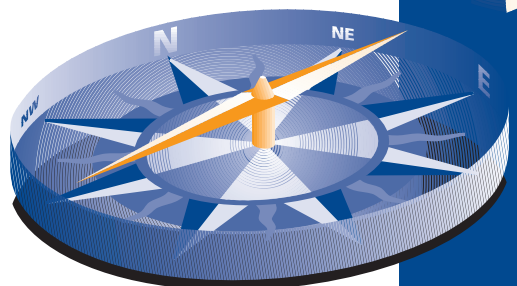


Catholic Health Australia

CODE OF
Ethical Standards
for
Catholic Health and Aged Care
Services in Australia



Catholic Health Australia
Speaking with one voice



6. Research

Introduction

- 6.1 Research may be defined as any systematic activity undertaken for the purpose of gaining new knowledge, understanding or insight or confirming current knowledge. Catholic health care affirms and promotes the value of research, recognising that new knowledge is good in itself and has the potential for application in new therapeutic options. Research into healthcare policy and bioethics, underpinned by the mission and values of Catholic health care, has the potential to contribute to the development of a compassionate and equitable healthcare system (see also 6.19). Those Catholic services in a position to do so should give special attention to research of particular relevance to Catholic teachings, for example, in relation to palliative care, fertility and infertility, and genetic interventions which respect the marital context of human conception (see also 2.1).
- 6.2 Research differs from *clinical practice* in that the primary purpose of research is to gain knowledge, whereas the primary purpose of clinical practice is to benefit the patient, whether by diagnosis, cure, stabilisation or

palliation, etc. It is also important to distinguish between research which is *therapeutic*, that is, conducted with the intention of providing a direct clinical benefit to the participant along with the gaining of knowledge, and research which is *non-therapeutic*, that is, conducted not with the intention of providing a direct benefit to the participant but rather with the intention of gaining information that may in time benefit others.

- 6.3 Research in Catholic facilities should meet all professional, scientific and legal requirements as determined by appropriate bodies. Relevant guidelines, for example those derived from privacy legislation and those of the National Health and Medical Research Council, should be taken into account.

Research involving humans

- 6.4 Research involving human beings must always both respect the personal dignity of the research participant and serve the common good. Research must never pose an unreasonable danger to a person's life, sanity or health. However, a person who understands the extent of the risks involved may choose to accept some risk, discomfort



6. RESEARCH

or inconvenience in order to contribute to developments in medicine and thereby contribute to the common good.

Consent

6.5 Research depends upon a partnership between participants and researchers with a view to meeting the needs of future beneficiaries. Researchers must, therefore, seek the adequately informed and freely given consent of potential research subjects. Each person must be informed of the risks and benefits involved in participating in the research. Participants must be free to withdraw at any time. Researchers, in particular those conducting clinical trials, have a responsibility to ensure that participants understand they are enrolled in a research project. Reimbursements should not be so large as to become unwarranted inducements. Where it is proposed that epidemiological or retrospective studies will use identifying data, as far as practicable consent should be obtained.

Vulnerable participants

6.6 In the case of any person, or group of people who may be particularly vulnerable (such as incompetent participants, older children, people with mild intellectual impairment, those highly dependent on medical

care, the poor and people who are institutionalised), there is a more stringent requirement to ensure that benefits justify risks. Research involving vulnerable people must only be undertaken when the knowledge to be obtained is sufficiently important to warrant involving such vulnerable people and this knowledge cannot be obtained by other means. The research method should be designed to meet the specific needs of the particular participants with their best interests being paramount. Non-therapeutic experimentation must involve no significant risk at all.

6.7 When a potential research participant is in a dependent position in relation to the researcher, for example, as the patient of a doctor-researcher, there is need for extra diligence in the obtaining of consent to ensure that the patient can distinguish between the procedures of the research trial and those needed for his or her care. Patients should be assured that their health care needs will be met, without discrimination, even if they choose not to participate in, or to withdraw from, a research project. Likewise subordinate staff, prisoners, students and others must be assured that they will not lose any



6. RESEARCH

entitlements if they choose not to participate in, or to withdraw from, a research project.

Incompetent participants

6.8 Consent for participation in a research project by an incompetent person is to be sought from the person who has legal responsibility for his or her medical treatment decisions. In these matters the person responsible and the researcher are to be guided by what is judged to be in the participant's best interests and by what is known of his or her wishes. Where possible the agreement of the participant should also be obtained and any refusals should be respected.

Research design and methodology

6.9 All reasonable precautions must be undertaken to minimise the potential harm to participants. Where appropriate, prior experimentation with non-living models and animals should be undertaken to determine possible harmful effects of the intervention.

6.10 To be ethically acceptable research must also be scientifically sound. When the research project fails to provide its expected benefits, or unexpectedly harms participants, either a new consent should be sought from the participants or the

research discontinued. Researchers should provide participants with any new information about the risks of participation.

6.11 Patients may choose to forgo standard treatments which offer little or no benefit in order to receive experimental treatments. However, patients should never be denied access to standard or accepted forms of treatment. The use of placebos, or non-treatment control groups, is acceptable only if they are necessary for the purposes of the research, do not deprive the patient of available, beneficial and needed standard treatment, and do not place the patient at risk of harm. Participants should be informed in advance of, and give their consent to, the possibility of receiving a placebo.

Donation of body for research and teaching

6.12 Some research and some teaching of healthcare practitioners requires the use of cadaveric tissue. The use of such tissue, where necessary and other than when required by law for autopsy, is permissible if the use is in accordance with the prior expressed wishes of the deceased person or the consent of the family or other relevant person has been obtained.



6. RESEARCH

*Research involving
human embryos and fetuses*

- 6.13 Medical research involving live embryos or fetuses may only be undertaken *in vivo* (within the body) and when there is a moral certainty of causing no harm to the life or the integrity of the embryo or the foetus. The informed consent of the parents, or at least that of the mother, is required prior to any research.
- 6.14 When embryos and fetuses die, they are to be given the same respect as is due to every human being who dies. Researchers may undertake an autopsy, or other forms of research, with the consent of the parents. Research is never to be undertaken on an embryo or foetus, or on tissue from an embryo or foetus, that has been procured through deliberate abortion. Nor is it ever permissible to produce embryos for research purposes or use embryos discarded from IVF programmes for research purposes. Such research is a grave violation of the human dignity of these embryos.

Genetic research

- 6.15 Research in genetic and molecular science is yielding new knowledge which is valuable in itself and has

diagnostic and therapeutic potential. Such research must always be pursued in ways which respect both the fundamental dignity of each human person in his or her uniqueness and the common genetic heritage of the human community. Research must never be premised upon the assumption that a person is wholly reducible to, or determined by, his or her genes. Furthermore, knowledge of the human organism, as distinct from applications of that knowledge, should never be treated as the commercial property of individuals or organisations.

- 6.16 Genetic information may have particular significance to the participant and his or her family (see also 1.10, 1.23 and 1.24). Special protocols may be needed to ensure the appropriate counselling of participants and the confidentiality of records containing genetic information, including family pedigrees.
- 6.17 Genetic research should not be undertaken with a view to changing either the fundamental human nature or the unique identity of an individual person. Rather, research should be directed to applications of diagnostic or therapeutic value. Researchers should seek to avoid contributing



6. RESEARCH

to the use of genetic information in a way which stigmatises or unjustly discriminates against certain people. Researchers in Catholic facilities should be prepared to explore possibilities which give witness to a respect for human embryos and the human genome.

- 6.18 Genetic research must not involve any techniques that may lead to the asexual creation or reproduction of human embryos or other eventualities that are contrary to respect for human life or human dignity. These techniques currently include: producing, damaging or dismembering a human embryo to remove stem cells or to ensure its truncated development; producing totipotent cells which (without the addition of other genetic material) may be capable of human embryogenesis; introducing the whole or parts of the human genome into animal gametes; forming a chimera with or to create a human embryo; and animal gestation of human embryos.

Health ethics research

- 6.19 Catholic health, aged and community care can make a distinctive contribution through its reflection upon ethical concerns from within the Catholic tradition. In addition to conducting health and medical research, Catholic facilities

should encourage research into the ethics of health care and contribute to the clarification and development of doctrine within the Catholic tradition.

Animal research

- 6.20 At all times animals must be treated with the respect due to them as creatures of God. Research may be conducted on animals only when non-living subjects or experimental models cannot be used to obtain the necessary information. Reasonable care should be taken and needless suffering prevented. Any such research in Catholic facilities should meet all relevant ethical, scientific and legal requirements as determined by the appropriate bodies.

Research ethics committees

- 6.21 Research involving human or animal subjects must be approved by a duly constituted and approved research ethics committee. Several facilities may contribute to the formation of a combined research committee to ensure the relevant expertise. The responsibility of the committee is to ensure that the interests of potential research participants are protected, to ensure that the research is ethically sound, and to audit the scientific, social, and legal validity of the research.



6. RESEARCH

6.22 Research ethics committees should be constituted in accordance with statutory norms and members should be chosen who are willing to act in accordance with this *Code of Ethical Standards*. The membership should include experts in research, the appropriate sciences that inform the research, health care, moral theology and/or philosophy and the law together with independent

members of the community. The interests of potential research participant groups should also be effectively represented. The independence of the committee should be ensured, for example, by including a sufficient number of members not employed by the facility. Any conflicts of interest must be declared, and researchers should never be involved in the approval of their own projects.

References

Research: *Gaudium et Spes* 15; *Evangelium Vitae* 26; *Populorum Progressio* 20; *Donum Vitae* 1-3; *Catechism* 159, 283, 2293-94; *Charter* 75-6

Research involving humans: Pope Pius XII, *The Moral Limits of Medical Research and Treatment*, Address given to the First International Congress on the Histopathology of the Nervous System (1952); *Catechism* 2295, 2301, 2375; *Charter* 75-81

Research involving human embryos and foetuses: *Evangelium Vitae* 14, 44-5, 63; *Donum Vitae* 1-5, I:1, I:3-6, III; *Catechism* 2271, 2275, 2323; Pope John Paul II, *Address to the 18th International Congress of the Transplantation Society* (2000);

Charter 82; Australian Catholic Bishops Conference, “Cloning” (2000)

Genetic research: *Gaudium et Spes* 14; Pope John Paul II, *Dangers of Genetic Manipulation*, Address given to the Members of the World Medical Association (1983); *Catechism* 2275; Secretariat of State, *Observations on the Universal Declaration on the Human Genome and Human Rights* (1997); Pontifical Academy for Life, *Concluding Remarks of the Fourth Plenary Assembly* (1998)

Animal research: *Catechism* 2415-18, 2456-57

