

The Wellcome Trust
**Social, Ethics and Public Policy Research on Biomedical
Science**

Research Summary

| | |
|---------------------------------|---|
| Title: | The legal, ethical and cultural contexts of consent to research (with particular reference to developing countries) |
| Investigator: | Ms Susan Bull |
| Supervisor: | Dr Calliope (Bobbie) Farsides |
| Institutions: | Centre of Medical Law and Ethics, King's College London. Field research will be conducted in collaboration with HIV/AIDS Vaccines Ethics Group (HAVEG) at the University of Natal, South Africa, and UK MRC Laboratories, The Gambia. |
| Type of grant: | PhD Studentship |
| Time period (in months): | 36 |
| Start date: | 26 September 2002 |

Background:

An increasing amount of healthcare research is being conducted within developing countries which is sponsored by developed countries and/or international agencies. While there is widespread agreement that consent is a vital pre-requisite for healthcare research, a number of factors will need to be taken into account when designing consent processes that are legally valid, culturally appropriate, and ethically acceptable to both hosts and sponsors of research. In practice a range of approaches have been taken to the design of consent processes for use in developing countries. These range from undertaking minimal amendment of consent processes originally designed for sophisticated populations in developed countries, to cases in which extensive consultation has taken place with relevant communities both before and during the design of the consent process.

Aims:

- To examine and compare the parameters within which consent processes and documentation are considered to be both legally valid and ethically acceptable in developed and developing countries.
- To establish the relevance of the cultural context to assessments of the legal validity and ethical acceptability of consent processes.

- To determine elements of best practice when designing legally valid, ethically acceptable and culturally appropriate consent processes in developing countries.

Methodology:

A combination of literature reviews and qualitative research.

The literature reviews will include consideration of:

- national and international regulation and guidance on consent to research,
- ethical texts discussing the principle of respect for persons and the requirement to obtain consent to research
- anthropological and sociological texts discussing respect for persons and decision-making within medical research contexts in developing countries
- Case studies of issues arising when designing consent processes in developing countries
- Reports of qualitative research conducted with participants and researchers, research sponsors and research ethics committees about issues arising when designing consent processes in developing countries

The qualitative research will be conducted at two sites during the second and third years of the PhD. Discussions are presently underway with the collaborating centres (HAVEG in KwaZulu Natal, South Africa and MRC Laboratories in The Gambia) to determine the most appropriate methods of qualitative data collection. It is anticipated that these will include questionnaires, observation, interviews, and focus group work. A variety of techniques are being considered because of the differing capacities and cultural sensitivities of the proposed participants, which include researchers, research workers, participants and prospective participants.

Main research questions:

- How much variation is there between countries with regard to the criteria consent processes have to fulfil to be legally valid and ethically acceptable?
- To what extent do consent processes need to be adapted to the social and cultural contexts in which they will be used in order to ensure that they are legally valid and ethically acceptable?
- What limits are there on the adaptation of consent processes to local social and cultural contexts, beyond which they are no longer legally valid and ethically acceptable?
- How can potential conflicts between cultural, legal and ethical considerations best be resolved?

Applications of research results:

This research is expected to both to provide novel information and to build on current knowledge. The findings will be presented in a manner that can inform researchers who are designing consent processes to be used with medical research in developing countries.

Further information

If you would like further information about this research please contact:

Ms Susan Bull

c/o CMLE, School of Law, King's College London, Strand London WC2R 2LS, UK

Email: susan.bull@kcl.ac.uk