



Vulnerability in human research

Ian J. Pieper¹ · Colin J. H. Thomson²

Published online: 27 April 2020
© Monash University 2020

Abstract

The conduct of prior ethics review of human research projects helps to protect vulnerable groups or populations from potential negative impacts of research. Contemporary considerations in human research considers the concept of vulnerability in terms of access to research opportunities, impacts on the consenting process, selection bias, and the generalisability of results. Recent work questions the validity of using enumerated lists as a check box approach to protect research participants from exploitation. Through the use of broad categories to treat cohorts of human research participants as homogenous classes and label some participants as vulnerable merely because they are members of a particular class, some ethics reviewers have used the National Statement on Ethical Conduct in Human Research to strip individuals of their “ethical equality”. Labelling people as vulnerable does not help researchers or human research ethics committee members develop an understanding of the complexities of applying the principles of respect and of justice in ethical decision-making. Conversely, defining specific cohorts of research participants as needing nuanced ethical consideration, due to their vulnerable nature, may imply that other population groups need not be considered vulnerable. We contend that this assumption is erroneous. This paper explores the way that human research ethics guidance documents treat vulnerability within the Australian context and draws on contemporary discussion to focus an alternative perspective based on the principles in the National Statement on Ethical Conduct in Human Research for researchers and human research ethics committee members to consider.

Keywords Vulnerability · Human Research Ethics · Human Research Ethics Committee (HREC) · IRB

✉ Ian J. Pieper
pieper@live.co.uk

Colin J. H. Thomson
colin.thomson@ahrecs.com

¹ Australian Centre for Health Law Research, Queensland University of Technology, 2 George St., Brisbane, QLD 4000, Australia

² Australasian Human Research Ethics Consultancy Services Pty Ltd, Brisbane, Australia

1 Background

One of the core reasons for the conduct of prior ethics review of human research projects is to protect vulnerable groups or populations during the conduct of human research. In 1979, the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, in what has become known as the Belmont Report, recommended that protection ought to be afforded to those who lacked sufficient power or status to decline participation in research and were, therefore, vulnerable. Since then, ongoing consideration of the ethical issues surrounding the conduct of human research has resulted in a continual refinement of what it is to be vulnerable in this context. This paper presents contemporary thinking about vulnerability in human research in a way that will help researchers and Human Research Ethics Committee members reach ethically sound decisions, particularly when considering the principles of the *National Statement on Ethical Conduct in Human Research 2018* (the National Statement).

2 Aims of this paper

Vulnerability remains a central tenet in research ethics guidelines and policies (Racine and Bracken-Roche 2019, pp. 19, 20). Current considerations of vulnerability in human research no longer only look at providing protection for those who cannot decline participation on the basis of power or status. A contemporary conception of vulnerability also considers the concept in terms of access to research opportunities, impacts on the consenting process, selection bias, and the generalisability of results. Recent work, particularly from Australian researchers, such as Margaret Meek Lange, Wendy Rogers, and Susan Dodds has questioned the validity of using enumerated lists as a check box approach to protect research participants from exploitation.

The National Statement mandates that full Human Research Ethics Committee (HREC) consideration be given to these research areas specified in Sect. 3:

- genomic research (Chap. 3.3)
- xenotransplantation research (Chap. 3.4).

These research areas specified in Sect. 3 are areas which have significant potential for ethical implications which may not be immediately obvious and may involve sources of vulnerability.

However, the National Statement also mandates full HREC consideration (paragraph 5.1.6) for research discussed in the various Chaps. of Sect. 4:

- Women who are pregnant and the human foetus (Chap. 4.1);
- People highly dependent on medical care who may be unable to give consent (Chap. 4.4);

- People with a cognitive impairment, an intellectual disability, or a mental illness (Chap. 4.5), and
- Aboriginal and Torres Strait Islander Peoples (Chap. 4.7).

These groups appear to be identified as requiring more in-depth consideration due to their inherent vulnerability to, or perhaps a history of, exploitation. Dubois et al. (2012) caution that regulatory measures, even when well-intentioned, may raise a host of ethical concerns through being insufficiently adaptive to the actual risks to individual participants leading to both over, and under, protective measures being required.

We contend that individual membership of specified groups does not inherently render them vulnerable through their inclusion in human research. The evaluation of vulnerability to exploitation or to risks within research should be made in the context of an informed understanding of the details of the proposal and potential impacts on foreseeable participants in the research, rather than on assumptions made about the vulnerability of participants based on their inclusion—or otherwise—in a group.

Indeed, a considered application of principles-based guidelines, such as the National Statement, and the Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS), ought to provide sufficient guidance for researchers and HREC members to understand their responsibilities to protect individuals, whether they can be categorised as members of groups or not. The foundational principles of the National Statement (respect, research merit and integrity, justice, and beneficence) help to develop and shape the relationship between researchers and participants in ways which reflect ‘trust, mutual responsibility and ethical equality’ (National Statement, p. 9). This places a responsibility on researchers to understand the impacts that their research may have on participants, cohorts and communities. However, the National Statement goes further and identifies, through Sect. 4, specific ethical considerations that need to be addressed when research involves specific, vulnerable, participant cohorts. These considerations are over and above those relevant to any individual participant. It is our contention that – by treating people who fit a particular broad category of members of an homogenous class as individually vulnerable merely because they are members of that class – the National Statement can be understood to, in effect, strip individuals of their “ethical equality”.

Conversely, by defining specific cohorts of research participants who need specific ethical consideration due to their vulnerable nature, it may be implied that other population groups need not be considered vulnerable. We contend that this assumption is erroneous. The National Statement makes it clear, in several places, that it is not to be taken as an exhaustive statement of ethical considerations. A wider discussion on the place of vulnerability in human research ethics considerations would make a valuable addition to the guidance within the National Statement – particularly in light of some of the excellent work emerging from Australian thinkers in this field.

3 What is vulnerability?

Vulnerability in human research has been considered in one way or another since the Belmont Report (1979) over 40 years ago. As a descriptor it is used to signify that certain participants warrant extra protection. The United Nations Educational, Scientific, and Cultural Organisation (UNESCO) Universal Declaration on Bioethics and Human Rights makes particular reference to vulnerable groups highlighting that ‘personal integrity of such individuals be respected’ (Article 8). The discussion and the thinking around protection of research participants has become more nuanced than at the time the Belmont Report was released. It is really only this century that the connection between vulnerability and human research ethics has been examined and gained acceptance (ten Have 2015, p. 396). The needs and interests of participants, as individuals, have come to warrant more deliberation. Therefore, the labelling of individuals by membership of homogenous groups is beginning to be seen as less desirable because distinctions are not always clear cut between those who are labelled as vulnerable (because they are seen to be members of such groups) and those who need similar protection during the course of research.

Recent work, notably by Rogers and Lange (2013) and ten Have (2015), provides in-depth discussion of the ethical implications of grouping individuals into vulnerable cohorts. It is not our intention to revisit this work, but to build upon it—specifically in relation to the implications for ethical review in the Australian context. In particular we will relate the discussion of personal agency and the broader conception of vulnerability to the four foundational principles in the National Statement.

The Belmont Report cautions researchers to ensure that the appropriateness of involving vulnerable groups should be demonstrated. The Belmont Report lists certain groups—such as racial minorities, the economically disadvantaged, the very sick, and the institutionalised—as vulnerable groups. The National Statement clarifies and expands on this list in Sect. 4. However, the Council for International Organisations of Medical Sciences in their *International Ethical Guidelines for Health-related Research Involving Humans* (CIOMS 2016) explicitly moves away from the practice of collectively identifying groups as vulnerable:

A traditional approach to vulnerability in research has been to label entire classes of individuals as vulnerable. The account of vulnerability in this Guideline seeks to avoid considering members of entire classes of individuals as vulnerable. (CIOMS 2016, p. 57).

CIOMS 2016 highlights that vulnerability can no longer be applied to entire groups (p. xi). Vulnerability arises where an individual is, or members of a group are, incapable of sufficiently protecting their own interests either because of an inability to provide initial consent to participate in research or through the course of their inclusion in research studies (CIOMS 2016). Instead of treating groups as homogenous, CIOMS 2016 explores the underlying issues that contribute to certain groups having been considered to be vulnerable (Guideline 15) and discusses

how the interests of participants can be protected. This allows for more emphasis to be placed on community engagement in research design. This, in turn, leads to the development of participant-researcher relationships based on the protection of individual participant interests.

4 A more nuanced discussion

Lange, Rogers, and Dodds (2013) provide a critique of the work of Luna and Hurst in this area before offering a nuanced consideration of vulnerability in the context of human research. They argue that vulnerability arises from three sources:

- *Inherent* sources of vulnerability are an inescapable element of the human condition;
- *Situational* sources of vulnerability are context specific; and
- *Pathogenic* sources of vulnerability arise from dysfunctional relationships.

When considering the protection of participants, it is identifying and managing the situations arising from these sources, and which contribute to the reduction of personal agency, that should be the focus of ethical deliberations, rather than grouping people into cohorts whose agency may be compromised. Researchers have a duty to ensure that they understand their proposed cohorts well enough to reliably identify the potential impact of their research on their participants.

5 Why does it matter?

The principles of the National Statement provide an understanding that ethical research demonstrates respect for individuals through supporting autonomous decision-making processes to the extent that participants have the capacity to make those decisions. Considerations of vulnerability can be seen as a special application of the principles of respect for persons and of justice (ten Have 2015, p. 395). There is a risk that by treating individuals as members of a group, rather than as autonomous agents, the principle of respect is not promoted.

To be autonomous is to live according to your values and principles. Autonomous decisions are made through informed, rational deliberation (Jennings 2016). However, the framework within which people make decisions is bounded by their relational existence. Therefore, the best-interests of participants are not necessarily self-interests. People exist within a community; they make decisions that take into account their familial and social beliefs, culture, and obligations. Although self-interests and best-interests often coincide, the development and exercise of competent and effective agency of individuals is intrinsically connected to other people (ten Have 2015). These relational impacts both constrain and support individual autonomy. The only way to establish what is in the best-interest of participants is to understand that they are individuals with different capabilities, vulnerabilities and relationships.

Labelling people as vulnerable does not help to understand, or to address, the underlying issues of respect and of justice. In order to address these issues, the researcher needs to address those conditions that negatively impact on the capacity of individuals to safeguard their own interests. There is a risk that individuals who are capable of protecting their own interests could be unjustly excluded from research from which they might benefit because they are deemed to be a member of a population that is categorised as vulnerable. This may result in unintended unethical or unreasonable consequences (Rhodes 2005).

Some of the possible risks that may be introduced through regulation that labels individuals, include:

- increased levels of stigmatisation and discrimination;
- exacerbation of the impacts of injustice by perpetuating stereo-types;
- over-regulation of certain types of research;
- inducing vulnerability and harming, rather than protecting, participants.

6 Why is a discussion about vulnerability needed?

The role of HRECs is to promote ethical human research through the application of the National Statement (National Statement 2018, p. 6). Central to this is the protection of participants from exploitation. Racine and Bracken-Roche (2019) highlight that a categorical approach to vulnerability is increasingly seen as problematic within the research ethics debate. As the understanding of the impacts of human research become more nuanced, ongoing discussion is required to ensure that the understanding of HREC members and researchers of what is ethically acceptable human research remains aligned with community expectations.

We suggest that the way in which Sect. 4 of the National Statement is interpreted by some users as categorising cohorts of people as inherently vulnerable can strip individuals within those cohorts of the respect which ought to be afforded them as equals. We do not disagree that vulnerable people require additional protections, but those considerations need to be much more nuanced; and guidance to researchers and reviewers needs to be carefully crafted so as to ensure individual respect. Research participant vulnerability may arise from more than one source or only in particular contexts (DuBois et al. 2012). We suggest that feedback from HRECs to researchers around protection of vulnerable participants be focused on developing clarity around the sources of vulnerability: those arising from the human condition (*Inherent*), those arising from the context (*Situational*), and those that are relational (*Pathogenic*).

It is incumbent on researchers to give due consideration to the risks involved in research that they conduct. Risks to individuals may arise in the context of their own circumstance as well as from societal conditions. However, to treat groups as homogenous runs the risk of not doing enough for vulnerable individuals within the group. Conversely, treating individuals as vulnerable because of their group membership, as opposed to their inability to protect their own interests, runs the risk of diminishing their autonomous agency.

An individual's capacity to protect their own interests may be impacted by a particular condition or situation that the participant has in common with other members of a cohort being studied. However, that common condition or situation may not have the same ethical impact on each individual. For example, it may be true that people in a pre-existing relationship with the researcher are at greater risk of exploitation and this may compromise the voluntary nature of participation (National Statement, Chap. 4.3). However, there may well be cases where a pre-existing relationship can support participants during the research and in doing so the relationship may enhance the agency of the individual (ten Have 2015, p. 400; Lange, Rogers, and Dodds, 2013, p. 337).

7 The National Statement and consent

The National Statement recognises vulnerability as ethically relevant to the giving of consent to participation in research. Particular care ought to be taken to ensure that consent remains ethically sound where there are changes to the circumstances of individual participants, or to the research project. This recognition is related to ensuring that engagement and involvement of participants through consent is on an individual basis (National Statement, paragraph 2.2.8).

The National Statement also recognises that some features shared by identifiable groups can contribute to or cause vulnerability of any individual member of those groups. Examples can be found in Chap. 4.2, particularly paragraphs 4.2.2, 4.2.8 and 4.2.9, relating to the participation of some children or young people; Chap. 4.3, particularly paragraphs 4.3.2 and 4.3.4, relating to the participation of people in dependent relationships; Chap. 4.4, particularly paragraphs 4.4.3 and 4.4.4, relating to participation of people who are highly dependent on medical care and may be unable to give consent; Chaps. 4.5, particularly paragraph 4.5.5, relating to the participation of people with cognitive impairments and 4.6, relating to participation of people who may have been involved in illegal activity.

In these examples, the National Statement relates the relevant features of membership of the group to the participation of a member of the group.

However, there is a risk that the National Statement will be interpreted as assigning vulnerability to any member of these groups solely because of their group membership. To do so, as we have indicated above, is to deny the individual agency of that member.

Accordingly, during the application of these Chaps. of the National Statement through the review process it is of great importance to retain an ethical focus on the protection of individual agency and not to allow this to be subsumed by an assignment of vulnerability to a category of participants—no matter how well intentioned.

8 A nuanced approach to National Statement categories of participants

The National Statement deals in separate Chaps. with each of:

- Women who are pregnant and the human foetus
- Children and young people
- People in dependent or unequal relationships
- People highly dependent on medical care who may be unable to give consent
- People with a cognitive impairment, an intellectual disability, or a mental illness
- People who may be involved in illegal activities
- Aboriginal and Torres Strait Islander Peoples
- People in other countries

Some examples of nuanced approaches to the sources of vulnerability can be identified.

9 Inherent example

The source of vulnerability within research involving people who display mental illness arises from their humanity. It is inherent to their human condition. Research protocols in the mental health arena should explicitly address how the conduct of the research will identify the impact of the research on individual participant's interests. Inherent sources of vulnerability cannot be removed, only managed and the effects mitigated through appropriate research design.

10 Situational example

As a matter of law, children and adults whose cognitive impairment, intellectual disability or mental illness are of sufficient severity cannot make lawfully effective decisions. This element could also be found among those people highly dependent on medical care who, at the relevant time, cannot make decisions. Their inability to conform to the legal requirement for the making and recording of decisions about participation is a situational source of vulnerability. Managing this situation may resolve the presenting source of vulnerability, although the ethical obligations about adequate disclosure may still remain relevant.

11 Pathogenic example

Research involving people who are members of a minority facing discrimination involves pathogenic sources of vulnerability. For instance, research into the effects of the Apology to Australia's Indigenous peoples (Rudd 2008) on Aboriginal and Torres Strait Islander people affected by the Stolen Generation may reasonably consider participants to be vulnerable. It is the past, and continuing, injustices suffered by this community which is a source of vulnerability. There should be explicit processes within any research in these areas that appropriately manage and mitigate the risk of harm arising from or being exacerbated by the research intervention. However, we acknowledge that other forms of research involving Aboriginal and Torres

Strait Islander people may find participants to be empowered and not requiring additional checks to be put in place.

The source of vulnerability for people in dependent or unequal relationships involved in research can also be pathogenic where the dependency or inequality in those relationships is relied on to render the relationship dysfunctional. Researchers, by virtue of having a deeper understanding of the nature of the research proposed, are in a position of power with respect to their participants. This potentially places all research participants in a position where they are vulnerable to exploitation through involvement in research (National Statement, paragraph 2.2.9). The need to guard against potential exploitation where there is an existing relationship between researcher and participant is especially evident where there is a power imbalance implicit in the nature of the relationship itself. As part of the consideration of a research proposal, researchers need to demonstrate to the reviewers that this potential has been identified, mitigated, and managed.

We do not suggest that researchers are deliberately manipulating participants in order to mislead or exploit them. Rather, we are pointing out that the perception or experience of exploitation is a possibility where researchers are not transparent about their purpose and their methods. It is the responsibility of researchers to provide sufficient evidence to the reviewers that they understand the inherent, situational, and pathological contexts of the cohort that they wish to research. One way of managing this situation is through a consenting process which genuinely informs and educates potential participants in a way that empowers meaningful decision-making. One option that can facilitate this is for the consent process to be negotiated outside the relationship that is the potential source of vulnerability. The level of mitigation required to protect against these risks will vary depending on the individual participant's capacity to defend themselves against exploitation (ten Have 2015, p. 405).

12 Research design

The ethics of research should be considered during the design phase: in planning recruitment, consent and participation, researchers need to recognise that participants are individuals. Throughout the conduct of any project, researchers should continue to remember that participants are individuals. Even when data are amalgamated and anonymised, participants in human research merit respect as individuals. Research should be ethical not only in design but also during each element of the research.

The introduction to Chap. 3.1 in the 2018 update of the National Statement includes the statement that 'effective research ethics review incorporates appropriate expertise related to relevant methods or areas of practice.' (National Statement, p. 25). However, we believe that there should also be a requirement for that review to incorporate appropriate expertise about issues relevant to the cohort to be studied. Without an understanding of the issues that contribute to vulnerability of those participants, the reviewers may not be in a position to understand if protocols

and procedures for anticipating and handling distress, or other forms of harm, are appropriate.

Chapter 3.1 of the National Statement sets out the process of conducting research into seven elements. We offer some guidance on the issues that are relevant to considerations of vulnerability within each element. This is not meant to be an exhaustive discussion but to highlight that issues of vulnerability are relevant at each stage of research.

Element 1: Research Scope, Aims, Themes, Questions and Methods Potential

3.1.1 (e) requires researchers to provide a clear understanding of how the design of the project will maintain respect for the participants. This aspect should not merely be a precis of the consenting process, but should also include discussion on how to address inherent sources of vulnerability. For example, where researchers are studying patients afflicted by a particular disease or illness, there ought to be consideration of how the participants' health will affect their capacity to protect their best-interests.

When discussing the ethical requirements related to interventional research conducted in the context of health care or public health (3.1.4), researchers and reviewers should be cognisant of pathological sources of vulnerability. This is particularly true in the power differential between researcher and participant or clinician and patient; but there may also be pathological sources of vulnerability arising from being in the health care setting itself, or being separated from family and community in cases where people have had to travel to seek treatment.

Element 2: Recruitment

It is worth restating the direction given about recruitment within the National Statement: 'it is essential that recruitment strategies adhere to the ethical principles of justice and respect' (p. 28). With that precept as guidance, researchers should clearly demonstrate that they have engaged with the research cohort in a sufficiently meaningful way that they can be respectful of their culture, traditions and beliefs (3.1.17). This should not only be a requirement because the studied population is predominantly Aboriginal and Torres Strait Islander or are overseas. Reviewers should be satisfied that researchers are aware of and have considered how to manage these forms of inherent sources of vulnerability in any researched population.

Minority populations, or populations that have been traditionally under- or over-researched, should not unreasonably be excluded but rather considered on the basis of ensuring methodological integrity of the sampling process. Research merit and integrity should not be compromised through convenience sampling as a way of avoiding difficult ethical considerations. The Consumer Health Forum recommends that 'researchers should consider how they will involve consumers and community members in the development, conduct and communication of their research' (CHF 2016). In doing so, researchers are able to conduct research with, rather than on, participants.

Element 3: Consent

Consent can be seen as the panacea to all considerations of participant vulnerability, risks, and injustice. A respectful and appropriate consenting process which supports participants in making decisions about participation is seen as the cornerstone of ethical research. However, consent, even when written and witnessed, does

not absolve researchers from their responsibility to conduct research responsibly and with due diligence (CIOMS 2016, p. 56).

In order to meet their responsibility under paragraph 3.1.26 of the National Statement, that a consenting process should be appropriate to the needs of the participants and proportional to the project's risks and ethical sensitivity, researchers need to be able to demonstrate that they understand the sources of vulnerability that are relevant to the study cohort. This should be more than providing a plain English statement of the risks and benefits of the research. The consenting process should be designed and conducted in a manner which engages with participants and communities in a way which is culturally meaningful, as paragraph 2.2.4 of the National Statement makes clear. A focus on individual, rather than relational, autonomy may not be the most appropriate approach, because it is likely to ignore the relationships on which a potential participant depends in reaching decisions.

Element 4: Collection, Use and Management of Data and Information

Data linkage and the preservation of privacy

One risk involved in the synthesis and interpretation of data is the risk of interpolation of population-wide statistics to individuals within the cohort. This is, in effect, what has been done with certain identified groups for years. For example, because there are certain considerations that should be given to research involving Aboriginal and Torres Strait Islander populations, that whole cohort of people has been classed as vulnerable in all instances. This assessment is neither helpful nor true. Researchers need to be able to articulate the processes that they will apply to the management, manipulation, and interpretation of data to ensure that their findings do not exacerbate vulnerability through creating or reinforcing stigmatising perceptions.

The dissemination of information to third parties is a potential source of vulnerability that is evident in some forms of research. These include:

- the implications of genetic information being used for secondary purposes such as:
 - Considerations of cultural or family heritage
 - Clarification of paternity
 - Identifying risks for genetic diseases in family members;
- reputational risks to individuals, communities, or institutions;
- and, in some instances,
- risk of criminal or civil liability.

Researchers and reviewers need to be aware of these risks and be assured that measures are in place to ensure that they are appropriately mitigated. Where there is the potential for disclosure of information to third parties, researchers should identify that potential early and discuss the issue with participants during the consenting phase.

Element 5: Communication of Research Findings or Results to Participants

The communication of research findings should be considered during the design phase. The means of disseminating information should be relevant to the intended

audience. This may need to be developed through a meaningful form of community engagement, particularly if the information was gathered without consent as is often the case with secondary use of administrative data.

If the findings are to be provided back to participants, then there ought to be an agreed understanding of how the findings will be presented and who else will see them. This should be explicitly stated during the consenting process and followed through.

Element 6: Dissemination of Research Outputs and Outcomes

Element 6 of Chap. 3.1 makes the *prima facie* statement that public dissemination of research outputs and outcomes is ‘consistent with the ethical principles of respect, beneficence, and justice’ (p. 40). Previously in this paper we have posited that such dissemination needs to be consistent with the expectations of the research cohort and the need to protect vulnerable people and groups from further stigmatisation or exacerbating alienation. Researchers have a responsibility to understand the implications for their participants when considering if the public dissemination of research outputs and outcomes is consistent with the ethical principles of respect, beneficence, and justice. Research merit can also be relevant (paragraph 1.1(d) of the National Statement). These values need to be weighed against the value of public disclosure of research results so that public disclosure can be justified.

Element 7: After the Project

Paragraphs 3.1.73 and 3.1.74 remind researchers that they have specific obligations to ensure that data, information, or artefacts collected during the course of research should be treated in a culturally appropriate manner. The management of research material ought to be decided during the design phase, agreed by the review body, and adhered to by researchers.

Researchers should also bear some responsibility for the manner in which their research findings are used. This is particularly the case when findings are applied in ways that cause harm. Where researchers become aware of the misuse of their findings they ought to take steps to mitigate the impact of that misuse and correct the record with a view to preventing further misuse.

Having amassed a related collection of information, researchers have an ongoing responsibility for its existence. Where researchers use data for future research, any secondary usage ought to be consistent with the intent of the original consent obtained or, where there was no consent, consistent with community and cultural expectations. Vulnerable populations should not be forced to continually defend themselves from the misuse or malappropriation, for research purposes, of their cultural heritage.

13 Managing vulnerability within research

There is no one way to manage vulnerability of participants in human research. Expectations about how vulnerable people and populations are included, or excluded, in research have evolved over time. Contemporary considerations of vulnerability are based on a much more nuanced understanding of the sources and

effects of vulnerability. However, there are a number of core considerations when managing vulnerability in research. Important among these are:

- supporting individual agency in a culturally appropriate manner;
- being aware of individual differences and risks within identified groups; and
- protecting individuals and communities from exploitation.

Labelling people as vulnerable is now recognised as an ineffective means to develop an understanding of, or address, underlying risks to participants in human research. It is no longer enough to base assumptions of vulnerability on the identification of participants as being part of identified groups or as displaying certain characteristics. A modern application of the concept of vulnerability considers the impacts of research on individual participants and cohorts in a nuanced application of the principles of the National Statement. The onus is upon researchers and HREC members to understand their role in the protection of participants, whether they can be categorised as members of identified groups or not. It is researchers who are responsible for ensuring that they are aware of the sources of vulnerability that are relevant to their research cohort. Although the conduct of prior ethics review focusses discussion and highlights areas for reflection, the consideration of the ethical issues surrounding the conduct of human research must be ongoing to ensure the protection of vulnerable participants.

14 Managing vulnerability within research ethics review

The National Statement Chaps. where paragraph 5.1.6(b) mandates HREC review—4.1, 4.4, 4.5 and 4.7—do not state that risk is a reason for this requirement. In our view, this requirement arises from the care needed in approving ethically acceptable participation of people from these groups and HREC review will best ensure this. It is that complexity and not the level of risk that counts. Research involving these participants does not necessarily involve more than low risk to them.

Of those Chaps., only one, 4.5, includes the word ‘vulnerable’—which appears in the introduction, not in the guidelines themselves. Further, when the word is used in other Chaps., such as Chap. 4.2, it is plainly about individual children or young people because of their unique circumstances (see paragraphs 4.2.8, 4.2.9).

Those Chaps. identify potential participants who, because of their circumstances or capacities, are unlikely to meet the essential participation standard of National Statement paragraph 2.2.2 unless care is taken to understand, address and mitigate the effects of those capacities or circumstances to enable them to meet that standard. By drawing on the full ranges of expertise and experience that an HREC membership can provide, that assessment and mitigation will be more effective than if it were made with less expertise. However, Chaps. 4.1, 4.4, 4.5 and 4.7 require HREC review because of the complexity of ethical consideration of the acceptable participation of each one of those participants, not because of the risk level.

The level of risk of research with people who are vulnerable is only one ethical indicator of the need for review by an HREC, rather than some other body. What is

equally important in ethical review are all of the other situational or historical factors that characterise members of groups currently (and colloquially) labelled vulnerable. The inclusion of any individual as a participant in human research requires recognition of their ethical equality as individuals. This underscores recognition of the factors that affect participant choices and participation.

Paragraph 5.1.19(a) of the National Statement allows for institutions to consider low risk research through means other than by HREC review with the following admonition:

non-HREC levels of ethical review for low risk research, that review must:

be carried out by people who are familiar with this National Statement and have an understanding of the ethical issues that can arise in the research under review;

While this is more likely to be done by drawing on the range of opinion and experience that membership of an HREC offers rather than the narrower range of opinion and expertise in less formally constituted review bodies, mandating the use of HREC review precludes other, more innovative, options which may produce equally robust ethical decisions.

15 Conclusion

By lumping people into broad categories to treat them as an homogenous class and label them as vulnerable merely because they are members of that class, the National Statement strips individuals of their “ethical equality”. The use of labels does not help researchers or HREC members to develop understanding of the complexities around the application of the principles of respect and of justice in real world contexts (Peter and Friedland 2017). Conversely, by defining specific cohorts of research participants who need specific ethical consideration due to their vulnerable nature, may imply that other population groups need not be considered vulnerable. This impression could be problematic and lead to unintended exploitation of participants.

The foundational principles of the National Statement (respect, research merit and integrity, justice, and beneficence) help to develop and shape the relationship between researchers and participants in ways which reflect ‘trust, mutual responsibility and ethical equality’ (National Statement, p. 9). Ensuring ethical recognition of individual vulnerability would be better served by a nuanced application of these principles than by the identification of those individuals as members of vulnerable groups.

Compliance with ethical standards

Conflict of interest The authors declare that no grant or funding was received for the production of this paper and that there are no interests that need to be declared.

References

- Belmont Report. 1979. *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- Consumers Health Forum of Australia (CHF). 2016. *Statement on Consumer and Community involvement in Health and Medical Research*, National Health and Medical Research Council (2016).
- CIOMS. 2016. Council for International Organisations of Medical Sciences in their *International Ethical Guidelines for Health-Related Research Involving Humans* (CIOMS 2016).
- DuBois, James M., Laura Beskow, Jean Campbell, Karen Dugosh, David Festinger, Sarah Hartz, Roslina James, and Charles Lidz. 2012. Restoring Balance: A Consensus Statement on the Protection of Vulnerable Research Participants. *American Journal of Public Health* 102 (2): 2220–2225.
- Jennings, Bruce. 2016. Reconceptualizing Autonomy: A Relational Turn in Bioethics. *Hastings Center Report* 46 (3): 11–16. <https://doi.org/10.1002/hast.544>.
- Lange, M.M., W. Rogers, and S. Dodds. 2013. Vulnerability in Research Ethics: A Way Forward. *Bioethics* 27 (6): 333–340. <https://doi.org/10.1111/bioe.12032>.
- National Statement on Ethical Conduct in Human Research 2007. 2018. *The National Health and Medical Research Council, the Australian Research Council and Universities Australia*. Canberra: Commonwealth of Australia.
- Peter, Elizabeth, and Judith Friedland. 2017. Recognizing Risk and Vulnerability in Research Ethics: Imagining the “What Ifs?”. *Journal of Empirical Research on Human Research Ethics* 12 (2): 107–116.
- Rogers, Wendy, and Margaret Meek Lange. 2013. Rethinking the Vulnerability of Minority Populations in Research. *American Journal of Public Health* 103 (12): 2141–2146.
- Racine, Eric, and Bracken Roche. 2019. Enriching the Concept of Vulnerability in Research Ethics: An Integrative and Functional Account. *Bioethics* 2019 (33): 19–34.
- Rhodes, Rosamond. 2005. Rethinking Research Ethics. *The American Journal of Bioethics* 5 (1): 7–28. <https://doi.org/10.1080/15265160590900678>.
- Rudd, Kevin. 2008. *Apology to Australia's Indigenous peoples*. <https://www.australia.gov.au/about-australia/our-country/our-people/apology-to-australias-indigenous-peoples>.
- ten Have, Henk. 2015. Respect for Human Vulnerability: The Emergence of a New Principle in Bioethics. *Bioethical Inquiry* 2015 (12): 395–408. <https://doi.org/10.1007/s11673-015-9641-9>.
- The United Nations Educational, Scientific, and Cultural Organisation (UNESCO) Universal Declaration on Bioethics and Human Rights.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.