



28 April 2017

Health and disability research involving adult participants who are unable to provide informed consent

Feedback from: New Zealand College of Midwives
PO Box 21-106
Edgware
Christchurch 8143

Phone (03) 377 2732

The New Zealand College of Midwives is the professional organisation for midwifery. Members are employed and self-employed and collectively represent 90% of the practising midwives in this country. There are around 2,900 midwives who hold an Annual Practising Certificate (APC). These midwives provide maternity care to on average 60,000 women and babies each year. New Zealand has a unique and efficient maternity service model which centres care around the needs of the woman and her baby. It provides women with the opportunity to have continuity of care from a chosen maternity carer (known as a Lead Maternity Carer or LMC) throughout pregnancy and for up to 6 weeks after the birth of the baby, and 92% of women choose a midwife to be their LMC. Primary maternity services provided by LMC midwives are integrated within the wider primary care and maternity services of their region or locality. The College offers information, education and advice to women, midwives, district health boards, health and social service agencies and the Ministry of Health regarding midwifery and maternity issues. Midwives interface with a multitude of other health professionals and agencies to support women to achieve the optimum outcome for their pregnancies, health and well-being.



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Health and Disability Commissioner
PO Box 1791
Auckland 1140

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The opportunity to make a submission was welcomed by the New Zealand College of Midwives (the College).

Midwives work in partnership with women and it is the midwife's professional responsibility to uphold each woman's right to informed decision making throughout the childbirth experience. It is respect for the woman's autonomy that underpins the requirement for informed consent, and informed decision-making emphasises the autonomy of the individual. The College considers that informed decision-making involves the exchange and understanding of relevant information. It respects the rights of individuals to make decisions about actions, which affect them. Making an informed decision is part of a process, which results in either informed consent or refusal.

Feedback from the College is below.

1. Midwives are evidence-based practitioners and the College recognises that because knowledge needs to increase, research is necessary. However, we do have significant concerns about non-consensual research and clinical trials.
2. As described by Ledward in 2011, because research is not treatment it should always be seen as distinct from clinical care, and therefore the ethical justification for research will be different. Ledward comments that assuming that a research study will always offer potential benefit to research participants represents a narrow interpretation. She goes on to say "There may sometimes be elements of direct benefit to participants (therapeutic research), or the research may offer a degree of benefit to both participants and future patients. However, research most frequently has the objective of benefiting others in the future (non-therapeutic research)."¹
3. The College considers that as a general rule research should not be carried out in non-consensual situations.

¹ Ledward, A. (2011). *Informed consent: Ethical issues for midwife research*. Evidence-based midwifery, Royal College of Midwives. <https://www.rcm.org.uk/learning-and-career/learning-and-research/ebm-articles/informed-consent-ethical-issues-for-midwife>

4. The College also considers that enrolling adults in research when there is an inability to consent, and where the research is not expected to provide benefit to them, is ethically troubling. Taking advantage of people who are unable to protect their own interests is a breach of human rights.
5. Ledward points out that “competence should not be seen as an ‘all or nothing’ concept, but might be dependent on the type of decision to be made.” What this means is that there may be competency to decide on some issues and not others, and this may also occur within varying time-frames. The College recommends this concept be recognised, and we emphasise the ethical obligations to ensure that all avenues to information provision are explored.
6. The College considers that research on people who cannot give informed consent should not proceed unless the research is deemed to be in the best interests of the person. We also consider that family and whānau, or authorised surrogate, need to be intimately involved in all decision making.
7. The College also consider informed consent as a dynamic process. As described by Johnson & Keenan, consent is not as a single act, but a process which involves open and honest communication.² If new evidence or information emerges, there should be a right for family/whānau to change their minds at any time.
8. The College considers that an appropriately qualified, diverse and independent ethics committee should be involved in all the decision making processes involving non-consensual research. This ethics committee should protect the interests of all research participants, but particularly those in situations of great vulnerability, where persons cannot protect their own interests and wellbeing.
9. The WHO, Standard 4: Independence of research ethics committees (REC) states, *“Policies governing the REC include mechanisms to ensure independence of the REC’s operations, in order to protect decision making from influence by any individual or entity that sponsors, conducts, or hosts the research it reviews. Such policies provide at a minimum that REC members (including the Chair) remove themselves from the review of any research in which they or close family members have a conflicting interest.”*³
10. The College understands that there have been forty medical studies in New Zealand since 2006 that included non-consenting ‘participants’ and that these studies were approved by ethics committees.⁴ We recommend that ethics committees should be required to prioritise the role of protection of human participants in research, and the ethics involved in non-consensual ‘participation’.
11. The College notes the argument in support on non-consensual research by Aspen New Zealand, who are a pharmaceutical company. We consider research on unconscious patients, without their prior consent, to be a major breach of their human rights, and we would like to express our alarm at suggestions made in the Aspen article, that excluding adults unable to consent from research, is some form of discrimination. Using language such as ‘opportunity to participate’ and ‘diminishing their ability to participate as fully as possible in society’ is frankly abhorrent in situations where the research is of no value to the person’s current, or future, health situation, and they are unable to consent or refuse.

² Johnson, S., & Keenan, R. (2010) *Consent*. In R Keenan, ed. Health Care and the Law, Chapter six, Brookers: Wellington.

³ World Health Organisation. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

⁴ Aspen New Zealand. Undated. *Research on people who lack capacity*. <http://www.aspenltd.co.nz/mc/assets/Ch-6.pdf>

12. International guidelines from the World Health Organisation cover ethics and clinical research, and state that it is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants.⁵ The College supports this statement.
13. Whilst carrying out background research for this submission the College was disturbed to find that entering 'non-consensual' into the search engine on the National Ethics Advisory Committee yielded zero results.
14. The College did find a statement within the National Ethics Advisory Committee's 2012, 'Ethical Guidelines for Intervention Studies: Revised edition' which states in 6.28 that "*Intervention studies with no therapeutic intent should be undertaken only with the prior informed consent of the competent individual, unless a legal proxy can consent for an incompetent individual.*"⁶ The College would not like to see this statement reduced in any way, and we support New Zealand law that substantially limits the powers of health practitioners to offer treatment without consent in the context of research.
15. In situations where there is an inability to provide informed consent by the person, the College considers that the tenets of informed consent remain and that the family/whānau, or authorised surrogate, should be afforded all information necessary.
16. If the person is unable to participate in decision making, and has temporarily lost autonomy, the College considers that information should still be provided to the family/whānau in a way that is easy to understand and engage with.
17. The information provided must still be accurate, objective, relevant and culturally appropriate.
18. Information to family/ whānau should include details of the proposed research, and a clear benefits and risks analysis.
19. Alternatives to the research proposed, and the risks and benefits, should be provided to family/ whānau, and this will include information about what will likely occur if consent is refused.
20. The information provided to family/whānau should remain free from coercion
21. Wherever possible a designated and reasonable amount of time should be given for family/whānau to discuss, consider, and seek further information to assist in their decision making.

Thank you for the opportunity to provide feedback on this document



Carol Bartle
Policy Analyst

⁵ World Health Organisation. (2011). *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. Geneva, WHO.

⁶ The National Ethics Advisory Committee. (2012). *Ethical Guidelines for Intervention Studies: Revised edition*. Wellington, MOH.