

Commentary

Potāto, potāto, proxy consent, permission – just don't call the whole thing off

Randi Zlotnik Shaul

Bioethicist, Bioethics Department, The Hospital for Sick Children, Toronto, Ontario, Canada, and Lecturer, Department of Paediatrics, University of Toronto, Toronto, Ontario, Canada

Corresponding author: Randi Zlotnik Shaul, randi.zlotnik-shaul@sickkids.ca

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Abstract

Research involving critically ill persons highlights challenging questions surrounding third party authorization. The ethical and legal viability of research involving persons who do not have the capacity to consent to participation is not universally accepted, and inconsistent standards are reflected in research ethics guidelines, law and practice. In order to ensure that research participants who are considered incapable of consenting to research are appropriately protected, and that minimal risk research on illnesses affecting those who are unable to consent is enabled, clear and justifiable parameters must be created and, where they are already established, they must be made more transparent.

Introduction

Research involving critically ill patients highlights challenging questions surrounding third party authorization. Can a proxy decision maker consent to research on another's behalf? Can a researcher enrol someone who is considered unable to consent, when the research is not specifically in that person's best interests? The ethical and legal viability of research involving persons who do not have the capacity to consent to participation is not universally accepted [1], and inconsistent standards are reflected in research ethics guidelines, law and practice. Some argue that inconsistent parameters for proxy authorization may have a 'chilling' effect on research involving incapable persons, and may result in researchers and research ethics committee members living in fear of liability [2–4]. Others point to little awareness among researchers of the rules governing surrogate consent to research [5]. Given that categorically excluding from research those persons who are unable to consent for themselves would deprive them of proven treatments designed to meet their requirements, participation should be allowed, subject to safeguards.

A range of perspectives

There are a wide range of references to third party authorization in research ethics documents and case law. The Nuremberg Code [6] precludes any research on persons

without their consent. The World Medical Association's Declaration of Helsinki [7] states that for a 'research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law'. The International Conference on Harmonisation (ICH) Harmonised Tripartite Guidelines: Good Clinical Practice document [8] uses the Helsinki language and defines 'legally acceptable representative' as 'an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subjects' participation in the clinical trial'. The Belmont Report from the USA [9] holds that, 'individuals should be treated as autonomous agents and ... persons with diminished autonomy are entitled to protection', meaning that the permission of 'other parties' may be sought. The Tri-Council Policy Statement from Canada [10] states that, 'Research ... may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent ...'. Case law, much like the guidelines, offers both examples of support and barriers to third party authorization [2].

Notwithstanding the general commitment to third party authorization included in most of the above documents, there is a common underlying distinction between research in the pursuit of knowledge with a possibility and added intent of improving the patient's health, and research that simply aims to extend knowledge with no attempt at improving the patient's health.

Ethics

The obligation of researchers to treat patients as autonomous actors who must provide informed and voluntary consent to participate in research is grounded in the ethical principle of respect for persons. Requirements for parental or guardian permission are grounded in the ethical obligation of researchers to respect and protect vulnerable individuals. Provisions for involving potential participants who are

considered incapable of providing informed consent to research in discussions about research participation and seeking their assent, where appropriate, reflect respect for the individuals' level of autonomy. Permission and assent are the foundations of ethical research involving those who do not have the capacity to consent to research [11].

Law

The use of third party authorization must comply with the legal requirements of the jurisdiction where the research is taking place. In many jurisdictions, proxy consent can only be given for treatment decisions. When research is intended on individuals who are incapable of providing informed consent, legal authority to authorize the research rests with parents or guardians, who are authorized to provide permission rather than consent [12]. In many jurisdictions it remains unclear whether research must be considered of direct benefit to the individual in order to be authorized by a third party. In addition, with respect for the level of understanding and independence of the potential participant, researchers may need to involve the research participant in discussions about research and obtain assent to participation.

If there is reason to believe that the individual, if they were competent, would have agreed to participate in research without the prospect of direct benefit to them, then the guardian may be able to provide proxy permission. Without such clear wishes previously expressed while the individual was capable, the requirement of direct benefit poses a genuine barrier to research in diseases such as Alzheimer's and other forms of dementia.

In some jurisdictions, a strict reading of the law holds that it is only permissible for individuals to participate in research that is considered to be in their best interests. Other jurisdictions have modified this position by establishing safeguards [13] that must be in place before a proxy decision maker can give permission for another to participate in research that is not specifically in their best interests. Such safeguards are intended to protect the individual from exploitation and from being exposed to potentially harmful research without the prospect of direct benefit.

Conclusion

Where a person is considered incapable of consenting to potentially beneficial research, a proxy decision maker will, in many jurisdictions, legally and ethically be able to give permission for participation. Where a person is considered incapable of consenting to nonbeneficial research, a proxy decision maker may require previously expressed and capable wishes that the potential participant would have wanted to participate in such research, and require assurance that designated safeguards are in place [14], or they may be unable to give permission at all. The legal and ethical acceptability of third party permission for nonbeneficial research is jurisdiction specific, which is a source of ongoing

debate and is often subject to inconsistent directives. In order to ensure that research participants who are considered incapable of consenting to research are appropriately protected and that minimal risk research on illnesses affecting those unable to consent is enabled, clear and justifiable parameters must be created and, where they are already established, they must be made more transparent.

Competing interests

The author(s) declare that they have no competing interests.

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