InFocus Article

# Revisiting "Freely Given Informed Consent" in Relation to the Developing World: Role of an Ombudsman

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*Background:* Establishment of Sri Lankan Twin Registry demanded development of ethical guidelines, as an effective ethical framework was not available in Sri Lanka.
*Design:* Objectives were to find out whether the ombudsman concept exists in current informed consent practices and to investigate opinion about ombudsmen. We searched Pub Med, conducted a postal survey, and monitored Internet discussion.
*Results:* The responses were categorized into current practices and existing models in informed consent process, reservations expressed about current practices, arguments supporting the concept, concerns and issues, alternatives, and how to implement the proposal. The concept of a third person is not entirely novel. How to find a truly independent person, the financial implication, confidentiality, obligations, and liabilities of ombudsmen, also emerged.
*Conclusions:* The concept of an ombudsman is conceptually and ethically sound and acceptable but the challenges posed by this very same solution to creating a better process of informed consent will have to be faced.

**Keywords**
developing countries
informed consent
ombudsman

### Introduction

The Sri Lankan Twin Registry (SLTR) was founded with the aim of furthering research capacity in Sri Lanka (Sumathipala, Fernando, et al. 2000). Although Sri Lanka has a longstanding tradition of scientific research, this tends to be individualistic and fragmented. As noted in the Annual Health Bulletin, an overarching research culture is lacking and there is a near absence of multidisciplinary and intersectional approaches to research (Ministry of Health 2000). As a consequence, debates over how best to facilitate, manage, and regulate scientific research are still in their infancy. Therefore, to incorporate local and international bioethical perspectives into current practice, development of ethical guidelines had to be an integral part of the research capacity building. The full guidelines we have proposed are now published as *Research Ethics from a Developing World Perspective* (Sumathipala and Siribaddana 2003a).

SLTR is the only functioning twin registry in the developing world. It is an island-wide register, for twins between the ages of 1 day and 85 years (Sumathipala et al. 2002). It is a volunteer twin registry, and currently we are in the process of transforming it into a population-based twin registry using different strategies (Sumathipala, De Silva, et al. 2000a; Sumathipala et al. 2001; Sumathipala et al. 2003b). Joining the SLTR does not imply consent to any research. Consent will have to be sought individually for each study after obtaining ethical clearance for the specific research project (Sumathiapala, Fernando, et al. 2000b). In the case of children, consent of the parent or responsible adult will be sought. However, if the minor does not consent, then that decision will be respected, even if the responsible adult consents (Sumathipala and Siribaddana 2003, 28). Because we will provide a database of twins for research, we have a responsibility to protect them during research. When there is an inadequate framework and public discussion on bioethics, the twin registrants may become vulnerable to exploitation if research occurs without additional mechanisms for protection of participants.

Hence we proposed the consent to be obtained by a designated member of the registry or by a

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representative of twins. We believe involving an independent person to be a better way of eliminating untoward compliance.

Informed consent alone is not protective enough, because of the asymmetry in knowledge and authority between researchers and participants. Clinicians have a tremendous influence over their patients (Kass, Sugarman et al. 1996). The weaker the personal competence of a research subject, the most stringent must be the procedural considerations (Syse 2000).

### *Justification of the Study*

We submitted the draft guidelines on bioethics to the Ethics Committee of the Sri Lanka Medical Association (SLMA). The SLMA Ethics Committee expressed reservations about using a designated member from the SLTR to obtain consent. They felt this was a novel concept and wanted us to justify the reasons for departing from current practice. If this was not a new concept, they wanted reference to the precedence. The Ethics Committee also questioned the role of an outsider in obtaining consent, because the Committee was of the opinion that such a person may not be as informed as the researcher about the research. Thereafter, we proposed an ombudsman to monitor the process of obtaining informed consent while the researcher obtains it. We decided to explore this idea further, relying on qualitative methods. Using a qualitative method and not using a systematic sampling was mainly due to two reasons. First, qualitative research probes "what," "why," and "how" rather than "how often" or "how many." The prime goal was not to enumerate, as in usually done in quantitative research (Busten et al. 1998). Second, qualitative research begins with an intention to explore a particular area, collects "data," and generates ideas and hypotheses from these data largely through what is known as inductive reasoning (Mays and Pope 1996).

### *Objectives*

1. To find out whether the concept of an ombudsman exists in current informed consent practices.
2. To find out the range of opinion about ombudsmen among local and international researchers and ethicists.

### *Methods*

1. We searched Pub Med (1966–2003) with the search terms ombudsman and informed consent using "MeSH major topic," "MeSH sub heading," and "all fields" for papers published in all languages.
2. A postal survey was carried out with reply-paid envelopes. The two questions specified below were circulated among a group of local academics. The international academics received the same questionnaire via e-mail. As biomedical ethics is still in its early stage of development, there are few experts and interested academics in the field of bioethics in Sri Lanka (Simpson 2001). Therefore, we had to approach researchers who we thought would be interested in this issue. We approached international academics who had collaborated with us and were sensitive to the issues in the developing world.
3. The questions were also posted on the Internet-based International Health Research Discussion List, sponsored by the Harvard School of Public Health, by Dr. Sumathipala (2001). The Harvard International Health Research Discussion List is moderated. It is designed to provide participants with a forum for open dialogue on ethical issues in international health research.

The two specified questions were posted with a paragraph of background information that appears below (Sumathipala 2001).

> We represent the National Twin Registry of Sri Lanka, which is the first of this kind in the developing world. This is one of the best possible options to obtain informed consent without undue influence of the investigator, who has an interest to get the research done. We proposed to have an "outsider (independent person)" to obtained informed consent so that it will truly be a "freely given" consent. As we know in particular in the developing world there is an asymmetry in knowledge and authority between the researchers and the research participants. When we proposed the ethical guidelines for the twin registry, we were concerned about the vulnerability of our participants especially as we are using a database to do research, so as the owners/protectors of the database we had a duty to safeguard the participant. So we proposed the above concept to ensure that there be freely given informed consent when a project is carried out.
>
> 1. We would like to have your opinion about "an independent person (ombudsman) either obtaining the consent or being an observer when the consent is taken by the investigators." What are the pros and cons of this?
> 2. We were challenged by some to show evidence for such practice elsewhere (precedent). Although on principle we disagree that something has to happen elsewhere for us to do it, we would like to know from you if any such practice is reported.

## Results

### Pub Med Search

The search carried out in Pub Med using the search words ombudsman and informed consent with "MeSH major topic," and "MeSH sub heading" as filters yielded no articles. Without the filter (using "all fields") there were nine papers (eight in English). However, none of them were related to an ombudsman's role in research settings.

### Questionnaire survey

Of twenty-seven local academics, five and of twenty-five international academics, six responded to the postal survey. Fourteen participants posted seventeen responses on the Harvard website. Altogether there were twenty international respondents, and they were from United States of America (6), United Kingdom (2), New Zealand (1), South Africa (2), India (3), Pakistan (1), Argentina (1), Finland (1), Ghana (1), Canada (1), and Sweden (1). Twenty-two participants, including all five from Sri Lanka, supported the proposal; two disagreed and one was neutral. One participant identified herself as an ombudsman at St. Jude Children's Research Hospital, in Memphis, Tennessee, USA. The lists of participants are acknowledged.

## Categorization of Responses

The responses were analysed and categorised into; current practices and existing models in informed consent process, reservations expressed about current informed consent practices, arguments supporting the concept of an ombudsman, concerns and issues about ombudsman concept, alternatives to ombudsman concept, and how to implement the ombudsman proposal.

### Current Practices and Existing Models in the Informed Consent Process

We now list the responses by the participants on current practices.

"We have used a clinic nurse who had no involvement in the study to witness the consent procedure and sign the form. With illiterate subjects, this is the only kind of signed consent which is ethical since we cannot make persons sign or thumb print a form they cannot read" [India].

You can introduce a system whereby you ask your registrants of the twin registry for their agreement to be approached by a researcher working on a particular topic. This system is used by ONS for NHSCR contact tracers, and by Dutch governments for all epidemiological studies. They have appalling response rates, but given the nature of the registry, you may do better [UK].

We have not used totally independent individuals to collect informed consent, but our employees do that. The employee has no vested interest in getting consent [Sweden].

In Uganda during HIV vaccine trial, the information and consent forms to be given to the volunteers was vetted by skilled independent institutions. Counselling by the research team was intensive. Since it is believed that consent is not a one-off exercise but an ongoing process, the subsequent verification of consent is done by skilled outsiders. The volunteers are informed of the process to get their prior consent [Canada].

In my institution, I am asked in my capacity as the patient's representative (I am also a member of the IRB) to witness the consent process of certain sensitive types of clinical trials. This model assures that someone is sitting on the patient's side of the table, with expertise to assure that the patient has adequate understanding of the risks, benefits, and alternatives to the proposed participation in the study [USA].

I am the co-director of a research-training program, and one of our future trainees is coming from an ombudsman agency [Argentina].

I am an ombudsman and this position is fairly new to the hospital. I work closely with our IRB, serving as an ex-officio member as well as serving on the institutional ethics committee. I meet with parents/patients following the informed consent process to assess their understanding. I participate in the informed consent process itself as requested by the investigator, IRB, social worker, or other staff member [USA].

The above ombudsman is presently working to develop mechanisms to report the findings back to the IRB and to investigators. She also serves as a neutral, impartial party in case conferences and as a mediator, if necessary.

### Reservations Expressed about the Current Informed Consent Process

Participants expressed reservations about the existing informed consent process, and these are listed below. The theme that repeatedly appeared during the survey was "conflicts of interest."

"In most cases the researchers from the developed countries bring about conflicts of interest, who always work on strict deadlines. While respecting the ethics of the developed countries, especially in the protocols, the researchers in the developing countries tend to overlook these ethics in their research for several reasons:

(a) Researchers from outside approach individuals who use the institute's name they work with to carry out research, but the main objective is personal career climbing.
(b) Researchers in the developing countries are actually not aware of these issues or just ignore them.
(c) The quality control bodies are not active enough, so these issues are not picked up, or if so, not meaningfully worked on.
(d) The very same societal and cultural dynamics of some areas do not believe that informed consent should be rigorously followed. And this is tacitly accepted among the actors and players.
(e) Informed consent issues are usually paid attention to in the protocol but in practice very little is done."

"With regards to the debate over conflict of interest, it is not reasonable to think that any human decision or activity is not beset with numerous conflicts of interests. Clinical investigators are often beset with conflicts that include financial interests, publication interests, desire for professional esteem and career advancement, deadlines, annual performance reviews/tenure applications, and so on. Some of these conflicts are easier to identify and apply safeguards against, but all must be considered in our deliberations."

"I find this discussion of ombudsmen fascinating. That it's even taking place and that so many participants are interested in it is an implicit admission that physicians conducting research do indeed have a conflict of interest. Why, then, is there no discussion of that conflict of interest dilemma as a/the problem?"

"It is time that we start addressing the whole issue of conflicts of interest in research programs: this needs to be understood at varied levels, starting with donor and host country, institution and the country, the researcher and the community. This needs to be sorted out accordingly."

### *Arguments Supporting the Concept of an Ombudsman*

One argument supporting the ombudsman concept ran as follows.

"In the ombudsman model there would be somebody sitting on the patient's side, with expertise to assure that the patient was provided with adequate information to understand the risks, benefits, and alternatives to the participation in research. On the other hand, an ombudsman will be able to assess whether the consent was voluntary. Therefore, inclusion of an ombudsman will assure that at least some of the conflicts of interest discussed above have been contained."

### *Concerns and Issues about the Ombudsman Concept*

Participants' views are summarized below.

"This is an alien or too formal procedure, which might heighten anxiety in the patient that something unusual or scary was being proposed."

"Involving a third person in the informed consent process may undermine the confidentiality. How comfortable is the participant with the ombudsman? What about the rapport that takes a long time to build in order to impart and get information from a participant? Are these jeopardized by the presence of an outsider?" [The opposing view was that any question of confidentiality does not arise, since as an employee of the institution the person is required to maintain confidentiality.]

"Likelihood of implicitly or explicitly undermining the autonomy of the potential participants by the presence of an ombudsman."

"How to find an 'independent' person?" [The process by which the ombudsman is agreed upon by all stakeholders as being truly impartial, credible and competent was considered important.] "This should be laid down in advance."

"Who should pay for the ombudsman? That is, individual researchers, institutions, local or national governments? And how would that affect the independence of the third party? How is neutrality maintained in the financing of an ombudsman? Will the researchers expecting better ethical standards agree to pay for such an initiative?" [The moderator of the discussion list observed that cost affordability of such a service is an issue.]

"If the researchers employed an ombudsman to obtain consent, could he be more coercive? What specific variables should such ombudsmen observe to ratify consent, as informed, understood, and voluntary?" "It will be necessary to have operational definitions to measure components of informed consent."

"The role of a third party beyond actually witnessing informed consent."

"What are the obligations and liabilities of the ombudsman?"

### *Alternatives to the Ombudsman Concept*

"Good consultation with user groups and stakeholders to ensure the work is supported is a way to improve the current practice." Also mentioned here: use of better and neutral information sheets; allowing sufficient time to consider when providing consent; the involvement of users and NGOs in writing consent and information sheets; and having a researcher with adequate training and supervision, instead of the principal investigator, conduct the consent procedure.

### *How to Implement the Ombudsman Proposal*

Formation of an organization to implement the ombudsmen program and a central fund contributed by the researchers to finance the program was suggested. "However, it has to be ensured that no specific research group have undue influence over the agency on how it operates in respect of obtaining consent." "Perhaps such an agency can be established with links to consumer groups which would then also undertake to ensure that participants get feedback and are provided with updates." One panelist was an owner of a company with expertise in clinical and medical genetics that is not aligned with a drug company or research institution. His opinion was that a company like his could act as an independent third party in obtaining consent and followup of protocols. However, he believed that this process is expensive and that those wishing to improve consent may not be willing to pay.

Another opinion was that an ombudsman should be knowledgable about the specific project and its pros and cons. In addition, the ombudsman should be fluent in the language of the research subjects and have knowledge of both the subjects' culture and the Western culture in which the science is embedded.

Another panelist reiterated the need for proper planning in the selection of an ombudsman and in the evaluation of the ombudsman's performance. Someone from a social service background was suggested as ideal.

## ***Discussion***

This survey revealed that the ombudsman concept is not alien. As reported by the participants, this concept is being practiced in various forms in different parts of the world. In fact, there is an ombudsman already practicing in the United States. The great majority of participants supported the concept. However, implementing the proposal will raise many issues and challenges.

In the Helsinki Declaration, the tenth clause of the twelve basic principles states that, "when obtaining informed consent for a research project, the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case a physician who is not engaged in the investigation and who is completely independent of this official relationship should obtain the informed consent" (World Medical Association 1997). This clause also suggests that a third party obtain informed consent, which falls within the broad concept of an ombudsman. The section above on "Current Practices" shows how a third party has been involved in informed consent procedures. Hence the ombudsman concept cannot be interpreted as a totally alien and overly formal procedure.

Potential breach of confidentiality by involving an ombudsman was another issue raised by the participants. However, as every person involved in research is required to maintain confidentiality, an ombudsman will not be an exception.

Another concern was the likelihood of undermining the autonomy of the research participant by the presence of an ombudsman. This will not be the case, as the intention of having an ombudsman is to reduce the clinician's tremendous influence over their patients (Sumathiapala and Siribaddana 2003a). Yet, the reasons for the presence of an ombudsman need to be explained to the research participant before the informed consent procedure. The ombudsman's role would be to decide whether the consent was really autonomous and voluntary. The operational "measures" of specific variables that should be observed in order to ratify consent as informed, understood, and voluntary will have to be defined. These will have to be piloted, tested, and a working manual compiled to guide the ombudsman.

Another aspect is the process by which the ombudsman is agreed upon by all stakeholders as being truly neutral, credible, and competent. How

neutrality is maintained in the financing of an ombudsman was one of the main concerns. In the case of the SLTR, the sister twins organization of (the Multiple Birth Foundation) can act as a consumer group to take up the ombudsman role. Twins can be trained to hold this responsibility. They may receive a fixed salary, and their contractual obligations will be to protect the interests of the twins. Another option is to solicit support from volunteers for this role, and then the issue of financial conflicts will not arise. The effectiveness of an ombudsman is very dependent upon the circumstances of his or her appointment and other factors impacting upon the ethical conduct of the research.

The roles of an ombudsman that we propose go beyond obtaining consent and include monitoring any significant departures from the protocol for which the ethical clearance was granted. According to the Oxford Dictionary (ninth edition), an ombudsman is an official appointed by a government to investigate individuals' complaints against public authorities. The structure we propose is not confined to investigating complaints or malpractices during research. Although in this survey we asked about "an independent person (ombudsman) who will either obtain the consent or be an observer when the consent is taken by the investigators," we envisaged a wider role that is beyond an independent witness to consent. The proposed role would also include continued monitoring of ethical issues such as adhering to standards approved by the ethics review board and investigating complaints and malpractices.

### *Strengths and Weaknesses of This Study*

The method we employed (questions limited to one round), as opposed to the Delphi technique or a focus group, may have limited the quality of the responses. We did not contact the participants again to quantify or develop consensus on the issues discussed during this study. Although in qualitative research, one would not rely too much on numbers, the low level of responses within Sri Lanka and abroad may have restricted the range of opinion. However, the most useful discussion took place through the Harvard International Health Research Discussion List.

This inquiry is only preliminary. It has provided a range of opinions by ethicists and researchers on the issues related to the concept that needs further investigation. It will also be important to investigate the opinions of research participants on this concept.

The proposal to involve an ombudsman appears to be conceptually and ethically sound and acceptable. However, it is only helpful when a range of other conditions are satisfied. They are the challenges posed by this very same solution to creating a better process of informed consent. More research and discussion is needed on this.

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### *Competing interests statement*

The authors declare that they have no competing financial interests.

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