# Re-imagining the "subject:"conceptual and ethical considerations on the participant in qualitative research

Re-imaginando o "sujeito": considerações éticas e conceituais sobre o participante de pesquisa qualitativa

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Abstract The conventional biomedical concept of the "human subject" is out of step with World Health Organization's (WHO) holistic definition of health. The "human subject" in international and national research-ethics policies is a highly individualistic, autonomous person, in contrast to WHO's holistic definition of the healthy person. Qualitative research, this paper suggests, offers a way out of this conundrum. We need to reconceptualize the human "subject" in line with WHO's holistic definition of health. The paper offers concepts of "research participants" derived from qualitative research as an essential way to reconceptualize the human "subject." Moreover, field work, or ethnographic research, as undertaken by qualitative researchers presents a useful way of gaining a fuller understanding of issues of health in a given population.

Key words The "subject", WHO, Ethics, Health research, Qualitative research

Resumo O conceito convencional biomédico de "sujeito humano" está distante da definição holística de saúde da Organização Mundial da Saúde (OMS). O "sujeito humano" nas políticas nacionais e internacionais sobre ética em pesquisa é altamente individualista, uma pessoa autônoma, em contraste com a definição holística de pessoa saudável da OMS. Este trabalho sugere que a pesquisa qualitativa oferece uma saída para este dilema. Nós precisamos re-conceituar o "sujeito" humano na linha da definição holística de saúde da OMS. Este trabalho oferece conceitos sobre "participantes de pesquisa" derivados da pesquisa qualitativa como uma maneira essencial de re-conceituar o "sujeito" humano. Além disso, o trabalho de campo, ou pesquisa etnográfica, tal como conduzida pelos pesquisadores qualitativos, oferece uma maneira útil de adquirir uma compreensão mais completa sobre saúde em uma dada população.

Palavras-chave O "sujeito", OMS, Ética, Pesquisa sobre saúde, Pesquisa qualitativa

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#### Introduction

The conventional biomedical concept of the "human subject" is out of step with WHO's holistic definition of health. Qualitative research, this paper suggests, offers a way out of this conundrum. This paper explores the ramifications of conceiving the "subject" in conventional terms for the purpose of conducting ethical qualitative research. First, the paper considers the idea of the human "subject" from the perspective of a number of representative research-ethics codes, internationally and nationally. It then examines how these conventional constructs of the "subject," originally conceived in the medical field, are permeating current research-ethics codes that govern the social sciences. The paper then presents a number of constructs as to what one imagines the research subject to be. It sees the biomedical concept of the "human subject" as inadequate to the task of following through on WHO's holistic concept of health.

The second main element of this paper consists of its central goal, namely to reconceptualize the human "subject" in line with WHO's holistic definition of "health." The paper offers concepts of "research participants" derived from qualitative research as an essential way to reconceptualize the human "subject." Moreover, field work, or ethnographic research, as undertaken by qualitative researchers presents a useful way of gaining a fuller understanding of issues of health in a given population.

## The "subject" in international and national research-ethics codes

Protecting "subjects" is a central purpose in all international and national research-ethics codes. The World Health Organization, in its Operational Guidelines for Ethics Committees that Review Biomedical Research1, clearly states that, compliance with these guidelines helps to "ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible." It furthermore claims that a "cardinal principle of research involving human participants is 'respect for the dignity of persons." Canada's Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans highlights the collaborative nature between researchers and human subjects which, "entails an active involvement by research subjects, and ensures both that their interests are central to the project or study, and that they will not be treated simply as objects." 
The Ethical Guidelines for Social Science Research in Health of India<sup>3</sup> elucidates four principles underlying research ethics. One of them is the principle of nonmaleficence: "Research must not cause harm to the participants in particular and to people in general." There are, of course, such principles in other codes throughout the world.

What stands out in international and national codes is their origins in medicine. The history of these codes are familiar to most readers, namely the Nuremberg Code (1947) in the aftermath of human experimentation in Nazi camps in World War II, followed by the Declaration of Helsinki in 1964, which the World Medical Association subsequently amended. The Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization followed suit. This international concern about experiments on humans (the current more neutral terms, "studies", "trials," or "research" point to the lingering worries about experimentation) penetrated national research-ethics codes and have subsequently shaped ethics codes that also govern social research, not just medical research. The protest of social researchers against the application of such codes to their research has been well documented, although rarely taken heed of4. The move around the world to set up and enforce research-ethics codes echoes the Western, deductive template. Structurally, these policies produce a dislocation of the research enterprise in the social sciences.

Currently standing at the cusp of governments' internationalizing research-ethics codes, we can already discern a number of features that stand to leave a mark on the future of research in the world. First, as alluded to above, the formal research-ethics codes are so extensively based on biomedical research that they have disenfranchised many other forms of research, or at least made it more problematic for those who wish to pass ethics review. At the same time, these disenfranchised researchers have become restive. While at first, complaints found their way to the surface in oblique and uncertain terms, often voiced by social scientists and sociologists and anthropologists in particular<sup>4</sup>, today, the trustees of these research-ethics regimes have opened more formal channels to find ways to make room for these researchers by means of structural and textual changes in the codes.

Still, international and national research-ethics codes are overwhelmingly biomedical in their conception and orientation, disfavouring research

in the social sciences, in North America and elsewhere. Florence Kellner<sup>4</sup> avers that the implementation of these ethics codes may "bring natural science even closer to us than it has been before the new policy came into effect." The "gold standard" for ethics review might, in fact, be tainted because of its blind eye to the reality of other forms of research, such as inductive and qualitative research. The Canadian Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS) contains 476 paragraphs, of which only four are devoted to "natural observation" research, with three of those paragraphs stated as cautionary notes. Moreover, the word "subject" is favoured in this and other codes over "research participant," a term that finds more resonance among qualitative researchers because the term "subject" has a pejorative connotation for these qualitative researchers. For while it is true that one occupies the position of "researcher," there is a far greater sense of collaboration with interviewees than is customary in **e**g survey research.

National research-ethics codes extend to judging the adequacy of the research design itself. They speak of the importance of maintaining a "common standard" of research and scrutinizes applications on the basis of various levels of harm that might be inflicted on research subjects. These codes speak of research "protocols," a term that makes eminent sense to medical researchers, but is quite unfamiliar among social researchers who see their work in a more emergent-research design sense.

While hypothesis testing is familiar to medical and other researchers, the idea of emergent research paradigms is wholly absent from national research ethics codes. Such ethical areas as publication that are crucial to social researchers are entirely ignored. While medical researchers are more likely to receive anonymized data, social researchers remain familiar with the identity of those whom they have interviewed or observed. As a consequence, ideas about anonymity, confidentiality, and privacy, taken on a different colour for social scientists.

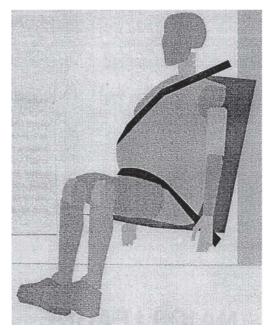
Returning to the dilemma of the human "subject," this paper presents a number of models of "subject." (Over the past few years, however, medical researchers are increasingly using the term "research participant," rather than "subject" – such a switch indicates the dynamic nature of change in research ethics across Canada, and possibly elsewhere, too.) Indeed, one might raise the question "what is a 'subject'?" It is a question

that significantly defines the kind of research one is pursuing. Figure 1 provides one idea as to what a research "subject" can look like.

Some would argue that the crash-test dummy does not represent a "living human subject," in the words of a number of ethics codes and therefore any research on crash-test dummies would not require ethics review. They are, in fact, inorganic objects in every sense of the word. But are they? Countless are the number of lives affected by the selection of particular crash-test dummies, including death if the "wrong" ones had been tested. The "pregnant" crash-test dummy in Figure 1 acknowledges its reality as a proxy human.

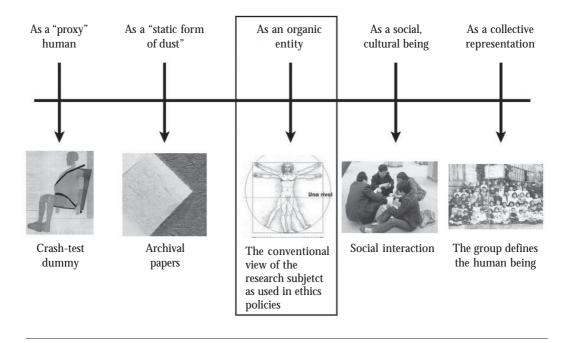
Figure 2 pulls the proxy human into a larger scheme of what is a human subject. The crashtest dummy, on the far left, represents one way to imagine a research subject, although there are no known places in the world where research on proxy humans would have to go through ethics review.

Figure 1. Meet proxy human "GHIII50%".



Source: Volvo Magazine, January 2003:7 (Reproduced by permission of Volvo Canada, 12 July 2006)

Figure 2. "What is Human Subject?"



The use of archival papers, as represented by the second item on the left in Figure 2, (as "a static form of dust") is another example of a research subject, albeit not used as such in any North American setting. However, enough about archival papers has been said to allow them as human "subjects" for research purposes as is the case in France. Who is to say that the living descendants of those collections are not affected by archival searches? Ironically, historical papers may shape the future and may invoke researchethics review as "static forms of dust."

The most commonly accepted view of the "human subject" is the perception that it is an organic entity. Little needs to be said about this orientation as common as it is. A heightened sense of individualism is one consequence of this view of the "human subject." The relevance of autonomy and independence of the *individual* research participant is salient from this perspective and it is this perspective that dominates the discourse on ethics in research. It is of considerable interest to note that the idea of invoking the human subject as "autonomous" seems to have a special appeal to medical researchers and physicians who are

"not too interested in ethical theory, but in need of a way of thinking through ethical dilemmas<sup>4</sup>". Thinkers have criticized this approach (named "principalist") since the 1990s. These criticisms have not found their way into any ethics regimes.

The next frame, the research participant as a social being, points to the social nature of the human being. It was George Herbert Mead<sup>4</sup> who links the "discovery of society," with the child's discovery of the self. There is therefore very little that is "personal data" in the individual. The term "personal data," from the perspective of sociologists functions more as a heuristic and functional device than one based on social reality. From the perspective of sociologists, much is assumed under this social nature, ranging from body postures and mental outlooks, to social interaction in, for example, a card game (including their receptivity to being photographed by a sociologist). Even illnesses and sickness fall into a moral hierarchy, entirely constructed by society, shaping their treatment or research4. The sufferings of children on account of an illness beyond their control are accorded a higher moral status, whereas adults bringing upon themselves illness on account of their own doings (e.g. smoking) occupy a lower status on the moral hierarchy. This hierarchy, which is entirely socially derived, shapes not only the self, but also the medical priorities proffered to the research, treatment, or cure of the relevant illness.

The final frame, the research subject as a "collective representation" is more difficult to visualize for those of us who are more acquainted with individualism as a running concept of the research subject. This frame suggests that the research participant forms part of a larger whole, and perceives him- or herself in that manner, too. The case of many Aboriginal communities in Canada comes to mind. What significance must one attach to getting ethical clearance from a leader to undertake research amongst his or her followers? Who should, ultimately, give consent? Do corporate structures fall into the same category? Who, in the final analysis, gives consent for the study of family-friendly policies at a corporation4. The CEO on behalf of the employees? However, the "total institution" (a sociological concept to designate a place where its inhabitants (inmates, mental patients, etc.) are provided with all of their basic needs within the institution) does not fall into this frame. These inhabitants do not, as part of their world view, surrender the individuality to the larger whole. If anything, some will fight that view.

Naturally, the boundaries between these differing conceptions of the human subject are blurry. For example, is a patient's medical record an archival artifact or does it fall under the category of "organic entity?" Does research involving the Munchausen-by-proxy syndrome fall under "organic entity," or as part of the subject as a "social being?"

The point is simple: the concept that research subjects are organic entities might be a moot point when it comes to social research.

### The "subject" in the medical paradigm

For the purpose of this paper, I would like to focus on the concept of the "subject," partly because that is the element that is central to the core of ethics policies, and partly because the meanings that medical researchers attach to that term can be significantly different than what social scientists mean when they come across human "subjects." As mentioned earlier, it is thus the medical paradigm of the "subject" that drives the researchethics debate and that confounds social researchers. I also suggested that this particular para-

digm runs counter to WHO's own holistic definition as to what constitutes health.

International and national ethics codes resonate with the following as core values of the human "subject:" individuality, autonomy, independence, and the "personal" nature of research information. *The Ethical Guidelines for Social Science Research in Health* of India highlights this individuality: "Research involving participation of individual(s) must not only respect, but also protect the autonomy, the rights and the dignity of participants. The participation of individual(s) must be voluntary and based on informed consent."<sup>4</sup>

Autonomy and independence are concepts that align themselves well with the idea of individuality. The most recent Australian draft document contains only two mentions of autonomy, including this one: It centrally involves recognising that each human being has a value in himself or herself, and that this value must govern all interaction between humans. Such respect includes recognising the value of human autonomy — the capacity to determine one's own life and make one's own decisions'.

Canada's TCPS mentions autonomy, autonomous, or independence (as related to research subjects) at least four times<sup>4</sup>. The Council for International Organizations of Medical Sciences refers five times to the concept of autonomy in its revised/updated *International Ethical Guidelines for Biomedical Research Involving Human Subjects*<sup>4</sup>. Even more numerous references to "autonomy" can be found in the 1979 *Belmont Report* of the United States which lists at least nine such references. For example: "Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection."<sup>4</sup>.

It is an important philosophical premise to see individual human beings as primarily "autonomous" entities. Such a premise conjures the view of a human being without relations to others. Such an extreme reduction of humans ignores the relevance and importance of wider social relations in which every decision and every consideration by a single person carries the bag of previous experience, culture, and history. Human subjects, of course, do have numerous instances of individuality and specific attributes, such as age, height, reactions to pain and pleasure, responses to treatment and clinical trials but even then there is so much invested in culture and society that it is impossible to claim that a human subject is autonomous. Let alone the social circumstances in which trials are administered by another human being. There is no escape from social relations.

It is a logical step to regard any data emanating from the "autonomous" human subject as "personal." Research ethics codes thus privilege the idea of "personal data" which then must be anonymized and protected. We have no disagreement with the fact that data must be protected. However, we are concerned that such narrow perceptions of human subjects as "autonomous," rendering "personal" data do not provide any avenues for conducting advanced qualitative research.

Advanced qualitative research works on a different premise than conventional medical research. The research is inductive, i.e. clues about the nature and direction of the research are usually driven by the research participant, not the researcher. Second, the sort of data that qualitative researchers seek are social-context based (while in medical science "control" are used to factor out social context). The data generated by participant observation, in-depth interviews, focus groups, conversations, chats, etc., are related to cultural and social facts. Qualitative researchers do not pursue "personal" data as an end of themselves; rather, they see their data as "social," for their analytic framework is a social one, not driven by personal information.

This conception of the non-autonomous human subject and the analysis of data as social concepts challenge conventional views of research. The qualitative researcher enters into the social world of the individual and describes that world as a social activity that has meanings that emerge through the interaction of that individual with others. What is significant for the qualitative researcher is not so much the "individual," as his or her thoughts, attitudes, activities, identities which are all lodged in social relations. An exclusive focus on the "person" would be quite meaningless for a qualitative researcher. It is the social world "within" that individual that is analytically significant. Qualitative researchers only come to "personal data" tangentially, and even then "personal" data are social scripts for the human subject, the researcher, and those who read the findings.

Here is one example of "personal" data as "social." In her study on older widowers, Deborah K. van den Hoonaard<sup>4</sup> held in-depth interviews to learn about the meanings that the men attach to having become widowed. Her analysis of the interviews is suffused with social, not personal data, from the manner in which the men

proceeded to answer her questions, the data pertaining to the interaction between her and each man, and to how the men explain their own personal experiences. All of these aspects would have remained below the analytical periscope if she had regarded the data she obtained as purely "personal." Instead, she could only make meaning out the data when she related to the social world of what it is like being an older, widowed, man where there are no masculine models available. Even aggregating personal data would not have helped her: she had to find themes that correlated with wider, social scripts about masculinity, and about meanings the men attach to be without work and without women.

It is crucial that we therefore see that the qualitative-research approach to the "research participant" can come to the rescue of how to approach the "human subject" in a manner more relevant to WHO's definition of health. As the World Health Organization incorporated newer definitions of "health," redefining the "research subject" becomes an urgent task. Üstün and Jakob4 point out that the "word 'health' was derived from the old English word 'hoelth', which meant a state of being sound, and was generally used to infer a soundness of the body." They also point to WHO's accepted definition of health: "a complete state of physical, mental and social wellbeing, and not merely the absence of disease or infirmity." The concept of the "research subject" in medical and health research has not kept up with this more current definition of health. A new paradigm of the research "subject" is essential in this process. It is vital that concepts of "autonomy, "independence," and "self-reliance" be abandoned as an inadequate cornerstone of researchethics policies. If, however, medical researchers have difficulty abandoning the older concept of the research subject, it is time to permit social scientists to take on the concepts that are vitally relevant to their research. In other words, the outdated medical definition of the research subject should be discarded in favour of a social concept of what it means to be human.

### Qualitative research in health as an answer to the conundrum

In many respects, qualitative research in health answers the conundrum posed by the conventional biomedical definition of "research subjects" versus WHO's new, holistic, definition of health. Qualitative research involves many research strat-

egies, such as life-history, interviews, focus group, etc., but I focus on field work (a.k.a., ethnographic research).

Field work involves the researcher's immersion in a culture or group. Given the social nature of the individual, it stands to reason that qualitative researchers must submerge themselves in "field work" as a means of understanding people within their social settings. Field work, however, has proven to pose a major challenge in terms of contemporary research-ethics codes. In light of this challenge and despite their promise to gain a fuller grasp of the human condition, fewer and fewer studies bear the stamp of field work. This decline is especially tragic given the venerable and rich history of field research. Van den Hoonaard and Connolly4 provide a summary of field work (or ethnographic or field research) which is, closely identified with anthropology for nearly 100 years. In its ideal form, it stands for complete immersion in a culture, learning enough about the culture to understand the native's interpretations of behaviour. Ethnographic research has become so compelling that other fields have adopted this approach[...] What distinguishes ethnographic research from other forms of research is the close interaction between researcher and research participant or informant (not "subject"), and the gradual emergence of issues and questions to be pursued as the research moves on. "Protocols" are quite unfamiliar to ethnographers as strategies and techniques of research only become obvious once one enters the field. Anthropologists were adept at "hanging out" as one of their chief means of gathering data. The usual requirements for consent forms or even for verbal consent are based on the medical model in which the subject learns exactly what is to be done, which does not fit the ethnographic model.

In Canada, field research has suffered a significant decline over the past ten years. In sociology alone, the proportion of Master's theses using research participants has dropped from 57% in 1995, in to close to 42% in 2004<sup>4</sup>. Before 2002, the proportion ranged from 8% to 40% (mean: 22%). When one considers that the proportion of theses after 2002, incl., using fieldwork averaged 21% per year, one notices an immense drop of such theses after the introduction of the national research-ethics codes with an annual average of 5.5%. Indeed, as if to reinforce W. van den Hoonaard's finding that field-work-based theses are in the decline, a researcher from a large Ontario university (Presentor R16) had noted there has been an immense decline at the Qualitative Analysis Conferences (which has a high attendance of graduate students) of subcultural research. This is partly due to ethics review and due to decline of participant observation research as a research tool (Notes on Presentations, 14 May 2004)4. In anthropology, van den Hoonaard and Connolly4 also discovered that Canadian Master's theses have increasingly come to rely on interviews as the sole data-gathering technique, namely 47.9% (in 2004-the latest with available data), rather than field work. In conventional field work, interviews were *not* a main component of research, although conversations, chats, and the like were more common then than they are now. There are, of course, many advantages to relying on interviews, but the problem is compounded when no advanced analysis is performed on the interview data, i.e., without bothering with concepts or generic social processes, or when the data are still analytically attached to each individual, on an individual-by-individual basis. In any event, these observations have underscored the process of the homogenization of methods-a research situation where several disciplines have adopted one data-gathering technique, i.e., the interview method. If interdisciplinarity in research is the goal, then surely it involves the integration of the plurality of methods, not the creation of a similar goal. The advent of interview-based research would lead one to conclude that we are also witnessing a pauperization of the disciplines: history, society, and culture are pushed to the background; the "voice" of the participants is privileged. For sure, it is important to hear these voices, but without placing them in a historical and social context, the voices will carry less power.

## The benefits of the approach in qualitative-research

One can visualize two kinds of shifts in qualitative health research vis-à-vis international and national research-ethics codes. On one hand, we can argue that the codes must make room for the social sciences and for qualitative research. They currently do not. On the other hand, we can suggest that the fundamental, biomedical concept of the "human subject" are so completely out of step with WHO's concepts of health, that one of the ways to rescue research is to adopt a qualitative model of the research participant. This paper, as is evident, proposes the latter.

Making international research-ethics policies relevant for qualitative researchers requires two

fundamental shifts. First, they require a more relevant (social) conception of the research participant. Second, they need to acknowledge that field (ethnographic) research requires a rather different approach than what conventional policies can offer.

#### The concept of the research participant

The term of "research participant," as derived from qualitative research has become more ubiguitous than "research subject," even though biomedical researchers still attach the conventional view to the new term. The new concept better expresses the social nature of subjects, including the inevitable relation with the researcher. The Social Sciences and Humanities Research Ethics Special Working Committee of the (Canadian) Interagency Advisory Panel on Research Ethics has already pointed out the "far more elusive and ephemeral" nature of the "human subject" in the social sciences than in biomedical and experimental research4. There are many and varied roles during the period in which a research relationship is being maintained — and the time period here could be anything from weeks to decades, depending on how one defines it — that can cut across any neat distinctions between researcher and human subject. The Committee makes the following, compelling observation about contemporary social research: [...] when the place one does one's research is not the laboratory [or during clinical trials] but daily life, the multiple and divergent roles humans adopt intersect with the research relationship, problematizing any neat distinctions between the researcher and a "human subject." Collaborative and participatory research engages members of a community as co-researchers as well as research subjects4.

The concept of the "human subject," as currently practised in research-ethics codes precedes the time when the World Health Organization has come to define health in a more inclusive way. Unfortunately, "human subject" does not adequately convey that new meaning (which is already over 50 years old). There are several ramifications in re-imagining the "human subject," one of which entails reconceptualizing "personal data."

Research ethicists need to walk a careful balance between acknowledging true personal data and social data. Social data are not just data that reside in the aggregate of individuals, but are also present in each person.

### Usefulness of field research (ethnographic research)

There is no question that current guidelines in research-ethics codes leave little room for field research. It is, however, beyond this paper to consider the historical, empirical, and theoretical intricacies of field work in social research.

It is clear that field research does not involve adding one "research subject", one at a time, building up an aggregate of such individuals for the purposes of research. It is, however, a matter of trying to experience or become familiar with the group or subgroup in question. Although interviews seem now to be part of the research "package," it is (was) more common to participate in that culture over an extended period of time, becoming a "native" as far as personal and social talents of the researcher permitted and depending on the degree of receptivity of the host group. The idea of collecting individually signed consent forms in this context is not only silly but might also be offensive to the group. There are not many examples on record of groups repelling researchers; for much field research, groups welcome the researcher. In the end, researchers have played a key role in dispelling prejudices or alleviating discrimination against the group.

To contribute to knowledge surrounding the holistic definition of health, it is vital that field research proceed along those same lines, i.e. researching the whole social context of the group under study. Significantly, society has gained a holistic understanding of all features of health related to that group or subculture.

To that end, research ethics committee should consider looking at plans of field researchers and to understand the overall objective of a particular research program. One common goal of the researcher (and the ethics committee) would be to find the pinched ethical nerves of the proposed research. How does the researcher plan to handle those pinched nerves? What can the ethics committee do to assist the researched group and the researcher to come to a collective understanding of potential ethical dilemmas? What are the principles of ethics that the researcher can employ when faced with unexpected ethical turn of events? Just as the researcher has the responsibility of frankly presenting the potential (or imagined) areas of ethical pinched nerves, the ethics committee would be obligated to immerse itself in the workings of ethnographic research. The following problematic areas could be handled in an expeditious manner, while fully retaining the dignity of the research participants: (a) there is no need to obsess about the single-focussed need to obtain individually signed consent forms; (b) there should be no compelling need to have the field researcher explain his or her plans as a "protocol" that, by its definition, implies no interpretation of procedures—something that does not make sense in social research. Every research strategy, every purported finding is subject to interpretations, often conflicting ones.

There are, no doubt, other perspectives that ought to be brought to bear on the differences between health research as defined by biomedical researchers and by social researchers. The aim of this paper is to take advantage of the holistic definition of health, as promoted by the World Health Organization. Two issues emerge from

this consideration. First, the term "human subject" in medical research has to be re-imagined to fit the new reality of health, making the social nature of the individual central to its definition. Second, as qualitative researchers are eminently qualified to find and analyze the social context, new research-ethics policies, whether international or national, must find a way of making room for these researchers. Better still, research-ethics policies will be better served by adopting the qualitative-research concept of "research participant" and what that concept implies. Is it not time to re-imagine the "human subject," or better still, the research participant? Is it not time to look at the "human subject" in the same manner as WHO looks at health? This paper suggests that qualitative research offers an answer.

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