Chapter IX
Social and Ethical Aspects of Biomedical Research

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ABSTRACT

At the beginning of this section the authors provide a definition of biomedical research and an interpretation of the meaning of ethics and social values of research. They continue with the introduction of the risk-benefit approach as basic requirement for any biomedical research involving human subjects and illustrate the need for uniformity with respect to social and ethical issues. The differences and similarities between social and ethical research are described in the core section; social and ethical aspects are presented according to central and peripheral dimensions. In reference to specific areas of research in biomedical science it is exemplary shown that more general principles are not sufficient to cover all types of research, and that depending on research characteristics, the techniques used and the purpose of the research, other specific aspects might need to be considered as well. The chapter ends with a short conclusion calling for continued reflection and review of social and ethical issues speeding an age of fast changes in science and technologies to thereby ensure proper protection of the individual and the best future for society.

DEFINITION OF SOCIAL AND ETHICAL ASPECTS OF BIOMEDICAL RESEARCH

This section focuses on the social and ethical dimensions of biomedical research and development. Biotechnology, including genetic engineering, as well as advances in areas such as but not limited to assisted reproductive technologies, organ transplantation, human genome analysis, gene therapy, and new recombinant DNA products do no longer belong to science fiction, but are our everyday reality and raise questions of social implications and ethics. All of these areas of biomedical research have added new dimensions to social and ethical issues and must be taken into consideration before evaluating their efficacy and safety and finally their benefit for the community. It is only possible to provide a basic introduction to social and ethical aspects of biomedical research and to some of its central issues. It is primarily intended to give an appreciation of the need for ongoing reflection on social and ethical aspects in this field of research.

Biomedical Research

In general, the term "research" refers to activities that are designed to gain knowledge which can be generalized. Modified by the adjective "biomedical" indicates its relation to health. In the present context biomedical research should be recognized as research involving human subjects and does not include "pre-clinical" or "post-marketing" research activities. Biomedical research is taken to mean specific actions conducted in a directed manner in order to gain knowledge in the field of biomedical science. Biomedical research comprises any study of specific diseases and conditions, either mental or physical. Those studies include detection of cause, prophylaxis, treatment and rehabilitation of subjects/patients. Biomedical research also means the design of methods, drugs and devices that are used for diagnosis and to support the subject/patient after completion of study treatment for specific diseases or/and conditions. In addition, any necessary medical, scientific investigation to further understand the underlying life processes which might have an impact on the disease and the well-being of the subject/patient, such as cellular and molecular bases of diseases, genetics, and immunology, as well as laboratory investigations and/or exposure to environmental agents[a], should be understood part of biomedical research. Human individuality, the culture a subject belongs to, religion, and /or the rights and responsibilities of the individual subject are the natural boundaries to biomedical research. Those issues form the essential basis for the need to continuously reflect on social and ethical aspects whenever biomedical research is being discussed.

What Exactly is Ethics?

Simply stated, ethics means the nature of morality, moral reasoning, and behavior, whereas morality is defined as the value dimension of human decision making and behavior. From a conceptual point of view a distinction is commonly made between meta-ethics, normative ethics, and applied ethics. Meta-ethics explores whether moral standards are relative and attempts to understand how values, reason for action, and individual motivation are connected. Normative ethics attempts to determine the content of morality and to provide guidance on moral behavior. Applied ethics deals with specific areas and attempts to identify criteria to be used as basis when discussing "ethical" questions coming out of those realms. Topics such as business ethics, engineering ethics, and bioethics are examples for applied ethics initiatives[b] [c].

Ethics in Biomedical Research and Moral Pluralism

Bioethics covers a broad spectrum of moral issues associated with (new) developments in biomedi-