PREFEITURA DA CIDADE DE SÃO PAULO SECRETARIA DA SAÚDE	**Research Ethics Committee** **São Paulo Municipal Health Secretary** **CEP/SMS**	TDR	**Special Programme for Research and Training in Tropical Diseases (TDR)** **Sponsored by** **UNICEF/UNDP/World Bank/WHO**

Meeting on Ethics in Qualitative Health Research, held in Guarujá, August 28-30, 2006

Report

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Report

1. Introduction

1.1. The publication of Resolution 196/96 CNS and the introduction of the system comprised of the Comissão Nacional de Ética em Pesquisa (National Research Ethics Committee – CONEP) and the Comitês de Ética em Pesquisa (Research Ethics Committees – CEP) has been a major step forward for the nation. Today, Brazil stands out internationally for its ability to analyze the ethical aspects of research involving humans. And it was precisely this advance, with this system fully underway, that new challenges in qualitative approaches in the health field have emerged.

1.2. Currently, a major challenge faces studies conducted by the researchers in the fields of social and human sciences, who conduct qualitative research in the health field with interpretive and critical paradigms, which are inductive rather than experimental. These studies are hampered by the manner in which the CONEP-CEP system has conducted its analyses, in particular certain formal requirements that are detailed in the text to follow.

It is important to highlight the increase of qualitative health research adopted in Brazil, which, in turn, increases the need to consider its specificities.

1.3. In an effort to contribute to the improvement of Brazilian guidelines on ethics in qualitative health research, the Comitê de Ética em Pesquisa da Secretaria Municipal de Saúde de São Paulo- CEP/SMS (Research Ethics Committee of Municipal Health Secretary of São Paulo), in conjunction with the Special Programme for Research and Training in Tropical Diseases - TDR/WHO, organized a meeting with 30 Brazilian and foreign specialists in Guarujá, August 28 – 30, 2006.

1.4. Domestic research institutions involved in qualitative health research were invited to appoint representatives. Health Ministry and Public Ministry representatives and editors from the Revista de Saúde Pública (Public Health Journal) and Cadernos de Saúde Pública (Reports in Public Health) were also present. International participation included researchers associated with the

American Psychological Association - APA (USA), Université Paul Cézanne (France) and the University of New Brunswick (Canada). A list of participants is attached.

1.5. This report presents a summary of the discussions that occurred over these three days as well as the recommendations and suggestions proposed. The writing process of this report included the following steps: 1) recording and transcribing of the three-day meeting, and writing of the first draft; 2) sending this draft to five readers who had taken part in the meeting, receiving their suggestions and defining the second draft in a meeting; 3) sending this draft to the thirty participants of the Guarujá meeting, receiving and incorporating their suggestions. When consensus was not achieved, the opinion of the majority during the meeting in Guaruja was kept; 4) sending the third draft to all CEPs and including this draft in the CEP/SMS website. Five hundred e-mails were sent and 32 answers received, as follows: 8 from universities CEPs, 1 from Hospital CEP and 2 from Canada; 5) meeting with the readers and two other consultants to conclude this report. This final report was sent to the National Health Council– CNS, to the National Commission on Research Ethics - CONEP and to the Ministry of Health.

1.6. To put this issue into context, we begin by presenting a few basic aspects that characterize qualitative research and the National Health Council's Resolution nº. 196/96. We then present recommendations that should be analyzed by the people responsible.

2. Ethical Aspects Inherent to Qualitative Research Based on Critical or Interpretive Paradigms

2.1. In the same research project different values and choices that must be considered can interact, i.e., those of the researchers, of the researched participants in their relationship with the principles stated in Resolution 196/96. The dialogue between them is therefore essential, because it is in this dialogical relationship that the research process will be defined, as well as its ethical aspects.

So, it is not adequate to consider that scientific knowledge can only be constructed according to one sole model of investigation that fits within the establhished ethical guidelines. In the interpretative and critical paradigms, research and researched participants have knowledge that, though possibly different, must be respected.

2.2. Therefore, qualitative research has **scientific merit** if the other is heard, situated and understood in his/her day-to-day context – or in other words, it is impossible to conduct an experiment by isolating specific factors, or removing the participants from their context or further distinguishing fact and value in search of linear causes. Even the researcher, with his/her beliefs and values, cannot be excluded from his/her relationship to the subject. So information yielded from research is inseparably linked to the relationship between researcher, participant and his/her community.

2.3. All of this means ethical concerns are not fully addressed during the first contact between researcher and participants, in terms of compliance to research ethics guidelines, but rather covers the entire research process, so common ground must be constantly found throughout. Ethics is therefore inherent to research paradigms of this nature.

2.4. It is important to note that ethical issues are not restricted to just the relationship between researcher and subject, but also include many other dimensions, such as: the relationship between the researcher and the community under study, professional relationships with other researchers, with the research institute and funding agencies. Along the same lines, it is necessary to respect the society to which the participant belongs, and not just each individual.

This knowledge is built in social relationships and incorporate the values of a given society, even thought these may be transformed in this process of incorporation. The concept of “subject” is intrinsic to its a specific social group and they cannot be dissociated from each other.

For example, there is the study by the anthropologist Cardoso de Oliveira (1998), who analyzed “the clash of perspectives between North American Indians and the museum community, determined to establish a code of ethics for its policy on obtaining indigenous cultural elements for its collection.” The author writes extensively about this controversy and raises two important points (for our report): “the museums claim their right in the name of science; the Indians respond

> with indigenous cultural needs which they assert take pCEPedence over science."

2.5. Therefore, the researcher is responsible for addressing the ethical questions of his/her study with the community under study. Issues such as anonymity or publishing the names of participants (of the community or individuals), use of information collected for the benefit of the study population, whenever possible, or for other communities with similar characteristics, fall squarely on the shoulders of the researcher.

2.6. Other characteristics of qualitative research deserve mention, to further clarify:

- Subject and object are inseparable socio-historical constructions;
- The research and the researched participant are in constant interaction in the situation of research, so the knowledge is produced in this *locus* of the intersubjectivity.
- As in every scientific research, the principles of autonomy, beneficence, non-maleficence and justice are inherent to research in the social and human sciences.
- The need of reciprocity (i.e., that the benefice of research must be shared among the researcher, researched participant, individual and community) - expected in every scientific research - is especially relevant in research of the social and human sciences, as an ethical requirement.

3. Qualitative Health Research and Resolution CNS 196/96

3.1. Resolution CNS 196/96 was created based on international research ethics documents, the oldest of which was the Code of Nuremberg, written to aid in the trial of Nazi scientists who caused suffering and death with their medical experiments. Next are the Helsinki Declaration, the documents produced by CIOMS/WHO and the Belmont Report. The scope of these documents is clearly delineated, whether for epidemiological or clinical and behavioral studies. In Brazil, however, Resolution 196/96 covers all research that involves human beings, as stated in item III.2;

" Any procedure which involves human subjects and has not been fully accepted in the scientific literature, regardless of its nature, will be considered research and, therefore, must comply with the guidelines set forth in this Resolution. The above mentioned include, *inter alia*, those of instrumental, environmental, nutritional, educational, sociological, economic, physical or biological nature…”

Therefore, the application breadth of Resolution 196/96 was increased without the review of the concept of research, nor of that of “subject” that frame the Brazilian guidelines. The Res CNS 196/96´s concept of research is that of clinical trials, especially of drug testing, immunotherapy, vaccines, new procedures, among others. The term research is taken as synonymous of experiment. Its conception of subjects, of human beings does not consider that their identities are socially built. So it is impossible to separate it from the environment where it is constructed. Thus, there is an over-value of individual autonomy at the expense of the interdependency between individual and society.

3.2. Since subjectivity is one of researcher’s tools, an ongoing concern is how he will be able to understand another using this type of logic. The researcher and subject must be considered inseparable socio-historical constructs; in other words, one cannot lose sight of the fact that the identification of the subject as an individual is also a historical construct. So when the social character of the subject is removed or denied, emphasis is placed on individual autonomy, pulling him out of context.

3.3. Since the subjectivity of the researcher is his/her work tool, there is a constant concern as to how he/she can understand the other from their own logic. One cannot take for granted that the identification of the subject as an individual is itself a historical construction. The individual is always in context.

3.4. As you can see, the definition of research as stated in Resolution CNS 196/96 is different from the concept of qualitative research in interpretative and critical paradigms. And this difference affects the development of a research project, as well as the relationship established between the researcher and subject, which must be considered upon analysis of the ethical aspects of the projects.

3.5. The nature of this research, generally based on interpretive and critical paradigms, is not fully addressed by Resolution CNS 196/96. Faced with this, specific guidelines for research of this nature designed to help researchers and referees of the CONEP-CEP system are justified, as follows:

4. Qualitative research has its own criteria for validity, which should be observed so that it can have scientific merit.

4.1. A well-founded research project should present a framework that guides the proposal, the objectives and procedures that will be carried out. It is not always possible to determine the universe of informants and/or present the sample calculation in advance; however, according to Resolution CNS 196/96, VI.3.a;d; this information must be included in the project for analysis by CEP. The qualitative research does not aim at generalization, in the same way of those that uses statistic samples.

It is necessary to have a carefully description of the characteristics of the target population, as well as of the procedures so as to enable peer review, in which the peers should evaluate if the research project has scientific merit and if the generalization is possible.

Thus, other researchers can verify if specific results can collaborate to the understanding of other populations with similar characteristics, i.e, if knowledge is transferable to allow for understanding of similar issues pertaining to populations whose characteristics are also similar to those of the studied group.

4.2. Following this reasoning, in research of this nature no sample calculations are employed. One criterion adopted is the theoretical saturation, i.e., when content brought by the researched participants begins to repeat itself, the researcher then stops collecting data. So, it is often impossible to preview the precise number of researched participants from the initial planning phase of the project. One possible exception is the case of intentional sample, as stated by Thiollent (1986), in which it is possible to preview the number of the researched participants from the beginning - for example interviewing all the professionals of one specific area working in a certain health service.

5. The research instrument(s), if used, can be developed after contact with the studied community and, therefore, is not always ready when the research project is being designed, or in time for presentation to CEP.

5.1. It is worth noting that qualitative research has an evolving nature, since it is created jointly by the researcher and participants, where decisions are negotiated.

5.2. Qualitative research is delineated differently. The study, or generation, of data can be carried out using various techniques (interview, participant observation, etc.) and can be formal (interview, for example) or informal (as in spontaneous discourse, for example). It is important to respect these characteristics, so guidelines for research ethics should not hamper ties between researcher and participants.

5.3. During a qualitative study, different means (such as the telephone) and technologies (internet, for example) can be employed. These means raise new challenges that deserve discussion in specific documents.

6. The material documented by qualitative research may include photos, films, cassette tapes, handicrafts, etc., which can be used in future analyses, yielding new interpretations.

6.1. This common practice in the field of social and human sciences may be made impracticable by items VI.3.c; IV.3.f. of Resolution 196/96.

6.2. In anthropology it is common to use field diaries for research data, which can subsequently be analyzed by others. The publication of this material is especially important for three reasons: 1) it is very useful material for the education of new researchers; 2) by the very nature of qualitative research or, in other words, the search for transferability, this material is useful in developing and carrying out new studies aimed at advancing theoretical and methodological knowledge on certain subjects and, 3) it is also fundamental that the researcher can review his/her analyses and publish his/her reflections, contributing to advances in the field. Therefore, it is impractical that these diaries be destroyed or have their use restricted to only one study. The publication of this material, i.e., the field diary, is a decision to be taken only by the researcher, guaranteeing the anonymity of the researched participant.

6.3. In other words, the requirement that the material is used in only one study is unworkable. Furthermore, the field diary, for example, reflects and is part of the experience of the researcher. It is not possible, nor would it be desirable, to limit it. It is important to mention that the field diary is a record of what the researcher learns about a community and is something produced from the relationship that is established between researcher and the study community. In this way, the record does not belong to any one study and, therefore it does not make sense to request a free informed consent (IC) each time it is used.

6.4. It is also worth noting the change in meaning and intentions attributed by the participants to the information offered to researchers, if they maintain contact with the researchers, even after the study.

6.5. It is important that the subject is explicitly informed and is in agreement with the storage location for information he has provided, to whom this material will belong (field diary, cassette tapes) and if it will be used for future research.

6.6. Increased emphasis on respect for authorship, especially recordings or photographs of performances, music, etc., in addition to deciding with researchers if, how, and where these materials will be published.

7. The evaluation of risk must also be conducted in qualitative health research.

7.1. Some common research procedures, such as filling out a form or specifying marital status: married, single or widowed may have an important effect on the subject, since it requires the person to reveal their identity. By doing this, it makes the person reflect on their life, which may be positive for personal development, but may also be alienating.

7.2. Risk is also cultural. It is important to understand how research subjects view this.

> A relevant example occurred in a study that included an interview with the parents of children with cancer that contained the following question: “Do you believe that the education you gave your child contributed to his/her cancer?” This question would at least make parents wonder if they had some blame in their child's disease. The CEP correctly requested the question be excluded.

7.3. The risk, however, must also be considered in relation to the researchers themselves. Since the researcher frequently goes into the usual environment of the researched participant, which could mean that their research will be developed in a slum, in the workplace of sex professionals, or in other similar places. As the researcher is the person who has less knowledge of the local conditions, they have a higher risk than the researched participants when saying in these places. The need to protect the researcher broadens the concern for protecting the researched participants – which is well taken into account in Resolution 196/96, items VI.3.f; VI.3.g. The research must preview the risks and how to avoid them, for example: that the team of researchers always should walk in pairs, or even stay with a member of the community at all times.

8. Free Informed Consent of the Research Subject

8.1. Informed consent is considered essential for both researchers who conduct qualitative studies and Resolution CNS 196/96. However, the manner with which it is obtained and recorded is not consensual.

8.2. Free informed consent (IC) has been recognized as an important document in the research process, however, its application, in accordance with the written, printed and previously established model, should not always be mandatory, since field situations can change; or in other words, the study is ongoing and it is impossible to determine everything in advance. There may also be variations in social, economic and cultural characteristics of the population, which need to be considered by the researcher; and, in addition, variations among methodologies may make it difficult or even unnecessary to apply the free and informed consent in the beginning of the research procedure. relationship in the context of the research that must preferably be spontaneous, in a sense of building mutual confidence.

8.3. Considering that the participant is a product of social interaction, whose autonomy is marked by his/her social group, the importance of the signed IC becomes relative. To respect the participant and his/her autonomy (independence), a signed IC is not always necessary and the opposite is also true: this signature does not always guarantee that the participant's independence was respected. Populations with little formal education and little experience in dealing with formal documents can, in fact, feel threatened by a written document. In this situation, the IC completely loses its meaning as a guarantee for research participants, reducing it to just an instrument to protect the researcher.

Another possibility could be if the researcher wrote a letter including all information about their research project, guaranteeing the anonymity of the researched participant that could be signed only by the researcher.

We can cite the field of indigenous ethnology. On a certain occasion, to conduct a study, the CONEP-CEP system requested an IC written in the native language of the Xavante tribe, which would be signed by all participants. However, Xavante does not have its own written language, but rather adapted versions of the Western alphabet according to distinguished linguist's who, in this case, include Salesian missionaries, Protestant pastors and linguistic anthropologists (academics). Moreover, unlike Western culture, decisions related to activities that involve the entire community are not made individually, but by consensus, in ritual daily meetings, which gather leaders and elders. It should be mentioned that the Xavante population is highly educated, compared to other indigenous societies, and many of its leaders have complete secondary educations, in addition to being well traveled in Brazil and abroad. Therefore, this requirement demonstrates a considerable lack of knowledge of these populations.

8.4. It is important to stress that these requirements are contradictory to the text of Resolution CNS 196/96, which states the importance of respect for local culture. Examples as these highlight that one sole set of guidelines cannot be applied to many different ways of producing scientific knowledge, let alone to works conducted with groups of other cultural traditions.

8.5. The IC document must express the ability of the researcher to promote a broad and deep interaction with the study participant. It should favour the communication process in a full and interactive way, therefore becoming an integral part of the research process. In order for this to happen, the document must guarantee that the guidelines and the intentions of qualitative research are secured, and make its dynamic process explicit.

8.6. The IC communication process can be carried out in different ways, by using a written document or expressed orally. What is important is that the information about the research is transmitted in an intelligible way, so as to build a relationship based on the exchange of precise information, as well as the research participants' contributions.

8.7. The researchers should take great care so as not to control participants. Therefore, whenever there is an opportunity, the researcher should make his/her intentions clear to the participant. The researcher must develop sensitivity to perceive the fear or doubts of participants and create the opportunity for them to put forward their uncertainties during the research process. In qualitative research, the research participants frequently give their opinion in the definition of the design of the study and, for this reason, they get some control in the way these are carried out.

8.8. Institutionalized people, indigenous people and others who often agree to participate because they are afraid to lose their benefits, which they have access to because of their relation with the institution. In this case, even if the explicit requirements of Resolution CNS 196/96 are met, the ethical question has not necessarily been addressed.

For example, there are hospitalized patients or those receiving treatment who may fear that treatment will be cut off if they provide or refuse to provide information. There are also reports of participants belonging to community groups who fear that access to health services, whether local or regional, will be compromised during the research process or thereafter. This is the case of immigrant Bolivian women who live in the downtown area of the city of São Paulo who are already in the public health system. They fear contact with the researchers because their situation is complex. Most of them are in the country illegally, suffer in the informal work market and live with domestic violence.

8.9. Another important aspect: consent could be requested after data collection, if the objective is to avoid distorting research results.

In a study that observed street children, the researcher explained the work to the children and asked their consent to then observe them.

The same procedure was also used in a study carried out with secondary school children to learn more about their moral development.

In fact, if the researcher reveals his/her objective in advance, the subjects may act as they believe she would like, which alters the results. So, she only told them that she was doing a study on values. After collecting the data, she spoke with the young people and described the objective, allowing each one remove the questionnaire they had filled out if they refused to participate.

8.10. In relation to the signature of the free and informed consent by the child's caretaker, one ought to discuss which would be the more adequate procedure when the research includes homeless children, who do not have any caretakers. In this situation, it would be adequate if a member of the CEP follows the consent process? Or, even if this consent were requested to the City Council's Children Representatives?

8.11. "Collective participants" must also be considered and not only individuals like groups, communities, NGOs, etc. When the aim is to study an institution or community, the need for obtaining an individual IC again comes into question.

8.12. In summary, the ethical commitment of the researcher to the participant cannot be restricted to compliance with the formalism of a written and signed document. The agreement of the participants must be expanded on by the capacity of the researcher to first explain his/her intentions and secondly to ensure every possible care is taken to protect the participant and his/her community.

9. Anonymity is essential to research since publishing the identity of subjects may bring them some type of harm

Anonymity must be considered essential in qualitative research when informing the identity of the research participant could be harmful to them. Some examples may include research projects about violence, drugs use, abortion etc.

9.1. It is frequently hard to keep the anonymity when the project includes members of the same community or institution because they recognize themselves, even if their names have not been cited. This is so due to some of the information provided (sex, age, civil status, education, style etc). This is a matter of internal confidentiality, i.e., how to keep confidentiality of personal information among the members of the same community or group. It includes research that involves people that have intimate relationships among them, as couples and families for example.

These situations must be considered by the researchers in a way that does not damage the collaborators, requiring methodological solutions and agreements among the parts.

9.2. However, there are situations where subjects want their identity revealed, which highlights the importance that this decision be made jointly, respecting the ethical conventions of the participants and researcher.

Taking these challenges into account is not something to be viewed as making ongoing rules flexible or relative. Quite the opposite, our concerns are to highlight that the respect for the participant's rights , in qualitative health research, is frequently intrinsic to the research process itself. The researchers must be guided by the characteristics of the studied people and/or groups, as well as by the exigencies of their scientific communities.

Two examples may be useful in this discussion and show that the inflexibility of regulations is not always the best solution for research ethics. Both of them come from socio-anthropological studies conducted by North American researchers. The first, Duneier carried out a "ethnography of the street" in the city of New York, where he made the ethical choice to identify his main subject, Hassam Hakim, a newsstand vendor. When asked to speak about the study, Hakim ended up becoming the co-author. In a second example, Diamond studied rest homes and out of a question of ethics and cause no harm to these subjects, he made them anonymous; benefits from the study were felt generally, given that the research served to reform care for the elderly.

So in both of these qualitative studies the choice to suppress or release the names of the subjects was based on an ethical evaluation: on the principles of beneficence, do no harm, justice, respect for the subject and also a concern with reaping further benefits from the results.

10. There is not always a need for privacy during data collection

Another issued posed in qualitative research is related to privacy during data collection. In other words, the contact between the researcher and the researched participants must be realized in a private space that does not allow anyone else, who is not involved in the research, to have access to the content brought by the researched participants whenever the subject relates to intimate information, which is usually not shared in the community.

10.1. Privacy is, in fact, essential in the collection of information for many studies in the field of health involving subjects with diseases that could result in stigmatizing people including studies on disabilities, violence, family matters, sexuality, pregnancy, abortion, illness related to work, among others.

However, it is important to remember that privacy is a concept that does not exist in many cultures, including some indigenous ethnic groups and therefore can be ignored. Some social groups or communities live in a collective more often than a dual setting. So, in these situations it is not a problem to interview someone in the presence of others, since this presence could be an important support for the interviewer in his/her act of telling histories.

11. The relationship between researcher and participants can be maintained or ended after the study

11.1. Its relationship can either be kept or not at the end of the study. It could also take other dimensions, such as sharing experience in different moments, taking part in different community activities (not related of the research process), to name a few. However, the researcher must be sure about his/her own intentions and communicate them to the researched participants and their communities.

11.2. There is also the obligation to take care when the research participant needs to be taken in, or needs support and follow-up from the researcher because of the emotional stress that some studies may cause. This is the situation when the study object is family relationships. During the research process, and may be as a result of this process, some family conflicts may be uncovered which may cause a crisis. The researcher must deal with this, supporting the family.

12. Return of Benefits and Publication of Results

12.1. The results should be presented by the researcher to the participants in an intelligible matter. The researcher may identify, with the researched community, “products” of their interest. For example, in a study that will register the community history, the researcher may organize a publication that will be available in a local school, and be accessible to the children.

In the publication of results, usually qualitative researchers quote what the researched participants have said. It is ethically and methodologically essential that the researchers do not change the meaning of what the researched participant said.

Qualitative researchers usually send their analyses to the researched participants asking them to verify if they were adequately represented. It contributes to improve the quality of the analyses, as well as to make the relationship between the researcher and the researched participants less hierarchical.

In the moment of result publication, the researcher may negotiate with the researched participants the possibility of sharing ownership.

However, some theoretical and academic analyses may not be sent to participants, even because they are not interesting for the researched participants.

In action-research, the return of results is part of the research process.

12.2. The results of research must return benefits to the study population whenever possible and when not possible, should benefit populations with similar characteristics even if indirectly by contributing to the creation of public policy, for example.

12.3. Direct return of benefits from the study of subjects is not always possible. However, there may be a direct benefit for the subject and his/her community if the researcher serves immediate needs such as interceding with a government agency, buying a water pump or medicine, developing educational processes, providing health care when necessary, among other measures.

13. The role of CEPs and CONEP for researchers

13.1. The relationships of power can be reproduced in a microcosm of CEPs. User representatives, who generally hold a lower position in society than health professionals, can reproduce this relationship within the CEP and remain quiet. This situation is similar to what happens between members of the social and human sciences, or between researchers of higher or lower rank. As a consequence, the different sets of knowledge (of the CEP members and researchers) are not shared, making it difficult for the CEPs to understand the research being analyzed. Although the multi-professional composition is important, there is no guarantee that the different research and subject concepts will be in fact considered in the analysis of the research protocols. It is necessary, therefore, to work to make relationships between the members of the CEP less hierarchical by using instruments that enable the expression of opinion by all.

13.2. On the other hand, it is known that representatives of users who understand the field and establish less hierarchal relationships with health professionals, express themselves more often in the CEP, because they are more knowledgeable about health issues and ethical research guidelines.

14. Recommendations

14.1. It is important that the system made up by CONEP and CEPs respects different research traditions and, during the analyses of each research project, considers the paradigm adopted by each researcher.

14.2. From the points presented, we suggest some guidelines for qualitative research that involves human beings and that adopt interpretive and critical paradigms. These guidelines on research ethics are suggested as parameters for the analysis of these projects.

15. Ethical guidelines for qualitative health research

15.1. There is a need to broaden the discussion of ethics and qualitative research. As can be seen, Resolutions CNS 196/96 and CNS 304/00 (for indigenous population research) do not address the specifics of qualitative health research, which are based on interpretive and critical paradigms. As such, the analysis conducted by the CONEP-CEP system, based on the resolutions cited, is unable to protect the subjects of these studies and may hamper studies which could produce valid and necessary scientific knowledge on a certain subject.

15.2. A specific resolution for analysis of ethical aspects of qualitative health research is needed. It must be based on interpretive and critical paradigms including differences to guide referees and researchers:

- Scientific merit is essential to every study. Upon evaluation, the CONEP-CEP system should respect different research traditions;
- Sometimes it is impossible to preview the number of researched participants that will be included in a research project.
- The research tools, if they exist, may be written after the contact with the studied community has been made, and, for this reason, will not be available in the moment of sending the research project to CEP.
- The material documented by the qualitative research may be used in future analyses, yielding new interpretations.
- The evaluation of risk must also be conducted in qualitative health research.
- The free and informed consent by researched participant is fundamental, but it is important to respect their cultural standards and that the consent be obtained in a way that is negotiated between researcher and researched participants. This may mean that the consent will not be in written form.
- Anonymity is essential in research projects when promoting the identification of the researched participant may damage them. However, the researched participants may be identified if they consider it appropriate.
- There is not always a need for privacy during data collection.
- The relationship between researcher and subject can be maintained or ended after the study.

- The results must be promoted not only in scientific publications and events, but also to the researched participants and their communities.
- It is important that benefits are returned to the studied population whenever possible, or even to populations with similar characteristics.

15.3. It is fundamental that the referees of the CONEP-CEP system receive education about the different methods of producing scientific knowledge, including interpretive and critical paradigms, and also on qualitative methodologies so they can judge whether these projects have scientific merit using suitable criteria.

154. Is important to increase the number of referee members in the CONEP-CEP system who understand qualitative health research, based on interpretive and critical paradigms.

15.5. Frequently in the social and human sciences, undergraduate and graduate courses on methodology include reflection on ethical aspects and science since these are inherent to the methodologies. The theoretical discussion on the objectives of scientific production and the social needs is as important as field experience - both are included in the course for the education of researchers, which usually covers philosophical studies also. Ethics is part of the investigation. The discussion of paradigms, methods and ethical issues are inseparable from the creation of research projects. In this sense, it is recommended that courses on research ethics also consider these topics.

15.6. A review is recommended of the approval process for research projects. It is questionable, for example, whether projects that involve indigenous populations need to be sent for evaluation to CONEP. They should be evaluated exclusively within the institutional CEP environment, since the idea that indigenous populations require guardianship by the government debatable and it is evident that Indians have the capacity to make their own decisions without this type of tutelage.

15.7. CEPs should monitor approved projects. Competent ethical monitoring of research transcends control and brings parties closer together: monitor and researcher, a partnership that is beneficial for the production of knowledge and the community studied. It is worth remembering, however, that the social and human sciences already serve as an ethical reference for the researcher.

LIST OF PARTICPANTS OF THE MEETING ON ETHICS IN QUALITATIVE RESEARCH, AUGUST 28-30, 2006,
GUARUJÁ

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