ABSTRACT This article discusses the process for obtaining genuine informed consent for the participation of human subjects in research in developing countries. We discuss the consent process in the light of recently published guidelines, the experience of nutrition and health research projects, and the ethics review process of the Instituto de Investigación Nutricional with peri-urban and rural populations in Peru. We discuss the cultural context in relation to (i) who should be involved in the decision for participation, especially for research in children and in community settings; (ii) when to use written or verbal consent; (iii) the format and presentation of the consent form to ensure understanding by the target population; and (iv) the process of how and by whom information is given and consent is obtained. Common concerns of participants with regard to their involvement in research studies are presented, as well as aspects that participants find difficult to understand. Some specific concerns of conducting research with Indigenous Peoples are discussed. We recommend future research to further understand and implement informed consent processes to assure genuine and voluntary consent in different developing country contexts.

KEY WORDS: • ethics • developing countries • consent process • children • indigenous peoples

The assurance of ethical conduct for research related to health care in developing countries has been the subject of much recent discussion, particularly with the increase of research in these countries and the need to address their high burden of disease (1–4). Recent publications give helpful guidelines addressing these specific ethical issues for developing countries: Nuffield Council on Bioethics. the ethics of research related to healthcare in developing countries (5), The Council for International Organizations of Medical Sciences (CIP), PO Box 1558, Lima-12, Peru. and general oversight of the scientific merit of each article. The opinions expressed in this publication are those of the authors and are not attributable to the sponsors or the publisher, editor, or editorial board of The Journal of Nutrition. The Guest Editors for the symposium publication are Ann M. Ferris, Center for Public Health and Health Policy and the Department of Nutritional Sciences, University of Connecticut, Storrs, CT, and Grace S. Marquis, Department of Food Science and Human Nutrition, Iowa State University, Ames, IA.


1 Presented as part of the symposium “Bioethics in Scientific Research: Conflicts between Subject’s Equitable Access to Participate in Research and Current Regulations” given at the 2004 Experimental Biology meeting on April 19, 2004, Washington, DC. The symposium was sponsored by the American Society for Nutritional Sciences and the Community and Public Health Nutrition and the American Journal of Clinical Nutrition Education Research Interest Sections, and supported in part by an unrestricted grant from the Dannon Institute. The proceedings are published as a supplement to The Journal of Nutrition. This supplement is the responsibility of the Guest Editors to whom the Editor of The Journal of Nutrition has delegated supervision of both technical conformity to the published regulations of The Journal of Nutrition and general oversight of the scientific merit of each article. The opinions expressed in this publication are those of the authors and are not attributable to the sponsors or the publisher, editor, or editorial board of The Journal of Nutrition. The Guest Editors for the symposium publication are Ann M. Ferris, Center for Public Health and Health Policy and the Department of Nutritional Sciences, University of Connecticut, Storrs, CT, and Grace S. Marquis, Department of Food Science and Human Nutrition, Iowa State University, Ames, IA.

2 To whom correspondence should be addressed. E-mail: hmoreed@iin.sld.pe.

Genuine informed consent

The Nuffield Council (5) emphasizes obtaining genuine informed consent for participation in a research protocol. In conducting collaborative studies, it is necessary to adapt the consent form and the process to the local situation, and this has been a central issue in the review of projects by the ethics committee of the IIN. As well as the cultural context and language; the perceptions of the participant population toward health, illness, life and life processes; the ownership of local knowledge; and who in the family or the community has the responsibility for giving consent, need to be considered, as well as ways of addressing local beliefs, myths, and rumors.

Who gives consent?

In research studies of the IIN, conducted in the community and especially when children are involved, the consent to participate is most commonly a family decision: fathers and grandmothers are frequently influential, and opportunities are sought by the field personnel presenting the project to talk with these family members. Our ethics committee recommends that children 7 y and older give their assent to participation, although their understanding will be limited (11).

For certain populations and study topics, prior consent by the community organization is appropriate, depending on the accepted role of the organization and its representation of the population (4,7,12). We have found this to be an essential part of the process in nutrition projects of populations of low literacy levels in the rural highlands and the rain forest areas of Peru, and helpful for community support in peri-urban populations. However, this is not a substitute for individual and family consent (4,5,9).

Verbal or written/signed consent?

Many collaborative projects insist on a written, signed, consent form, but this is not always appropriate for developing country populations (13). For certain protocols, such as epidemiological or nutrition surveys, the IIN Ethics Committee does not require the signing of a form, although it does need to see and approve the consent statement presented verbally to the participant explaining the project. Even with more complex protocols, we have had occasion where signing was unacceptable to the study population: members of a rural community in the highlands of Peru were suspicious of signing a document they were unable to read because they had “lost land by signing a document,” and, in this case, participants accepted participation in a nutrition study involving extended periods of observation of feeding practices in the home if the community leaders were in agreement with the project, even though some protocols require a more senior member of the team to witness the giving of consent. The field workers usually explain the study and the procedures in their own words, as well as reading the form. They do not necessarily read the consent form but do explain each section to be sure of leaving no surprises of new information for later.

The consent process

The consent process often occurs during several visits to a potential participant. The consent form or the information sheet is explained and is left in the home to allow for consultation with other family members. For more complex studies, there may be an average of 3 visits. Visual aids, such as a flip chart or a brochure, are frequently used in projects to facilitate understanding.

To check understanding of the consent form, the health workers use “checking questions.” Examples of these are “What is the study about,” “is everyone who participates going to receive the supplement,” “how many visits to the health facility will you have,” “how many blood samples will be taken,” or, even, “do you have to pay?”

Some common concerns expressed by potential participants

Participants primarily want to know what benefits there may be to participating in the study, and this has been found to be the key concern to acceptance. Consequently, the benefits, such as the potential benefit of the “treatment,” or the health services that are provided during the study, tend to be stressed by the field or health workers.

There are often negative connotations associated with the words “investigation” and “study” and a suspicion of “experimenting” or “practicing on my child.” When any risks are presented, this sometimes incites concern that “something bad will happen to my child.” Participants are concerned about confidentiality but mainly require the assurance that their neighbors do not learn of personal information.

Our study populations want to know who is financing the research. Because it is “cost free,” does that mean that it might be “harmful?” They need to be assured that there will be no charge at the end. The clause of “not offering compensation” in the case of damages unrelated to the study, included in some clinical trials, often creates concern that harm might occur. The local knowledge and the reputation of the research institution influence the decision to participate in the study. We have found that it is important to share information about the study with local organizations, e.g., the government health services, because the population does check with these credible sources about the research projects.

We have found that it is difficult for potential participants to evaluate the risk/benefit ratio of participation in a study. The benefits that they perceive, frequently including access to...
good health care, are the strongest influence. In a controlled clinical trial, such as the testing of a new vaccine, the use of a placebo is often taken lightly. Participants tend to expect that they will receive the vaccine rather than placebo, even though this may be clearly explained. It is not always clear to participants that they can withdraw from a study at any time once they have signed the consent form.

Refusals

The most common reason for refusing to participate in a study is the taking of blood samples, especially in the case of young children, due to a fear that it will “weaken” the child, or even that “they are selling our blood.” Refusals are frequently due to the opinion of a close family member other than the mother, particularly the father.

Continued participation

Once subjects have been enrolled, strategies to maintain their voluntary participation need to be considered and reviewed by the ethics committee. In projects of the IIN, strategies have included additional home visits and educational and social activities. Special consideration to avoid coercion is needed in certain circumstances, such as pressure to enroll in a defined period of time, competitive enrollment rates between sites, or payment to an investigation team for the number of subjects enrolled, and this has to be carefully monitored.

The consent process with indigenous peoples

There are specific ethical concerns when conducting research with Indigenous Peoples, and useful guidelines have recently been published by WHO-CINE (Center for Indigenous Peoples Nutrition and the Environment) (7). These are special ethnic groups that have been discriminated against and that often have a suspicion toward outsiders due to previous colonizing experiences, as do many populations of developing countries. It is often harder to explain what is being investigated with social science or descriptive research and how the results will be used. As with other research in developing countries, it is essential that the research addresses the community’s priorities. Sharing of collective knowledge requires a collective agreement, for example, for studying the perceptions of the nutritive value and the use of traditional foods, or the medicinal properties of plants. In the experience of our recent work with Indigenous Peoples in Peru, in collaboration with the CINE, we have had a three-level consent process: a research agreement with the Indigenous Peoples’ organization; a research agreement with each of the communities, presented and discussed in their community meetings; and, finally, individual and family consent for the individual interview. The research agreement includes similar elements to an individual consent process but, in addition, specifically includes the responsibilities of the researchers and the community, the community participation in the study, the use of the information by the researchers and the community, and the dissemination outside of the community (7).

DISCUSSION

The Nuffield Council (5) and the Council for International Organizations of Medical Sciences (6) stress the importance of genuine informed consent before participation in a research study. The U.S. regulatory procedures focus on the informed consent document itself (13), often to cover legal aspects of the study. Whereas the IIN ethics committee places consider-

able importance on the document, especially for language, length, format, and presentation for clarity of understanding by the target population, there is equal concern for the consent process, such as educational aids, who presents the study and to whom, who takes the decisions, and the number of home visits (9,10).

We have found that verbal rather than written consent is appropriate in some populations, depending on the type of study, as long as the consent process is reviewed by the ethics committee. This flexibility has been suggested for research in developing countries in certain circumstances (13). It has been proposed that the development of guidelines for this would be helpful, especially for collaborative studies (14).

Our experiences of the consent process are similar to studies reported from Africa and Latin America (9,10,15). The prime motivation for subject participation was the expected health benefits from the treatment and the health care to be received, and which tended to color the assessment of risk/benefit. Similarly, knowledge and trust for the research agency and in the health workers influenced acceptance.

Repeated visits to the home to give information before obtaining consent and the use of print material and visual aids have been helpful in our experience. In the African studies, in 2 vaccine trials with young children (9,10), there was difficulty in understanding randomization to vaccine or to placebo, and double blinding. Different methods of informing the population were used. In Senegal, presenting the study to the community before individual consent and using comparisons with agricultural situations, was helpful for understanding, for sharing in community consensus, and for facilitating interest to participate (9). In The Gambia study, there was greater understanding of the placebo group when an information sheet was left with the family before consent, allowing for family consultation, although the mother was the prime decision maker. In fact, participants in this study recommended home visits to allow more private discussion (10). Illiterate women enrolled in an iron supplementation trial in Bangladesh reported being informed of the objectives of the trial, but many did not understand that they were free to decline or could choose to leave the study (16). Thus, experiences indicate that seeking ways for giving maximum information in the home and for allowing time for family discussion is favorable.

We found that the principal motives for refusal include the blood sampling in small children and a distrust of “experiments,” similar to The Gambia study, where a distrust of the product for babies and insufficient information were also mentioned (10). Experience has been gained in the IIN in continuing the consent process after the initial acceptance and throughout the life of the project, an important aspect to be considered in the implementation of research (17) and not only when “things go wrong.” We have found that conducting research studies in the communities with which we work, and specifically through the consent process, has given opportunities for enhancing knowledge in the population about their health and nutrition.

Community involvement can often facilitate the research when this is built into the project from the beginning; both in the approval process and implementation (4); in Senegal, this was central to participation (9). We have found this to be an important part of the information and consent process in peri-urban, rural, and indigenous Peruvian communities. Setting up of community advisory boards (12) or inclusion of community members on research study steering committees has been successful in assuring community relevance of research goals and the cultural appropriateness of interven-
tions (4), and it influences how researchers relate to participants (12).

Finally, we recommend that further research be undertaken to understand and to find ways of implementing the consent process in populations of differing circumstances and contexts in a variety of developing countries, to assure genuine and voluntary informed consent. Specifically, we need examples of best practices on how to help potential participants understand the study and to assess true risk/benefit, aspects that motivate initial and ongoing participation, and how and when to involve the community organizations.

ACKNOWLEDGMENTS

We thank Enrique Morales, Eduardo Verne, Aldo Maruy, and Enrique Massa, colleagues of the IIN Ethics Committee and to the personnel of the Canto Grande field site, for sharing their experiences of the consent process with participants of many IIN projects in the community.

LITERATURE CITED