Strengthening Structures for Research Ethics in Kenya: Landscape Analysis of the Actors and Processes of Clinical Research Review

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II. Executive Summary

To reinforce Kenya's position as a leading site for international research, the National Council of Science and Technology (NCST) seeks to develop national guidelines for research oversight in Kenya. This report provides a landscape analysis of the clinical research review process in Kenya, outlining the laws, regulations, and stakeholders governing research and laying a foundation by which key stakeholders can consider revisions to this regulatory framework.

To inform the development of national guidelines, the Kenya Medical Research Institute (KEMRI) was asked to chair a Steering Committee—including NCST, University of Nairobi and the Pharmacy and Poisons board—to develop a comprehensive understanding of policies surrounding the review of research protocols in Kenya. Dr. Elizabeth Bukusi, a Chief Research Officer at KEMRI and the team leader of the Committee, invited the Global Campaign for Microbicides to collaborate in this initial study of the ethics review process.

In order to examine the landscape for the review and approval of biomedical and health research, a team led by Dr. Bukusi and an international consultant conducted interviews with key actors (governmental and nongovernmental) during the week of 8-12 March 2010.

With the division of logistical responsibility for oversight traditionally divided between the Ministry of Higher Education, Science and Technology (parent ministry of NCST) and the newly formed Ministry of Public Health and Sanitation and Ministry of Medical Services the ethical review process for research is fairly decentralized and not all roles are presently clearly defined between:

(1) government stakeholders (between ministries; between the ministries and the NCST; between ministries and NGOs),
(2) ethical review committees (many inside educational institutions), and
(3) other organizations (relevant to the review and conduct of clinical research).

This report outlines the official and stated roles of these organizations in the review of research proposals, highlighting gaps in current understandings of the regulatory process that may be discussed and clarified through a meeting of key stakeholders (currently planned for July 2010).