

The Wellcome Trust

Social, Ethics and Public Policy Research on Biomedical Science

Research Summary

- Title:** Informed consent in Sri Lanka: Current practices, quality of information leaflets, consent forms and participants understanding of the process.
- Investigator/s:** 1 Dr. Athula Sumathipala (PI)
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- Type of grant:** Project grant
- Time period (in months):** 12 months
- Start date:** 1 July 2004

Background

The pace and complexity of recent developments in biomedical research have created a wide range of concerns about the extent to which research participants are aware of just what it means to participate in a research project. In the developing world these problems are particularly acute given that subjects may not be familiar with either the methods or objectives of scientific research.

In Sri Lanka an over-arching research culture is lacking. As a consequence, debates over how best to facilitate, manage and regulate scientific research are still in their infancy.

We initiated a capacity building program in bioethics. As a first step in this, we carried out an intensive course in bioethics, funded by The Wellcome Trust. As an important component in this capacity building, we wish to include empirical research in ethics. This proposal is a step towards that direction.

Aims

In this study we draw particular attention to the issue of informed consent in contemporary Sri Lanka: what it means and how it is used in policy and practice. The issue of informed consent can be studied from two main angles; efforts made by the researchers to provide the required information and the process adopted to ensure 'freely given consent', and the capability of the research participant to comprehend the given information.

Methodology

The study has five stages. In the first stage a consultation with participants of the intensive course in bioethics will be carried out with the intention of fine-tuning the existing study protocol. This is followed by the second stage, where published theses are studied to record

details of the ethical clearance, information leaflets and consent forms of the research that they were based on.

In the third stage, information leaflets and consent forms of their studies will be requested from authors of published research originating from Sri Lanka, as identified from a Medline search. The documents thus obtained will be evaluated with their content.

In the fourth stage, views on the essential components of information leaflets and consent forms will be discussed with members of ethics committees. Different qualitative methods will be used to generate information and build consensus.

In the final stage of the study, research participants are interviewed to evaluate their understanding of scientific research and the informed consent process. Semi-structured interviews are carried out by someone other than the principle investigator or a member of the research team of such research projects.

Main research questions

The aim of this study is to provide a comprehensive review of consent practices as they have featured in research projects carried out in Sri Lanka over the last five years. The study also aims to capture the perspectives of researchers, research participants and those involved with ethical review.

Applications of research results

Findings in this study will reveal consent practices in contemporary Sri Lanka, degree of adherence to the international standards in the informed consent process, quality of the information leaflets and consent forms, degree of understanding of research participants. This understanding will have implications for the change in practices if required.

Further information

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