Consent and protection of adults and children: common and peculiar dilemmas in developing countries

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Abstract The present work is a review of recent articles published in Brazilian and international medical journals on the informed consent topic. It introduces the historical aspects and the global dimension of judicial and legal issues, stating the ethical importance of the topic at hand. Next, it pinpoints some peculiarities of using informed consent with the pediatric patient arguing the necessity to respect the child and adolescent's autonomy. It develops a bioethical analysis of this practice in neonatal intensive care units in developing countries, where, besides the patient's vulnerability - mostly premature babies - other important aspects, such as medical, educational, cultural, religious, social, economic, etc also come into play. It concludes by highlighting the complexity of this procedure and it alerts that its use alone does not effectively ensure patients' protection and respect, be them involved or not in a research protocol.

Key words: Bioethics. Informed consent. Neonatal intensive care.

Informed consent – general aspects

When the atrocities committed by the Nazi *experiments* came to light at the Nuremberg trials, a process of reflection on research involving human-beings began. At court's end, consensus was reached between the allies that produced the *Nuremberg Declaration*, document which guaranteed the pioneer right of a research subject to autonomously decide to participate or not. The formalization of this wish originated the informed consent.

The goal of which is to provide the potential subjects the necessary information for them to make a decision on taking part or not, voluntarily, in a study. From an ethical viewpoint, however, the requirement of informed consent focuses on the respect for subjects' autonomy, as well as observance of the principles of beneficence and justice [1]. Informed consent is the cornerstone of regulation and ethical conduct in research and has become the focal point of guidelines in several clinical researches and ethical good practices in this field [2].

In recent years the main international guidelines have reserved, in all of their versions, space for important guiding on informed consent, as did the *National Advisory Committee* (2000), the *Nuffield Council of Bioethics* (2002), the *World Medical Association, Helsinki Guidelines* (2003), the *Council for International Organizations of Medical Sciences* (2003). In our country, according to the directives set forth by Resolution 196/96 of the National Health Council (CNS), informed consent is denominated 'term of free and informed consent', an instrument to ensure the autonomy of the research subject, by means of their consent and participation [3].

In all of these documents that serve as reference to professionals and especially to researchers, some aspects of the informed consent are stressed as potential generators of problems in the process of obtaining the consent from the subject:

1. the written document being more important than the possibility of the participant understanding the whole research process;
2. the written document must be prepared in simple language and contain the necessary information for the decision;
3. the amount of information (autonomy, confidentiality, secrecy, risks, and benefits, endorsements etc.) can become excessive and harm the understanding of the participant;
4. it is fundamental to guarantee that the potential participant has understood the risks and benefits that the research in question represents;
5. there is no conclusive data on the meaning of informed consent in traditional communities and societies;
6. in cases illiteracy and educational deficit it is necessary to utilize alternative means to ensure the understanding and comprehension by the participant [2].

Important aspects of this relation are linked to the moment of consent obtainment – both from the consent solicitant and the person who autonomously or, as legal representative, will grant consent. A qualitative study carried out at the Campinas University (Unicamp) with women that were taking part or had taken part in clinical research investigated the opinion of the very same on the obtainment of informed consent, revealing that the professional fulfilling this task should not be a physician and should demonstrate good level of knowledge on the study and confidence and capacity to answer questions and clear doubts. The findings of this study point to the fact that because the main investigator is a very busy person, it harms the consent obtainment process, as well as to the physician-patient relation being one of power [4].

In a research carried out at the end of the 1960's, in France, Botansky shows the gap formed between scientific medicine generated knowledge and the patients belonging to popular classes, either in rural or urban areas [5]. Standing on the premises of that work, Bento asserts that members of working classes are incapable of assessing the technical competence of a physician and, for this; they focus their assessment on attitudes, for instance, if they are gentle, delicate, and patient [4]. This finding corroborates the opinion of the women interviewed by the Unicamp study, which consider that the information provided about the research should be complementarily transmitted both orally and *in scriptum*. Moreover, they believe the information about the research should be presented individually and collectively the group of would-be participants. In this group dynamics, the answers to the questions of potential participant would clear other

women's doubts or generate new inquiries. Individually the participants would feel more comfortable to formulate intimate questions, clearing doubts on the research aspects that might be embarrassing to ask in group [4]. In certain cases, the collective transmission of information for the consent obtainment by means of a speech was proposed by a study carried out in Porto Alegre by Goldim and collaborators [6].

In reference to the research patient or subject, Biode-Simoes [7], in a study on the understanding of the term of consent, concluded that the subject selected to participate in a research must have the best levels of education possible, being able to read, and a higher income, as well as internet access. He further affirms that in medical practice, the conditions of each of the sick must be observed, understanding their limitations of comprehension, reading together with them all items of the term of consent, explaining all points that might not be clear [7].

In Brazil, the problem of functional illiteracy is of such magnitude for the obtainment of informed consent that if we were to follow the criteria established by the Functional Illiteracy National Index (Inaf) the functional illiteracy indicator, then only 26% of the population – fully literate persons - could actually understand the terms of consent wholly [8]. Even if we consider basic literacy as sufficient for the integral understand of the consent term, we would still be talking about only 37% of the adult population [8]. These hardships increase when the interest of the research involves children, to investigate propositions of treatments.

Informed consent in pediatrics

To act according to ethics any health professional must defends the best interests of a child and protect them from potential research risks, side effects from treatments and unnecessary or complementary inadequate exams, whenever possible respecting autonomy. It might be perceived as simple to agree on and execute these guidelines of ethical conduct. However, each step of process brings up doubts, reflections, and insecurities. Especially when these actions should be subordinated to the autonomy of the child or adolescent. For this, the great ethical dilemma of pediatrics is: when is the child capable of consenting?

We can approach this issue from two lines of philosophical thought, amongst several others: *deontology* and *utilitarism*. For deontology, action must be based on the morally correct, in spite of its consequences. Individuals are considered to be an end itself and never as a means to achieve an end. From this point of view, the only ethically acceptable research on children would be that which would potentially bring benefits to the children themselves. On the other side of the spectrum, the utilitarian perspective sees ethically correct action as that which brings about benefits to largest number of people, maximizing the amount of benefits without taking into account its distribution. Thus, if a research bear fruits for a lot of children, but poses risk to one pediatric participant, then it is justifiable from the utilitarian standpoint, and in these cases, consent need not be mandatory [9].

There are barriers that represent obstacles for health professional to defend the rights of children. Of the most significant, are the ones constituted by the beliefs and values of the professional. In relation to the respect to autonomy fulfillment by the children, we can point out that at least three postures are often identified: *libertarianism*,

protectionism, and *paternalism*. As far as libertarianism is concerned, the child must be allowed to fulfill the rights of adults as soon as such capability is achieved. Protectionism states that children need protection and intervention by professionals to prevent or avoid risk situations; and finally, paternalism believes that children can only be understood by an adult who is close to them, the *psychological genitor*, who will protect them until full age [10]. Despite their intrinsic differences, all of these stances advocate for the respect of child autonomy, influencing pediatrics in relation to the need of consent obtainment.

Up until recent times, the cultural patterns that predominated in Brazilian society (as well as in western societies in general) were much more directed towards obedience than autonomy of children. For this, it can still be tough to have the right of choice of children recognize by parents or legal guardians and health professionals. This change in the cultural parameter also seems to be reflected on the normative dimension, which establishes when the child is ready to make decisions, from an ethical and legal standpoint. Pursuant to the judicial aspect, there is a great variation in the age defined for legal competence from one country to another, which can go anywhere from 12 to 19. From the ethical viewpoint, today, all guidelines extensively discuss and offer orientation regarding this issue. This can be exemplified by the *United Nations Convention on the Rights of Child* - UNCRC - 1989, voted on by all countries, except the United States of America (USA) and Somalia, whose article 12 and 13 sets forth: *States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child. For this purpose, the child shall in particular be provided the opportunity to be heard in any judicial and administrative proceedings affecting the child, either directly, or through a representative or an appropriate body. The child shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds* [11].

This way, it is all the more important to evaluate the participation of children in consultations and decision making for health service provision. Up to a certain degree, it is consensual that children have the right to autonomy and that hospital and health services must be encouraged to participate actively in the conducts and decisions. Imeld Coyned, in a review article, concludes that the wish of the children to participate is repressed by adults. Parents and health professionals are skeptical about children participating in decision-making processes which can affect their own life significantly. Their participation in consultations and decisions still is undergoing under scientific investigation, inasmuch it is regarded a complex issue, surrounded by conflicting opinions. However, there is evidence that children do wish to participate and there are various benefits with this participation [12]. It is also necessary to understand the demands of the genitors and/or legal guardians and offer them due support for them to make decisions individually and/or regarding a child's opinion. It would be ideal for the information to be updated, consistent, and based on evidence, in a individualized manner *mutatis mutandis*, employing several reliable means of communication. As demonstrated by researches carried out in Brazil [4,6], allowing for genitors to meet with others who have been through the similar situation, to exchange experience and ideas, might come as a way to effectively promote communication and clear doubts. Finally it is indispensable to respect the level of involvement that they might want to adopt in the making decisions [13].

To conclude, even if children and adolescents have difficulty understanding and appreciating the nature of consent for a clinical research or treatment, this cannot be used as a justification as to not encourage them, for when comparison is made with studies conducted with adults, the latter (60%) also had trouble understanding the content of informed consents and were not capable of understanding the difference between treatment indicated by randomization and a personalized one [14]. The intelligence quotient (IQ), age, and maturity can influence the understanding of both children and adults alike in specific points of the informed consent document, but in this study [14] on children there was no decrease in the capacity of understanding the free choice of abandoning research, without onus to future treatments. Both parents and children received pamphlets with information before oral explanation and the hardships of understanding persisted [14]. Thus, we stress that regarding pediatric patients, there is a need to protect children. Soliciting formal consent from parents, involving children in the decision making, with respect for their autonomy, as well as sharing with parents the responsibility over their participation in researches or treatments.

The informed consent in neonatal ICU

If informed consent involving children and youngsters arouses contradictions, this same term can become so much more polemic when applied to neonates and all the more so when these neonates are incurring risk of death at ICU. The European Society of Intensive Care Medicine (Escim) makes the following recommendations for cases of researches and treatments in patients at ICU [15]: 1st) clinical research at ICU is essential for the developing quality of care to the patients; 2nd) most patients at ICU are incompetent in terms of understanding and deciding, all the more true when unconscious. Even though, as adults, some of these patients enjoy legal capacity.

The third recommendation adverts that it is anti-ethical to deny these patients, in face of their permanent or temporary incompetence, the benefits of research or treatment. In these cases, consent must be obtained from a substitute, who should be chosen from amongst their family members or friends by the doctor responsible. It also manifests against the indication of substitutes by judicial authority and considers that only medical emergencies (emergency clause) can go without obtaining consent. Such cases are listed below:

a. risk to life;
b. scarce time;
c. benefit expected for the patient:
d. minimum risks when compared to conventional therapy;

In spite of setting a benchmark for informed consent in emergency situations, the European Society exhorts that details be informed subsequently, considering that the research protocol has been approved by the committee of institutional ethics [15]. Such warning seems to derive from the fact that while in the therapeutic environment physician and patient interests are one and the same, but relative to clinical research, the interest of the investigator can compete with the intention to provide the best possible treatment to subjects individually. It is worth noting that ever since 1997 seven European countries (Austria, Denmark, Germany, Portugal, Sweden, Switzerland, and

the Netherlands) do not allow, under any circumstances, research without previous informed consent [15].

This concern over informed consent is due to the fact that studies have already identified that a significant percentage of parent who voluntarily consented their children to participate in clinical research, did not understand there was risk associated with participation. There is also evidence that the parents who agreed to letting their children participate presented more emotional and social disadvantages than those who refused participation [16]. Parents have the right to know all aspects regarding their children's treatment, in some situations with tension and fear, they are forced to make decisions that they normally would not comply with. In these cases, refusing participation in a research is a absolutely understandable reaction to a situation of stress[17]. Other evidence show that patients often overestimate the benefits, and underestimate the risks, failing to understand the procedures of research (such as the treatment randomization) and confuse research treatment with conventional treatments[18].

The perception of parents in terms of their own newborns at ICU participating in research is not negative. In a study conducted in Australia with 50 mothers and 58 fathers, 93% of genitors agreed to have their babies participating in researches and believed they would receive equal or better care in virtue of participating in a research. Only seven parents (14%) refused, considering that their babies were too small [19]. Despite these findings, another study shows that parents do not support the idea that decision making on participation in researches be removed from them and placed under doctors' authority. So, the health team must support and stimulate genitors in decision making, increase the possibility of contact with other researchers, and provide more information on research [20].

The complexity of clinical and ethical issues involving premature newborn care makes any decision on the care of the same stir up deep long-term evaluation for children and their family. When circumstances and choices are nebulous regarding continuity or interruption of neonatal treatment, the professionals must use ethics based on evidence to support their options of care [21].

Even though, much has been done in terms of reflection and informed consent practices - in relation to its necessity, the encouragement of parents, quality of approach, efficiency of written documents, alternative means to facilitate the understanding -, the processes that involve informed consent obtainment in general and especially at neonatal units, are still not fully investigated and call for deeper scientific studies [22].

Informed consent in developing countries

In the last years there has been plenty controversy concerning ethics in biomedical research financed by rich nations, but carried out in poor ones. However, few empirical researches have been conducted in field of research ethics in these countries. This caused many researchers and administrators to suggest that studies in underdeveloped countries have the same ethical review as that which is applied in rich countries. Moreover, considering the most appropriate and suitable mode of presentation for that country where the research if effectively carried out.

Besides the specific concern over research protocol and investigation methodology, especially in non-therapeutic studies, it is important to note that many ethics studies have expressed concern over the hegemonic role of developed nations in determining the high agenda for research and that the politics of 'big pharma' differs in central countries than in peripheral nations [23, 24].

A study on the perspective of underdeveloped countries' researchers in relation to the ethical review of research in the health area depicted that most investigators had good experience with ethical review, local and internationally. Almost all of the interviewees (95%) stated that American ethics guidelines ensure a high standard of ethics and two thirds agree that collaborators of underdeveloped nations draw from these documents. Also, mostly everyone (63%), believe the institutional committees of ethics in poor countries are more worried with politics than with protecting the research subject [25].

Moreover, members of a research ethics committee of an important European entity alert that in many underdeveloped States, several committees on ethics exist only to fulfill a specific resolution or legal requirement, but in practice are not adequately constituted. Therefore, it would not be ethical to be associated with research that had its way through an independent committee. As a result of this, it is advocated that the before submitting research for approval in the country where it will actually be conducted, it should first request approval from the ethical institution of its home country [26].

In another study, Appiah-poku and Newton demonstrate that in the view of underdeveloped nations' researchers the ethical topics of informed consent are the same as that of the rich countries, despite where the research is carried out. They observe, though, that the fashion of going about obtaining consent is what varies according to culture, location, and knowledge level of the population, thus, there must be adaptation and adjustment to these realities. Another important aspect also observed in the study is the need of consent from the community, which must be obtained, but not substitute the need to obtain individual consent [27].

Wali and Hyder also reinforce the importance of that fact that in some groups, initial approval and permission to carry out the study must come from the leader, considering such measure a critical step to gain trust from the community. The study also revealed the diversity of the methods currently used to present informed consent, which are often cheaper than the ones usually used in rich countries that produce research in homogeneous societies [28].

Correspondingly, the complexity of informed consent documents is a limiting factor in these countries, in that many times there is a need to change some items or even delete them altogether. They alert to the fact that we could avail ourselves of other methods of presenting the document to illiterate persons. This condition cannot be justification to abandoning consent, for being illiterate does not imply incompetence to understand the meaning of the matter [27].

Another important issue relative to the value of informed consent in underdeveloped nations is the socioeconomic vulnerability of its inhabitants. In many of these countries, gaining access to medical treatment is only possible through participation in a clinical research. Poverty, low or no education, precarious health assistance, dependent situation

and desperation for any treatment are signs of population vulnerability. Therefore, in places where the health system is poor or non-existent, the possibility of the research subject get access to treatment is an important incentive for them to participate. In such adverse circumstances, could consent be truly regarded as voluntary? [29,30] All of this converges with the important concept of the *Helsinki Declaration* which affirms that informed consent must be genuine and given freely.

Final Considerations

Informed consent is fundamental to autonomy fulfillment of the research subject or for the individual that receives treatment. If we can guarantee that its obtainment in research was already a routine practice, the same cannot be said in the therapeutic field, especially in underdeveloped countries in which there is no health system - most of them.

However, the simple obtainment of informed consent does mean to say that acceptance was consented out of free will, autonomously, voluntarily, openly and that the research/treatment subject really understands all the risks and benefits of action.

Multiple factors (stress level of the patient, education, economic vulnerability, incipient health services) can represent limitations to the perfect fulfillment of informed consent. These limitations become more complex when the target of the actions presents incapacity to enjoy such right, as is the case of small children and newborns, and when its legal representative has a vulnerable socioeconomic condition. In respect, a last reflection must be brought up: if evidence demonstrates that the fulfillment of autonomy is better practiced by individuals with higher level of education, good economic status, access to the internet, then why do we seek underdeveloped countries to carry out researches on human beings?

Study conducted within the doctorate program in Bioethics at FMUP/CFM

Resumo

Consentimento e proteção de adultos e crianças: dilemas comuns e peculiares em países em desenvolvimento

O presente trabalho faz revisão dos artigos recentemente publicados em revistas médicas de circulação nacional e internacional sobre o tema do consentimento informado. Apresenta, em sua introdução, os aspectos históricos e a dimensão global das questões jurídicas e legais, discorrendo sobre a importância ética do assunto. A seguir, pontua algumas das peculiaridades da prática do uso do consentimento informado na pediatria, arguindo sobre a necessidade do respeito à autonomia da criança e do adolescente. Desenvolve uma linha de análise bioética desta prática em unidades de terapia intensiva neonatal em países em desenvolvimento, nas quais além da vulnerabilidade dos pacientes, na maioria bebês prematuros, somam-se outros aspectos técnicos, culturais, religiosos, educacionais, econômicos, sociais etc. Conclui ressaltando a complexidade deste procedimento e alerta que apenas seu uso não garante efetivamente o respeito e a proteção dos pacientes, quer envolvidos ou não em protocolos de pesquisas.

Palavras-chave: Bioética. Consentimento informado. Terapia intensiva neonatal.

Resumen

Consentimiento y protección de adultos y niños: dilemas comunes y peculiares en países en desarrollo
El autor hace una revisión narrativa de artículos recientes publicados en revistas médicas de circulación nacional e internacional sobre el tema del consentimiento informado. Presenta una introducción sobre algunos aspectos históricos, dimensión global de las cuestiones jurídicas y legales, y la importancia ética del tema. Destaca algunas de las peculiaridades de la práctica del uso del consentimiento informado en pediatría argumentando sobre la necesidad del respeto a la autonomía de niños y adolescentes. Desarrolla una línea de análisis bioético de esta práctica en unidades de terapia intensiva neonatales en países en desarrollo, donde además de la vulnerabilidad de los pacientes, en su mayoría bebes prematuros, se suman varios aspectos de tipo técnico, cultural, religioso, educacional, económico, social y otros. El autor concluye destacando la complejidad de este procedimiento y alerta que solamente su uso no garantiza efectivamente el respeto y la protección de los pacientes, estén o no incorporados a protocolos de pesquisa.

Palabras-clave: Bioética. Consentimiento informado. Terapia intensive neonatal.

References

1. Brenes V, Mesa A, Ortiz O. El derecho al consentimiento informado: un ejercicio en construcción. Leyes, casos y procedimientos de queja en los servicios de planificación familiar en México. New York: Population Council; 1998. p. 56.
2. Bhutta ZA. Beyond informed consent. Bull World Health Organ 2004 Oct,82(10):771-7.
3. Silva CMP, Oliveira F, Muccioli C. O processo de consentimento na pesquisa clínica: da elaboração à obtenção. Arq Bras Oftalmol 2005;68(5):704-7.
4. Bento SF, Hardy E, Osis MJ. Process for obtaining informed consent: women's opinions. Dev World Bioeth 2008;8(3):197-206.
5. L Bodansky. As classes sociais e o corpo. Rio de Janeiro: Edições Graal; 1979. (Biblioteca de Saúde e Sociedade). Apud Bento SF, Hardy E, Osis MJ. Op. cit.
6. Goldim JR, Pithan CF, Oliveira JG, Raymundo MM. O processo de consentimento livre e esclarecido em pesquisa: uma nova abordagem. Rev Assoc Méd Bras 2003;49(4):372-4.
7. Bionde-Simões MLP, Ueda FMK, Olandoski M. Compreensão do termo de consentimento informado. Rev Col Bras Cir 2007;34(3):183-8.
8. Lorenzo CFG. O consentimento livre e esclarecido e a realidade do analfabetismo funcional no Brasil: uma abordagem para a norma e para além da norma. Rev Bioét 2007;15(2):268-82.
9. Pieper P. Ethical perspectives of children's assent for research participation: deontology and utilitarianism. Pediatr Nurs 2008;34(4):319-23.
10. Kitching D. The empowerment of children: who decides? Accid Emerg Nurs 1998;6(1):11-4.
11. Alderson P. Competent children? Minors' consent to health care treatment and research. Soc Sci Med 2007;65(11):2272-83.
12. Coyne I. Children's participation on consultations and decision-making at health service level: a review of the literature. Int J Nurs Stud 2008;45(11):1682-9.
13. Jackson C, Cheater F M, Reid I. A systematic review of decision support needs of parents making child health decisions. Health Expect 2008;11(3):232-51.

14. Koelch M, Singer H, Prestel A, Burkert J, Schulze U, Fegert JM. "...because I am something special" or "I think I will be something like a guinea pig": information and assent of legal minors' in clinical trials-assessment of understanding, appreciation and reasoning. Child Adolesc Psychiat Ment Health 2009;3(2):1-26.
15. Lemaire L, Blanch L, Cohen S L, Sprung C. Informed consent for research purposes in intensive care patients in Europe - part II: an official statement of the European Society of Intensive Care Medicine. Intensive Care Med 1997;23(3):435-9.
16. Singhal N, Oberle K, Burgess E, Huber-Okrainec J. Parents perceptions of research with newborns. J Perinatol 2002;22(1):57-63.
17. Modi N. Informed consent difficult in paediatric intensive care [letter]. BMJ 1993;307(12):1495.
18. Schweickert W, Hall J. Informed consent in the intensive care unit: ensuring understanding in a complex environment. Curr Opin Crit Care 2005;11(6):624-8.
19. Morley C J, Lau R, Davis P G, Morse C. What do parents think about enrolling their premature babies in several research studies? Arch Dis Child Fetal Neonatal Ed 2005;90(3):225-8.
20. Burgess E, Singhal N, Amin H, Macmillan DD, Devrome H. Consent for clinical research in the neonatal intensive care unit: a retrospective survey and a prospective study. Arch Dis Child Fetal Neonatal 2005;88(4):280-6.
21. Purdy IB, Wadhwani RT. Embracing bioethics in neonatal intensive care, part II: case histories in neonatal ethics. Neonatal Netw 2006;25(1):43-53.
22. Chenaud C, Merlani P, Luyasu S, Ricou B. Informed consent for research obtained during the intensive care unit stay. Crit Care [internet] 2006 [cited 20 Dec 2009];10(6). Available: http://ccforum.com/content/10/6/R170.
23. Wilmhurst P. Scientific imperialism. BMJ 1997;314(7084):840-1.
24. Tapajós AM. Sistemas hegemônicos e pesquisa no terceiro mundo. Rev Bioét 2007;15(2):238-47
25. Hyder AA, Wali SA, Khan AN, Teoh NB, Kass NE, Dawson L. Ethical review of heath research: a perspective from developing country researches. J Med Ethics 2004;80(1):68-72.
26.Squire SB, Gray N, Hawley R, Hayward C, Ali A, Macfarlane S et al. Informed consent: british institutions collaborating in projects overseas may face dilemma [letter]. BMJ 1997;315(7102):248.
27. Newton SK, Appiah-poku J. The perspectives of researches on obtaining informed consent in developing countries. Dev World Bioeth 2007;7(1):19-24.
28. Hyder AA, Wali SA. Informed consent and collaborative research: perspective from developing world. Dev World Bioeth 2006;6(1):33-40.
29. Verástegui EL. Consenting of the vulnerable: the informed consent procedure in advanced cancer patients in Mexico. BMC Medical Ethics [internet] 2006 [cited 20 Dec 2009];7:13. Available: http://www.biomedcentral.com/1472-6939/7/13
30. D'Alessandro V, Boelart M. The 5th Amendment of the Declaration of Helsinki: implications for medical research in developing countries**.** Tropical Medicine and International Health 2001; 6(4):245-7.

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