

# Ethical Aspects in Research with Adolescents

Ana Laura Carneiro Gomes Ferreira <sup>1</sup>, Ariani Impieri de Souza <sup>2</sup>

## Abstract

### Ethical issues in research with adolescents

This article reports an experience related to the need for parents or guardians' consent to include adolescents in research involving contraception and abortion. Ethically, a teenager can receive contraceptive advice without mandatory permission from their parents or guardians. Thus, they could answer, in principle, confidential health questions as a research subject. The reported experience aims to contribute to better understanding of the problems involved with research in this age group, contributing to the discussion on methodological issues and problematization of ethical regulation related to studies with adolescents.

**Key words:** Abortion. Contraception. Adolescent. Ethic. Informed consent.

## Resumo

Este artigo relata experiência relativa a necessidade da anuência dos pais ou responsáveis na inclusão de adolescentes em pesquisas envolvendo contracepção e abortamento. Eticamente, uma adolescente pode receber orientação contraceptiva sem a obrigatoriedade da autorização dos pais ou responsáveis. Poderia também, em princípio, responder questões confidenciais sobre a sua saúde como participante de uma pesquisa. A experiência relatada visa proporcionar melhor compreensão dos problemas envolvidos nas pesquisas nessa faixa etária, contribuindo para a discussão acerca das questões metodológicas e da problematização sobre regulamentação ética dos estudos realizados com adolescentes.

**Palavras-chave:** Abortamento. Contracepção. Adolescente. Ética. Consentimento livre e esclarecido.

## Resumen

### Cuestiones éticas en la investigación con los adolescentes

Este artículo informa sobre la experiencia de la necesidad de consentimiento de los padres o tutores en la inclusión de los adolescentes en la investigación sobre anticoncepción y el aborto. Éticamente una adolescente puede recibir asesoramiento sobre métodos anticonceptivos sin el requisito de autorización de los padres o tutores. También podría, en principio, responder a las preguntas confidenciales sobre su salud como un tema de investigación. La experiencia reportada tiene como objetivo proporcionar una mejor comprensión de las cuestiones implicadas en la investigación en este grupo de edad, lo cual contribuye a la discusión de cuestiones metodológicas y de los problemas sobre reglamentación ética de los estudios realizados con adolescentes.

**Palabras-clave:** El aborto. La anticoncepción. Adolescente. Ética. Consentimiento informado.

**1. Doctor** analaura@imip.org.br **2. Doctor** ariani@imip.org.br - Instituto de Medicina Integral Prof. Fernando Figueira (Imip), Recife/PE, Brazil

### Contact address

Ana Laura Carneiro Gomes Ferreira - Rua dos Coelhoos, 300 Boa Vista CEP 50070-550. Recife/PE, Brazil.

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Frequently, during the research planning in the field of health, researchers face *ethical dilemmas*. Of these, the most notable refers to the principle of autonomy or respect for people, which presupposes that no one can fully exert the right of decision/consent for other than the individual act is inalienable. Said principle is constituted in the capability that people have for making their own decisions relative to their choices and actions. In research with human beings, it becomes necessary to guarantee the preservation of the information's confidentiality, explicit in the term of informed consent (TCLE) <sup>1,2</sup>.

Adolescents, like children, require the parent or guardian's permission and signature on the TCLE. However, it is imperative to consider that, in some situations, teenagers themselves would have the autonomy to give their own signature should they wish to be research subjects or not, as long as they can understand its objectives and rules. To secure the absence of any harm to the adolescent, the researcher should evaluate the participant's level of cognitive development and their adequate comprehension, and guarantee their privacy <sup>1</sup>.

The privacy in question involves the *contract* between the adolescent, the family and the doctor, stressing that this proposal is not intended to distance the family or dilute their responsibility, stimulating constant dialogue between teenagers and their guardians, even in private life. Situations of exemption should be considered, such as relevant intellectual *deficit*, lack of judgment (psychiatric disorders and addiction) and the adolescent's wish to be accompanied by their parents <sup>3</sup>.

These aspects were recently experienced in an intervention study of the post-abortion period, with the objective of comparing the acceptance and use of contraceptive methods between the intervention group and the control group, during the first six months post-abortion, by means of questionnaire applied upon admission into the research and after a sixth month monitoring period. The intervention is evident in the providing of a contraceptive method with personalized and individualized counseling<sup>4</sup>. The *counseling in family planning* component, one of the three elements in post-abortion care

(acronym in Portuguese - APA), has been recognized as an educational strategy of impact in reducing the number of undesired pregnancies <sup>5</sup>.

Therefore, the research would offer a favorable cost-benefit relation, permitting the free and autonomous use of sexuality. The participants would be monitored while using the contraceptive methods of their choice, precluded by education and information on the risks and benefits of each method. As such, they themselves could be benefited by their participation in the research.

In this study all women at a fertile age (10 to 49 years of age) were included who underwent a abortion procedure in the city of Recife and were monitored during the post-abortion period at the Women's Ward at the *Instituto de Medicina Integral Prof. Fernando Figueira* (Imip), between July 2008 to September 2009 <sup>4</sup>. Therefore, a portion of this population would be adolescents (10 to 19 years of age). It was exactly at this stage that the ethical dilemma surfaced: how to include the adolescents in the research? According to Decree 196/96 of the National Health Council (CNS), minors under 18 years old may only be included in studies with their parents or guardians' permission <sup>6</sup>. On another note, teenagers under 18 years old have the right to be treated and receive contraceptive advice without the knowledge of their parents <sup>7</sup>. This confidentiality and privacy are ensured by both the *Medical Code of Ethics* and by the *Statutes of the Child and the Adolescent* (ECA) <sup>8,9</sup>.

The respect for these precepts of privacy, autonomy, secrecy and confidentiality relative to sexuality and reproduction was legitimized by the International Conference on Population and Development, held in 1994, in Cairo <sup>10</sup>. The Conference's Action Program reaffirmed the sexual and reproductive rights of adolescents, assured by the 179 signatory countries - including Brazil - with the aim of reducing the rate of unwanted pregnancies in this age group.

## Description

Still in the phase of project design and actions planning, reflection was made on the importance

of including adolescents in the study without the mandatory authorization of their parents or guardians. It was contemplated that the exclusion of adolescents who did not wish to reveal their post-abortive condition to their parents could alienate them from the opportunity of receiving contraceptive advice <sup>11</sup>, one of the actions provided for in the research.

Furthermore, it was considered that when this study was applied, post-discharge, these adolescents would no longer be in a life-threatening risk and their inclusion in the study without the consent of their parents, contrary to posing a risk, would provide an additional benefit at an opportune moment in their reproductive lives. In view that the target-population were women in the post-abortion period, the proposed intervention would represent an action for the promotion and protection of health, which would work to their benefit. Moreover, in the post-abortion period women would be more motivated to use contraceptive methods <sup>5</sup>.

Initially, the research project had been approved by the research ethics committee (CEP) with the requirement of approval from the parents or guardians, as established in Decree CNS 196/96 <sup>6</sup>. After a request to CEP for the teenager themselves to sign the TCLE without the mandatory signature of parents or guardians, the case was sent to the Judicial Power in the capital - 1<sup>st</sup> Court of Childhood and Youth. The statement was that researchers should begin with the request for a *charter for its own actions endorsed by a lawyer*.

Considering that the proceeding suggested by the Judicial Power could delay the period of data collection, a request was made for CEP to refer our application to the National Research Ethics Commission (Conep). To better support the request to include adolescents exempt from their parents or guardians' consent, some documents were annexed and, among these, the concern of the Brazilian Pediatric Society (SBP) on the issue <sup>3</sup>.

The *2002 Contraception, Adolescence and Ethics Forum* promoted by the SBP in the city of Sao Paulo, which included the participation of representatives of health professionals and the courts, as well as professionals connected to the bioethics committees and representatives of the Ministry of

Health, reported that: *contraception in adolescence represents, even today, controversial aspects that continue to merit deeper discussions with the aim of establishing basic principles that guide its use by professionals in the field of health*<sup>3</sup>.

The adolescent has the right to information about contraception, to confidentiality and secrecy about their sexual activity and to the prescription of contraceptive methods as long as they have the capacity for evaluating their problem and for steering themselves toward a solution by their own means, except when nondisclosure may entail injuries to them, as established in article 74 of the Medical Code of Ethics (CEM) <sup>8</sup>. It should be highlighted that *confidentiality* is not a principle based on the *hidden*, but upon the intent of recognizing the individual as a protagonist of his or her own actions supported by responsible choices <sup>1</sup>.

As such, it is understood that the adolescent that freely accepts the receiving of contraceptive information after an abortion episode could also, in principle, be capable of answering confidential questions about their health and sexuality as a research subject<sup>11</sup>. Two other documents were added with the purpose of supporting the request for forwarding the case to Conep:

1. Document from the Ministry of Health entitled *Legal Framework*, based on a 1999 document from the United Nations Organization (UN) which conducted a process of revision and evaluation on the implementation of the APA program (Cairo +5), relative to the rights of the adolescents to privacy and secrecy, including the right to sign their own informed consent<sup>10</sup>;

2. An article published in the magazine *Revista Brasileira em Promoção da Saúde* about the substances used for abortion, with adolescents and youth from 13 to 21 years of age, in which it is explicit that the adolescents themselves signed the TCLE and that the project was approved by the CEP of the University of Fortaleza without alterations<sup>12</sup>.

In October of 2008, Conep, by means of a letter, understood that the *project deserves approval, permitting the participation of adolescents in research upon their signing of the TCLE regardless of their parents or guardians'*

*signature, as long as the adolescent so wishes and as long as they have, no matter their youth, the capacity for understanding.* The time expended from the first request to the local CEP until the final statement by Conep tallied roughly two and a half years. Many studies might not have enough time at their disposal to await all the legal proceedings, forsaking the participation of adolescents

### Final considerations

The succinct presentation of the process undertaken for the approval of this research project intends to stimulate the debate about ethical dilemmas that involve studies with adolescents. Particularly, in this case, those involving equally

conflicting situations and issues, such as abortion.

It is hoped that the description made here may offer support to professionals who intend to develop research with adolescents while respecting their autonomy. Furthermore, it is thought that the report contributes to an increase in the inclusion of adolescents in research, providing a better comprehension of the problems in which they are involved.

Lastly, it is hoped that the difficulties faced by the researchers who endeavored this study, as well as by others who work with adolescents, may serve as an incentive for the betterment of the CEP/Conep System, in favor of the credibility, trustworthiness and security of research conducted in our country.

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### Authors' participation in the article

- Ana Laura Ferreira and Ariani Souza jointly wrote the article in all of its stages.

