CASE STUDIES

Case Study 4

Background

Is Community Consent Authentic and Legitimate?

A grant has been given by the Global Initiative 1-a partnership between several institutes of the U.S. National Institutes of Health-to a U.S. university investigator and a team of African collaborators to study the effect of high dose Vitamin A on the incidence of diarrhea and ARI (acute respiratory infections) in children less than five years of age in a West African country .The research unit of the Ministry of Health is very interested in the study and has contributed an epidemiologist to the project. High dose vitamin A capsules or placebo would be administered in a double blind fashion every four months for one year to children from 6 months to 5 years of age. A weekly record of morbidity (diarrhea and ARI) and mortality would be maintained and blood samples would be drawn (less than 2cc) at 0, 6, and 12 months to measure Vitamin A levels.

To inform the community of the impending study the village was called together by the chief and council. A traditional leader and council of elders governs the community in its daily affairs, and may be thought of as a legitimate political authority 1 although the national government retains control of things like tax collection, the police and the military. The community can be said to have a common culture and traditions and a unique canon of knowledge and shared history. As well, the members of the community readily identify themselves as being members of the community, with its cultural, social and ethical norms informing their beliefs and actions.
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In a festive environment, the investigators described the study and answered all questions from members of the community (men, women, and children) and the council. After the description, and question and answer period, the village chief and council met briefly and gave their approval. Shortly thereafter, in accordance with U.S. regulations (which must be followed as a condition of funding) and following the approval of the Institutional Review Board (research ethics review committee) at the U.S. university, the principal investigator and her field team went from house to house to obtain signed informed consent from the parents for their children to participate in the study.

The mothers (usually the ones at home during the visit) said that the chief had already approved the study and therefore they did not need to sign anything; besides they usually do not sign anything because illiteracy rates are high and women often cannot read what they are signing. On the second day the field team was summoned to the chiefs house where they were politely informed that approval had been given for the study and it was both unnecessary and unacceptable to seek individual signatures. The chief's approval and the support of council was sufficient. When the field staff said that they were required by the regulations governing the terms of the grant to obtain signed informed consent they were told that if they insisted on doing so they would have to leave the community.

Questions

You are the consultant bioethicist to the Global Initiative. You have been asked by the program staff for your opinion and advice about the following specific questions:

1. What are the necessary conditions for community consent to be considered authentic/appropriate?

2. Does this study satisfy these conditions?

3. Is community consent permitted under the existing U.S. Regulations?
4. Should the study be permitted to proceed even if the community does not agree to individual consent?

5. Are there strategies that might be employed that would reconcile these apparently divergent positions?

Bibliography

1. Weijer C, Emanuel EJ. Protecting communities in biomedical research. Science 2000; 289 (5482): 1142-1144.

2. Weijer C, Goldsand G, Emanuel EJ. Protecting communities in research: current guidelines and limits of extrapolation. Nature Genetics 1999; 23: 275-280.

3. Weijer C. Protecting communities in research: philosophical and pragmatic challenges. Cambridge Quarterly Healthcare Ethics 1999; 8: 501-513.

4. U.S- Regulations on Research involving human subjects 45 CFR 46 (relevant sections)

5. Declaration of Helsinki, 2000

6. CIOMS Guidelines, 2001

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