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The need for adequate ethical guidelines for qualitative health research

A necessidade de diretrizes éticas adequadas às pesquisas qualitativas em saúde

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Abstract *This paper discusses adequacy as to the application of Brazilian guidelines, Resolution 196/96¹ and complementaries to qualitative health researches, considering that these are based on non-positivistic paradigms. Frequently, decisions about the research are made together with the studied community. There is a concern with justice and social change. And, since subjectivity can be considered their privileged instrument, such researchers seek a balance between objectivity and subjectivity, discussing how to overcome the researcher's view. We have studied the application and the concept of research found in international and in the Brazilian guidelines. We have noticed that they adopt a positivist conception of research, which establishes 1) the hypothesis test, 2) that all procedures are previously defined by the researcher; 3) neutrality of the researcher and of the knowledge produced. We will present some characteristics of qualitative research; the ethical implications in the way as qualitative research is conceived in non-positivist paradigms and a brief history of these guidelines. Our conclusion: it is inadequate to analyze qualitative researches using these documents, and we suggest the design of specific guidelines for them.*

Key words *Ethics in research, Qualitative research, Health services research, Ethics in research in Human and Social Sciences, Bioethics*

Resumo *O artigo discute a adequação de aplicar a Resolução 196/96¹ do Conselho Nacional de Saúde - CNS, às pesquisas qualitativas em saúde, que se baseiam em paradigmas não positivistas. Nestas pesquisas, frequentemente as decisões sobre a pesquisa são tomadas conjuntamente com a comunidade em estudo. Há a preocupação de favorecer a justiça e a mudança social. E, uma vez que a subjetividade pode ser considerada seu instrumento privilegiado, busca-se o balanço entre objetividade e subjetividade, e discute-se como superar a visão do pesquisador. Estudamos o âmbito de aplicação e a concepção de pesquisa presentes nas diretrizes éticas internacionais e brasileiras. Verificamos que elas adotam uma concepção positivista de pesquisa, que prevê: teste de hipótese, definição prévia de todos os procedimentos pelo pesquisador e neutralidade do pesquisador e do conhecimento produzido. Serão apresentadas algumas características das pesquisas qualitativas, as implicações éticas da maneira como a pesquisa qualitativa é concebida nos paradigmas não positivistas e um breve histórico dos documentos sobre ética em pesquisa. Concluímos que não é adequado analisar estas pesquisas com base nestes documentos e sugerimos a elaboração de diretrizes específicas.*

Palavras chave *Ética em pesquisa, Pesquisa qualitativa, Pesquisa em serviço de saúde, Ética em pesquisa em Ciências Humanas e Sociais, Bioética*

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Health researches in Social Sciences and Humanities

The objects of study for researchers in Social Sciences and the Humanities are generally not reached by means of the methodologies used by the Natural Sciences. For this reason the former has been discussing epistemological and methodological matters, since the early ages of sciences and research education, with a view to constructing more adequate methods to deal with these objects of study.

Even when dealing with body related issues, these researches generally consider the meanings ascribed to the body, how these meanings are experienced by each person, rather than dealing with the physical body *per se*. By selecting another's subjectivity or the relationship between people, or even the attribution of meaning as their objects of study – to cite just a few examples –, these works cannot exclude the researcher and, instead of seeking impartiality (here understood as non-interference from the part of the researcher's subjectivity), they assume that it is impossible to exclude such subjectivity, thus becoming concerned with reaching an appropriate balance between subjectivity and objectivity – which is partially achieved by acknowledging the social place from which one speaks and the quality of the relationship established with the researched. In such studies, the researcher's subjectivity is, so to speak, their privileged working instrument. In this sense, we should resort to Gadamer's² words when he states that the person who understands does not know or judge from merely facing the others without being affected by them; it is through a specific sense of belonging that binds him to the others that understanding takes place, in such a way that he is affected with them and thinks as they do.

Qualitative research has come a long and important way within the areas that compose the Social Sciences and Humanities, and has been used with increasing frequency in the Collective Health field – essentially interdisciplinary. Qualitative research is a field of investigation *per se*^{3,4}. It introduces a number of complex and interrelated lexical terms into the realm of sciences. There is no paradigm to which it specifically adheres; instead, a number of subject areas and theories adopt qualitative approaches³.

Different techniques may be employed by qualitative research, and these may be divided into: data collecting techniques, data registry techniques and data analysis/interpretation techniques⁵. Vast literature on such techniques is available. Among

those referring to data collection, one will find: life stories, interviews, focal groups, and participant observation, to name a few. Those for data registry include: field notes, photography, audios/video recordings, etc. The ones referring to data analysis/interpretation include: discourse analysis, content analysis, among others. The combination of several techniques, empirical material, perspectives and observers in one sole study, all coherently articulated, is a strategy that adds rigor, complexity, besides enriching and deepening the research. This allows everyone to know and tell the same story from different points of view.

Often there is no hypothesis testing in qualitative research. Instead there is a search for the understanding of meaning and intention – as inseparable from actions, relations and social structures⁶. It is thus an interpretative and naturalistic approach to seeing the world, since it studies *things* in their natural environment, seeking to make sense of phenomena or to interpret them from the meanings attributed to them by people who do *things* together in places where these *things* are habitually done. The research field consists of a group of material and interpretive practices that make this world visible in a different way³.

Qualitative research is a contextualized activity that locates the observer in the world. In texts produced from a piece of qualitative research, many differing aspects will be pictured simultaneously: different voices and points of view. Each metaphor used can be employed so as to create simultaneity, rather than a linear sequence. These texts move from the personal to the historical and cultural realms; they are dialogic and assume an active audience, such as readers who are invited to explore different views of a context, to dive into it and surface with new realities to understand³.

The idea of being adopted in different paradigms and of making use of different techniques – which may be combined in one sole study – makes it difficult for researchers to agree with one sole definition of field, simply because it is never the sole field. For this reason, we agree with Nelson, as stated in Denzin and Lincoln³, adopting the following definition: *Qualitative research is an interdisciplinary, transdisciplinary [...] field. It cross-cuts the humanities and the social and physical sciences. Qualitative research is many things at same time [...] Its practitioners are sensitive to the value of the multimethod approach. They are committed to the naturalistic perspective and to the interpretative understanding of human experience. At the same time, the field is inherently political and shaped by multiple ethical and political positions*

Paradigms and ethics

It is important to highlight that researchers who use qualitative methods may combine several techniques in one single study, however there is no consensus as to the possibility of used different paradigms in one single piece of research.

Methods employed to generalize, analyze and organize data are context-bound. They are defined by an intersubjectively pre-determined background, by "truths" through which social values and ideology are expressed in research and are inscribed within theories, hypotheses and models that define the research projects. Thus, research and knowledge production are not produced by means of an individual cognitive process; they are rather social productions. Objectivity is, consequently, manifest by social relations⁷, much as the outside perception is marked by the researcher's assumptions, as argued by Bateson⁸: *Outside experience always experiences interference from the specific sensorial organ and from neural paths. The objects are therefore my creation, and my experience with them is subjective, not objective. [...] The two generic processes – firstly, that I am unconscious of the formation process of images that I consciously see and, secondly, that through these unconscious processes I use a number of assumptions that become inbuilt in the finished image – are, for me, the beginning of empirical epistemology.*

Thus, the explanation is supported by description that depends upon perception. This perception is, in turn, intimately related to each one's assumptions. We therefore highlight the relevance of scientific assumptions – paradigms – and the importance of explicating them. It is both difficult to consider a scientific production as individual, since the researcher is strongly context and time-bound, and to consider it as a mere social production, since the individual does not simply carry out what the social environment "proposes", but also re-creates this environment. In other words, the researcher collects or generates empirical material related to the matter of investigation and then analyses and writes about it, always from a specific interpretive community. Each community has their own historical research tradition, which constitutes a specific point of view. According to Gadamer², [...] *the interpreter's belonging to their text is just like the belonging of the point of view in the perspective one confers a picture [...] someone who understands, does not arbitrarily choose their point of view; rather, they find their fixed place beforehand.*

Paradigms adopted by the researcher previously define the researcher's place in the field, and the quality of relationship that will be established with the researched group.

Thomas Kuhn⁹ is an important author when it comes to discussing the question of paradigms. He reports his surprise when working with social scientists and noticing the number and the extension of disagreements when it came to the nature of methods and scientific problems. This led him to question if practitioners of Natural Sciences had more solid or permanent answers for these questions. He noticed that, although astronomers, physicists, chemists and biologists were not used to evoking controversies about the basis they did not have answers to these questions either – even though they did not discuss them frequently. It was the search for the reason of this difference that made him notice the role of paradigms in scientific researches, or, in his words: "[...] paradigms (are) the universally accepted scientific accomplishments that, for some time supply problems and model solutions for a community of practitioners in one given science".

Once the paradigms are established, the scientists from a given area can seek support in them and proceed in their researches, without the need to process any daily methodological discussion. In calm moments, these paradigms are unchallengeable, and facts that do not seem to fit them are often not even noticed or worthy of being noticed by researchers. However, as these anomalous events are seen, and become numerous, competing paradigms arise. A scientific revolution is, therefore, preceded by a pre-paradigmatic period, whose characteristic is the co-existence of several paradigms, none being hegemonic. When one of them is established as superior, the others are abandoned.

Following this reasoning, Kuhn⁹ states that Science takes the paths of discontinuity and ruptures, rather than that of linear growth, with continuous incorporation of new knowledge. What happens is that in post-paradigmatic period, or after each scientific revolution is processed, ruptures are hidden in the subsequent texts and with the incorporation of new paradigms; the authors start to write as if they had always been there to determine the interpretation of data. This may give the reader the impression of continuity, which in fact did not happen. In this perspective, paradigms are incommensurable and, for this reason, it is not possible for one person to "combine them".

Denzin and Lincoln¹⁰, in turn, consider that the paradigm is a human construction that en-

compasses four concepts: ethics, epistemology, ontology and methodology. Ethics is the concept that “asks”: How can I be a moral person in the world? Epistemology poses the questions: How do I know the world? What is the relation between the researcher and knowledge? In other words, all epistemology implies an ethical-moral position about the world and about the researcher, as assumes Christians¹¹. Ontology poses basic questions about the nature of reality and the nature of humans in the world. And methodology focuses on the best means to obtain knowledge about the world.

However, Denzin and Lincoln¹⁰ consider that there are situations in which it is possible to combine paradigms. They exemplify by stating that positivist and post-positivist paradigms can be combined between them, though none of them can be combined with paradigms such as the interpretive, the post-modern critical theory, constructivism and participative inquiry. We believe that this impossibility is due to the very nature of paradigms, especially the positivist paradigms, which do not admit ambiguities or contradictions. If we take the paradigm of complexity into account¹², with its assumption of co-existence and articulation between contradictions, then the dialogue would be possible.

In this paper, inspired by Kuhn's⁹, and Denzin and Lincoln's¹⁰ texts, we use the term paradigm to refer to the beliefs that the researcher has and shares with their peers even before designing a research project – which includes their understanding of the world and about the human being, about the way knowledge is produced, about how to scientifically validate their work, and about their role in the application of this knowledge. We believe that the assumptions guiding the researcher's work can contribute to defining how their relation with the participant will be, which has key ethical implications. And, much as Nelson and McPherson¹³, we consider that in order to facilitate discussions, it is possible to establish three groups of paradigms: positivists – which include positivism and post-positivism –, interpretive – which includes constructionism and hermeneutics –, and critical – which includes the critical theory and the neo-Marxism.

We consider it fundamental that the researcher should know in which paradigm they are basing their work, and, if appropriate, that they make their combinations. What seems undesirable to us is the lack of reflection about such aspects since this could lead not to a combination of paradigms, but to a confusion that may place

the researcher in ambiguous situations in the research realm. It is necessary that the researcher should know their place in the field of research – if they seek impartiality or if their subjectivity is assumedly present, and how it will be taken care of. This is fundamental to the definition of quality of the relationship that will be established between the researcher and the researched.

To give an example, we can say that a constructivist study – in which the researcher aims at constructing, with participants, a consensus from the many realities each one brings – is unattainable if there is no trust relationship between participants and researcher. Besides, if the researched has not fully understood what the research will be about, they will not be in a situation to participate, which will then alter the result of the study. Thus, the competent use of this scientific method presumes respect to ethical aspects, especially in terms of previously informing participants about the research and of only conducting it after the consent from the researched group. Thus, we can see that, in interpretive and critical paradigms, ethics is intrinsic to the research methodology.

We conclude that it is essential to consider the paradigms that guide each research, so that it is possible to proceed to the analysis of ethical aspects. Next, we present the international guidelines on ethics in research – which were reference for the writing of Resolution CNS 196/96 – and we analyze their declared scope of application, as well as their research definitions, which will allow us to identify in which paradigm each one of them is situated.

Standardizing documents for ethics in research with human beings

Ethical aspects about research with human beings have been standardized with international relevance since the publication of the Nuremberg Code¹⁴ in 1947 (before that, there were documents for local use in some places such as Prussia (1901) and Germany (1931), which did not, however, have international reach). The World Medical Association published the Helsinki Declaration¹⁵ in 1964 (reviewed in 1975, 1983, 1989, 1996, 2000, 2002), whose current version dates of 2004. The Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO) designed, in 1991, the International Guidelines for Ethical Review of Epidemiological Studies¹⁶, currently under revision, and the In-

ternational Guidelines for Biomedical Research Involving Human Beings¹⁷, of 1982 (reviewed in 1993 and 2002). These documents have broadly been promoted and, in several countries – Brazil included – they have become important reference for the design of national guidelines on ethics in research with human beings. For this paper, the cited versions of the Resolution 196/96 were analyzed.

Another document of international relevance was the Belmont Report¹⁸, published in 1979. It is the work result of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, set up by the government of the United States. This report presents ethical principles to be taken into account in such pieces of research, and has become a reference for a number of different documents.

We need to highlight that these documents delimit their field of application and present a definition of research that is adequate to them. The Helsinki Declaration¹⁵, for example, is designed for medical researches, and informs the reader that the “purpose of biomedical research involving human beings must be to improve the diagnostic, therapeutic and prophylactic procedures, as well as to understand the etiology and pathogenesis of the ailment.”

CIOMS¹⁶ have been concerned with epidemiologic researches and consider that “research is conceived so as to produce new knowledge, which is generalizable, differing from the kind of knowledge about one single individual or a program”. The Belmont Report¹⁸ adopts the term research to “[...] design an activity that is planned to test a hypothesis, which allows one to reach a conclusion and develop or contribute to generalizable knowledge (expressed, for example, by theories, principles or by the establishment of relations)”. Understanding assumed by this document states that the research should usually be described by a formal protocol, which presents objectives and procedures. CIOMS¹⁷ were designed to assist in the definition of national policies on ethics in biomedical research, and employs the term “research” to refer to *the class of activities whose objective is to develop or contribute to generalizable knowledge. Generalizable knowledge consists of a set of theories, principles and relations, or in the accumulation of information on which those theories are based, that may be confirmed by scientific methods of observation and inference accepted.*

The 196/96 CNS Resolution adopts the same research concept as the 1993¹⁷, though the Brazil-

ian norm broadens its scope to *all procedure, of any nature, involving human beings, whose acceptance may not yet be established in scientific literature, will be considered research and should, therefore, follow the guidelines of this resolution. Referred procedures include, among others, those of instrumental, environmental, nutritional, educational, sociological, economical, physical, psycho or biological natures, regardless of their being pharmacological, clinical or surgical in approach and of their preventative, diagnostic or therapeutic purposes*

One can therefore see that much as the Belmont Report¹⁸, also the CIOMS (1982, 1993)¹⁷ norm and the 196/96¹ CNS Resolution have showed, from the beginning, a biomedical concern, and all of them assume the same research paradigm. The situation with the 196/96 CNS Resolution is, however, extreme, being applied to researches that involve human beings from any epistemological area. We need to also state that the Belmont Report¹⁸, whose application scope are biomedical and behavioral researches, suggests the design of specific guidelines for social researches, as seen in the extract below, taken from the Report's third footnote: *Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specially declines to make any policy determination regarding such research at this time. Rather, the commission believes that the problem ought to be addressed by one of its successor bodies.*

If one compares the research definition found in the 196/96 CNS Resolution with what has been discussed here about qualitative research and non-positivist paradigms, it is possible to see that these approaches to research are very different.

Characteristics of qualitative research in the health area, which do not follow a positivist paradigm and the 196/96 Resolution: incommensurable differences

Ethical aspects are intrinsic

In positivist paradigms there is a search for non-interference from both the researcher's and the researched group's subjectivities. The search for “neuter” knowledge implies that values are considered unwanted since they could lead to the questioning of the study's results. In interpretive and critical paradigms, however, researcher's subjectivity is an important instrument in the

research. It is not possible to isolate the knowledge produced from the person that produced it – which makes the researcher's reflective ability a permanent need. "[...] look at oneself; understand oneself; correct oneself, which is both a principle of thought and an ethical need"¹⁹. Ethics becomes part of the research – not an outside aspect to be separately evaluated. Ethical aspects are intrinsic to qualitative, non-positivist researches.

This does not mean that the discussion of ethical aspects in research can be forgotten. On the contrary, it must be continuously maintained throughout the research. It is worth mentioning that the consequences of an action, even if righteous, are not totally predictable. For this reason, it is necessary to make an "ethical bet", as suggested by Morin¹⁹, assuming uncertainty, recognizing the risks and designing a strategy.

The incorporation of a strategy admits the actor's permanent vigilance during the whole action, considers the unexpected, modifies the strategy during the action and, eventually, stops the action if there is prejudicial deviance. The strategy remains an errant navigation in an uncertain sea, and evidently requires pertinent reasoning⁹.

The researcher-researched relationship

Qualitative research, often conducted by researchers in the Social and Humanistic areas, is carried out *with* human beings; the researched do, in fact play a role of subjects, since they "[...] are regarded and treated as people, i.e., as social-cultural entities; and not only as human beings, i.e., as biological entities [...]"²⁰. With this concept of the researched in mind, many times the researcher defines the object of the study itself, as well as the strategies, with the researched. In Schmidt's²¹ words: ***The interlocutor (researched) explicitly places in the scene their need to negotiate the common and diverging interests belonging to the researcher and the group of individuals that take part in the research. This happens because the observation, the field co-existence and the interviews are conceived as shared situations of work that must interest both sides, as process and as work. The dialogue is the vehicle used for the construction of a kind of knowledge whose authorship and ownership are also shared.***

While discussing the specificities of Clinical Psychology research, Figueiredo²² considers that the result is not sought by the researcher, but is found by them, since the clinical space may be defined as the establishment of a time and place in which "the other can become and show them-

selves in their otherness." Certain findings can only be made in such clinical space precisely because "and as far as the clinic provides a unique ethical experience, that of the unexpected in their irreducible alterity". This is a kind of relationship that incorporates ethical aspects, since, as stated by Emmanuel Levinas, ethics implies respect for the other in their otherness; and that, on the other hand, if not adequately established, prevents the fulfillment of the research.

Anthropology has established ethnography as their own method to investigate social reality. Ethnography implies a social relation between the researched and the researcher. Ethnographers seek to establish a close relationship, one of trust, with their researched groups since this would define the quality of data. Without the establishment of this trust relationship, the research can even be void⁵.

In qualitative research, which operates outside positivist paradigms, the relationship between researcher and researched is close, based on trust, in which differing interests are discussed in the open, and decisions about the research may be shared – including its objectives and strategies. Thus, the very design of the research is being constructed throughout its process, in such a way that the researched is actively participating; defending their interests and is taking part in the research while it is of their interest to do so. We have therefore noticed that the principles of autonomy and beneficence, that base the 196/96 CNS Resolution are contemplated in these researches, due to their characteristics; they are compatible with their paradigm, and will be considered when it comes to peer validation.

The researched exercises their autonomy not only because they can consent to participate in a piece of research, but also because they can interfere in its construction process.

Informed consent

Among researchers that adopt qualitative approaches, the importance of presenting their work proposal to the probable researched group or individual and of including in the study only those who have agreed to take part in the research is unquestioned. However, the way this process of information and consent is going to occur is intimately related to the quality of relationship that the researcher intends to establish with the participant. Therefore, the free and informed term of consent must be considered in principle, but not in procedure to be followed, as per the 196/

96 CNS Resolution. In qualitative research, consent is procedural, which is coherent with its emerging design. The requirement that the informed consent be in written form is often not appropriate – for cultural reasons, or due to the researched conditions, such as illiteracy, or even in order to protect them – in the case of researches with people who are in conflict with the law.

Scientific merit

Scientific merit is fundamental. However, criteria to judge them are different in differing paradigms, and must be respected. To cite just one example, Lincoln²³ sought to understand how ethics would relate both with the interpersonal and the epistemological aspects. And she proposed a number of quality criteria linking epistemology and ethics, to judge the texts produced by qualitative researchers. The criteria are: (1) Introduction of researcher's point of view and judgments; (2) The fact that the researcher assumes that the researched and their speeches are quality controllers; (3) Notice the voice that is expressed in the text, or to what extent the text presents different voices; (4) The presence of critical or self-reflective subjectivity; (5) Reciprocity observation, i.e., to what extent the relationship in the research becomes reciprocal rather than hierarchical; (6) Sacrality observation, i.e., to what extent does scientific knowledge contribute to the full development of the human being; (7) Observation of the researcher's availability to share privileges to which they have access due to their professional situation.

These criteria also evidence that ethical aspects are intrinsic to methodological aspects in these researches; and that it is not adequate to evaluate scientific merit by taking into account criteria from a paradigm that is strange to the project.

Anonymity

In qualitative research, the researcher usually knows the researched personally and by their names. Besides, the researched often know each other. It is the researcher's role to discuss with their researched if they wish their names to be kept a secret when the research results are published or, if they prefer to be identified.

Keeping the researched's identities secret is a very intricate task in qualitative research, because, as we have seen, it is contextualized and habitually cites speech excerpts. It is quite rare that the members of the researched community will not

identify each other when reading the results of the publication. However, there are situations in which maintaining anonymity is essential, and the researcher actually needs to make this commitment – for example in researches about violence, drug trafficking, etc.

A procedure that is usually adopted in qualitative researches is to send the collected material, as well as the analyses carried out to the researched, requesting that they evaluate if they consider they have been adequately represented, if anonymity was sufficiently respected or if the opposite occurred: if the participant was inadequately identified, and if the study results can somehow damage the community. Besides allowing for the researcher to confirm if they have been adequately identified or if anonymity was adequately kept, this exercise improves the quality of analysis, and allows the researched to participate in the result construction²⁴.

Maintenance of anonymity – or lack thereof – must be carefully analyzed and decision must be jointly made by researcher and researched. It is essential that this decision be explicit for all involved.

Emerging design

Qualitative research may present an emerging design, i.e., one that is built throughout the work, with decisions being jointly made by researcher and researched. For this reason, it is not always possible to describe all the procedures of the study, presenting them in detail, in a previously conceived project, as per the 196/96 CNS Resolution. This happens because the researcher may choose to share decisions about the study with the researched, throughout the investigation.

However, we need to point out that this does not exempt the researcher from a previous research project, in which their proposal is clearly defined, as well as objectives and techniques that will be used in the research because, though it is not possible to detail every step, it is still important to explicit the means by which each decision will be made, and what criteria will be followed.

Conclusion

The CNS 196/96 Resolution does not identify its support in the positivist paradigms, and states that the resolution should apply to all researches that involve human beings. Thus, the reader, and especially the ethical committees are left with the false

impression that there is one sole way of carrying out scientific research, and to this, the resolution is applicable. This makes it difficult to identify incompatibility in the application of these guidelines in concrete cases due to the diversity of paradigms involved: what is at stake is the use of a resolution that is supported by a certain paradigm to analyze a project that may be supported by another paradigm. And, as Kuhn⁹ said, different paradigms are incommensurable. Even authors^{13,10} that consider it possible to commensurate some paradigms, such as the interpretive paradigms, do not consider it possible for the establishment of a dialogue between positivist, interpretive and critical paradigms – which is our discussion.

We thus conclude that, since different researches can work with very diverse logics, it is inadequate to treat them in the same way. We think it is essential that the design of specific guidelines for researches guided by paradigms other than the positivist. Operationally speaking, it is crucial that the ethical committees, that evaluate a large number of researches with human beings, include researchers that adopt different paradigms and use different methodologies, and also that all the members of these committees be capable of discussing different research paradigms, stressing that, in some, the ethical aspects are intrinsic to the methodological aspects.

Collaborators

Dallari SG advised the doctorate thesis written by Guerriero ICZ and they both worked on the elaboration of this paper.

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