66. Comments by the Israeli Medical Association on the bill for Medical Trials on Humans, 5767-2007

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Introduction

The Israeli Medical Association welcomes the regulation of the issue of medical trials on humans, as part of the bill for Medical Trials on Humans, 5767-2007 (hereinafter: "the bill"), after waiting for many years, during which the Israeli Medical Association repeatedly emphasized the vital need for regulation of this important and material issue as part of primary legislation.

Clinical trials are essential for the advancement of medicine, and without them, it would be impossible to develop new drugs and technologies that promise great hope. At the same time, we must preserve and protect the health and safety of the participants in clinical trials while strictly observing the obligation to obtain the informed consent of the participants in the trial.

Therefore, it is essential to have a clear legal framework and ethical rules covering the execution of the trials. It is important to remember that we are speaking of an extremely dynamic subject, one that constantly raises throughout the world varied and complex ethical, moral, medical, philosophical, social, and legal questions requiring a suitable answer, especially in light of the development of technology. The field of pharmacogenetics, which has grown over the last several years, is an example of one such development that contains within it complex issues, for instance regarding special and vulnerable populations, such as pregnant women, children, and others.

This constantly changing complexity, as well as the increased exposure and participation of the State of Israel in numerous instances of multi-center and multi-national research, obligates the State to adapt itself to international norms and rules and to act in accordance with existing international standards existing in the field, as well as to create legal mechanisms that will permit flexibility and the adoption of dynamic rules.

In recent years the Israeli Medical Association has acted in the international arena and has formed part of the working team that updated the Helsinki Declaration in the framework of the WMA, whose current president is the chairman of the Israeli Medical Association, Dr Yoram Blachar. Now, prior to the debates of the committee regarding the bill, the Israeli Medical Association has contacted both the WMA and other international organizations to receive their comments regarding recent developments in the field.

Summary of selected comments from the position of the Israeli Medical Association regarding the bill.

The Helsinki Declaration, as updated from time to time, should obligate every medical trial on humans.

- The definition of sensitive populations should be extended to include additional populations such as soldiers, and to strengthen the protection of populations of this kind.
- The definition of a medical trial shall not include the collection of research data that is not in itself a trial.
- The relevant definition for use of a placebo, as set forth in the Helsinki Declaration, shall be adopted.
- Discretion regarding the recommendations for approval of a medical trial should be left to the trials committee, which possesses the ethical authority to do so. Under no circumstances should the director of a medical institution approve a trial that has not been approved by the trials committee, not even for special, noted reasons.
- The issue of insurance in medical research on humans must be addressed.
- The protections regarding the giving of informed consent should be expanded, especially for sensitive populations. For example, we recommend adopting the relevant sections from the Helsinki Declaration that address the importance of giving informed consent to a practitioner not involved in the research where there is a dependent relationship between the patient and the physician, and to verify that consent was not given, in any way, under any pressure or threat. In addition, in cases of doubt regarding the competence of the participant to give informed consent, and when the patient has no legal representative, the researcher must receive the evaluation of a suitable professional who is independent of the research.
- The institutional trials committee should have discretion to exempt retrospective research on existing pathological samples from the need for informed consent, while receiving approval that sufficient material remains from the pathological sample for future needs. These research studies are very important and often form a foundation stone for prospective research.
- The information furnished to research participants to receive informed consent, in cases in which the drug or the treatment are liable to influence fertility or increase any risks, should also include relevant information for men similar to information furnished to pregnant or nursing women and to women of childbearing age.
- In selected research, in which no special risk exists for the participants, the local trials committees should continue to be authorized to approve the research in order to prevent significant harm to the advancement of the research and to the health of the patients, since a requirement to receive approval from the Ministry of Health is liable to significantly and unjustifiably delay the approval of such research.
- The composition of the institutional trials committee (the Helsinki Committee) should be changed so that it may function in the best possible way and as professionally as possible. Its members should include professionals from the fields of biostatistics, epidemiology, molecular biology, and the laboratory.

- The legal arrangement, according to which one of the representatives of the Supreme Trials Committee of the Ministry of Health will be the chairman of the Israeli Medical Association or his representative, should remain in effect.
- Steps should be taken to secure in legislation the possibility of an institution being aided by the medical trials committee of another institution. In practice, there are currently institutions that do not have their own trials committee, such as medical institutions with a small number of research studies, and consequently they are aided by an institutional trials committee belonging to another medical institution.
- One of the most significant difficulties in the State of Israel in the field of medical trials is the slow and protracted approval process. This situation is created both because of the great load imposed on members of the committees and because they work on a voluntary basis. In order to improve the quality and standard of the medical trials and the advancement of research in general in the State of Israel. the work of the members of the institutional committees should be regarded as an integral part of their routine work. Such recognition will permit members of the committee to devote the time required for study of the approvals and to become familiar with the scientific background material. It will also indicate the great importance that the public in Israel attaches to the work of the committee and its vital function, and the expectation that the members of the committee will fulfill their duty in the most professional way possible.
- A multi-disciplinary steering committee should be set up for discussion of ethical, medical, legal, philosophical, social, and other questions regarding medical research, in order to create uniform, finalized, and binding rules. The committee should include representatives of the Israeli Medical Association, which has been involved in updating the Helsinki Declaration in recent years, and which, by means of its professional associations, the Scientific Council and the Ethics Board, will reflect the relevant international situation picture.
- The scope of the unit for supervision and monitoring of research in Israel should be formulated. In order to prevent any fear of possible conflict of interests, the head of the supervision unit should not be permitted to actually conduct medical trials on humans.
- The ethical obligation existing in the State of Israel to provide the research drug to participants for up to three years after the end of the medical trials should be left in effect, barring exceptional circumstances. The Director-General of the Ministry of Health should not have discretion to grant sweeping exemptions ahead of the trial. Instead, it should be expressly determined in advance when the granting of such an exemption will be permitted. The fact of the exemption and the reason for it shall be included in the informed consent.
- No excessively sweeping limitation shall be imposed on the number of innovative

activities that are not part of medical trials on humans, in order to avoid harming, for "procedural reasons", in an arbitrary and unjustified manner, patients who require the innovative activity. Rather, proper supervision and monitoring mechanisms should be created.

- Increased obligations of disclosure should be imposed on the researchers in connection with the publication of the findings of the trial, including negative results.