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***Issues in Research with Human Subjects***

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***Preamble***

This symposium demonstrates the extent of collaboration between the USA and UK being sponsored by the Royal Society of Medicine; The Royal Society of Medicine Foundation Inc; Bureau of Biologics, Food and Drug Administration; Bureau of Drugs, Food and Drug Administration; Center for Disease Control; National Cancer Institute; National Eye Institute; National Heart, Lung and Blood Institute; National Institute on Aging; National Institute of Allergy and Infectious Diseases; National Institute of Child Health and Human Development; National Institute of Mental Health; Veterans Administration; and the Fogarty International Center.

***Aims***

*Clinical research studies are vital to the development of new medical procedures and new drugs and biologics used for the prevention, diagnosis, and treatment of disease. Such studies involve a variety of individuals and organizations: research investigators (including medical practitioners and statisticians), industrial and funding organizations, regulatory agencies, and the public. There is the obvious concern that the study design be scientifically adequate, but planners must consider a number of other aspects. The first is the necessity of the study; then further decisions must be made on the length of the study, a system of record-keeping, recruitment of subjects, the use of children or other special study groups, and compensation for injured subjects. The public's role in planning, approving, and monitoring clinical studies must be kept in mind, particularly in light of growing issues regarding ethical aspects of research. Although the elements of clinical studies are common to all countries, the ease and security with which they are handled varies. Different laws, procedures for conducting studies, and health service delivery systems in different countries influence the experience and success rates of clinical trials. This conference was designed to facilitate an exchange of information and experiences on the major issues in research with human subjects. This volume reports the ways in which the United States and the United Kingdom handle some important ethical and administrative problems in the conduct of clinical research (Preface, page v).*

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