
Male N (%)	24 (37.1)	45 (59.2)	92 (43.2)
Higher Degree Research qualification = <i>Masters by Research</i> N (%)	4 (6.5)	11 (14.5)	3 (1.4)
Higher Degree Research qualification = <i>PhD</i> N (%)	48 (77.4)	0 (0)	1 (0.5)
Medical degree N (%)	12 (19.4)	76 (100)	0 (0)
Past research experience <2 years N (%)	16 (25.8)	32 (42.1)	52 (24.4)
Past research experience ≥2 years N (%)	39 (62.9)	19 (25)	3 (1.4)
Completed at least one human research ethics application N (%)	52 (83.9)	40 (52.6)	34 (16.0)
Read National Statement on Ethical Conduct in Human Research <sup>a</sup> N (%)	44 (71.0)	34 (44.7)	49 (23.0)
Any human research ethics training N (%)	26 (41.9)	16 (21.1)	18 (8.5)
Member of Human Research Ethics Committee or reviewer N (%)	14 (22.6)	10 (13.2)	2 (0.9)
<i>For respondents with any research experience</i>			
Past research experience - median	> 4 years	6-12 months	6-12 months
Research projects – median N	11-50	5-10	1-4
Publications – median N	11-50	<5	<5

<sup>a</sup>Australian Government (2007)

### Training in research ethics and experience

Training in human research ethics was low across academic staff and clinicians; less than half the academic staff (41.9%) and only one-fifth (21.1%) of clinicians had received research ethics training (Table 1). About one-third of academic staff and clinicians indicated that they would like some training in human research ethics, with varying preferences for content including general principles of human research ethics, specific information about consent and recruiting participants, the ethical undertaking of research, information about how to complete ethics application forms, case-based examples of research projects and issues, interactive discussion sessions, and online learning.

Most academics (71%) had read the National Statement on Ethical Conduct in Human Research (hereafter called the *National Statement*) (Australian Government 2007). In contrast fewer than half of the clinicians and less than one-quarter of medical students had done so. Relatively few respondents

had been a member or reviewer for a Human Research Ethics Committee (HREC). Analysis of responses from participants claiming to have research experience indicated that 76.4% of research-experienced academics had read the National Statement, compared to 52.5% of clinician academics with research experience, and 32.7% of medical students with research experience (Table 1).

### Participant information and consent requirements

Respondents were asked *When is a written participant information sheet or verbal information required?* Five response options were offered (see Table 2 for response options). Relatively fewer clinicians and medical students correctly identified situations requiring participant information than did academics. Only about 40% of clinicians (40.6%) and medical students (40.2%) indicated that all situations listed required provision of participant information, whereas over 60% of academic staff ( $p = 0.007$ ) nominated all five answers (Table 2). In all groups, the answer least likely to be chosen was when the participant was invited to complete an anonymous survey. Only about half of the clinicians (50.7%) and medical students (55.0%) indicated that participant information was required for an anonymous survey, while more academic staff were aware of this requirement (64.4%) ( $p = 0.28$ , not significant). The option where most participants thought participant information was required was when the survey participant was part of a drug trial. Even for this option, however, only 82.6% of clinicians indicated information for participants was required, whereas over 96% of academic staff selected this option ( $p < 0.0001$ ). Proportionally fewer students than academics or clinicians selected this option as requiring provision of participant information (69.9%).

Table 2: Participant responses to the question: *When is a written participant information sheet or verbal information required?*

Response	Academic staff <sup>a</sup> N=59	Clinicians <sup>a</sup> N=69	Medical students <sup>a</sup> N=209
<b>All 5 options indicated, N (%)</b>	<b>37 (62.7) *</b>	<b>28 (40.6)</b>	<b>84 (40.2)</b>
When a research participant is invited to complete an anonymous survey, N (%)	38 (64.4)	35 (50.7)	115 (55.0)
When a participant is asked for access to his/her medical records, N (%)	53 (89.8)	47 (68.1)	131 (62.7)
When a participant is asked to be part of a drug trial, N (%)	57 (96.6)*	57 (82.6)	146 (69.9)
When a research participant is asked for health information that may identify them to others, N (%)	56 (94.9)	53 (76.8)	138 (66.0)
When a research participant is from a vulnerable group, such as a non-English speaking, N (%)	48 (81.4)	43 (62.3)	116 (55.5)
Don't know, N (%)	1 (1.7)*	10 (14.5)	52 (24.9)

<sup>a</sup> N is the number who provided a response to this question (denominator)

\* significantly different – observed versus expected  $p < 0.05$

Participants were also asked to indicate when a consent form would be required. The same options were provided as for the participant information question above. In this case, four answers were considered correct, i.e. all options except for *When a research participant is invited to complete an anonymous survey* (see Table 3 for response options). Although proportionally more academics indicated each of the correct options than did clinicians or medical students, only 50% of all academics, 36.2% of clinicians and fewer than one-fifth of all students (18.2%) identified all four correct options. All academics indicated consent was required for those involved in a clinical trial, in contrast to 88.4% of clinicians and 83.3% of students who indicated this requirement ( $p = 0.009$ ). More medical students (33.0%) than clinicians (20.3%) or academic staff (27.6%) believed a consent form was required for an anonymous survey.

Table 3: Participant responses to the question: *When is a written consent form required?*

Response	Academic staff <sup>a</sup> N=58	Clinicians <sup>a</sup> N=69	Medical students <sup>a</sup> N=209
All 4 correct options indicated, N (%)	29 (50.0)	25 (36.2)	38 (18.2) *
When a research participant is invited to complete an anonymous survey, N (%)	16 (27.6)	14 (20.3)	69 (33.0)
When a participant is asked for access to his/her medical records, N (%)	57 (98.3)	54 (78.3)	164 (78.5)
When a participant is asked to be part of a drug trial, N (%)	58 (100)	61 (88.4)	169 (83.3)
When a research participant is asked for health information that may identify them to others, N(%)	57 (98.3)	60 (87.0)	175 (83.7)
When a research participant is from a vulnerable group, such as a non-English speaking, N (%)	45 (77.6)	38 (55.1)	102 (48.8)
Don't know, N (%)	0	8 (11.6)	33 (16.3)

<sup>a</sup> N is the number who provided a response to this question (denominator)

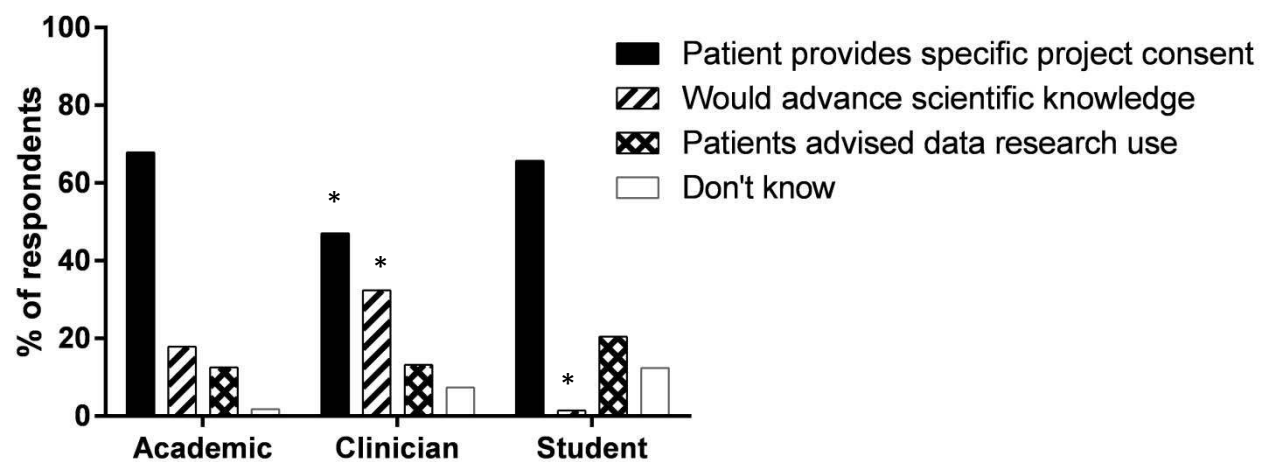
\* significantly different – observed versus expected  $p < 0.05$

### Attitudes towards a doctor using information from medical records for a research publication

Figure 1 summarises the responses to the question *When can a doctor use information from the medical records of his/her patients for a research publication?* Of note, similar proportions of academic staff (67.9%) and medical students (65.7%) gave the preferred answer that *specific patient*

consent was required for medical records to be used for research, in contrast to the 47.1% of clinicians who chose this answer ( $p = 0.014$ ) (Fig. 1). More clinicians and fewer medical students than academic staff favoured the answer that a doctor can use the records *if the doctor decides it would advance scientific knowledge* ( $p < 0.0001$ ). It is interesting to note that very few medical students chose this option (1.4%). The option least chosen by all groups was: *when patients have been informed that their records might be used for research* (Fig 1). No respondents chose the only other option: *when 7 years has passed after the last consultation with that doctor*.

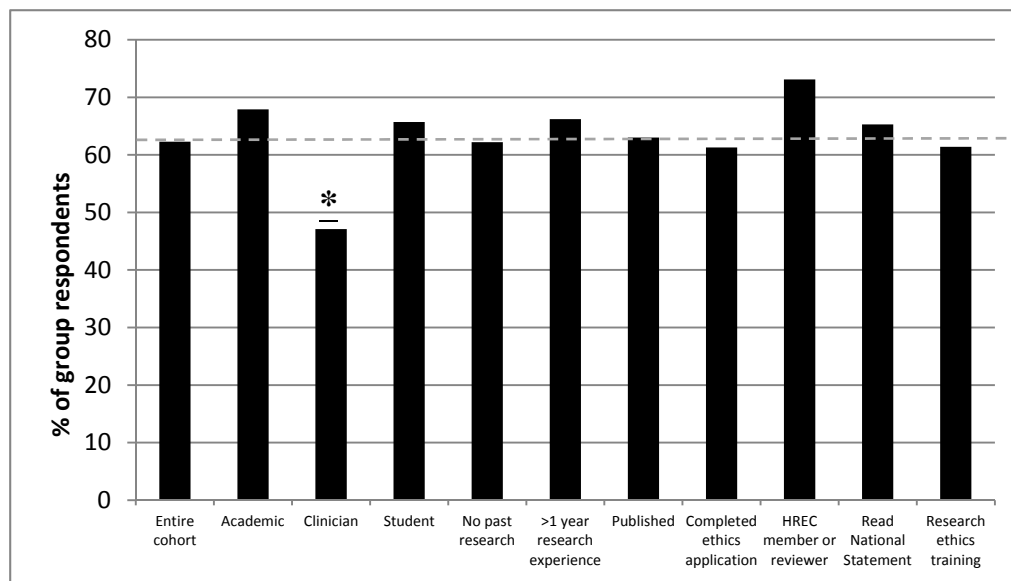
**Fig. 1** Participant responses to the question: *When can a doctor use information from the medical records of his/her patients for a research publication?* Legend: black: patient provides specific project consent; diagonal hatch: would advance scientific knowledge; cross hatch: patients advised data research use; white: don't know



\* Significantly different (observed versus expected) Fisher's exact test ( $p < 0.05$ )

To investigate whether any factors could be identified that may have impacted on the choice of answer in Fig. 1, the association between responses to the preferred option (specific patient consent is required) and research and publication experience, or experience with research ethics, was analysed (Fig. 2). Extent of research or publication experience or having read either the National Statement or completed an ethics application or ethics training in the past were not significantly associated with the preferred response to this question. Respondents who were or had been members of, or reviewers for, a human research ethics committee had the highest proportion choosing the preferred option (73.1%); however this finding was not statistically significant.

**Fig. 2** Respondents indicating patient consent was required to use patient records for research



Dashed line: cohort average.

\* significantly different – observed versus expected  $p < 0.05$

### Attitudes towards a possible health issue revealed while conducting research

Table 4 outlines the participants' responses to a scenario where a research participant revealed symptoms indicative of depression. Participants were asked their responsibility as a researcher and to fill in as many answers as required.

Of note, over half of the academic staff (54.7%) and clinicians (53.7%) chose the option of including information about symptoms of depression on the participant information sheet, more so than student respondents (33.7%,  $p = 0.002$ ). Academic staff and clinicians were also more likely than students to provide more information on seeking help, or to approach the general practitioner (GP) or practice staff about a research participants' disclosure of depression. About one-third of medical students (32.1%) indicated they did not know the answer ( $p < 0.0001$ ).

Table 4: Participant responses to a possible mental health issue revealed during data collection and research. The scenario was: *While undertaking the survey, the researcher notices that a participant has a significantly high score on a depression rating scale.*

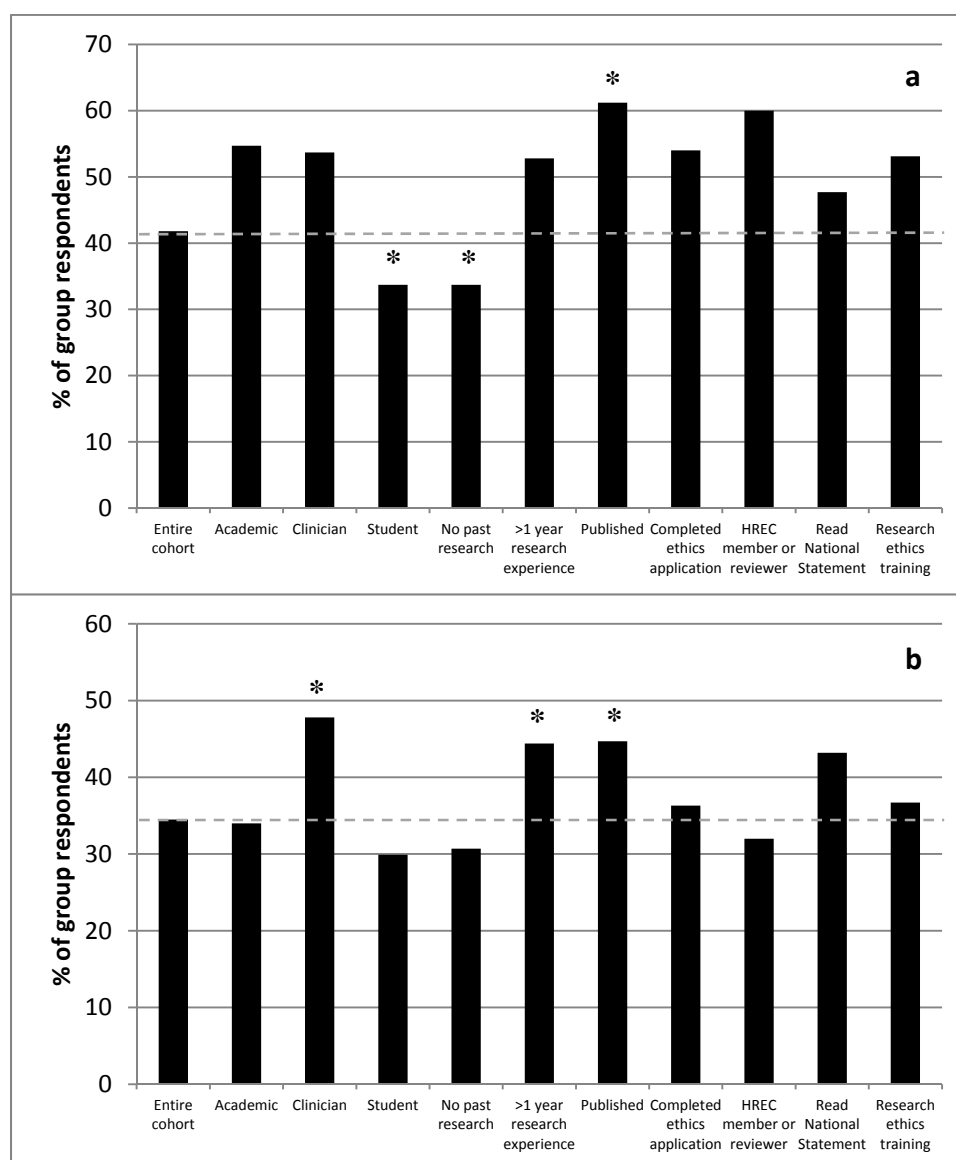
Response	Academic staff <sup>a</sup> N=53	Clinicians <sup>a</sup> N=67	Medical students <sup>a</sup> N=184
Include information on the participant information sheet about symptoms of depression, N (%)	29 (54.7)	36 (53.7)	62 (33.7) *
Include information on the participant information sheet about where to seek help, N (%)	42 (79.2)	47 (70.1)	93 (50.5) *
Approach the patient and inquire about symptoms of depression, N (%)	2 (3.8)	6 (9.0)	23 (12.5)
Refer the patient to a counselling or mental health service, N (%)	15 (28.3)	14 (20.9)	41 (22.3)
Inform practice staff about the patient's self-report so they can inform the GP, N (%)	2 (3.8)	5 (7.5)	12 (6.5)
Inform the patient's GP about the patient's self-report, N (%)	18 (34.0)	32 (47.8) *	55 (29.9)
Don't know, N (%)	5 (9.4)	7 (10.4)	59 (32.1) *

<sup>a</sup> N is the number who provided a response to this question (denominator).

\* significantly different – observed versus expected  $p < 0.05$ .

The responses to the option to include symptoms of depression on the participant information sheet were further analysed according to the groupings used earlier in Fig. 2. The groups least likely to include information about depression on the participant information sheet were students and those with no past research experience (Table 4; Fig. 3a), whereas clinicians and those who had published ( $p < 0.0025$ ) were significantly more likely to do so (Fig. 3a). Clinicians, those with one year or more of research experience, and those who had published were significantly more likely to inform the patient's GP about the patient's self-report of depression ( $p = 0.031$ ,  $p = 0.048$ ,  $p = 0.023$  respectively) (Fig. 3b).

**Fig. 3** Respondents indicating that they would include information about symptoms of depression on the participant information sheet (a) or inform the patient's GP about the patient's self-report (b)



Dashed line: cohort average.

\* significantly different – observed versus expected  $p < 0.05$

### Human ethics principles

Participants were asked to consider the following scenario about human ethics principles: *You are undertaking a research project and would like to find out how patients at a local health clinic prepare themselves for a consultation. For example, how much reading they do, whether they prepare questions to ask the doctor etc.* They were asked to identify which one of the following principles of research ethics is a reviewing HREC most likely to focus on (see Table 5 for response options).

Table 5: Participant responses relating to main focus of an ethics committee to patient recruitment scenario

Response	Academic staff <sup>a</sup> N=52	Clinicians <sup>a</sup> N=67	Medical students <sup>a</sup> N=205
Research merit – how well your project is designed, N (%)	4 (7.7)	7 (10.4)	10 (4.9)
Justice – the fairness of your recruitment methods, N (%)	1 (0.1)	1 (1.5)	4 (2.0)
Beneficence – whether the risks to patients are justified, N (%)	21 (40.4)	18 (26.9)	49 (23.9)
<b>Respect – how patients will be approached and give their consent for an interview, N (%)</b>	<b>19 (36.5)</b>	<b>34 (50.7)</b>	<b>77 (37.6)</b>
Don't know, N (%)	7 (13.5)	7 (10.4)	65 (31.7)

<sup>a</sup>N is the number of respondents who answered this question (denominator)

There were significant associations between respondent groups and the answer choice (Chi squared,  $p = 0.006$ ). The proportion of the preferred answer 'respect' was highest for clinicians (50.7%) and members or reviewers of HRECs (45.8%; data not shown), while only just over one-third of academics and medical students indicated this answer. More academic staff (40.4%) chose 'beneficence' as the answer while this was chosen by only one-quarter of clinicians (26.9%) and medical students (23.9%). There was a high proportion of 'don't know' or missing responses to this question (Table 5).

## Discussion

The ethical conduct of research is of paramount importance in any medical research, and particularly in developing good practice amongst early-career researchers (Costello Ingham 2003). Supervisors play a valuable role in modelling and encouraging the development of research integrity amongst students (Gray and Jordon 2012). It is concerning that fewer than half of the university academic staff surveyed in this study, and only one-fifth of the clinicians, had undertaken any research ethics training in the past, although more indicated they had read Australia's National Statement on the ethical conduct of research. Babl and Sharwood (2008) found a similar lack of training among clinical researchers at a non-government Australian research institute. They also drew attention to the problem of junior researchers being involved in research and obtaining patient consent under supervision of



more senior clinician researchers who themselves were not necessarily more experienced or aware of some aspects of contemporary ethical standards for research.

The incorrect responses given by participants about provision of participant information and consent forms in this study predicate the need for ethics education for research supervisors in these basic human research ethics requirements. The finding that some respondents considered consent may not be required even to participate in a clinical trial signals a need to address this issue amongst inexperienced clinical staff who may be approached to supervise student research. The issue of informed consent also relates to the broader issue of the ethics committee focus on respect and dignity, and the way cultural differences and sensitivities of participants are valued and incorporated into the research process (Pieper and Thomson 2015). In this study, there was generally poor recognition of the focus of the ethics committee on respect during the recruitment process.

The lack of experience and knowledge in human research ethics amongst the clinician participants is at odds with their professional roles, which often include involvement in clinical research, either as researchers or mentors/supervisors. Clinicians were amongst those survey respondents significantly more likely to inform the patient's GP about the research participant's self-report of depression, which may constitute a breach of the patient's privacy. The extent to which medical training or professional experience influenced the clinicians' responses to the human research ethics scenarios is not clear. Cook and Hoas (2014) investigated attitudes of clinicians to clinical research and found a blurring in the distinction between clinician and researcher in practice-based research, and a similar overlap between goals of research and improved clinical care. Clearly, the practice of evidence-based medicine requires an understanding of research and its interpretation and, in clinical practice, this is translated into good clinical care. At the same time, the professional identity and responsibilities of the clinician researcher require knowledge of the application of ethical principles when undertaking clinical research. Guidelines such as the Medical Board of Australia's Code of Conduct (Medical Board of Australia 2014) are valuable in focussing the clinician researcher on the importance of objectivity when undertaking research involving humans. Moreover, an understanding of potential impediments to ethical decision-making and incorporation of such information in research ethics training for medical researchers may result in more appropriate responses to ethically-challenging situations faced by health professionals undertaking research (DuBois et al. 2015) and improved ability of researchers to engage research students in recognising and managing these issues (Titus and Ballou 2014).

In the current study, a greater proportion of medical students than clinicians correctly indicated the requirement for patient consent to access medical records, illustrating the possible role of other areas of the medical curriculum relating to clinical practice in influencing student knowledge and attitudes about research practice. Just under ten percent of the medical students surveyed had received training

in human research ethics, and about one-quarter had read the National Statement. All but one of those medical students indicating they had read the National Statement were graduate-entry medical students from Univ. A (data not shown). The Univ. B students who participated in the study had not yet received any dedicated teaching on research ethics or curriculum-based research experience and only about seven percent of this cohort had previous research experience before entering medical school. Ensuring that course-related research activities are appropriately supervised by researchers who are aware of ethical requirements for human research should assist in developing and enhancing positive attitudes already established through prior experiences or earlier course work provided within a research-focussed curriculum.

The increasing involvement of medical students in research indicates recognition of the value of enquiry, reflective practice and analysis of evidence in the development of research-aware and research-oriented doctors, and competent evidence-based clinicians (Lawson et al. 2014; Laidlaw et al. 2012). Many medical student projects investigate clinical or community issues and involve human participants. The requirement for approval from a human research ethics committee before undertaking a project provides an important safeguard to protect the research participants as well as the researcher(s), and to ensure the research will be of benefit (Australian Government [2007A,B]). Some students are frustrated by the formal ethics requirements of research (Rosenkranz et al. 2015) and a good understanding of the principles of ethical conduct of research amongst their academic and clinical supervisors can expedite the ethics review process, cultivate a positive attitude among students towards research ethics, as well as improve the quality of medical student research.

Although some significant associations were found in this study, no particular factor was consistently associated with the preferred choices in this survey. While the participants who had been members or reviewers of a human research ethics committee did not score particularly well in our study, a study by Thompson (2014) found that people who had served as chairs of dissertation committees had better knowledge of research ethics than those who had not served as chairs. Acting as chair of an ethics committee represents a greater participation in the process of applying the standards of ethical conduct of research compared to being a reviewer or committee member, which in turn is a greater participation than someone who has only read the National Statement. With this in mind, a more practical approach to developing students' awareness of human research ethics may include introducing students to the application of the standards of ethical conduct of research rather than didactic instruction in principles and processes. A recent pilot study by Gromski et al. (2015) supports the involvement of medical students on HRECs, suggesting it could also be useful in developing knowledge in research design and analytical skill. Combining small group learning, practical cases, role-play and interdisciplinary learning have also been reported as effective approaches to providing education in research ethics (Zawati et al. 2015). Similarly, programs reported to improve capacity in

research supervision have included short courses, workshops or specific training (Balster et al. 2010; Ramalingam et al. 2014; Ajuwon and Kass 2008).

The practical impact of these findings is relevant at an institutional level. Academic institutions have overall responsibility for research undertaken therein, and support for ethics committees and in establishing a culture of excellence in ethical conduct of research is paramount (Davey 2009). It is important that institutional support for student research extends to short-term or relatively small medical student research projects which nonetheless deserve the same research ethics consideration that is applied to other faculty (Edwards 2009; Gallagher et al. 2014). The results presented here would suggest that establishing a standard in human research ethics knowledge for current and potential academic and clinical research supervisors is a pressing issue. However, while provision of research ethics training opportunities for medical student research supervisors may be helpful, there is no guarantee they will undertake such opportunities. Mandatory training for potential supervisors may be an option to consider, and would be an improvement on a mere acknowledgment of researchers having read the National Statement when submitting applications for research ethics review. In North America, many institutions require all research team members to complete an on-line human research ethics course prior to approval by an Institutional Review Board (Collaborative Institutional Training Initiative, 2014). Such a strategy may be of benefit to novice student researchers, inexperienced supervisors and ultimately, the quality of research administered by academic institutions.

There are some limitations to this research. The two medical programs are dissimilar in structure and delivery although the same learning outcomes in research are expected. While this is unlikely to be relevant to the responses of clinicians and academic staff, the entry requirements and curriculum structures may have impacted on the responses provided by the student participants. Student responses were combined in order to provide an overall response for the purposes of reporting in this paper. In order to test the robustness of this approach, further investigation was undertaken and found similar results from each institution. The question about the use of patient data (Fig 1) returned similar results (64.3% of students from Univ. A gave the preferred answer versus 67.7% from Univ. B). Moreover, similar proportions from each institution selected all four correct options in Table 3 (17.0% for Univ. A versus 19.4% for Univ. B).

## **Conclusion**

Medical student research is an important component of a medical curriculum and has the potential to influence future doctors in their practice of evidence-based medicine, in their understanding of new therapies and treatments, and in their capacity to undertake clinical and/or community-based research.

Academic institutions graduating new doctors would be well-served by ensuring a high quality of supervision of medical student research projects, including leadership and direction in the ethical conduct of the research. This will provide the best starting point for a career in medical practice that includes evidence-based care and relevant and ethical clinical research.

## References:

Ajuwon, A.J., Kass, N. (2008). Outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university. *BMC Medical Ethics*,9:1.

Australian Government (2015). Australian Health Ethics Committee. National Health and Medical Research Council. <https://www.nhmrc.gov.au/about/nhmrc-committees/australian-health-ethics-committee-ahec> Accessed 29 October 2015.

Australian Medical Council Limited (2012). AMC Graduate Outcomes. <http://amc.org.au/index.php/ar/bme>. Accessed 29 October 2015.

Australian Government. (2007A). Australian Code for the Responsible Conduct of Research. <https://www.nhmrc.gov.au/guidelines-publications/r39>. Accessed 8 July 2015.

Australian Government. (2007B). National Statement on Ethical Conduct in Human Research, 2007 (National Statement). <https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research>. Accessed 8 July 2015.

Babl, F.E., Sharwood, L. N. (2008). Research governance: current knowledge among clinical researchers. *Medical Journal of Australia*, 188(11):649–652.

Balster, N., Pfund, C., Rediske, R., Branchaw, J. (2010). Entering research: A course that creates community and structure for beginning undergraduate researchers in the STEM disciplines. *CBE Life Sciences Education*, 9(2):108-112.

Black, M.L., Curran, M.C., Golshan, S., Daly, R., Depp, C., Kelly, C., Jeste, D.V. (2013). Summer research training for medical students: Impact on research self-efficacy. *Clinical and Translational Science*, 6(6):487-489.

Boyd, M. and Wesemann, J. (eds.) (2009). Broadening participation in undergraduate research: fostering excellence and enhancing the impact. Washington, DC: Council on Undergraduate Research.

Collaborative Institutional Training Initiative (CITI) (2014). University of Miami. <https://www.citiprogram.org/index.cfm?pageID=86>. Accessed 29 October 2015.

Cook, A.F., Hoas, H. (2014). Clinicians or researchers, patients or participants: Exploring human subject protection when clinical research is conducted in non-academic settings. *AJOB Empirical Bioethics*, 5(1):3-11.

Costello Ingham, J, (2003). Research Ethics 101: The Responsible Conduct of Research. *Seminars in Speech and Language*, 24(4):323-338.

Davey, K.G. (2009). Reflections on My Experience in Human Research Ethics. *Journal of Academic Ethics*, 7:7-31.

DuBois, J.M., Chibnall, J.T., Tait, R.C., Vander Wal, J.S., Baldwin, K.A., Antes, A.L., Mumford, M.D. (2015). Professional Decision-Making in Research (PDR): The Validity of a New Measure. *Science and Engineering Ethics*, doi: 10.1007/s11948-015-9667-8.

Edwards, S.J.L. (2009). Student Projects in Medicine: a Lesson in Science and Ethics. *Accountability in Research: Policies and Quality Assurance*, 16(6):285-306.

Gallagher, C.T., McDonald, L.J., McCormack, N.P. (2014). Undergraduate research involving human subjects should not be granted ethical approval unless it is likely to be of publishable quality. *HEC Forum*, 26(2):169-180.

Gray, P.W., Jordan, S.R. (2012). Supervisors and Academic Integrity: Supervisors as Exemplars and Mentors. *Journal of Academic Ethics*, 10(4):299-311.

Gromski, M.A., Miller, C.A., Seifter, J.L. (2015). Medical student membership on a hospital-based institutional review board: A unique educational opportunity. *Academic Medicine*, 90(3):266-267.

Halpain, M.C., Jeste, D.V., Trinidad, G.I., Wetherell, J.L., Lebowitz, B.D. (2005). Intensive short-term research training for undergraduate, graduate, and medical students: early experience with a new national-level approach in geriatric mental health. *Academic Psychiatry*, 29(1):58-65.

Health Workforce Australia (2012), Australia's Health Workforce Series - Doctors in focus. Health Workforce Australia, Adelaide, South Australia.

Houlden, R.L., Raja, J.B., Collier, C.P., Clark, A.F., Waugh, J.M. (2004). Medical students' perceptions of an undergraduate research elective. *Medical Teacher*, 26(7):659-661.

Irby, D. (2011). Educating physicians for the future: Carnegie's calls for reform, *Medical Teacher*, 33:547–550.

Laidlaw, A., Guild, S., Struthers, J. (2009). Graduate attributes in the disciplines of Medicine, Dentistry and Veterinary medicine: A survey of expert opinions. *BMC Medical Education*, 9:28.

Laidlaw, A., Aiton, L., Struthers, J., Guild, S. (2012). Developing research skills in medical students: AMEE Guide No. 69. *Medical Teacher*, 34:754-771.

Lawson, P.J., Smith, S., Mason, M.J., Zyzanski, S.J., Stange, K.C., Werner, J.J., Flocke, S.A. (2014). Creating a culture of inquiry in family medicine. *Family Medicine*, 46(7):515-521.

Medical Board of Australia. Good medical practice: a code of conduct for doctors in Australia. (2014). <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>. Accessed 6 July 2015.

Mullan, J.R., Weston, K.M., Rich, W.C., McLennan, P.L. (2014). Investigating the impact of a research-based integrated curriculum on self-perceived research capabilities of medical students in rural and regional placements: a pre- and post-test analysis of three student cohorts. *BMC Medical Education*, 14:161.

O'Connor Grochowski, C., Halperin, E.C., Buckley, E.G. (2007). A curricular model for the training of physician scientists: the evolution of the Duke University School of Medicine curriculum. *Academic Medicine*, 82(4):375-382.

Pieper, I.J., Thomson, C.J. (2014). The value of respect in human research ethics: a conceptual analysis and a practical guide. *Monash Bioethics Review*, 32(3-4):232-253.

Ramalingam, S., Bhuvaneswari, S., Sankaran, R. (2014). Ethics workshops - Are they effective in improving the competencies of faculty and postgraduates? *Journal of Clinical and Diagnostic Research*, 8(7):XC01-XC03.

Riley, S.C. (2009). Student Selected Components (SSCs): AMEE Guide No 46. *Medical Teacher*, 31(10):885-894.

Rosenkranz, S.K., Wang, S., Hu, W. (2015). Motivating medical students to do research: a mixed methods study using Self-Determination Theory. *BMC Medical Education*, 15:95.

Rosenthal, M.S., Lucas, G.I., Tinney, B., Mangione, C., Schuster, M.A., Wells, K., et al. (2009). Teaching community-based participatory research principles to physicians enrolled in a health services research fellowship. *Academic Medicine*, 84(4):478-484.

Schor, N.F., Troen, P., Kanter, S.L., Levine, A.S. (2005). The Scholarly Project Initiative: Introducing Scholarship in Medicine through a Longitudinal, Mentored Curricular Program. *Academic Medicine*, 80:824-831.

Thompson, C.J. (2014). Responsible Conduct of Research Assessment of Doctor of Education Candidates, Graduate Faculty, and Curriculum Considerations. *Innovative Higher Education* 39:349–360.

Titus, S.L., Ballou, J.M. (2014). Ensuring PhD Development of Responsible Conduct of Research Behaviors: Who's Responsible? *Science and Engineering Ethics*, 20:221–235.

World Medical Association Inc. (2015). WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. <http://www.wma.net/en/30publications/10policies/b3/>. Accessed 8 July 2015.