Chapter VIII
Ethics Review on Externally-Sponsored Research in Developing Countries

Alireza Bagheri
University of Toronto, Canada

ABSTRACT

This chapter elaborates on some of the existing concerns and ethical issues that may arise when biomedical research protocols are proposed or funded by research institutes (private or public) in developed countries but human subjects are recruited from resource-poor countries. Over the last two decades, clinical research conducted by sponsors and researchers from developed countries to be carried out in developing countries has increased dramatically. The article examines the situations in which vulnerable populations in developing countries are likely to be exploited and/or there is no guarantee of any benefit from the research product, if proven successful, to the local community. By examining the structure and functions of ethics committees in developing countries, the article focuses on the issues which a local ethics committee should take into account when reviewing externally-sponsored research. In conclusion, by emphasizing capacity building for local research ethics committees, the article suggests that assigning the national ethics committee (if one exists) or an ethics committee specifically charged with the task of reviewing externally-sponsored proposals would bring better results in protecting human subjects as well as ensuring benefit-sharing with the local community.

INTRODUCTION

In developed and developing countries alike, biomedical research is an essential component of improving human health and welfare. However many developing countries are unable to address their research-based health needs, due to the inadequate research capacity and healthcare infrastructure. These needs, along with some other factors such as accessibility of human subjects, lower costs of research and lack of a clear research policy and

ethics review, cause them to be targeted as host countries for clinical trials.

Early debates about ethics in medical research were sparked primarily in response to the ways in which medical research was conducted in developed countries and its limited relevance to developing countries. However HIV/AIDS-related clinical trials in Africa and South East Asia can be cited as a hallmark in debates on morality of conducting externally-sponsored research in developing countries. These studies that were sponsored by the National Institute of Health (NIH) and the Center for Disease Control have fueled controversies and disagreements (The participants 2004). For instance, should standard of care be provided to participants in control groups in clinical trials? This was thrown into the international spotlight in 1997, when US-funded research into the prevention of mother-to-child transmission of HIV in Thailand was criticized in The New England Journal of Medicine (Lurie and Wolfe 1997) and The Lancet (The Lancet 1997). Participants in the control group were given a placebo, rather than a long course of antiretroviral treatment, which had been demonstrated to be effective in developed countries.

The critics argued that all participants should be provided with the best available treatment anywhere in the world to prevent the exploitation of those in control groups, regardless of where the research is conducted. However, other researchers and research sponsors argued that it was not always possible, affordable, or appropriate, to supply a "universal" standard of care in developing countries, and that the difficulties of meeting such a requirement would prevent beneficial medical research from being conducted.

Another issue which became a focus of attention, particularly within the context of access to antiretroviral treatments for HIV/AIDS, is what should happen once a research project in a developing country is completed. Should the products of the clinical trials, new therapeutic methods, drugs, etc, be made available (and affordable) to the local community in which the trial was conducted or not?

To address these issues and concerns, several ethical guidelines have been developed by international organizations, e.g. Council for International Organizations of Medical Sciences (CIOMS 2002), World Medical Association (Helsinki Declaration 2000), Nuffield Council on Bioethics (2002) and UNESCO Declaration on Bioethics and Human Rights (2005).

In practice, applying these guidelines is often fraught with difficulty and some times provides conflicting advice (Nuffield Council on Bioethics 2002). In addition, there is no documentation on the application of these guidelines, or how ethics committees in developing countries deal with externally-sponsored proposals (Bagheri and Macer 2005).

HISTORICAL BACKGROUND

The long history of medicine is glorified by the fight against diseases through new innovations, methods, and drugs which cure millions of patients. However the short history of research ethics started with scandals of abuse and exploitation of human subjects. The bitter history of clinical research is full of vulnerable individuals who participated in medical experiments unwittingly.

Atrocities of Nazi physicians are widely known, and abuse in US government-sponsored research is also well documented (Moreno 2001). There are also less publicized scandals such as abuses of human subjects by Japanese physicians' biological warfare research on Chinese prisoners during World War II (Tsuchiya 2000 and Powell Tia 2006). Despite the existence of international ethical guidelines such as the Nuremberg Code, some of this clinical research continued, e.g. the Tuskegee study which actually went on for 40 years (1932-1972), and radiation experiments on children at the Fernald and Wrentham schools (1943-1973) which violated ethical codes in research (West 1998).