

Biomedical Research Ethics:
Updating International Guidelines

A Consultation
Geneva, Switzerland 15-17 March 2000

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with James Gallagher

CIOMS
Geneva 2000

INTERCULTURAL COMMUNICATION AND INFORMED CONSENT

Commentary on INFORMED CONSENT IN INTERNATIONAL HEALTH RESEARCH: (1) CULTURAL INFLUENCES ON COMMUNICATION

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Research-based health care

It is a privilege and a pleasure to offer my comments on transcultural aspects of informed consent presented in the paper of Patricia Marshall, whose contributions to health anthropology are both substantive and inspiring. In order to stay within my own limits in perspective I shall restrict my remarks to medicine, although it should be understood that I employ the word medicine to refer to all social practices related to health¹.

We tend to forget that research-based medicine is a rather recent development in historical time. The very idea of research as a means of attaining certitude and replacing beliefs by evidence stems from the 19th century and probably had its origins in the change that took place in the meaning of "experiment". The experiment in the modern sense is a means, not of observing nature, but of constraining nature to a set of predefined answers. Experiment is not the ancient experience, and the ideal experiment is one in which most, if not all, conditions are carefully controlled or at least monitored, phenomena are provoked or induced, and the personal biases and views of the experimenter do not interfere with the data-gathering process. The ideal in the biological and experimental sciences was to have neutrality, objectivity and universality as guiding values in obtaining generalizable knowledge. Although it was recognized that several conditions affected this picture, among them economic and social contexts, the context of justification, as distinct from the context of discovery, emphasized the production of value-free, culturally neutral and context-insensitive data².

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In point of fact, the professionalization of research activity was modelled on the notion that the scientific method was such a powerful conceptual device that it precluded any spurious influence upon the products of research activities. Students were trained in the methods of their disciplines and in the intricacies of statistical analysis and data-reporting as though these methods and intricacies belonged to a universe of cosmopolitan, timeless and "objective" information. Even today the idea of "scientific" decision-making takes physics as the prime science and all others, particularly the social and behavioural sciences, are considered in a stage of pre-paradigmatic development in need of further refinement to approach the modelic objective disciplines.

It is against this background that I wish to comment on the scope and implications of language and culture in the pursuit of research involving human subjects. This type of research necessarily demands other skills on the part of investigators, and the notion of objectivity and neutrality should at least be re-examined in the light of concurrent developments in the bioethical, legal and economic implications of research conducted in a multicultural setting, where researcher and research subjects belong to different cultures.

Different types of research

It is probably necessary to reiterate that research is not a unitary activity. It varies as to context and goals. Some research is designed to invent new concepts and organize information into knowledge of a generalizable nature. Other types of research are aimed at modifying existing practices or changing the state of previous knowledge. And finally, some research is conducted in the expectation that it will transform those who practise it, or the institutions in which they work, so as to enrich culture and provide new insights to those engaged in the construction of culture.

For the outcome of these three types of research I use the terms *invention*, *innovation*, and *transformation*. In some ways, it may be said that invention is akin to basic or fundamental research, innovation is related to applied research, and transformation is a by-product of research itself, affecting people and institutions explicitly or implicitly. I retain the proposed terms, however, to indicate that "applied" does not always imply application and that there is no unilinear relationship between "having ideas" and "putting them to work". Indeed, fundamental research is no longer "disinterested" research, and "applied" cannot be considered less demanding, less exacting or less important. *Invention* and *innovation* are terms that capture the full dimension of the distinction between science and technology, without implying any hierarchy or importance. Technology breeds technology, and its associated research implies increasing the output of a given conceptual framework, whereas invention means the discovery of ways of increasing input to a body of knowledge.

There are several implications and consequences of this distinction. The important one in the present context is that it greatly modifies the relationship between researchers and subjects. It could even be said that innovation always takes into consideration possible immediate benefits for those involved and may be related to the notion of "therapeutic" research, as formulated in the current text of the Declaration of Helsinki. Invention is geared towards conceptual enrichment.

Research involving human subjects

The involvement of human subjects qualifies research in many ways - not only in terms of the new forms of encounter created between people different from other relationships, but also because, despite all formulations agreed upon by international bodies and accepted by governments and institutions, research can be conducted on human! subjects, with human subjects, and through human subjects.

In research *on* human subjects, they are treated as carriers of traits of diseases that happen to be of interest. In research with human subjects they are treated as partners in the process of creating new knowledge, and in research *through* human subjects, they are interesting, not as individuals, but as numbers or cases. Clearly, biomedical research in pathogenesis is an example of the first category, research in psychotherapy could be considered part of the second, and epidemiological research is representative of the third type. Thus, even within the single category "research involving human subjects", context-dependent factors suggest a taxonomy of different types of research, which should be considered from a transcultural perspective. To request consent for an investigation in which subjects allow the investigator to draw a blood sample is quite different from asking them to engage in a series of confidential conversations about their inner lives or to respond to a survey.

I am Aware that the important issue is probably not the type of research context or situation but, rather, the involvement of persons as such. Nevertheless, I still think that international guidelines and regulations should consider the setting in which research activities are performed. This has to do also with the training required on the part of investigators and the prevention of harm or risks.

Informed consent

One of the critical challenges to existing guidelines, a challenge arising from transcultural research involving human subjects, relates to informed consent. In its simplest form, transcultural research simply means that researcher and participants come to the research with different cultural values and beliefs. The clash between world-views involves perceptions, forms of literacy, expectations and language.

Language is probably the most important -the essential one -of these elements. It embraces *Weltanschauung*, culture, perception of the surroundings, beliefs, and values. The monocultural view, which has prevailed in the development and formulation of ethical norms and guidelines, carries the implicit assumption that Western culture has primacy over other cultures. Most of those norms and guidelines fail to interpret or even to consider participants' points of view.

It can be said that there are societies that create texts, and societies that , are created by texts. Most ideas about aboriginal peoples have been fantasies developed by Europeans, and even today lack of true knowledge or understanding of a culture is a serious methodological barrier to any endeavour, ranging from commerce to scientific research. The need to find ways to take account of cultural, ideological, ethnic, gender, and religious differences comes at the end of an era when the emphasis has been in the direction of attempting to find ways of transcending cultural differences to achieve universal principles binding on all, under all or most circumstances³.

Psychometric testing is a case in point. Even the most sophisticated procedure -let us say, backward translation of questionnaires, revision by native speakers, extensive control for meaning -cannot ensure that respondents truly understand what is demanded of them. To overcome these deficiencies, we have for years employed some forms of content analysis of verbal behaviour, which has the advantage that both interviewer and interviewee come from the same linguistic background and tend to employ similar systems of meaning- inhabiting, so to speak, the same semantic space. This procedure allows a differentiated probing into affective expression as conveyed through verbal expression⁴.

Informed consent is three things at the same time. First, it is a social *process* by which people come into contact and enter into a particular form of dialogue or conversation. Second, it is a *technical procedure* by means of which respect for persons is manifested and proper aims of research are demonstrated. Third, it brings about a *social product*, which may be the successful completion of an investigation, the generation of generalizable knowledge, or satisfaction for participants and researchers. As a process, a procedure or a product, informed consent must be documented in some form of permanent behavioural record such as a written signed statement, a thumbprint, a particular form of behaviour.

The term *consent* should be replaced by "option" if we are to be consistent with the very idea underlying the concept. Participants may withdraw at any time during the research process so that their free choice should always be respected. This is certainly not the case in many situations, where researchers, compelled by the need to gather data or meet deadlines, are liable to apply some form of coercion or undue persuasion.

Patricia Marshall demonstrates forcefully the importance of appropriately handling the subtle aspects of communication in the process of obtaining consent and having research well done. Many difficulties have to do with the use of language to convey information that might not be comprehensible to indigenous populations even if they were in a position to have good translators. Such complex scientific concepts as *genotype* or *genome* may not be easily understood or may in other languages have renditions that have no meaning for a lay person.

Although communication poses several problems, they are not insurmountable and the results are worth the trouble of overcoming them. If research is not done in certain populations, groups of people will be denied the benefits of research results, and data will lack the necessary specificity. The strong individualistic orientation that bioethical thinking has because of its origin must be reframed in a holistic understanding that human beings are relational beings and that not all societies conceive of individuality alike. Open communication demands careful attention to the needs of researchers, participants and community leaders or significant others in the life of research subjects⁵.

Dialogue: the foundation of bioethics

The dialogical principle has become a foundation of the behavioural and social sciences, and this can be discerned also in many other disciplines. It implies that no reality is construed outside the linguistic universe of observers who engage in dialogue. Even the most objective disciplines rely on language when it comes to communicating

information and knowledge. Every paper that is written in science is a dialogue with potential readers, anticipates objections, quotes supportive writings, and is based on confrontation with alternative views or interpretations.

Bioethics has made dialogue the very foundation of the research enterprise⁶. One of its main principles -respect for persons- affirms that every human being has autonomy to decide and should be treated accordingly. It is also an imperative that any participant in a research project should be protected from harm or risk.

Dialogue has many functions. It may serve for exchanging information, for partnership building, for a shared construction of reality, and for the development of affective meaning. The "consent dialogue", namely the dialogue that aims at establishing the researcher- participant bond, has characteristics that no other form of dialogue has, and should be tailored in accordance with setting, situation, and type of research. Research in the transcultural setting always involves some form of communicative praxis in the sense of Habermas⁷. Like the psychotherapeutic dialogue, the consent dialogue must be studied in its own right and be distinguished from the research dialogue, which is a dialogue aimed, not at generating acceptance, but at generating data for research. The consent dialogue should take into consideration the implicit and explicit beliefs of those who engage in communication, and they are not always easy to identify.

Guidelines as texts

Existing guidelines and regulations have usually been developed in response to particular circumstances and reflect dominant moral beliefs. Like any other text, they may be read in multiple ways and they create the objects they talk about. An "axiographic analysis" -that is, an analysis oriented towards uncovering their hidden moral assumptions- would certainly be of value before translating them into actual practice. Like any translation, translation of guidelines into practice or into other languages is already an interpretation of their meaning and scope. They serve their purpose if the alleged protection of subjects is achieved, if research is not hampered, and if they can be used to mediate between universal moral standards and particular local variations⁸. Intercultural conflict can be avoided if guidelines are interpreted and used within a climate of confidence and trust, and for research with goals that are mutually acceptable and beneficial for all those involved. Ethical review does not simply mean complying with regulations: it implies continuous evaluation of objectives, methodologies and results in the light of emerging circumstances or priorities. It means taking seriously the idea that dialogue is a true bioethical foundation of all research.

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