Medical Research Involving Incapacitated Persons: What Are the Standards?

H.D.C. ROSCAM ABBING
Professor in Health Law, State University of Utrecht, The Netherlands

"Should sciences be the servant of man or man the slave of sciences?"
(Mr. Cassin, France, UN Commission on Human Rights, Eighth Session)

Introduction

Over the past decades, medical research involving human beings (i.e. research which entails physical or mental involvement of man) has expanded considerably. This development has brought about increased attention for the protection of the research subject. With medical research, a variety of interests is at stake. They include the interests of the research subject in case of therapeutic research, the interest of scientific progress, the individual interests of the researcher, the interests of industry, of health insurance companies and the like. As such, these interests are legitimate, but taken together, they easily conflict with each other. This, together with the need for protection of the research subject's integrity and dignity, has brought about interference by the legislator. Presently, in Europe, rules are predominant in the field of pharmaceutical research; comprehensive legislation covering various types of medical research is less prominent. Research projects also very often have an international dimension. Hence, the growing importance of international consensus on rules and principles for the protection of the research subject. These provisions may differ according to the kind of research-methods involved.

The purpose of medical research is to develop or contribute to generalisable medical knowledge (preventive, diagnostic or therapeutic). Medical research involving human beings are usually classed as therapeutic and non-therapeutic research. Therapeutic medical research means that the research may substantially benefit the individual participant. Non-therapeutic research is designed for scientific advancement without a therapeutic intention for the
research subject, the research will not or is unlikely to benefit the individual
participant. Another classification refers to the sort of the medical inter-
vention; medical research involving human beings may be carried out through an
"innovative intervention" (experimental) or by applying an accepted medical
intervention (non-experimental). In case of research involving an "innovative
medical intervention" (physical, chemical or psychological), a procedure,
method or product which has not yet been (sufficiently) tested, is tried in man
for its therapeutic, preventive or diagnostic value. In that case, the medical
intervention in itself is experimental in relation to its effect ("intervention-
research").

In case of medical research involving an accepted medical intervention,
background information is gathered through systematic investigation by using
generally accepted, normal medical procedures (standard procedures, which
in itself are not put to trial). This information enables comparison of groups
of persons who are in different conditions, measurement of normal values
and the like (aetiology and pathogenesis of a medical condition). In the frame
of such research the human being is involved through, for instance, measur-
ing of the blood pressure, removal of bodily material, introduction into the
body of contrast fluids and the like. This kind of research involves making
observations ("observation-research"). Medical research involving human
beings can be invasive or non-invasive, with or without burden (discomfort,
distress) and/or risk for (physical or mental) harm. “Intervention-research”
always involves interference with the subject (physical or mental integri-
ty) and always involves risk, somatic intervention-research is always inva-
sive. “Observation-research” involves the human person (physical or mental
integrity), but does not necessarily imply interference, it is not necessarily
invasive, in case it is invasive the risks are known from the routine medical
practice.

International variety of rules

Internationally, there is overall consensus on three basic requirements regard-
ing medical research involving human subjects: the scientific value of the
research, the free and informed consent of the person participating in the
research project, an optimal risk-benefit ratio. Legal rules concerning the
position of the participant in the research project mostly pertain to the last
two requirements. Special attention is given to vulnerable groups of persons,
namely children and de facto or de jure incapacitated adults, in particular
when it comes to non-therapeutic research. This article concentrates on this
aspect.