Loosen informed consent requirement in research context

Loosen Informed Consent Requirement in Research Context: Two Notions of Exception of Informed Consent and Default Options

The Terrain of Autonomy

Autonomy is an important principle in bioethics. In Northern America, which emphasises the value of individualism, autonomy is often used as a principle to defend unethical manipulation and undue invasion, as well as to claim the right to certain treatments. Throughout the history of medical ethics, autonomy has won many battles in different clinical situations. For example, patient autonomy has been recognised in cases of physician-assisted suicide, palliative care, abortion, medical treatment of minors,[1] and the right to medical marijuana.[2] In the context of research, autonomy highlights the essential requirements of informed and voluntary consent of the research subject. It seems that autonomy has been continuously extending its territory. People may ask: what is the border of the realm of autonomy? Are there any situations that justify limiting autonomy?

Informed consent (IC) is the specified moral rule of autonomy. We measure the extent of autonomy and its limitation by measuring the extent of application of IC and its limitation. This article will discuss the following questions: What limitation does IC have? Under what circumstance and to what extent should we amend or even abandon the requirement of IC and recognise the notion of exception of consent?

What Are the Values and Elements of Informed Consent?

IC is the most effective doctrine to fulfill the patients' right to self-determination and well-being, and to protect them from undue manipulation and inhumane

treatment in both clinical and experimental contexts.[3, 4] In order to obtain valid IC, one should realise the elements of IC and fulfill them. They consist of: (1) competence of the subject; (2) voluntariness, which means that the subject makes a decision without coercion and manipulation; (3) adequate disclosure of information; (4) understanding, and (5) consent. Regarding consent, there are several dichotomies being discussed in different contexts, for example, self-determining vs. proxy consent, explicit vs. implicit consent, generic vs. specific consent, and prospective vs. retrospective (or deferred) consent. This article will discuss issues related to prospective and retrospective consent.

What Are the Limitations of Informed Consent in Research?

We identify the limitations of IC in research context by asking: is IC a sufficient and necessary condition of an ethical experiment? Emanuel et al. asserted that "while IC is necessary in most but not all cases, in no case is it sufficient for ethical clinical research."[5] They noted that ethical clinical research should consist of, at least, the following seven essential requirements: (1) social or scientific value; (2) scientific validity; (3) fair subject selection and concern of justice; (4) favorable and proportional risk-benefit ratio; (5) independent review such as institution review board (IRB); (6) respect of research subject through confidentiality and protection of privacy; and (7) IC requirement.[6] Here we can see that IC alone does not guarantee an ethical research. As Truog et al. observe: "… the process of informed consent is not a goal or ideal in itself. Rather, informed consent is important because it is frequently essential for ensuring that the patient's right to self-determination is respected."[7]

Is IC necessary for an ethical conduct of research? According to the experience of one researcher, IC requirement does affect the study design and result. In order to obtain subjects' IC, the study was postponed for six months because the subjects felt anxious after receiving the information. The result of the research may also be biased unless the original study design is reconstructed.[8] In addition, fully IC may be cruel to the patients.[9] Spending huge effort, time, money, and exposing subjects to potential risk but, as a result, obtaining an unscientific and incorrect outcome is not ethical. So, arguably, under particular circumstances IC is not a necessary condition.

Exception of Informed Consent in Treatment Context

Cases of exception of IC happen in both treatment and research contexts. In the treatment context, there are five well-recognised situations where no IC is required.[10] The first one is public health emergency such as the outbreak of

an unknown, severe contagious pathogen. In that situation there is no need to obtain IC for intervention such as mandatory treatment or isolation despite the limitation of individual liberty. Second, certain medical emergencies are also recognised as exceptions because the time of decision making is too limited. Third, consent from an incompetent patient is not possible. Therapeutic privilege, which means the physician might withhold information from the patient when the risk is reasonably foreseeable after disclosure, is another exception. At that time the physician needs good reasons to defend himself against the challenge of medical paternalism. The last one is informed waiver by the patient. Waiver of IC denotes that "a patient voluntarily relinquishes the right to an informed consent"[11] and authorises someone else to choose for oneself.

Two Notions of Exception of Informed Consent in Research Context

In this section, I differentiate two notions of exception of IC in the research context. The first one is "exception from IC" and the second one is "exemption from IC".

Three bodies including the U.S. Food and Drug Administration (FDA), Department of Health & Human Services (DHHS), and American Medical Association (AMA) adopt the notion of *exception from IC* in certain situations (e.g., emergency research). In the FDA regulation, although it permits intervention without prospective IC, it requires the research protocol to include a design of process of obtaining IC and mandates obtaining IC from the patients or families later whenever possible.[12] Meanwhile, DHHS states that:

> An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
> (1) The research involves no more than minimal risk to the subjects;
> (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
> (3) The research could not practicably be carried out without the waiver or alteration; and
> (4) *Whenever appropriate, the subjects will be provided with additional pertinent information after participation.* (emphasis added)[13]

There are similar stipulations in AMA's *Code of Medical Ethics*, which also emphasises that:

> Where informed consent is waived, *subjects or their representatives must be informed as soon as possible about inclusion in the study and be asked to consent*

> *to further participation.* (emphasis added) Subjects, or their representatives, may choose to discontinue participation at any time after being fully informed about the possible consequences.[14]

I emphasise two points of the above regulations and code. First, obtaining IC as soon as possible after intervention is one form of consent, i.e. retrospective consent or deferred consent, rather than "total exemption from consent". Second, IC is not required only under certain circumstances (in this case, emergency research). Showing that "obtaining IC" is still the principle, "permitting research without prospective IC" is the exception. The default option therefore is "obtaining IC but permitting exception". Exception from IC is different from exemption from IC, discussed later, because the latter does not require any form of consent from the subjects or their families afterwards, i.e. IC is not needed totally.

Two scholars' views belong to the category of *exemption from IC*.[15] Truog et al. argued that specific consent[16] should not be required in randomised clinical trials under five conditions: (1) treatments could be provided outside the trial without specific consent; (2) treatments with no more than minimal additional risk; (3) genuine clinical equipoise among treatments; (4) patient does not favour one treatment over others; and (5) standards of consent being informed to patients.[17] No deferred consent is needed in these circumstances. Doyal also contended that consent should not be required totally in three situations including incompetence, usage of medical records, and usage of stored tissue from anonymous donors.[18]

In contrast with exception from IC, no retrospective consent or deferred consent is required throughout the course of research. It means that IC is not required totally in these circumstances. Here, the principle changes from "obtaining IC" to "not obtaining IC" silently, and the exception is "obtaining IC" rather than "permitting research without prospective IC". The default position shifts to "not obtaining IC unless in certain situations".

I try to differentiate two notions of exception of IC. These two notions have two main differences: requiring retrospective consent or not and the default option. Exception from IC does require retrospective consent whenever possible and its default option is "obtaining IC but not in certain circumstances". Exemption from IC does not require retrospective consent and its default option is "not obtaining IC unless in certain circumstances".

Two Default Options of Policy

In general, there are two possible defaults of policy option. One is "yes, but" and the other one is "no, unless". Regarding our concern for IC in the research

context, these two defaults are "obtaining IC but not in certain circumstances" and "no need to obtain IC unless in certain circumstances", respectively. Two points related to this distinction will be discussed. The first one concerns the burden of proof. The default of "obtaining IC but not in certain circumstances" sides with the research subjects. It protects subjects from arbitrary interventions by researchers because the burden of proof is imposed on the researchers. Whenever researchers want to break the principle and to perform interventions without IC, they are responsible for giving legitimate reasons.

On the contrary, if the default is "no need to obtain IC unless in certain circumstances", it sides with the researchers and it is the subjects who insist the right to IC bear the onus of proof. The more trivial the potential risk caused by the study and the greater the likelihood of public interest gained by the study, the more reasonable that the burden of proof is imposed on the subjects. The second point relates to research climate. "No need to obtain IC unless in certain circumstances" default may nourish the climate of research and, consequently, investigators will find doing research more friendly and easier under this default option.

In short, exception from IC takes the default of "obtaining IC but not in certain circumstances" and exemption from IC the opposite. This article articulates this distinction and affirms the legitimacy of adopting "no need to obtain IC unless in certain circumstances" as the default in case of, for example, usage of medical records in epidemiologic research in which no identification of patients' private information happens. There are at least two reasons to stand for such position. One is the impracticability of obtaining prospective or retrospective consent in such study. Another reason is that when we consider an ethical policy option, we also need to be concerned about the interest of the society as a whole rather than just individual interest. Performing research which promises great benefit to all with minimal risk is justified from the wider point of view of community interest and common good rather than from the narrower point of view of individual interest and autonomy.

Conclusion

This article examines the conception of IC, its limitations and exceptions, especially in the research context. The author makes a distinction between two different notions of exception of IC (exception from IC and exemption from IC) and their respective default positions. These two notions represent different degrees of loosening of IC requirement: exception from IC loosens IC at a lesser degree and exemption from IC at a greater degree. It is argued that we should choose a default of "no need to obtain IC unless in certain circumstances" rather

than just "obtaining IC but not in certain circumstances" in epidemiological researches using medical records with minimal risk or no linkage to patients' identity. The question which one of the two defaults should be chosen at other situations should depend on the balance between individual autonomy and public interest.

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Notes

1. Boonstra, H. & Nash, E. (2000). Minors and the right to consent to health care. *The Guttmacher Report on Public Policy*. Retrieved on 5 May 2008 from http://www.guttmacher.org/pubs/tgr/03/4/gr030404.pdf.
2. Hill, J. (2007). The constitutional right to make medical treatment decisions: a tale of two doctrines. *Texas Law Review*, **86**, 277–345.
3. Beauchamp, T.L. & Childress, J.F. (2001). *Principles of Biomedical Ethics*. New York: Oxford University Press.
4. Brock, D.W. (1993). *Life and Death*. New York: Cambridge University Press.
5 Emanuel, E.J., Wendler, D., Grady, C. (2000). What makes clinical research ethical? *The Journal of the American Medical Association*, **283**, 2701–11.
6. *Supra* note 5.
7. Truog, R.D., Robinson, W., Randolph, A., Morris, A. (1999). Is informed consent always necessary for randomised, controlled trials? *The New England Journal of Medicine*, **340**, 804–7.
8. Kanis, J.A. & Bergmann, J.F. (1993). Full consent may bias outcome of trials. *British Medical Journal*, **307**, 1497.
9. Tobias, J.S. & Souhami, R.L. (1993). Fully informed consent can be needlessly cruel. *British Medical Journal*, **307**, 1199–201.
10. Faden, R. & Beauchamp, T.L. (1986) *A History and Theory of Informed Consent*. New York: Oxford University Press.
11. *Supra* note 3, p. 92.
12. Please see 21 CFR 50.24. Retrieved on 9 April 2009 from http://www.clarian.org/features/homepage/fdaexception.pdf.
13. Please see 45 CFR 46.116. Retrieved on 9 April 2009 from http://www.palmettohealth.org/facilities/cancer/trials/07_I.doc.
14. AMA Council on Ethical and Judicial Affairs. *Code of Medical Ethics*. E-8.085. Retrieved on 9 April 2009 from http://www.ama-assn.org/ama1/pub/upload/mm/Code_of_Med_Eth/opinion/opinion8085.html.
15. I avoid using the term "waiver of IC" because the patients indeed do not "waive" their right to IC actively. Their right to IC is just taken away from them. So I use "exemption from IC" instead of "waiver of IC".

16. Truog et al. differentiate specific consent from general consent. His notion of specific consent is similar to my notion of deferred notion.
17. *Supra* note 7.
18. Doyal, L. (1997). Informed consent in medical research: journals should not publish research to which patients have not given fully informed consent — with three exceptions. *British Medical Journal*, **314**, 1107–1111.