



The American Journal of Bioethics >

Volume 4, 2004 - Issue 3

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

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Pages W1-w7 | Published online: 17 Aug 2010

Cite this article <https://doi.org/10.1080/15265160490505498>



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Abstract

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

Acknowledgments

The authors acknowledge grant support from The Wellcome Trust, UK.

The members of the SLTR supervisory committee are Prof. Narada Warnasooriya, Prof. Devaka Fernando, Dr. MRN Abeysingha, Dr. DARK Dayaratne, and Dr. Deepthi De Silva.

The twenty panelists who commented on the proposal are Dr. Vickram Patel, Senior Lecturer, London School of Hygiene & Tropical Medicine and Sangath Centre Goa, India; Prof. Martin Prince, Head of Section of Epidemiology Institute of Psychiatry, UK; Sophia Mukasa Monico, Coordinator International HIV/AIDS Vaccine Network, ICASO Canada; Nita Mawar, Assistant Director, SBR Unit, National AIDS Research Institute Pune, India; Laura Weil, Director, Patient Representative Department, Beth Israel Medical Center, New York, USA; Okyere Boateng, Assistant Registrar and Ethical Review Board Administrator, Noguchi Memorial Institute for Medical Research, University of Ghana; Anthony B. Zwi, Head, Health Policy Unit, London School of Hygiene and Tropical Medicine, UK; Dr. Melanie Abas, Department of Psychiatry and Behavioural Science, Institute of Psychiatry, New Zealand; Prof. S. R. Benatar, Department of Medicine, University College of Transval, South Africa; Dr. Jaakko Kaprio, Co-Director, Finnish Twin Cohort Study, University of Helsinki, Helsinki, Finland, & Secretary-General, International Society for Twin Studies; Doug Wassenaar and Catherine Slack, HIV/AIDS vaccine ethics group, University of Natal, South Africa; Paul R. Billings, Co-Founder and Executive Vice President, Chief Scientific and Medical Officer GeneSage, Inc., USA; Dr. Tracy Rabin, Moderator of the Ethical Issues in International Health Research Discussion List, sponsored by the Harvard School of Public Health; Linda Taylor, Ombudsperson, St.

Jude Children's Research Hospital, Memphis, TN, USA; Nandani Kumar, Assistant Director General, Indian Council of Medical Research, New Delhi, India; Philip Neiburg, Visiting Scholar, Center for Bio Medical Ethics, University of Virginia, Virginia, USA; Prof. Nancy Pedersen, Founder and the Head of the Swedish Twin Registry; Don Workman, IRB Administrator, St. Jude Children's Research Hospital Memphis, TN, USA; Florencia Luna, Director and Academic Coordinator of the Certificate of Superior Studies in Bioética of FLACSO, Co-Director of the Program of Training in Ethics of the Investigation (Albert Einstein College of Medecine, FLACSO, Argentina, and Vice President, International Association of Bioethics; Kausar S. Khan, Pakistan Bioethics Programme, Aga Khan University, Pakistan.

We also would like to acknowledge the two anonymous reviewers who provided valuable comments that brought this paper to its current standard.

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