

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

Research Summary

Title: The application of ethical principles in practice in low income settings: building a research agenda and strengthening local capacity to contribute to international debates

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Background

Numerous guidelines for meeting ethical principles have been developed, but few are informed by good quality empirical research from low income settings on how they can realistically be achieved. Fewer still have been based on the views and opinions of the local communities who are the subjects of research, the local researchers and research assistants who are primarily responsible for implementing 'ethically appropriate' practices, and the health managers and policy makers who are expected to put research findings into practice. The proposed research will begin to fill these gaps through building a research agenda around the application of ethical principles in practice in low-income settings. This process will produce empirical data and viewpoints from research communities and participants to feed into international ethical debates, and strengthen the capacity of local researchers to engage in these debates.

Aims

The project aims:

1. To build a research agenda around the application of ethical principles in practice in low income settings
2. To use this process to strengthen capacity of local researchers and research subjects to engage in international ethical debates.

Methodology

The work will be guided by Emanuel *et al's* framework for multinational clinical research. The framework is distilled from existing guidelines to assist researchers and research ethics committees assess how well ethical principles are being fulfilled in practice in developing countries.

It will involve:

1. Reviewing published and unpublished empirical data on meeting ethical principles in practice in low-income settings
2. Gathering stakeholder perspectives on the scientific-ethical review process for KEMRI-Wellcome Trust research studies in order to strengthen ethical considerations and informed consent procedures in study planning, including identification of areas requiring community involvement.
3. Designing and carrying out three action research studies that will: 1) document perceived relevance and representativeness of existing structures to engage with community members; 2) explore ministry of health and other key stakeholders' views of the current and potential role of health research in their policies and activities; and 3) involve community members, researchers and other key stakeholders' in considering alternative approaches to informed consent for in-patient clinical studies.
4. Developing larger scale research proposals through a workshop with local and external experts in ethics, communication and community participation for future submission for funding.

Main research questions

1. What has been learned from empirical studies about how ethical principles are best met in low-income settings?
2. What are most effective approaches to strengthening partnerships between researchers and community members?
3. What are the most effective ways of strengthening partnerships with Ministry of Health staff and other key district level stakeholders, based on their own and research staff perspectives?
4. What do community members, researchers and other key stakeholders suggest regarding appropriate approaches to informed consent processes for in-patient clinical studies in low-income settings?
5. What further research and action is needed to ensure that local realities and players feed more effectively into international discussions and initiatives?

Applications of research results

1. Input into intervention initiatives being carried out as part of a communication strategy at the KEMRI/Wellcome Trust Collaborative Programme in Kenya
2. Contributing to discussion, debate and change in ethical policy and practice in Kilifi, elsewhere in Kenya and beyond.

Further information

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