Residência Pediátrica
Publicação Oficial da Sociedade Brasileira de Pediatria

REVIEW ARTICLE

Ethics research among children and adolescents

Rosana Alves[1]

Keywords:
Ethics,
Research,
Child

Abstract

This review aims to present brief history of ethics research evolution with the participation of children, with further discussion on the Brazilian legislation that deals of the subject. Points out weaknesses in the performance of professional health , resulting to poor training in the humanities and points needs to better understanding of research in children and adolescents.

[1] Assistant Professor of Pediatrics of the Federal University of Espírito Santo. Doctor in Clinical Research from the Federal University of Rio de Janeiro and Post-doctorate in Health Education from the State University of Campinas. President of the Bioethics Department of the Brazilian Society of Pediatrics.

Correspondence to:
Rosana Alves.
Universidade Federal do Espírito Santo. Centro de Ciências da Saúde. Av. Marechal Campos, 1468, Maruípe, Vitória - ES, Brasil. CEP 29.043-900
E-mail: rosana.medufes@gmail.com

Residência Pediátrica 2016;6(suppl 1):55-58.

"We cannot accept ourselves as subjects of search, decision, rupture, choice, as historical subjects, transformers, unless we accept ourselves as ethical subjects"

Paulo Freire

Pedagogy of Autonomy, 1996

This review proposes to present a brief history of the evolution of ethics in research involving children, and a later discussion on the Brazilian legislation on this subject. The shortcomings in the practice of health professionals, as a result of deficient professional training in the human sciences, and the requirements to better understand research involving children and adolescents are presented.

I. HISTORICAL BACKGROUND

1767 – First outlines of consent and information between patients and orthopedists.

1830 – First publication on legislation and professional practice of medicine.

1833 – First set of guidelines for research involving human beings, organized by Beaumont.

Until the 19th century there was total freedom in research, and the respect for the dignity of children as persons was not acknowledged. There are several reports of tests and experiments involving children, mostly with vaccines[1].

The book "Memoirs of a Physician," published in 1901 and written by the Russian physician Veresaev, described numerous experiments that were abusive to children, whom he called "martyrs of science"[2].

1874 – Creation of the Society for the Prevention of Cruelty to Children of New York, inspired on the American Society for the Prevention of Cruelty to Animals, of 1866.

1947 – Declaration of Nuremberg, with its 10 principles. Its first article established the essential requirement for the conduction of experiments on human beings: voluntary consent. Children and adolescents were excluded as a result of their legal incapacity.

1964 – Declaration of Helsinki, a document promulgated by the World Medical Association (WMA). It introduces the possibility of children participating in research, provided that there is consent from the legal guardians. Research with children proves beneficial, because it creates new knowledge and treatments that are more adequate to children, thus reducing their discomfort[1].

The Declaration is considered a "living document" because, after its promulgation in 1964, its principles have been updated (1975, 1983, 1989, 1996, 2000, and 2008), there have been two notes of clarification (2002, 2004), and finally the most recent review process (2013) in the WMA General Assembly that took place in Brazil.

1978 – The Belmont Report, which established, for the first time, the systematic use of principles (respect for persons, beneficence, and justice) in the approach to bioethical dilemmas.

1988 – Brazilian Code of Medical Ethics (Resolution 1246/88 of the Brazilian Federal Council of Medicine, published in the Brazilian government's Official Gazette on January 26, 1988). The Brazilian National Health Council approved norms for research in health (Resolution no 1/1988 of the National Health Council and Ministry of Health)[3,4]

1996 – The National Health Council divulges the new Brazilian Regulation for Ethics in Research Involving Human Beings (Resolution 196/96)[5]. In a comprehensive and practical text, the Resolution establishes the Research Ethics Committees (CEP) by defining their composition, mandates, attributions and, most importantly, multidisciplinary. It creates the National Research Ethics Committee (CONEP) and the CEP-CONEP system.

"All research involving human beings must be submitted to the approval of a Research Ethics Committee, and it the responsibility of the institution where the research is conducted to establish the CEP."

2000 - Declaration of Monaco. International Symposium on Bioethics and the Rights of the Child, organized by the World Association of Children's Friends (AMADE) and UNESCO. It was organized with the aim of promoting the respect for the dignity and the protection of the rights of the child with regard to the origin, family relationships, and the body of the child. One of the main propositions refers to the promotion particularly of research on rare diseases and the development of effective therapies[6].

2004 - Universal Declaration on Bioethics and Human Rights[7].

2012 - 2013 – Review of the guidelines and regulatory norms for research involving human beings (Resolution 466 of 12/12/2012, CNS, MS)[8].

II. BRAZILIAN AND INTERNATIONAL LEGISLATION ON RESEARCH IN HEALTH, SOCIAL AND HUMAN SCIENCES

Resolution 466/2012 of the Brazilian National Health Council and the Ministry of Health governs research involving human beings in Brazil through the CEP-CONEP system, which aims to protect participants in research conducted in Brazil in a coordinated and decentralized manner via an accreditation process[8].

The role and objectives of the CEPs are described in the Resolution in section VII.2 – "The CEPs are interdisciplinary and independent bodies of public relevance, and of an advisory, deliberative, and educational nature, which were created to defend the interests of those participating in research, namely their integrity and dignity, and to contribute to the development of research within ethical standards."[8]

In the last survey of this system, conducted in November 2015, there were 739 approved CEPs and 12 in the process of approval by the CONEP[9].

The definition of which projects should be submitted to a CEP is stated in section II.14 - research involving human beings – a research in which a human being participates, individually or collectively, either as a whole or a part thereof, and involves the person directly or indirectly, including the management of his/her data, information, or biological materials[8].

It also involves interviews, questionnaires, the use of databanks, and reviews of medical records. The CEP should reinforce its educational role among health professionals, especially with regard to understanding what ethics in research is.

Kipper[10] draws the attention to the exclusion of children from research, as a result of their lack of autonomy to give consent, after the Code of Nuremberg, which is a historical milestone for research ethics. This measure was extremely important to reduce the atrocities on children and adolescents committed in the name of science. However, many years of what Kipper[10] calls "therapeutic orphans" led to a delay in the development of diagnoses and therapies for several illnesses that either are specific to this age group or have specificities when occurring in it. Since then, the balance between beneficence and non-maleficence has been the objective.

Families seek medical assistance to get attention and care, and they are not aware that the patient can be recruited for research at any moment. Thus, they need to understand what the research entails, namely if the research will be beneficial to the patient or, at least, non-harmful. This understanding goes beyond signing a free and informed consent form. Special attention should be given to case-control studies in which the individuals participate in as controls and undergo procedures for research purposes only and not for their own good.

Guideline number 5 of the International Guidelines of the Council for International Organizations of Medical Sciences (CIOMS), of 1993, is totally dedicated to research involving children and adolescents[2]:

- Children must not be involved in research that could be equally conducted with adults instead;
- The purpose of the research must be to generate knowledge that is relevant to the health of children;
- Parents or legal representatives must give consent by proxy;
- The consent of each child must be obtained to the extent of their capacity. Nowadays, according to Resolution 466/2012 of the Brazilian National Health Council and the Ministry of Health, the consent should be called "Free and Informed Consent;"
- The child's refusal to participate in the research must always be respected, unless, according to the research protocol, there is no medically acceptable alternative to the treatment that has been proposed for the child;
- The risk presented by interventions that do not individually benefit the child involved in the research must be low and proportional to the importance of the knowledge to be gained. The term "child subject of research" is currently "child invited to participate in research;"
- Interventions that yield therapeutic benefits must be at least as advantageous for the child invited to participate in the research as any other available alternative.

Article 12 of the Rights of the Hospitalized Child and Adolescent in Brazil establishes the right not to be a subject of a clinical trial, diagnostic or therapeutic test without the informed consent of parents or guardians and their own, when they are capable of judgment. This document was established by Resolution 41/1995, by the National Council for the Rights of the Child and Adolescent (CONANDA) of the Ministry of Justice, in which a text from the Brazilian Society of Pediatrics relative to the Rights of the Hospitalized Child and Adolescent was fully approved[11].

Because researchers are ethical human beings who act in different areas of scientific knowledge and search for evidence in different ways, one can see how difficult it is to evaluate research studies involving children, in which the analysis of social control should consider all the specificities. Research involving children and adolescents must consider not only their vulnerability, but also their capacity to understand the research, to the extent that when there is conflict of interest, the child's interest should, in principle, prevail over that of the adult[6].

In all research whose approach requires contact with the child, the researcher should have knowledge in quantitative research, and in aspects of qualitative research and of human sciences. Quantitative research that deals with secondary data, e.g., laboratory results, would be an exception.

Another approach to research involving children and adolescents, which biomedical researchers are sometimes not aware of, addresses relationships and perceptions. In this case it is fundamental to observe and listen. In this type of research the narrative, i.e., understanding the story is important. Observing and listening are crucial if one is to understand gestures, discourse, and actions[12].

It had been expected that the CEP-CONEP system would lead the process of evaluation of this type of research to be more valued and even to grow significantly, but Resolution 466/2012 only foresaw the proposal of a complementary resolution to address the specificities of research in these areas:

"XIII.3 – The ethical specificities of research in social and human sciences, as well as other sciences that use methodologies specific to those areas, will be dealt with in a complementary resolution, given their particularities."[8]

Thus, in 2013 a working group was set up to prepare the resolution. This group included representatives of research associations and societies in various areas of knowledge, particularly in human and social areas.

Because of the need to address the specificities of non-biomedical research, the CONEP carried out a public consultation

so that society as a whole could contribute to reduce the controversy associated with the approval of research studies in the areas of human and social sciences within the CEP-CONEP system[13].

III. SHORTCOMINGS AND REQUIREMENTS

a) Training in ethics and bioethics in health.

Medical training, which deals with complex ethical problems that depend on the sociocultural context, needs to focus its curricula on training professionals who are more committed to the respect for others, tolerant towards difference, and capable of making decisions involving critical thinking[14].

Understanding consent and refusal. This principle should be reinforced, especially with regard to tests and/or sample collection in children, which should only be performed in the interest of the child's health, when there is no other alternative to protect it[6].

b) The child's image

The child's face, photos and videos of the child. Authors are instructed not to divulge the face of a child and, if necessary, to insert a black stripe over the eyes to protect his/her identity. In this case the image shows a lesion, a clinical sign. But the image can be treated a method of qualitative research. Recording a child's activities in his/her environment (in nurseries, during playtime, in orphanages, being victims of abuse and violence) is considered a past event when seen through the eyes of the present, because it is influenced by the observer, the person who observes the photo. It is the same research object seen from different angles.

As the presentation and interpretation of the child's photo used for research purposes becomes a problem, even when there is a written authorization from those responsible for its use, there is an increasing need to determine authorization and diffusion criteria, especially in social and human sciences[16].

"Images speak and, even when their diffusion has been authorized, they say things that sound different from what was said, to the ears of the person who said them."[15]

c) Research as a benefit to the invited child and to society

A research study does not have to produce immediate returns, because its results may be indirect returns for other researchers and groups. However, research has a commitment with society, and the latter should get the returns from it. This is how the CEPs should evaluate research projects.

"*Avoid past errors in research to be repeated*"[16]
(Guilherme Diniz)

REFERENCES

1. Kipper DJ, Goldim JR. A pesquisa em crianças e adolescentes. Pediatr (Rio J). 1999;75(4):211-2.
2. CIOMS. International ethical guidelines for biomedical research involving humans subjects. Geneva: WHO; 1993.
3. Conselho Federal de Medicina. Código de Ética Médica. Resolução nº 1.246/88. Diário Oficial da União, 26 jan 1988; Seção I.
4. Conselho Nacional de Saúde. Ministério da Saúde (Brasil). Resolução nº 1, de 1988. Normas de pesquisa em saúde. Diário Oficial da União 14 jun 1988. (págs. 10.713 a 10.718)
5. Conselho Nacional de Saúde. Ministério da Saúde (Brasil). Resolução nº 196, de 10 de outubro de 1996. Diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Encontrar em qual Diário Oficial foi publicado
6. Declaração de Mônaco. 2000. Considerações sobre a Bioética e os Direitos da Criança. Disponível em http://fmj.br/Pdfs/bioetica.pdf. Acesso em 01/06/2016.
7. Organização das Nações Unidas para a Educação, Ciência e Cultura. Divisão de Ética das Ciências e Tecnologias. Sector de Ciências Sociais e Humanas. Paris: UNESCO, 2006.
8. Conselho Nacional de Saúde. Ministério da Saúde (Brasil). Resolução nº 466, de 12 de dezembro de 2012. Diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos.
9. Conselho Nacional de Saúde. Ministério da Saúde (Brasil). CEP por Macrorregiões. 2015. Disponível em: http://www.conselho.saude.gov.br/Web_comissoes/conep/aquivos/MAPA_CEP_ATUALIZADO_2015_nov.pdf. Acesso em 01 jun. 2016.
10. Kipper DJ. Ética em pesquisa com crianças e adolescentes: à procura de normas e diretrizes virtuosas. Rev. Bioét. 2016;24(1):37-48.
11. Conselho Nacional dos Direitos da Criança e do Adolescente. Ministério da Justiça (Brasil). Resolução nº 41, de 13 de outubro de 1995. Aprova em sua íntegra o texto oriundo da Sociedade Brasileira de Pediatria, relativo aos Direitos da Criança e do Adolescente hospitalizados. Diário Oficial da União, 17 out 1995; Seção I.
12. Silva JP, Barbosa SNF, Kramer S. Questões teórico-metodológicas da pesquisa com crianças. Perspec. 2005; 23(01):41-64.
13. Barbosa AS, Corrales CM, Silbermann M. Controvérsias sobre a revisão ética de pesquisas em ciências humanas e sociais pelo Sistema CEP/CONEP. Rev. bioét. (Impr.). 2014;22(3):482-92.
14. Rego S. A formação ética dos médicos: saindo da adolescência com a vida (dos outros nas mãos). Rio de Janeiro: Fiocruz, 2003.
15. Kramer S. Autoria e autorização: questões éticas na pesquisa com crianças. Cadernos de Pesquisa. 2002; 116:41-59.
16. Guilhem D, Diniz D. O que é Ética em Pesquisa. Coleção Primeiros Passos. São Paulo: Brasiliense; 2008.