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ETHICAL CONSIDERATIONS RELATED TO THE PROVISION OF CARE AND TREATMENT IN VACCINE TRIALS

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OBJECTIVES: To propose a structured approach to consensual decision making on access to care, treatment and support by participants in clinical trials of HIV and other new vaccines.

METHODS: Setting standards of care provided to participants in vaccine clinical trials has been the subject of long-standing debate. The central questions that arise are: Is there an obligation to provide care to trial participants? What is the source of the obligation? Who should benefit from care? What care and prevention should be offered and for how long? Who bears the responsibility of providing care, in what form and within what limits? In 2005-2006, recognizing the pressing need for practical guidance to researchers, research institutions and sponsors, national health authorities and communities hosting clinical vaccine trials, the World Health Organization Initiative on Vaccine Research (WHO/IVR) embarked on a series of regional consultations. These consultations mapped out current guidance and approaches applied in field situations; set out criteria for defining obligations and obstacles to providing care in the context of vaccine trials; and developed mechanisms and approaches conducive to the attainment of the highest possible synergy between scientific quality, outcome of research, and protection of trial participants.

RESULTS: The series of consultations resulted in a guidance revolving around a concept of Good Research Governance. The guidance document, to be presented, proposes a pathway for consensual decision making on standards applicable to care and treatment in vaccine trials.

CONCLUSIONS: A structured approach involving investigators, sponsors, trial communities and other stakeholders in research should ensure that the needs and legitimate expectations of trial participants are appropriately met and obligations towards them delivered. This is a necessary, if not sufficient, condition for facilitating ethical research in the interest of public health. The experience acquired in actual field settings will be applied to the further elaboration of the guidance provided.



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Ethics In Biomedical Prevention

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