18 Protecting Individual Subjects

Herein lies the importance of Ethics Review Committees for human subjects research.

18.1 INDIVIDUAL VOLUNTEERS ARE PROTECTED

The primary function of the ERC is to oversee and insure the protection of the individual human beings who will be volunteering for this particular research protocol.

[A]ccording to the National Commission [for the Protection of Human Subjects of Biomedical and Behavioral Research], the primary purpose of the IRB is to assist the investigator in safeguarding the rights and welfare of human research subjects.¹

The primary charge of these committees to insure the protection of human subjects must be underscored. The US Department of Health and Human Services established its ethics policy (in 1983) for ethical review of "all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by [the Department, as well as all] research conducted or funded [by HHS] outside the United States."² This policy is now federal law,³ and is titled "Basic HHS Policy for Protection of Human Research Subjects." The whole focus of this law is on the responsibility of the IRB "for protecting the rights and welfare of human subjects of research."⁴ The clear thrust of The Nuremberg Code also, as well as the thrust of the CIOMS Guidelines is in their mandate to safeguard the rights and welfare of subjects participating in medical research. As Robert Levine, one of the principal authors of the CIOMS Guidelines says in his earlier landmark publication, Ethics and Regulation of Clinical Research, "The primary purpose of the IRB is essentially as stated by the Surgeon
General in 1966: to safeguard the rights and welfare of human research subjects.\(^5\)

I underscore this primary charge of the ERCs at some length because of a fundamental problem that can easily occur in our thinking about ethical review of human subjects research. The problem I refer to is the mistake of weighing the risks borne by *individual* subjects against potential benefits that might accrue to *society at large*. In the concentration camps, for example, individual research subjects from the camps were the ones enduring the burdens and harms of the research, and the benefits of the research were supposed to accrue (at least in the best case) to society at large. We might, for example, imagine one of the Nazi doctors, perhaps one with a small bit of conscience, thinking “Yes, it is too bad that these individual prisoners must suffer in our experiments, but their suffering will at least work for the greater good of society, and for the good of many thousands of human beings to come.”

One of the Nazi doctors tried at Nuremberg did, in fact, express exactly these rationalizations. Dr Gerhard Rose, head of the Koch Institute of Tropical Medicine in Berlin during the war, said that

while he initially opposed performing lethal experiments on camp inmates, he came to believe that it made no sense not to involve 100 or 200 people in research, even lethal research, in pursuit of a vaccine for typhus when the Reich was losing 1000 men a day to this disease on the Eastern front. What, he asked, were the deaths of 100 men compared to the possible benefit of developing a prophylactic vaccine capable of saving tens of thousands?\(^6\)

Philosophers term this approach to moral decision making – i.e., the attempt to make moral judgments based on a quantification of the costs and benefits of human acts – the utilitarian approach. This approach originated with British thinkers Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873), and has always appealed to those who would like to find a way to quantify human happiness and suffering as a way of simplifying, or clarifying, moral decision-making. Because the Nuremberg Tribunals found this particular application of a utilitarian justification of human suffering