Ciência & Saúde Coletiva
ISSN: 1413-8123
cecilia@claves.fiocruz.br
Associação Brasileira de Pós-Graduação em Saúde Coletiva
Brasil

Villas Bôas Concone, Maria Helena; De Oliveira Cerveny, Ceneide Maria
Research and the (free and) informed consent
Ciência & Saúde Coletiva, vol. 13, núm. 2, marzo-abril, 2008, pp. 341-349
Associação Brasileira de Pós-Graduação em Saúde Coletiva
Rio de Janeiro, Brasil

Research and the (free and) informed consent

A pesquisa e o termo de consentimento livre e esclarecido

Maria Helena Villas Bôas Concone [1]
Ceneide Maria De Oliveira Cerveny [2]

Abstract *The aim of this article was to reflect about the Free and Informed Consent (IC) in qualitative researches in the health field. Coming from the experience of being part of a CER (Committee for Ethic in Research) in the health area the authoresses place in debate some important questions, exploring them and conducting suggestions. One of these questions and topic of analysis is the meaning of IC, as for the participant as for the researcher.*

Key words *IC (Informed Consent), Qualitative research in health area*

Resumo *Este artigo teve como objetivo refletir sobre o Termo de Consentimento Livre e Esclarecido (TCLE) em pesquisas qualitativas no campo da saúde. Partindo da sua experiência de pertencimento a um CEP (Comitê de Ética em Pesquisa), na área da saúde, as autoras colocam em discussão algumas questões importantes, problematizando-as e encaminhando sugestões. Uma dessas questões e objeto da reflexão é o significado do TCLE, tanto para o participante como para o pesquisador.*

Palavras-chave *TCLE (Termo de Consentimento Livre e Esclarecido), Pesquisa qualitativa em saúde*

[1] Department of Anthropology, Pontifícia Universidade Católica de São Paulo. Rua Monte Alegre 984, Perdizes. 05014-901 São Paulo SP. trcconcone@yahoo.com.br
[2] Department of Psychology, Pontifícia Universidade Católica de São Paulo.

The central point in our reflections is the question of the "Free and Informed Consent" (IC) linked to so-called "qualitative" research in the area of health. At first glance, the theme does not pose any difficulty and could seem almost irrelevant: there are exigencies in terms of keeping the Term of Consent. There are some points, which these exigencies can be seen. What we can discuss? Some questions about that: What are they? How are they met by researchers? How are they solved in practice?

When taking a close look at it, however, the IC poses a number of questions and presents linkage with other themes for debate in many directions. Therefore, our first difficulty was to select a path and favor some topics for discussion.

We will begin with some questions: Why the Free and Informed Consent? What does IC mean for the researcher? What is its meaning for the participant?

Our discussion will seek to answer and challenge these questions, as well as to provide some follow-up suggestions.

Starting from the questions

Why the IC?

It is not necessary to remind that the Free and Informed Consent is a requirement of Resolution 196/96, and that it concretely translates the ethical concerns and cares that the mentioned Resolution incorporates: any investigative work that involves the participation of people must respect the autonomy of participants (respect to people), respect the principle of beneficence, and respect the principle of justice.

In other words, the Resolution 196/96 understands that the guarantee of participants' autonomy requires that each one receive complete and honest information so as to take a conscious decision to take part or not in a given research. In order for the decision to actually be conscious, the expected benefits, as well as the injuries for participants must be clearly posed and, unmistakably, it is expected that the benefits rise above the eventual damages. Autonomy also implies in that each participant's adhesion is voluntary: it would be against ethics, if participants' adhesion were coerced or induced in any way. Finally, the principle of justice assumes that benefits and injuries (or risks) are equally shared in a social context: it would definitively be against ethics to use participants (even if voluntary ones) from a group, a segment, social class or nationality that actually is not (as a group, segment, social class or nationality) in condition to benefit from the new knowledge brought by the research. In other words, taking, for example, the health services end-users as preferential subjects in a piece of research for the development of new techniques, drugs, or knowledge if these will, later on, be left our of their reach due to the costs involved, which let us at a ethic conflict that cannot be discuss. In these cases, we have an actual conflict between participants and virtual beneficiaries, individuals and collectivity. As participant, the individual can have their rights guaranteed (including in terms of access to the innovative practices during the research), however, this might not happen for the members of their groups (segment, social class, etc.) of origin. There is radical distinction between individual rights, collective rights and the rights of consumers.

No IC, no matter how complete it is, can fully account for all these conflicts. These are issues that deal with the researcher's ethics, to their critical view and to the critical ability developed by participants.

We cannot deny, however, that despite limits and distortions, there is an ethical concern, today, in the field of research, and one of the aspects for this concern is precisely the IC.

What does IC mean for the researcher?

- Protection (or self-protection) against possible risks?
- Formality of requirement from the CEPs (Committee for Ethics in Research)?
- An ethical attitude within research?
- Respect to individual participant?

Undoubtedly, sometimes, the IC seems to be a greater guarantee for the researcher, and the fulfillment of some formality than actually as ethical concerns. The task that the Ethical Committees have in their hands is to examine a project, checking for the existence and the formulation of IC: To what extent has the researcher responded to the requirements posed by Resolution 196/96 in the writing up of a specific text – within the context of a specific project – addressed to specific participants? The Committees seek to guarantee careful analysis of each project, multiplying it by the analysis perspectives, thanks to its multi-professional composition. However, the Committees can only indirectly evaluate the meaning of the Term of Consent for the researcher, by assessing the transparency and completeness, as

Ciência & Saúde Coletiva, 13(2):341-349, 2008

well as the effectiveness of information, and analyzing objectives and methodology.

In this forum, however, issues pertaining to the real meaning of the Term of Consent for the researcher are intrinsic part of our reflections. To what extent do the ICs that we produce for each project reflect an ethical attitude and the respect for the participant? Is the IC enough as a text? Is it always possible and desirable to use written text?

We would provide a negative answer to these two questions: the written text is not enough (though it is necessary in most cases); nor is it always possible or desirable to use it.

IC can be signed and dated, but the need for explanation does not stop there. It is the participant's right to question and seek information as often as they need. Only then will they feel informed to continue to participate or to stall their participation. In this case, the idea of saying that the researcher can give more information about the research is not only a formal attitude, it is a real need of intention.

However, there are researches in which presenting a written IC would in fact simply be a formality. Let us imagine that we are working with a population segment that is not literate, or with an indigenous group that is not familiar with the same writing technique as the researcher. The participant will be able to add their fingerprint to the text, but would this not be a safeguard only for the researcher? There are also situations in which the signature of a Consent Term could be undesirable: let us imagine research work on violence. The very fact that a document such as this exists could be risky for the participant.

Situations such as these can make the IC useless or dangerous, when in its written form, but they do not nullify the principles that the document raises. These are situations in which the researcher's ethics, and their ability to find solutions without going against the individual's or the group's rights, are tested to the limit. It does not seem to be the case of establishing a general rule; the researcher should find a solution for each case in the dialogue with virtual participants. Ethical principles should always come first. In the project evaluation, peers and the committee of ethics should equally know how to read beyond the written character and preserve the spirit of Consent.

IC should, above all, serve as information, justification and guarantee for the participant, besides being a consent of acceptance from the researcher as to this function of the document. The IC cannot be seen as a "declaration of intentions" from the researcher or a means by which the participant provides them with "authorization" for the former's protection. It is more than that. It is a consent from both parts. It is clear that, in order for consent to be freely accepted by participant, they need to understand not only the procedure and what is expected of them, but the objectives of the proposed work; they must agree with such objectives and find them useful personally and socially speaking. They must consider such objectives beneficial for them and for the others. In any case, internal differences found in our Nation Continent do not advise for the use of a single IC model.

From the point of view of the researcher, an ethical attitude implies in critical capacity, awareness of roles and continuous learning. Being ethical is not following formalities.

The meaning of the IC for the participant

- Is it a real Free and Informed Consent?
- What to do when there is an implicit situation of power?
-When does the researcher need, for example, the drug that is being provided as part of the research?
- When does the researched have a connection with the researcher, as in a clinical case study?

Some of these questions have inevitably been considered in the item above. But there are still some other perspectives to be explored as far as the meaning that IC has for the research participants.

Of which research, i.e., of what kind of research are we talking about? Even if we direct the question solely to the field of the so called qualitative researches, and to those carried out in the area of Social and Humanistic Sciences, there is a great variety of techniques, a truthful relativity of instruments and IC. There are, of course, techniques, which more or less invasive.

The researcher can opt for the use of questionnaires to be individually answered by the participants; or of a questionnaire to be filled in by the researcher or the research assistant, in front of the interviewee; questionnaires may be solely of the closed-questions type or contain some open questions; they may be designed in a multiple choice version; the participants may be asked to establish a hierarchy from the alternatives presented to them; one may choose to adopt the use of questionnaires via internet; or a form to be answered in the presence of the researcher may

be adopted. If there is an option for the use of interviews, they can also be of different types: open, quasi-open., structured. One can also adopt life history techniques, etc.

The field of observation also presents a number of possibilities: observation, participant observation (or observant participation in some cases), assembly or games observation (carried out with children or adults). Observations registered on video or photographs. Home visits. Focal groups (filmed or audio-recorded). There may even be a combination of several investigation techniques or strategies and the list of possibilities may be quite long.

Of course the options will depend on the objectives of the research, of the theoretical choices, of the kind of research (social and psychological) and of the research participants. If the research focus is, for example, aimed at old people or at children there must be some compatibility in terms of research methods (techniques, strategies) and the types (characteristics) of participants.

There are also some especially delicate questions which involve qualitative researches: those relative to drug users, violence or the organized crime, domestic violence, sexual abuse, research with children and or adolescents. In those cases, the Consent issue gets new proportions.

Ethical questions will always be present no matter the research and/or the group involved, but what should be part of the IC? What is really important? Certainly it does not need to contain a list of techniques and a detailed description of the procedures, even though the participant should be informed if they will answer a questionnaire, give an interview, participate of a focal group and the type of observation that will be carried out. They should be informed about the intention of taking photos or filming, for example, and should give permission to be filmed, photographed or recorded. To give permission, they should also be informed about what the researcher intends to do with those photos and recordings; and about what will exactly be photographed and recorded.

It seems to us that the most important thing of all is that the participant be clearly informed about the research (objectives and general procedures, goals) the researcher's qualifications, type of research (academic – at which level – non-academic, etc.) who will the information (interviews, observations, etc.) readers be; what is expected from them (what their role is in that project); they should be informed that their participation is voluntary, their anonymity will be guaranteed (we will come back to this point) as well as the secrecy of the "information they gives" and their right to quit at any time of the research, of the expected benefits and eventual risks. The researcher must (as we said before) assume the consent of giving explanations as many times as the participant asks for them, respecting the anonymity, preventing the participant from having any kind of problem (dismissal, restriction to their services received or even restraint to their freedom) following their participation (the institution or group that the researcher could be with); finally, the researcher has to predict the means by which to "return" the results obtained to the participants. They should always be guided by the general principles of beneficence and justice.

Challenges

Stating that the participant should be informed about the objectives of the research, should accept them and know the precautions that are offered to them in order to participate is not enough. We have previously talked about internal diversity in our "Nation Continent", but we should also consider that we live in a world that is marked by diversity in which groups, segments and even nations are not in isonomic positions. Even in a State of equal political rights there are hegemonic discourses and subaltern discourses; hegemonic positions and subaltern positions. It is exactly in such an ever contrasting scenario that the need for an inter or trans-social and cultural ethical perspective is seen as essential. A clarifying example may be borrowed from Cardoso de Oliveira. This anthropologist analyzes "the shock between the native North Americans" point of view and that of a "museum community which has decided to establish a regulatory code of ethics of its policy for obtaining the cultural indigenous elements for its collections[2]." The author presents a long example of the controversy, of which we will cite only one of the points: ***the museums vindicate their rights in the name of science; the Native Americans answer that their cultural needs – i.e., those of the indigenous culture – are much more important that the needs of science***[2].

Two warnings from that scholar must be considered in this discussion as far as the relationship between researchers and participants is concerned: First, "one must guarantee the best possible conditions for non-distorted communication"; these conditions are more necessary "the greater the distance between the interacting se-

Ciência & Saúde Coletiva, 13(2):341-349, 2008

mantic fields". Second, in case of a "conflict" as the one previously mentioned, between Native Americans and museums, there is not a case of rationality disagreement, but of differing perspectives; there is a great distance between the world views and their specific ethical translations.

That said, let us return to the Norm, based on Resolution 196/96. In order to do this we will consider the Guidelines on Ethics in Research with Human Beings, whose design was coordinated by CEPSMS (Committee for Ethics in Research - Local Health Department) of São Paulo and printed was in August, 2004[1]. (In an effort to broadly discuss and produce some guidance for the Ethic Councils, counselors and researchers, the CEP - Committee for Ethics in Research- at the SMS - Local Health Department - printed the cited guideline that was the result of the discussions – in several workshops – with representatives from Regional Health Departments of the Local Health Department, representatives from segments of the civil society, end-users representatives, and other interested people.)

Taking as a reference the Free and Informed Consent, the Guideline says that: " the IC has to be designed by the researcher and offered to the person that is being invited to participate in the study". According to the Guideline, the Term must have:

a) the justification, the objectives and the procedures that will be used in the research.

b) the discomfort and possible risks, as well as the expected benefits;

c) the existing alternative methods;

d) the means by which follow-up and assistance will take place, as well as the names of people responsible for such assistance.

e) a guarantee of clarification, before and while the development of the research, about the methodology and about the possibility for the participant to be included in a control group (placebo).

f) freedom for the individual to refuse to participate or to stop participating, withdrawing their consent in any phase of the research, without being penalized or suffering any harm in terms of their care or in terms of the quality of service they receive;

g) the guarantee of confidentiality assuring subject privacy as far as the confidential data involved in the research;

h) the compensation derived from the participation in the research;

i) the compensation for possible damages derived from the research.

Quick analysis of those 9 items shows that the IC was primarily conceived for medical, drug related researches, and other similar investigations. Does this mean, for instance, that qualitative researches cannot "cause discomfort and risks", or admit benefits? Of course not. The discomfort (which does not relate only to the participant's time) may be translated as harassment, a feeling of privacy invasion (aggravated by the fact that there is no real, "properly medical" justification for such an invasion).

For the participant, the explanation of doing a social research in a health field involves some difficulties. In the context of a medicalized society we can assume that the hegemonic relation of the "medical" field can facilitate the "participant" adherence to the research. We use the term medicalized in a broad sense: professionalized attendance (formalized, official) to health, use of industrialized drugs, use of public or private health services, the "right to use health services" recognized in the Constitution – all these perceived (in practice and in the social representations) as needs and rights; and their lack thereof "requested" from the public services, understood as "health problems in Brazil", or as a significant part of it. Its importance is reinforced in political campaigns and in the Media. In other words, the understanding of the reach and of the importance of a "medical research" by the participant may be more immediate (broadly speaking) than their understanding of another research in the humanistic sciences. It means that the Free and Informed Consent in the case of researches in the health or behavioral fields, developed by social scientists (broadly speaking) must be formulated with extreme care. Let us consider, for example, a research related to sexual behavior of adolescents made by an anthropologist or a sociologist. The IC can damage the work, because is a difficult issue that can involves relatives and adolescents.

Going back to the hypothetical example of research related to the sexual life of teenagers, it is evident that the researcher will have two moments of consent – from the person responsible for the adolescent and from the youngster themselves. It is clear that the IC must inform the objectives of the research and emphasize its necessity and the benefits they aim at, besides showing the importance of looking for the adolescents' perspective, but it must avoid implying, even indirectly, in the parent's IC, that their children "are part of the problem". This could, undoubtedly cause distrust and domestic conflicts. Once the consent is obtained from the parents, the same must be done with the adolescents themselves - who have the right of refusal.

As far as risk is concerned (item b of Norm (IC)), one can notice that even a socially beneficial research can cause problems to the participants. Some examples can clarify this argument.

Let us suppose a research carried out with the staff of a public health unit, aiming at evaluating their knowledge concerning the handling and conservation of vaccines. Such work would be beneficial for the user and would respond to their right to get safe vaccine; it would be beneficial to the Service, in as much as it could be a step towards the increase of its trustworthiness and to show respect for citizenship; however, if the workers were immediately dismissed instead of going through a "recycling" process or instead of being transferred to a sector which would be more adequate to their knowledge, we can say that the participation has caused damage to the participants.

A particularly smart users' representative of the CEP/SMS [Committee for Ethics in Research at the Local Health Department] in São Paulo, taking part in a piece of research about the use of protection in the work environment (masks, gloves, etc.) and the incidence of professional diseases – undoubtedly a very important research and of great human value, has pointed out that it involved some risk. Their experience has shown that in the case of any index of worker's vulnerability to the toxicity of the environment, the worker would be dismissed (before the manifestation of the professional diseases) in order to avoid future compensation, which is relatively expensive from the entrepreneurial point of view. Undoubtedly the reason for the dismissal would never be the health issue. In such cases what is the ethical procedure? Would it not be lacking in ethical standpoint to avoid pointing out the health consequences or the job accidents? On the other hand, to cause even involuntarily the dismissal of a worker and to prevent them from being compensated for developing (or for prospectively developing) a professional disease, cannot be a ethic point to be questioned? Undoubtedly the researcher (medic, pharmacist, psychologist or anthropologist) would find a difficult ethical dilemma. Can the researcher guarantee that there will be no harm from for the worker participating in the research? Maybe not, but the researcher should take that possibility into consideration and try to avoid it. The users' representatives of Committees are important part of the process because they can see those dilemmas. Would the anonymity and confidentiality (item g) be the solution to avoid risks? We cannot forget that anonymity is not a guarantee of non identification. Within a specific group, the uses of pseudonyms or other artifacts means very little: there are many ways of identifying those we know. There must be double care to avoid damages of any type.

The dilemma, however, is not related only to social ethics, but also to the ethics of research. In fact, in qualitative research the researcher will have to guarantee a minimum of "data" trustworthiness, and for this reason they cannot omit all the information. Once again, there is an ethical, humane dilemma, and one that is related to the science model.

If some of the items of the guidelines for the adequate writing of the IC can and must be appropriate for any type of investigation, there are others that are solely related to epidemiological researches, aimed at health in strictly speaking, and to technical drugs researches (for example, items b, c and d in the guidelines).

As far as the rights of the participants are concerned, however, there are consensual points among researchers of social and humanistic sciences, regardless of their adoption of a qualitative technique or not. We can easily list some of these points:

1 - Voluntary participation.

2 - Guarantee of anonymity, as a general rule (there are exceptions).

3 - Guarantee of withdrawal, without loss for the participant.

4 - Clarification about the research (for which the participation is required), its aim, eventual reach and the meaning of each one's participation.

There are other rules that must be followed, especially when the research is developed in the health field, and more specifically when it involves the use of drugs: the "participants, subjects, informants, collaborators" (the terminology changes according to the field and the researchers' theoretical perspectives), should not receive any payment for his participation in this kind of research.

In other words, the financial stimulus cannot and must not substitute the voluntary and fully informed adhesion. In situations, like the Brazilian one - of extreme economic diversity - the idea of payment goes against such disparities and could be considered a way of inducing subjects to the participation, which would be contrary to the informed and voluntary decision preached in the Resolution 196/96. It cannot be denied that the expenses related to the participation in the research (transportation, meals, etc) must be considered for compensation in the project budget.

Ciência & Saúde Coletiva, 13(2):341-349, 2008

Even here the researcher may be faced with problems that have not been predicted – that may require ad hoc adjustments. Therefore, beyond the general valid principles, one needs to be sensible to solve problems without jeopardizing the scope of research or harming the participants. Situations that require changes are common in researches run in the social and humanistic sciences; in fact, they are seen as part of the conditions for the running of these researches. This does not make them less valid or less serious than works, which assume other paradigms. They prove their difference. One cannot researches or researchers in plaster cases.

We can say that they are different, but the reason or worry about the research's participants and the ethic code are a general exigency today.

The general principles indicated above (under this item), implicitly or explicitly guide any investigation. To get an example from a non-academic field, one can verify that the market survey is guided by a rather detailed code (The ICC/ESOMAR Code of Ethics for Market Survey and Social Research)[3], which establishes from general principles (objectivity and scientific principles) and the rights of those researched, to the researchers' professional responsibilities. In this context, the researched, or participants, are called "collaborators". Such collaborators have the right to choose if they want to participate, they have their rights guaranteed, as well as their anonymity (except for the cases in which they have explicitly authorized the recording of data that may identify them), they have the right to be informed of the research, its aims, and of the agreement of the data end-user (the client) to respect the exigencies made in the referred code of ethics; the researcher must guarantee that the collaborator is not, under any circumstances, harmed or unfavorably affected as a result of their participation in the market survey project.

Also in this context, children and youths deserve special care from the researcher/interviewer, and it is necessary to get previous consent from parents or adults responsible for them in order for the interviews to be carried out.

The ICC/ESOMAR code also states that the interviewed people should be previously informed as to the observation techniques, and as to the use of recording equipment (except when it occurs in public places); if the interviewee wishes to have the session or the recording referring to their participation destroyed, it should be destroyed or erased: anonymity cannot be broken by the recording methods (for researches in the health field, the Resolution 196/96 states that this type of material must be filed for 5 years so as to allow for verification by CONEP [National Commission for Ethics in Research] or ANVISA [National Agency for Sanitary Vigilance])

Also, as far as anonymity goes, the ICC/ESOMAR code recommends that if there a need arises from the research, the data that identify the collaborator can be accessed (to further interview the same person, to complete information, to evaluate the work), but must be of limited access, and kept separately from the collected information. There are cases, however, in which anonymity can be broken solely by authorization from the researched, but they must previously be informed of who will receive this information and what for; the researcher must guarantee that the information will not be used for any purpose or activity other than for the research ***per se,*** and that the information end-user (client, person who requested the research) has agreed to respect the exigencies of the code of ethics. One can therefore see that there are some concerns and ethical procedures that are practically universal in the research field, whatever its scope.

In qualitative researches in general we have already pointed out that the rule of anonymity admit exceptions (besides being no guarantee of no identification). "Given Voice to the Spectrum"[5], Eysenbach and Till[6], Richards and Schwartz[7] discuss this issue. There are situations in which participants themselves want to have their names recorded: this is, for example, the case in which memory is taken both as object and technique; cases of research with certain minorities (researches that want to "give voice to those that do not have a voice"); researches of a socio-historical nature which nominate important people of a certain period, and so on. There are cases in which identifying the participant is an ethical attitude.

There are also the (practical or applied) works carried out in Psychology in which the psychologist can take notes in the participant's residence. This situation requires twice as much care: the care to safeguard the identity of the participants, and to preserve the family's intimacy. Many times, families that have been experiences of legal problems (pertaining to the children's legal care, or to situations of violence) fear that if they open their homes to the researcher, their homes might be used in the legal course of action. In such cases, the IC must provide the family with the maximum guarantee, its writing should mention and respond to these specific fears.

Ethics and research: conclusion and suggestions

As we have pointed out from the beginning, the ICs are concrete manifestations of ethical concerns: they are consequences of ethical concerns and attempts to clearly position research and its objectives, clearly position the researcher, and mostly so, the "researched" in the construction of knowledge or of interpretation; stating their rights, the possible gains and losses, and the consent to avoid (or to minimize) damages, maximizing benefits.

A short incursion through ethical codes will allow us to raise other issues that we think are important. In order to do this, we will seek support in the invaluable doctorate thesis dissertation completed by Iara Guerriero. The author gathered and discussed the existing codes, tracing their histories – which helps us to directly focus on their key points and on their consequences to qualitative research.

Before checking the Resolution 196/96, the scholar analyzed the most pertinent aspects of preceding resolutions in the country and abroad. Therefore, we will find the Nuremberg Code (1947), the Helsinki Declaration (1964,75,83,89), the Belmont Report (1978), the International Ethical Guidelines for Biomedical Researches – produced by CIOMS/WHO (1982,93) and the International Guidelines for Ethical Analysis of Epidemiologic Research (1991, also from the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization: CIOMS/WHO)[4].

One of the most important of these guidelines is the Belmont Report, due to its repercussion in so many more recent texts. This report proposes principles to be taken into account in all situations (according to Iara Guerriero, this report is not cited in the Resolution 196/96, though the principles that the report contain are incorporated in the resolution). This report states that, in general, the codes present general and specific rules pertaining to investigators or to research revisers. However, these are often inadequate when it comes to covering complex situations – the rules might either be conflictous or difficult to be implemented. This considered, the Belmont Report proposes the adoption of principles (but not rules). General ethical principles could, then, be the basis for the formulations, criticism and interpretation of rules. The same document distinguishes two activities (which might, in fact, occur in parallel) in the health field: the practice and the research.

It is the research that is of particular interest for us in this research since one can see that the definition of research occupies a considerable part of the codes and guidelines, and there is a certain agreement among researchers of the Social and Humanistic Sciences that even the Resolution 196/96 is not complete, generating two types of problems – both of which are of a grave nature: it is unable to really set down general principles that may assist the researcher to critically analyze the ethical limitations of their works; it put the concept of research into a plaster case and seeks to include under this idea investigations that follow different paradigms than that which implicitly or explicitly are accepted in the several codes. In fact, depending on the research understanding, the general or specific rules may not respond to the needs of ethical reflection and even to qualitative research itself. This was what we were trying to highlight previously.

IC, as it is defended, is a result of the biomedical and behavioral research. Some researchers consider that the Resolution 196/96 establishes one sole valid paradigm: that which is known as "positivist", and does not cover the possibility of other paradigms. It is understood there that in order to "be scientific", an investigation must start with well defined hypotheses, and that the work must be developed so as to test them, following an experimental path and allowing for verification. The field of humanistic sciences is in an uneasy situation within this model, regardless of whether it is qualitative or quantitative research that is being developed.

In a world of changes and new requirements, when it is the interlocution between areas, the crossdisciplinarity, the multidisciplinarity, the pluridisciplinarity and even the transdisciplinarity that are being promoted, there is urgent need to admit other paradigms, models, methodologies, techniques and especially, new objectives (for short, medium and long terms). One of the practical and ethical issues that is of greater relevance today is that of respecting the rights of people and the rights of social groups.

These requirements make the ethics discussion more urgent, thus even more complex and difficult. Bearing these reflections in mind, we would like to make some suggestions:

· Ethical issues and dilemmas, as well as practical conflicts must be part of any course of methodology, regardless of whether the research is at an undergraduate level or at the post-graduate level.

· The methodology courses or research tutorials must prepare the future researcher to reflect

Ciência & Saúde Coletiva, 13(2):341-349, 2008

about their motivations to select research themes.

Critically reflecting about their own paths and selections is fundamental for one's "free and informed adhesion".

· The future researcher must know the epistemological and formal aspects of a piece of research, and the foundations of each different investigation paradigm so that they may be able to make their choices and to formulate informed criticism.

· The codes of ethics must be discussed in these courses. Many times, there is a form that is ready for the student that is writing their monographs in the field of health, and this form is given to them. They have no previous knowledge of the whole Resolution 196/96. It would be necessary to have the resolution become an integral part of the material used in Research Methodology Courses within the health area. Other contemporary codes, resolutions and debates on ethics and on ethics in research must be included in these courses.

Only with a teaching program open to critical thinking and to reflection about the place that the researcher occupies in society, their social responsibilities, and their role as citizens will there be a possibility to transform the IC design, or the adhesion to principles of respect into something other than mere formality, or even worse, mere instrument to safeguard the researcher.

After all, it is not possible to think of a IC in a context which is separate from ethics, from the researcher, from the approach setting, from the research objectives and from the researcher, their benefits and harms, since all of these aspects are interwoven.

Collaborators

MHVB Concone and C Cerveny worked together in all phases of the writing of the paper.

References

1. São Paulo. Prefeitura do. Município de São Paulo. Secretaria Municipal da Saúde. Comitê de Ética em Pesquisa. ***Manual sobre ética em pesquisa com seres humanos***. São Paulo; 2004.
2. Oliveira RC. Etnicidade, eticidade e globalização. In: Oliveira RC. ***O trabalho do Antropólogo.*** São Paulo: UNESP; 1998. p. 168-188.
3. Associação Nacional de Empresas de Pesquisa. ***Código de Ética ICC/ESOMAR para pesquisa de mercado e pesquisa social.*** São Paulo. Available from: http://www.anep.org.br
4. Guerriero ICZ. ***Aspectos éticos das pesquisas qualitativas em saúde*** [tese]. São Paulo (SP): Faculdade de Saúde Pública/Universidade do Estado de São Paulo; 2006.
5. Social Sciences and Humanities Research Ethics Special Working Committee. ***Giving voice to the spectrum: Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics***. Ottawa: Interagency Advisory Panel on Research Ethics; 2004. Available from: http://www.pre.ethics.gc.ca/English/workgroups/sshwc/reporttopre.cfm april22/2006
6. Eysenbach G, Till JE. Ethical issues in qualitative research on internet communities. ***BMJ*** 2001; 323: 1103-1115.
7. Richards H, Schwartz L. Ethics of qualitative research: are there special issues for health services research? ***Family Practice*** 2002; 19(2):135-139.

Artigo apresentado em 07/05/2007
Aprovado em 08/10/2007
Versão final apresentada em 10/10/2007