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Human Research Ethics Committee experiences and views about children's participation in research: results from the MESSI Study

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Abstract:	As part of a larger study, Australian Human Research Ethics Committee (HREC) members and managers were surveyed about their decision-making and views about social research studies with child participants. Responses of 229 HREC members and 42 HREC managers are reported. While most HREC members had received ethical training, HREC training and guidelines specific to research involving children were rare. Most applications involving children had to go through a full ethical review, but few adverse events were reported to HRECs regarding the conduct of the studies. Revisions to study proposals requested by HRECs were mostly related to consent processes and age-appropriate language. One-third of HREC members said that they would approve research on any topic. Most were also concerned that the methodology was appropriate, and the risks and benefits were clearly articulated. Specific training and guidance are needed to increase HREC members' confidence to judge ethical research with children.

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6 **participation in research: results from the *MESSI* Study.**
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10 **Abstract**
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16 and managers were surveyed about their decision-making and views about social research
17 studies with child participants. Responses of 229 HREC members and 42 HREC managers
18 are reported. While most HREC members had received ethical training, HREC training and
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Human Research Ethics Committee experiences and views about children's participation in research: results from the *MESSI* Study.

1. Introduction

The role of Human Research Ethics Committees (HRECs), also known as Research Ethics Committees (UK) and Institutional Review Boards (USA), is to provide ethical oversight of research involving humans. HRECs are charged with ensuring that risks to research participants are minimized and are reasonable in relation to anticipated benefits, that the selection of participants is equitable, informed consent is obtained, data are appropriately monitored to protect participants' safety, and adequate provisions are in place to protect participant privacy and confidentiality, among other criteria (Lynch, 2018). HRECs most frequently operate within university or health institutions, may have specific foci or expertise, and their own application forms, processes and guidelines. Each HREC is comprised of people from a variety of backgrounds, each of whom bring specific expertise to ethical review (Page & Nyeboer, 2017).

In Australia, under the *National Statement on Ethical Conduct in Human Research (National Statement)*, HRECs are required to abide by the values of: respect for human beings, research merit and integrity, justice and beneficence (NHMRC, 2007). Specific guidance is provided in relation to research with children and young people, with emphasis placed on their capacity to understand what the research entails; their possible coercion by parents, peers, researchers or others to participate in research; and potentially conflicting values and interests of parents and children. (NHMRC, 2007:65). Furthermore, because they are considered to be a vulnerable group, additional safeguards, including added layers of institutional approvals and parental consent, are generally required to undertake research with children and young people. For example, an additional approval process is required to conduct research studies within schools in most of Australia. These additional approvals to access particular sites

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3 and/or individual children, however, are only instituted once the HREC approval for the
4 research to be conducted at any site has been obtained (Harger & Quintela, 2017). Decisions
5 made in relation to research with children are also governed by the relevant child protection
6 legislations.
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12 While the role of HRECs has been discussed widely, this role and HREC processes have also
13 been subject to some criticism. Harger and Quintela have commented that HREC members
14 “evaluate proposed studies based not on specific knowledge of a particular context, but on
15 their perception of facts, in addition to personal and professional experiences” (Harger &
16 Quintela, 2017):12). Guillemin and colleagues found that while HREC members agreed their
17 primary role was to protect participants, some considered that HRECs were also working to
18 protect the institutions’ interests (Guillemin, Gillam, Rosenthal, & Bolitho, 2012). Criticisms
19 have also been made about perceived increases in the bureaucratic processes of research
20 ethics committees, the expanding reach of ethics review, the substantial power and authority
21 wielded by HRECs, the variability between research ethics committees’ recommendations
22 and approvals of research studies, and the potential for these to adversely impact on the
23 approval and conduct of research (Abbott & Grady, 2011; Guta, Nixon, & Wilson, 2013;
24 Lynch, 2018). On the other hand, the process of ethical review helps researchers to consider
25 their research methods more deeply (Head, 2020).
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45 Some authors have commented that there is little transparency about HREC processes and
46 decisions, which are usually not published or shared; it has been suggested that this could
47 result in researchers opting for more conservative research designs and “self-censoring” in
48 order to ensure a smoother ethics approval process (Lynch, 2018). Little research has been
49 undertaken on HRECs themselves, and the limited studies to date have rarely asked HREC
50 members directly about their role (see, for example, (Egan, Stockley, Lam, Kinderman, &
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3 Youmans, 2016; Guillemin et al., 2012; Van Essen, Story, Poustie, Griffiths, & Marwood,
4
5 2004).

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7
8 Fewer studies have examined HREC member expertise and decision-making in relation to
9
10 research with children, which likely contributes to lower levels of transparency and
11
12 consistency. One study which surveyed 188 IRB (or HREC) chairs about pediatric assent,
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14 information requirements, and research payments in medical research projects found that
15
16 when there is no adult regulation to follow in relation to children, IRBs varied widely in their
17
18 practices, suggesting the need for additional guidance for pediatric research studies (Shah,
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20 Whittle, Wilfond, Gensler, & Wendler, 2004; Whittle, Shah, Wilfond, Gensler, & Wendler,
21
22 2004). Furthermore, there is little research exploring the levels of training and experience that
23
24 HRECs obtain to assist them in making decisions about research with children, nor their
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26 views of the research that involves children and young people.
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31 The *Managing Ethical Studies about Sensitive Issues (MESSI)* study aimed to address some
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33 of these gaps in existing research. Specifically, it explored the barriers and enablers to social
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35 research with children, including how adults and children make decisions about children's
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37 participation in social research about sensitive topics in Australia. This paper reports on
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39 aspects of this study, exploring the decision-making of Australian HREC members and
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41 HREC managers when considering research applications to conduct social research studies
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43 with children as participants. It focuses on their responses to survey questions about their
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45 role, training, processes and recent experiences in reviewing social research studies involving
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47 children as research participants, and their views about research with children. The paper
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49 aims to answer the following research questions:
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54 1. What is the experience and expertise of Australian HRECs in approving social
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56 research applications involving children or young people? What is the nature and
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3 extent of adverse events reported in research projects involving children or young
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5 people?
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9 2. How do members of Australian HRECs rate the importance of various factors when
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11 considering whether to approve a social research study involving children as
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13 participants?
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15 3. Are there research topics that Australian HREC members would not approve under
16
17 any circumstance?
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21 The findings aim to provide greater transparency and information for both researchers and
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23 HRECs in Australia and beyond about HREC decision-making and expectations related to
24
25 the conduct of social research with children and young people.
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28 29 **2. Methods**

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31 The MESSI study was approved by the Australian Catholic University (ACU) HREC (2016-
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33 110H) and ratified by the study partners' universities.
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37 The research used a mixed methods design. Stage 1 involved interviews (n = 64) with various
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39 stakeholders (researchers, HREC members, government and others who make decisions about
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41 children's research participation, parents and children), the results of which informed the
42
43 design of the subsequent stages. Stages 2 and 3 consisted of online surveys (with HREC
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45 managers, HREC members, professionals making decisions about children in research, parents,
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47 children and young people), and Stage 4 involved focus group interviews with children and
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49 young people.
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53 This paper focuses on the Stage 2 online survey responses of the HREC managers and
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55 members.
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2.1 Recruitment of HRECs

A published list of Human Research Ethics Committees (HRECs) registered with the Australian National Health and Medical Research Council (NHMRC)¹, with contact details added from HREC websites, was used to identify potential participants. The list was updated in May 2017, just prior to recruitment. We emailed HREC Chairpersons and/or Research Ethics managers on up to three occasions, requesting firstly that the manager complete the online manager survey and secondly that the email invitation be forwarded to their HREC members to complete the online member survey.

We emailed all 213 HRECs registered with the NHMRC at the time of recruitment. Of these HRECs:

- 5 HRECs had been disbanded
- 7 reported that they received no applications involving research with children
- 4 email addresses were incorrect
- 2 refused as additional approvals were required for them to participate (1 from their university senior management, and 1 from their own HREC).

Of the remaining 195 HRECs, seven replied saying they had distributed the emails and the remainder did not reply. Only the 5 disbanded HRECs were excluded from the HREC population for the purposes of calculating response rates, resulting in 208 eligible HRECs. As more than one HREC member per committee could respond to the survey, and individual research ethics committees from which members responded were not able to be identified, an accurate response rate for HRECs could not be calculated.

¹ <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/embryo%20research%20licence/human-research-ethics-committees-registered-with-nhmrc.pdf>

2.2 Individual participants and response rates

A total of 255 individual HREC members clicked on the online survey link, 26 of whom did not continue; 229 completed the entire survey, all of whom are included in the current study responses.

The minimum membership of a HREC is eight members (paragraph 5.1.30, *National Statement*: NHMRC, 2007). This includes two individuals assigned to each of the following categories: “persons with current research experience that is relevant to research proposals to be considered”; and “lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work” (ORIMA, 2017). As far as possible, HRECs should be comprised of equal numbers of men and women.

If we assume that there are eight members on each of 208 eligible HRECs, then there were at least 1664 potential respondents (208 x 8). If this assumption is correct, 229 respondents implies a response rate of 13.8% for the member survey. In addition, a total of 42 HREC managers responded to the manager’s online survey from 42 different HRECs (out of a potential 208). This represents a response rate of 20.2% for the manager survey.

2.3 Online survey content for HREC managers and members

Both the HREC manager and member surveys were administered online using Qualtrics Survey Software, accessed through the ACU university website in 2017. If respondents elected to click on the survey-link they were taken to a participant information page and asked to provide their informed consent by confirming that they agreed to participate, after which they commenced the survey.

Research ethics managers were questioned about the processes of the HREC and the volume of work undertaken by the HREC. They were asked to provide information about the research

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3 ethics applications submitted to their HREC in 2016, particularly those involving children as
4 participants, and the nature of any complaints or adverse events reported. In order to reduce
5 respondent burden and maximize response rates, the manager surveys were kept as short as
6 possible.
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12 HREC members make decisions about whether to approve research ethics applications
13 submitted to their committee, and questions were designed to capture information about their
14 experience and expertise. Several of the questions were based on the *National Statement*
15 (NHMRC, 2007) and the *NHMRC Report on the Activity of HRECs and Certified Institutions*
16 (ORIMA, 2017). HREC members were also asked for basic demographic information and
17 their HREC experience, training and role.
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27 Stage 1 participants' views and experiences of research ethics approval processes
28 (summarized elsewhere: Powell et al., 2020) were reflected in the online survey questions
29 about revisions to applications, adverse events, and topics they would not approve for
30 research with children. Using a 5-point Likert scale from 'extremely important' to 'not at all
31 important', HREC members were asked to rate the importance of a list of factors (developed
32 from the Stage 1 results) when considering whether to grant approval for research involving
33 children aged 7-14 years. This age range was chosen as it related to children who were old
34 enough to provide their own assent/consent but also required parental consent, and because of
35 a lack of guidance on research with this age group (Sargeant, 2014). Opportunities to respond
36 to open-ended questions or to provide additional information were also provided and
37 examples of these responses have been presented. The survey was kept short to reduce
38 respondent burden, which meant that some relevant issues were not investigated.
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55 On completion of the survey, HREC member and manager participants were told that they
56 could elect to enter a draw for a prize, consisting of a presentation of the study results to their
57 HREC, by separately providing their email address.
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2.4 Data analysis

Survey responses were downloaded into IBM SPSS version 25 for analysis. HREC and research application characteristics, demographic characteristics and other factors potentially important in undertaking research with children were summarized descriptively; medians and ranges are provided for continuous variables, and percentages for dichotomous or categorical variables.

Responses to the open-ended questions were grouped according to themes. Examples have been included to illustrate the range of responses and themes.

3. Results

The survey responses by both HREC managers and members are provided below.

3.1 Characteristics of respondent HREC managers and members

HREC members responded to the survey in similar proportions to the distribution of HRECs nationally and across Australian states and territories, with the largest proportions from Victoria, NSW and Queensland (70.8% across these three states) (Table 1).

[INSERT TABLE 1 ABOUT HERE]

Just under half of the HREC managers (45.2%) and members (48.5%) were from university HRECs, and approximately another third were from hospital or health service HRECs (Table 2).

[INSERT TABLE 2 ABOUT HERE]

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3 Table 3 shows that the HREC member respondents represented the range of roles required by
4 the National Health and Medical Research Council for HREC membership (NHMRC, 2007,
5 Section 5.1), but the highest number of respondents were researchers (n = 66, 28.8%). Over
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10 half the members were female (56.8%).
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16 [INSERT TABLE 3 ABOUT HERE]
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21 ***3.2 Experience and expertise*** 22

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24 HREC members reported that they had a median of four years' experience as a research
25 ethics committee member, with the longest experience being 34 years.
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29 Table 4 shows the HREC member respondents' experience and training in research ethics.
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31 Only a small minority of members reported having received no formal or informal research
32 ethics training (4.8%); the most common form of training reported was via a conference
33 (63.8%) or specific training on the *National Statement* (52.0%).
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39 Questions were asked of both managers and members about their expertise in research with
40 children. Just over half the 42 HREC managers (54.8%) reported that in 2016 they had
41 committee members with particular knowledge or understanding about conducting research
42 studies using children as participants. However, the vast majority (72.9%) of individual
43 HREC members reported they had received no research ethics training specifically related to
44 children's participation in research. Just over a quarter (26.2%) of HREC members reported
45 that their HREC had guidelines in addition to the *National Statement* in relation to research
46 with children. Notably, nearly half the members (44.5%) responded that they thought their
47 HREC needed more guidance or training in assessing applications with children. Of the 102
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3 HREC members who thought their HREC required more training or guidance, 28 (27.5%)
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5 already had additional guidelines regarding research with children.
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10 [INSERT TABLE 4 ABOUT HERE]
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15 Some of the respondents who said they wanted more guidance or training to assess
16 applications with children provided specific ideas about the types of training or guidance they
17 sought. Their responses were wide-ranging, and included:
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23 “Acceptable practices, case scenarios, written materials helping to understand the
24 factors we need to consider with children” (Hospital/health service, Professional)
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28 “More up to date information on children's issues with engaging with research”
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30 (Hospital/health service, Lay person)
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32

33 “The focus of ethics currently is safety and protection with less understanding of
34 children's rights to participate and [to] have opportunities as co-researchers”
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36 (Hospital/health service, Researcher).
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41 “Yes, especially in relation to highly vulnerable populations including those in out-
42 of-home, juvenile justice, homeless or at-risk of homelessness, engaged with mental
43 health services etc. Also, more guidance is needed about the circumstances under
44 which parental/guardian consent can be waived, especially for younger children (i.e.,
45 10 years old)” (Non-government organization, Researcher)
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52 Topics that more than one HREC member sought training and/or guidance on were: child
53 psychology/development; parental consent and child assent; risks; privacy and confidentiality
54 issues; and research in online environments.
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60 ***3.3 HREC activities and assessments of applications involving children***

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3 Both HREC managers and members were asked a series of questions about the activities of
4 their HREC in 2016 (Table 5); managers were more complete in their responses than were
5 the HREC members who had high proportions of “Don’t know” or missing responses. More
6 than half of HREC managers (54.8%) reported that their HREC had assessed more than 70
7 applications in 2016, while members reported just under half. More HREC managers (66.7%)
8 than members (37.1%) reported that the applications their HREC reviewed involved children
9 as participants, but most of the members were not able to answer this question. Similar
10 proportions of HREC managers (57.1%) and members (54.6%) reported that their HREC
11 requires that all research applications involving children as participants go through a full
12 ethical review, although managers were clearer about this issue than were members (36.7%
13 of whom did not know). Approximately half the managers said that some research ethics
14 applications involving children raised issues that required further ethical review, which were
15 subsequently addressed by the researcher.

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33 [INSERT TABLE 5 ABOUT HERE]
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39 HREC members were asked to nominate (from a list) the types of revisions made to the last
40 research ethics application they reviewed involving children (Figure 1). Sixty-seven percent
41 provided responses to the listed revisions, while 33% responded “not applicable” or did not
42 provide an answer.

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48 The most common revisions nominated by respondents involved simplifying language
49 (61.7%), child consent/assent (49.4%), parental consent (42.2%), and/or potential distress or
50 harm to the participants (39.6%). Of the members who responded to the subsequent question
51 “were the issues subsequently addressed to the HREC’s satisfaction by the researchers?”,
52 only a very small number of these issues were reportedly not addressed.
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[INSERT FIGURE 1 ABOUT HERE]

Seven HREC members reported that they knew of researchers who had avoided submitting applications involving children as participants, because of the “hassle” and difficulty in getting applications approved by the HREC. One HREC member commented:

‘Researchers are discouraged from conducting research with children, even when the methodology is thoughtful and sensitive to the developmental stage of participants and explicitly acknowledges the higher risk involved in engaging children who have experienced considerable trauma’. (Nongovernment organization, Researcher)

HREC managers were asked about any complaints or adverse event reports their HREC received about the conduct of approved social research involving children as participants in 2016. The vast majority reported no adverse events (83.3%). The small number of adverse events reported related to concerns about methodology, breaches of or deviations from the approved research, consent processes, questionnaires, and recruitment processes.

3.4 Important factors HREC members considered when approving research studies with children

HREC members were asked to rate the importance of eight listed factors they might consider when deciding whether to approve a social research study involving children as participants.

Each of the factors, with the exception of payment and time, was considered important or extremely important by at least 50% of the sample. In stark contrast 79% of respondents reported payment as ‘not at all important’ (Figure 2).

[INSERT FIGURE 2 ABOUT HERE]

3.5 Topics HREC members would not approve for research with children

All HREC members were asked if there were any topics, from a list provided, that they would not, under any circumstances, provide approval for researchers to study with children (aged 7-14 years) (Figure 3). Over one-third (37%) of the HREC members and 46% of those who responded to this question said there were no topics that could not be studied. Of the 56% of HREC members who nominated topics from the list, they nominated a median of three topics (Range 1 to 16) that they would not approve children to take part in. The top five most commonly nominated topics were violent extremism/radicalization (24%), child abuse (20%), crime (19%), family violence (15%) and sex/sexuality (14%).

[INSERT FIGURE 3 ABOUT HERE]

3.6 Other issues raised by HREC members

In the final survey question, HREC members were asked: “Do you have anything else you would like to say about young people taking part in social research?”

Of the 84 respondents who commented, a large number stated their opinion that it was acceptable for any topic to be considered in research with children as long as the methods were robust and the risks and benefits clearly managed. For example:

“It is important that they take part, but I think that methods are key to undertaking the research ethically. In most cases I have encountered, we are rarely concerned with the

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3 research question, just how the researcher plans to go about it.” (University/college ,
4
5 Lay person)

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8 “I think any topic can be researched but it is about the method and the way the child is
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10 kept safe in the process of research.” (Hospital/health service, Professional care)

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13 “As long as protocols are of high quality, information statements are clear and the
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15 study is ethically sound, there should be no problem involving 7-14 year old
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17 participants.” (Hospital/health service, Professional care)

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20 One commented that “children are much more resilient that we often think.”
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23 (University/college, Professional care).

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26 Several respondents were concerned that the age range (7-14 years) presented in the survey
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28 questions was too broad, with different responses required for the younger and older ages,
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30 due to maturity and developmental differences.
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33 “Age range is too broad. 10 or 11 to 14 years require a different methodology to 7 to 9
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35 years old. Ethnic backgrounds need greater consideration with children as does the
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37 qualifications of the researcher and the method of research.” (Non-government
38
39 organization, Lay person)

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43 “I think everything depends on how the topic is treated by researchers, and the group
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45 of children participating. Some topics I might not like a 7 year-old talking about, but
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47 would be more comfortable with older 12-14 year old participation. Risk mitigation
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49 and appropriate support really change our opinions on whether or not we approve
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51 research. Each case needs to be considered independently.” (University/college,
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54 Researcher)
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3 Several spoke about the importance of research that is beneficial for children: studies that
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5 give children “a voice” and which can be utilised to make policies and practices more
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7 responsive to their needs and views.
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11 “It's imperative that children and young people's perspectives are captured in research
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13 - especially in sectors that are ostensibly concerned with improving the well-being of
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15 children who have typically been the 'subjects' of policies, programs and research.
16
17 HRECs also need to be more courageous in balancing the potential risks of children
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19 participating with the benefits that can accrue from research - especially in terms of
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21 giving children a sense of agency over their stories and their needs.” (Non-
22
23 government organisation, Researcher)
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28 “I feel it is vitally important for young people to be heard regarding all topics.”
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31 (Hospital/health service, Lay person)
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34 Others were primarily concerned about the protection of children participating in research.

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36 “The protection of the wellbeing of the child is paramount. Children should be
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38 required to give consent where suitable and possible e.g. we have longitudinal child /
39
40 baby studies and we require consent of the child once an age of consent is reached.”
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43 (Hospital/health service, Chair of HREC)
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45

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47 “It is an important area of research, and it should not deter people from conducting
48
49 the research, but children 7-14 are vulnerable and incapable of consenting for
50
51 themselves. They also cannot foresee any risk and may not be able to follow up any
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53 distress on their own.” (Hospital/health service, Pastoral care)
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56 A small number said that they did not think children should be paid to participate in research
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58 and one respondent reported their ambivalence about research with children more broadly:
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3 “As the responses indicate, I am not a fan of children involved in 'Social Research'.
4
5 Such research might satisfy researchers 'curiosity', but in general I don't see it being of
6
7 great benefit. I think most of the answers are already known and we are simply
8
9 seeking to confirm them with such research and don't see this as a 'benefit' which
10
11 would justify questioning children about such things.” (Hospital/health Service, Lay
12
13 person)
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18 **4. Discussion**

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20 This study makes a substantial contribution to the limited research that has been undertaken
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22 with HRECs on their processes and decision-making in relation to social research with
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24 children. The study findings illustrate the range of views held by HREC members and
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26 managers, the importance of robust research methods, the gaps in their knowledge about
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28 children's research and their desire for more comprehensive training.
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32 ***4.1 The large HREC sample allows for confident conclusions***

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34 This study recruited one of the largest samples of HREC members (n = 229) and HREC
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36 managers (n = 42) to respond to its online surveys about their processes and decision-making
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38 about children's participation in social research. Previous research with HREC members has
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40 either been qualitative or surveyed smaller samples. For example, Guillemin and colleagues
41
42 (2012) interviewed 34 Australian HREC members about their role and function, while Egan
43
44 and colleagues (2016) obtained 166 HREC respondents to their survey about their knowledge
45
46 of research ethics in Canada.
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50
51 The sample recruited in the current study was generally representative of the HREC member
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53 population in Australian HRECs, in terms of its distribution across jurisdictions. The type of
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55 HREC, gender and the role of the members represented the range required by the NHMRC
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57 (2007). Furthermore, HRECs represented in the manager survey assessed similar numbers of
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3 applications to those reported in the NHMRC report: 44.6% of managers in the current study
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5 reported that their HREC assessed more than 70 applications compared with 40.5% of all
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7 Australian HRECs in 2016 (ORIMA, 2017).
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10 The size and representativeness of the samples allow strong conclusions to be made about
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12 how HREC members and managers consider and respond to applications to conduct social
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14 studies research with children, particularly in relation to sensitive topics, an area which has
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16 received minimal investigation to date. These conclusions are discussed further below.
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20 **4.2 Variability in training and expertise**

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22
23 It is positive to note that almost all (95.2%) HREC members had received training in research
24
25 ethics as part of their role on their committee. However, despite it being a requirement that
26
27 members be familiar with the *National Statement* (under 5.2.3) only half had received
28
29 specific training on the *National Statement*, somewhat a cause for concern. The *National*
30
31 *Statement* is the essential guide for all HRECs in Australia (NHMRC, 2007). Perhaps HREC
32
33 members simply did not consider training to consist of discussions with their fellow members
34
35 about research ethics applications and the *National Statement*, and the accompanying
36
37 feedback that would be a normal part of their role on the HREC.
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42 HREC members were asked about their expertise and training in research with children. A
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44 very small proportion of member respondents (13.1%) reported they had received specific
45
46 training related to ethical approvals for children's participation in research, while a quarter
47
48 (26.2%) reported that their HREC had additional guidelines for research with children. Just
49
50 over half the HREC managers said they had committee members with specific expertise
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52 related to research with children. As most of these HRECs assessed some applications
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54 involving children, there appears to be a gap in the expertise, training and resources within
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56 the HRECs in relation to research with children. It appears that the ethical guidance that
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3 exists does not satisfy all HREC members' needs and requires more development, perhaps
4 including examples and case studies. Furthermore, nearly half the members wanted more
5 training or guidance in relation to research with children, to fill this apparent gap, with some
6 wanting more in addition to the guidance they had already had.
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12 This finding is similar to a US study of the decision-making of committees related to medical
13 research involving children (Shah et al., 2004; Whittle et al., 2004) which surveyed 188
14 HREC Chairs about the application of risk levels in pediatric research. They found a
15 variability in the responses from Chairs, and recommended that to ensure a balance between
16 the protection of children and approval of ethically appropriate research, Chairs needed
17 guidance on decision-making in relation to risks and benefits. Similarly, whilst not focusing
18 on children's research, an Australian study about the roles and practices of research ethics
19 committees found that 38 % of research ethics committee members (13 out of 34
20 participants) were aware of the *National Statement*, but did not often refer to it when making
21 decisions (Guillemin et al., 2012). Instead, these research ethics committee members relied
22 on the chair or committee administrator for their knowledge of research ethics guidelines
23 (Guillemin et al., 2012).
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40 Although other authors have commented on the need for additional HREC training and
41 expertise in assessing research ethics applications, no previous research has quantified this
42 need in relation to social research involving children. Furthermore, it is not clear that such
43 training and resources are generally available; these issues have only become more prominent
44 with the relatively recent recognition of children's rights in this area.
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51 ***4.3 HREC assessments of research ethics applications involving children***

52 Just over half the respondents said that their HREC required all applications involving
53 research with children go through a full ethical approval process, presumably because of the
54 perceived risks inherent in the research. HREC members lack of expertise and confidence in
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3 assessing these research applications may be a contributing factor. However, this finding
4
5 raises also the question of the extent to which a full ethical review is necessary for all
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7 research with children, even research involving low risk, when most HREC members have no
8
9 specific training or expertise by which to assess to research ethics applications involving
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11 children.
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15 Furthermore, on the one hand, one-quarter of all HREC members were concerned about
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17 potential distress to the child or some type of harm as a result of the research. On the other
18
19 hand, very few HREC managers reported any adverse events or complaints in relation to
20
21 research involving children within the reporting period. Some studies that have assessed the
22
23 impacts of being engaged in social research on sensitive issues found that when children
24
25 experienced negative impacts or distress they were minimal and often compensated by the
26
27 positive benefits they identified (Ellonen & Pösö, 2011; Finkelhor, Hamby, Turner, & Walsh,
28
29 2012; Murray, 2005). HREC members' concerns about distress being caused by participation
30
31 in research may be mitigated by additional training for HREC members specifically about the
32
33 potential impacts or lack thereof of participating in social research of differing sensitivities.
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39 The most common revisions HRECs required for research ethics applications with child
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41 participants were simplifying the language and revisions to the parental and/or child
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43 consent/assent: this suggests that there is a lack of guidance and clarity being provided to
44
45 researchers regarding the expectations of HRECs. Research ethics committees often develop
46
47 consent templates for adults that are also used with children but may, in fact, be so complex
48
49 in language that the child is unable to understand to what they are consenting (Moore,
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51 McArthur, & Noble-Carr, 2018). Child-friendly formats that are able to be comprehended by
52
53 their intended audience are recommended as an alternative. Additional guidance to assist
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55 researchers in better developing and articulating these processes may result in improved
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57 research ethics applications and expedited approvals. Researcher avoidance of research with
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3 children because of reported difficulties in obtaining ethics approvals, identified by some
4
5 HREC members, may also be addressed by having clearer processes and additional guidance.
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7 This would ensure that children’s right to protection might be achieved while respecting their
8
9 right to participate (Sargeant, 2014).
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13 ***4.4 Important factors in considering research with children***

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16 In relation to which factors HREC members considered when approving research
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18 applications involving children, “risk” and ensuring “privacy” were most likely to be seen as
19
20 “extremely important”. These factors are central to research ethics committees’ deliberations
21
22 and to their core responsibility to ensure that research does not cause participants significant
23
24 harm (Berry, 2009).
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29 The next most likely factors to be seen as “extremely important” by HREC members were
30
31 “benefit to individual” and “benefit to others”. These factors speak to the “social value” of
32
33 research and the view that research is ethically acceptable only when it might be used to
34
35 improve outcomes for the target population (a sentiment more apparent in clinical rather than
36
37 social research) (Wassenaar & Mamotte, 2012; Wendler & Rid, 2017). While “benefits” were
38
39 given a high importance rating in the current study, their rating behind the management of
40
41 “risks” and “privacy” suggests that research ethics committees are more focused on risks and
42
43 privacy issues because the “benefit” has been made apparent by the researchers, but it is still
44
45 of great importance. Silaigwana and Wassenaar (2019) similarly concluded the social value
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47 of the research was raised less often as a concern by research ethics committees than issues
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49 such as informed consent because it had been adequately dealt with by the researchers in
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51 preparing their application.
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57 Only payments were considered unimportant by the HREC member respondents. The offer of
58
59 payments to child research participants has been a contentious matter for many HRECs,
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3 predominantly because of concerns that children might be coerced by the offer to participate
4 in research in which they would not have otherwise participated (Taplin et al., 2019). A lack
5 of clear guidance on these issues has led some research ethics committees historically to
6 refuse research payments for children (Bagley, Reynolds, & Nelson, 2007) which can then
7 reduce the likelihood of children participating in such research. In the current study, only a
8 small proportion (6.6%) of HREC members reported that revisions in relation to payments or
9 incentives to children were requested by their HREC. Also, payment was the only aspect of
10 decision-making about research ethics applications with children considered unimportant by
11 HREC members. One interpretation of these findings is that researchers tend not to apply to
12 pay children amounts that HRECs might reject or amend, perhaps to satisfy perceived HREC
13 requirements. Alternatively, these findings may indicate a greater acceptance by HRECs of
14 research with child participants more generally, and for their payment specifically.

31 ***4.5 Topics HREC members would not approve for research with children***

32
33 The finding that one-third of HREC members (but nearly half of all respondents to the
34 question) said that they would approve research with children aged 7-14 years on any topic
35 was an unexpected finding. Clarification of responses to this question was provided within
36 the qualitative responses that any topic was an acceptable one for research with children as
37 long as there was a benefit arising from the research, the methods were robust, and the risks
38 clearly managed. This point reflects findings from stakeholders in other stages of this
39 research that included parents and children themselves (Powell et al., 2018).

40
41 Many respondents were, however, concerned about topics related to violence: some HREC
42 members were reluctant to consider topics including violent extremism, crime, child abuse or
43 issues on sex or sexuality. Interestingly, bullying, a more common issue in schools, was not
44 considered a topic to avoid. The range of responses to this question indicates that different
45 views are held across and within HRECs about the world and their conceptualization of risks

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3 to children. Better guidance and training may result in more consistency in the responses of
4
5 HREC members in their judgements about the ethical conduct of research with children.
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8 ***4.6 Other issues raised by HREC members***

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11 A range of other ethical issues were raised by HREC members when they were given an open
12
13 opportunity, illustrating the breadth of views held within and between research ethics
14
15 committees. While some were more concerned about the methods used rather than the topic
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17 researched with children, others identified the need for different research and ethics practices
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19 across different age-groups. Furthermore, some prioritized the need for children to have their
20
21 voices heard, while others were more concerned about protecting children.
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26 A number of participants appeared to consider the extent to which the studies could benefit
27
28 children, knowledge, policies and practices in relation to children, and whether researchers
29
30 could ensure that children could participate safely. One lay HREC member challenged the
31
32 benefit of conducting social research with children, believing that they could not offer
33
34 anything to the evidence that was not already known. However, this was a minority view, and
35
36 does not reflect the dominant opinion of the other HREC members other participants in our
37
38 study who stressed the value and importance of providing children and young people
39
40 opportunities to express their views in research (Moore et al., 2020; Powell et al., 2020).
41
42 Further research may consider how research ethics committees make judgements about
43
44 whether specific research projects have social value and how this affects their decision-
45
46 making, particularly as such debates play out in other research fields (that is, in clinical and
47
48 other health-related research) (Wassenaar & Mamotte, 2012).
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54 ***5. Best Practices***

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57 The importance of undertaking research with children has been recognized, so as to help
58
59 develop better understanding about the issues that affect them and to create more responsive
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3 policies, practices and processes (Melton, Gross-Manos, Ben-Arieh, & Yazykova, 2014;
4
5 Moore et al., 2011; Powell et al., 2020). We have shown elsewhere that children and young
6
7 people are able to identify and adjust their responses to requests to participate in research of
8
9 different risk levels, and that younger children are less likely to consent to higher sensitivity
10
11 or riskier research than are older children (Taplin et al., 2019). This study of HREC members
12
13 and managers provides evidence that research with children is regularly approved. There was
14
15 also a view identified by some HREC respondents that children and young people have the
16
17 right to participate in research and that these rights need to be considered along with the risks
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19 when assessing applications.
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24 It is therefore important to facilitate their participation in research where it is ethical and safe
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26 for them to do so. Previous studies have found that research with children is questioned (or
27
28 even prevented) by HREC members with little knowledge of common methodologies, and
29
30 that they do not operate uniformly when making recommendations about research
31
32 participation (Harger & Quintela, 2017). HREC members in this study were concerned about
33
34 risks, privacy and the benefit of the research, and some were reluctant to consider topics
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36 related to violence. Despite this, there were few adverse effects or complaints about research
37
38 involving children.
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43 A clear finding from this research is that most HREC participants feel they need further and
44
45 better guidance in making decisions about research with children. Currently, most children
46
47 and young people are only involved in making decisions about their participation in studies
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49 when they are asked to provide their consent, after ethics (and usually other) approvals have
50
51 been granted; institutional requirements can preclude the involvement of children until after
52
53 ethical approval has been obtained (Moore, Noble-Carr, & McArthur, 2016). Obtaining
54
55 children and young people's direct perspectives on some of the ethical and associated issues
56
57 surrounding research projects is an innovative way that could be used more widely to provide
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3 guidance about children's participation. Two methods by which to do this have been
4
5 proposed. (i) Navratil and colleagues argue for the establishment of children and young
6
7 people's advisory committees to represent and provide advice to research ethics committees
8
9 in relation to research projects involving children and young people. Their example of this
10
11 model is the Youth Research Advisory Board (YRAB) of the Pittsburgh Medical Center
12
13 which has, since 2013, provided guidance to researchers to ensure studies are acceptable for
14
15 children and young people (Navratil, McCauley, Marmol, Barone, & Miller, 2015). (ii) A
16
17 second model, discussed by authors such as Moore and colleagues, is incorporating children
18
19 and young people's reference groups to assist guide and provide ethical advice to particular
20
21 projects. HRECs might expect that researchers have convened such a group, where
22
23 appropriate, and in their application for ethics approval identify the specific advice and views
24
25 children and young people have provided about the key research factors (such as risk,
26
27 language, and privacy) (Moore et al., 2016). Instead of such a reference group being
28
29 convened after the ethics application has been approved, children and young people's views
30
31 would be integrated into the application. The best approach would be dependent on the
32
33 context and nature of particular HRECs and the research ethics applications they receive.
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35 HREC members who responded in the current study were mostly concerned with how the
36
37 research was conducted. They also recognized some lack of expertise on their own part in
38
39 relation to research with children and sought more training and resources. By providing
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41 specific training and additional guidance and input in relation to the ethical issues in
42
43 undertaking research with children, HREC members may be more confident and consistent in
44
45 their ability to make judgements about the ethical conduct of research with children. The
46
47 provision of greater guidance for and transparency in HREC decision-making, plus increased
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49 dialogue between HRECs and researchers, may also improve the research ethics process. In
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51 addition, researchers need to commit to improving their completion of the ethical review
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3 processes that outlines age-appropriate research methods and the approaches they will use to
4
5 address potential risks in their research with children.
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8 **6. Research Agenda**

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10 Research with HRECs is very limited, thereby reducing the transparency of their ethics
11 approval processes, particularly in relation to research involving children and young people.
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13 Additional research with HREC members in other countries is needed to better understand
14
15 the processes used elsewhere that might better facilitate robust and inclusive research with
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17 children and young people.
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22 **7. Educational Implications**

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24 The Australian research ethics committee members who participated in this study were
25
26 limited in their training and expertise in relation to ethics approvals of research involving
27
28 children and young people indicating a gap in this area; a large number expressed a desire for
29
30 more training or guidance in relation to research with children. A majority of research ethics
31
32 applications involving children as participants were required to go through a full ethical
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34 approval process: the need for full review based on the age of the participant rather than the
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36 risks involved is questioned, particularly in view of the fact that most HREC members had
37
38 limited relevant expertise. While a number of respondents were concerned about risks and
39
40 potential distress to the child, it is suggested that their concerns are inflated as very few
41
42 adverse events were reported. Furthermore, it has been found that any distress from research
43
44 participation is usually minimal and compensated for by the benefits from facilitating
45
46 children's input on issues that affect them, and that children are able to identify risks in
47
48 research. Most submitted research ethics applications are approved and required revisions
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50 able to be resolved, although the frequency with which they related to consent and adapting
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52 language-levels indicates the need for researchers and HRECs to communicate better
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3 regarding child-friendly consents. A message from this study is that the methodological rigor,
4
5 clear management of risks, and the benefits of any research with children should be more
6
7 important considerations than the research topic. Researchers and HRECs would benefit from
8
9 adopting more transparent, child-inclusive and child-friendly processes, with additional
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11 training and guidance for HRECs indicated.
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14 15 **8. Limitations** 16

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18 These samples of HREC managers and members is from an Australian study and may not be
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20 applicable to other countries with different research ethics review processes. There are also
21
22 some limitations from low response rates and incomplete survey responses, although the
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24 survey respondents were representative of HREC membership.
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Table 1: Distribution of HREC member respondents compared to national HREC distribution

Jurisdiction	Percentage of HRECs (committees) from each jurisdiction who reported to NHMRC in 2016 (n = 210)	Percentage of HREC members responding to survey from each jurisdiction (n = 229) *
Victoria	28.5	21.0
New South Wales	25.2	28.8
Queensland	19.0	21.0
Western Australia	9.5	9.2
South Australia	9.5	9.2
Australian Capital Territory	5.7	3.5
Northern Territory	1.4	0.9
Tasmania	1.0	2.2
National	-	3.5
Missing	-	0.7

* More than one respondent from a HREC was possible

Table 2: Type of HRECs and survey respondents

HREC type	HREC Managers (n=42) %	HREC members (n=229) %
University/college	45.2	48.5
Hospital/ health service (public or private)	35.7	34.1
Government department/service	7.1	5.2
Non-government organization/charity	4.8	7.4
Company/business	2.4	3.1
Other	4.8	1.7

Table 3: Roles and gender of HREC member respondents (n = 229)

Member responses	Percentage
What is your role on the ethics committee?	
Chair	10.9
Lay person	22.7
Professional	12.2
Pastoral care *	10.9
Law *	6.1
Researcher	28.8
Other *	8.3
Gender	
Female	56.8
Male	42.5
Other/Missing	0.8

* HREC roles of pastoral care, lawyer and other were combined for further analyses

Table 4: HREC member responses to questions on their ethics experience (n = 229)

Questions and responses	Percentage
What ethics training have you ever received? (multiple responses)	
Formal ethics education (University course or subjects)	37.6
Conference	63.8
Training on the National Statement	52.0
Privacy/confidentiality training	41.0
Low risk research	23.6
Other	14.4
None	4.8
Have you ever had any ethics training specifically related to children's participation in research?	
Yes	13.1
No	72.9
Missing	14.0
Does your HREC have additional guidelines re research with children?	
Yes	26.2
No	31.4
Don't know/missing	42.3
Do you think your HREC needs more guidance or training to assess applications with children?	
Yes	44.5
No	41.5
Don't know/missing	14.0

Table 5: HREC members' and managers' ethics application experience

Ethics application experience	Managers	Members
	(n = 42) %	(n = 229) %
In 2016, approximately how many applications for research ethics review did your HREC receive?		
0-70	35.7	21.8
71+	54.8	44.5
Don't know/missing	9.5	33.6
Approximately what percentage of the applications your HREC reviewed in 2016 involved children as research participants?		
Zero	4.8	5.2
1 or more ¹	66.7	37.1
Don't know/missing	28.6	57.6
Do all of the social research applications submitted to your HREC involving children as participants go to full HREC review?		
Yes	57.1	54.6
No	40.5	8.7
Don't know/missing	2.4	36.7
What percentage of applications involving children as research participants have to go back to HREC for further review after the initial comments and requests from the committee?		
Zero	23.8	n/a
1 or more %	47.6	n/a
Don't know	28.6	n/a

¹ Most were 10% or under

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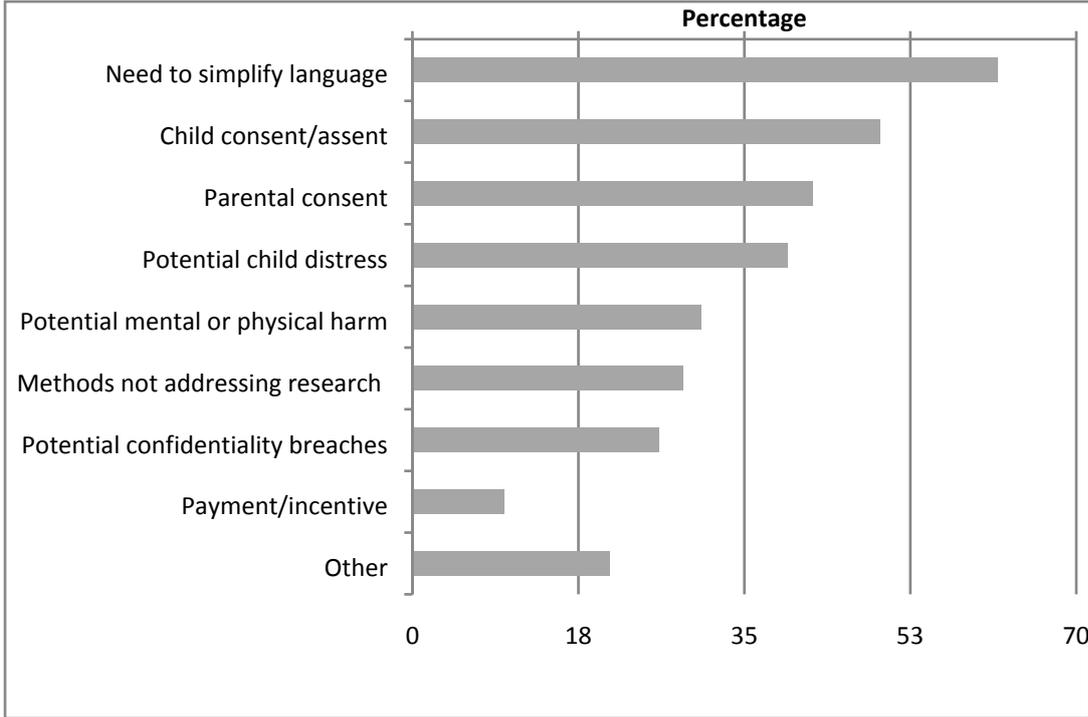


FIGURE 1: *Thinking of the last application for approval to conduct a social research study with children that required major revisions, what type of revisions were needed? (HREC members: n = 154) (Percentages)*

Peer Review

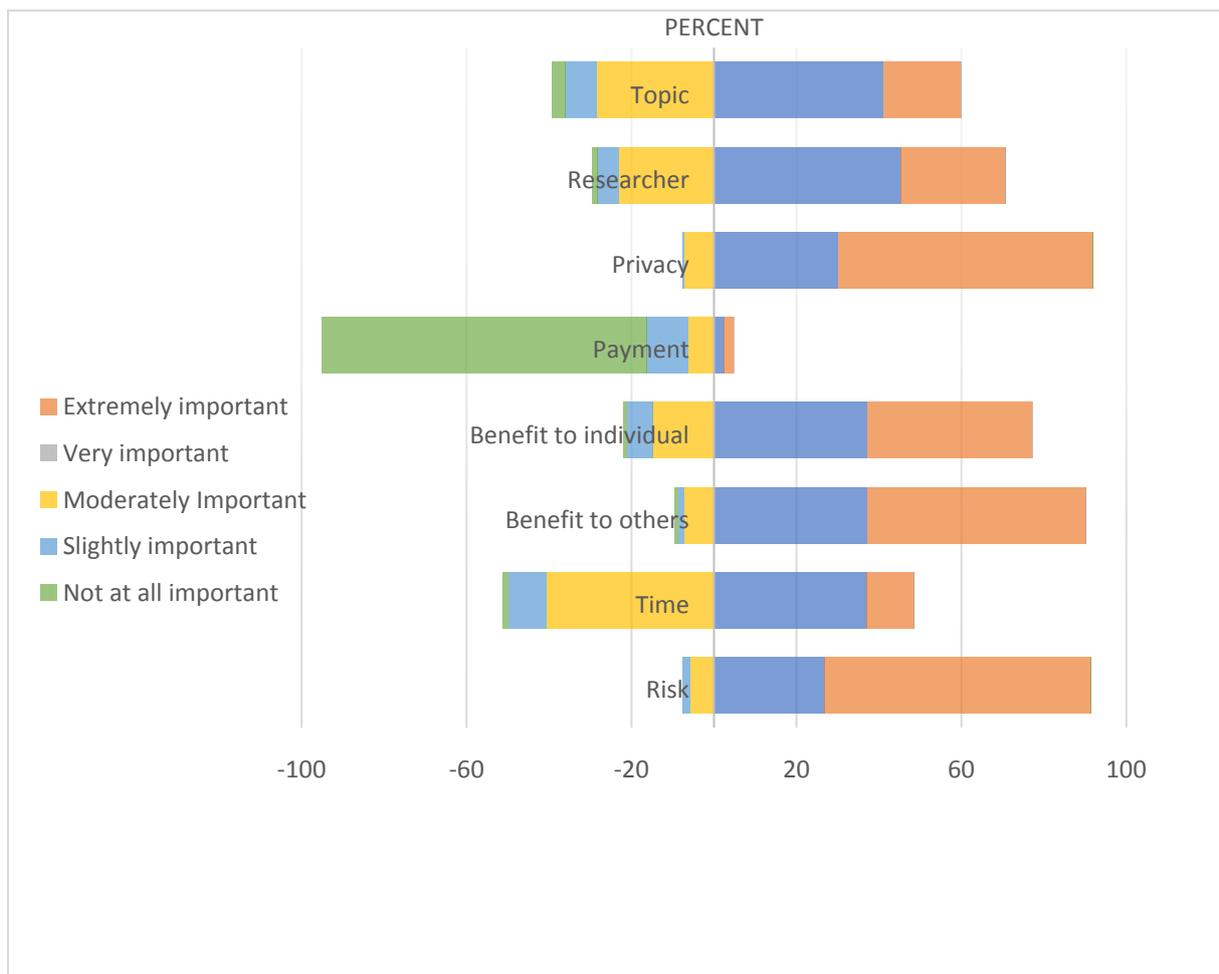


FIGURE 2- Responses of HREC members to the listed factors considered when approving social research projects involving children as participants (Percentages)

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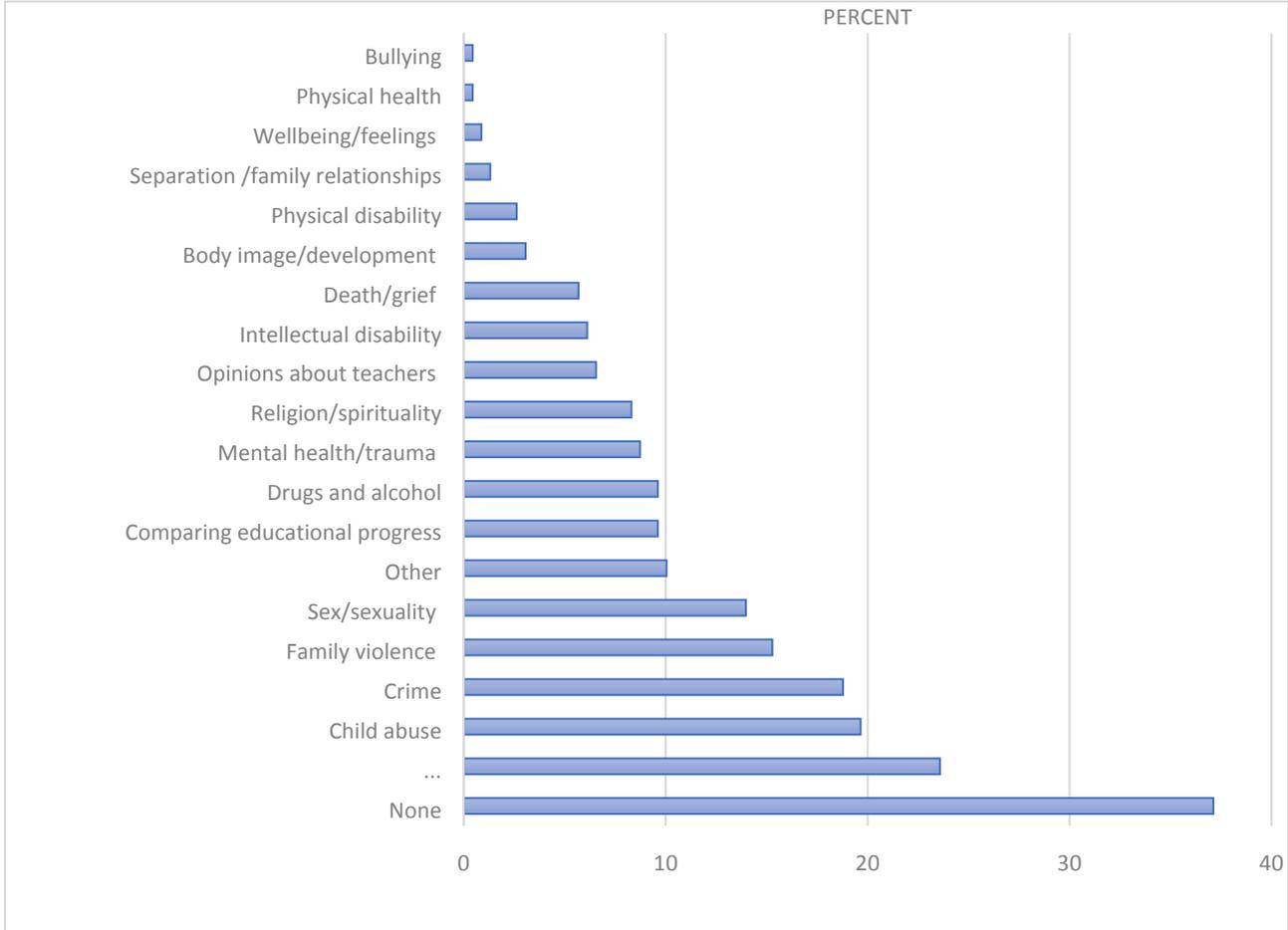


FIGURE 3- *Social research topics involving children as participants that HREC members would not approve under any circumstances.*

Preview