Ethical Standards in Scientific Research involving Human Subjects

1. Introduction

The purpose of scientific research is to expand human knowledge and to understand processes in nature and in the human world. The principle of academic freedom is a basic principle in academic thought. However, this is not an absolute principle. Although in most cases it will take precedence over other competing principles, it does not have an exclusive standing. Although it has a strong presumptive power, academic freedom does not always take precedence and does not grant the scientist sweeping immunity.

Scientific research involving humans must be subject to moral limitations relating both to the manner of administration of the research and to its results and implications. The rights of the people involved in the research, directly or indirectly - their welfare and their dignity, must be the concern of those conducting the scientific research. Concern for the person participating in the research as well as the broader implications of the research must always be taken into account along with the scientific goal. Although the object of the principles below is first and foremost to protect the persons involved directly in the research, the research must take proper precautions also with regard to its potential effects on society at large. Every scientific research involving humans will be subject to these principles.

2. Definitions

"Scientific research involving human subjects": Any scientific research in which humans are involved by their direct and active participation, by providing material from their bodies (including genetic material), by taking part in interviews, by filling out questionnaires, etc. which is carried out by the researcher and takes place on the Hebrew University's grounds or in its laboratories or in the name of the Hebrew University (hereinafter: "research").

"Researcher": Any academic employee as defined in the Statutes of the Academic Employees of the Hebrew University, and any student doing research work.

"Participant": Any person who takes part in scientific research involving people, whether for payment or without payment, and who is not the researcher or an administrative/technical employee who is assisting with the research.

3. Ethics Committees

a. The Standing Committee of the Senate shall appoint an overall Ethics Committee for the entire University (hereinafter: The Central Ethics Committee) which will deal with composing University policy regarding ethical standards in scientific research, will advise the Faculty Ethics Committees (see section b. below) regarding ethical issues which they bring to it, approve the procedures that the Faculty Ethics Committees determine and serve as an appeals board for the decisions of these Committees regarding approval of research.

b. The Deans and the Directors of the Schools will appoint professional Ethics Committees in each Faculty or in a number of Faculties together, as they see fit (hereinafter: The Faculty Ethics Committees). The Faculty Ethics Committee will be responsible for granting approval for all research according to these Regulations.

Furthermore, the Faculty Ethics Committees shall be authorized, subject to the rules of these Regulations and with the approval of the Central Ethics Committee, to determine rules that would apply to research in their professional field in accordance with the special needs of each field.

The work procedures of the Faculty Ethics Committees shall be determined by each Committee separately and shall be brought for the approval of the Central Ethics Committee.

4. Approval of Research

a. All research requires approval by the Faculty or the Central Ethics Committee. If the Faculty Ethics Committee should decide not to approve some research, the researcher is entitled to appeal this decision before the Central Ethics Committee, within a period of time as shall be determined in the work regulations of the Faculty Ethics Committee.
b. The Faculty Ethics Committees are authorized, with the approval of the Central Ethics Committee, to waive certain types of research (such as biographies and various types of surveys) from the need to have approval of the Committee.
c. No research may be carried out that is contrary to law. The approval for research given according to these Regulations, does not mean that the experiment is not contrary to the law. This matter shall be brought to the attention of the researcher.
d. Research involving a serious risk to the participant will not be approved, even if the participant gives his or her willing consent.

5. Planning the Research

a. a. At the planning stages of the research, it is the personal obligation of the researcher to carefully evaluate whether the research will meet the ethical standards detailed in these Regulations.
b. At the time of planning of the research, a cautious estimate should be made of the risks that can be forecast (including risks of physical harm, mental harm, harm to reputation or harm to self esteem), as compared to the anticipated benefit.
c. Planning of the manner of carrying out the research shall include full compliance with the preservation of the dignity of the participant, his physical safety and his privacy. The identity of the participant may not be disclosed at any stage of the research without his explicit consent. The rights, dignity and privacy of persons directly related to the participant (like spouse and genetic relatives), who might be harmed from the research even though they themselves are not participating in it, shall be taken into account.
d. Every research proposal submitted to the Faculty Ethics Committee must contain a protocol which shows the purposes, manner of implementation, expected implications, anticipated risks and manner of handling these risks. This protocol shall include reference relating explicitly to every ethical problem that might arise in the course of carrying out the research. If the research protocol includes any item that does not meet the ethical standards determined in these Regulations, the protocol will be returned to the researcher for correction before it can be approved.

6. Unexpected Damage

If the researcher finds, in the course of the research, that damage is being done to the participant that was not anticipated, he must act immediately to remove or correct the damage, including the termination of the research when necessary.

7. Informed Consent

a. No person should participate in research without giving his informed consent in advance.

1) Informed consent shall be given on the basis of a clear explanation of the purposes of the research, its significance, the risks or discomfort involved in it, both to the participant himself and to others who are not directly involved in the research (such as members of the family or of one's ethnic community).
2) The wording of the explanation and the wording of the informed consent shall constitute part of the protocol as stated in article 5(d) and shall require the approval of the Faculty Ethics Committee.
3) The consent shall be given in writing; however, in anonymous research, where the identity of the participant does not constitute an essential component, the Faculty Ethics Committee may approve an oral consent.

b. No person shall be pressured, directly or indirectly, to agree to participate in research, and the participant must be told that he has the right to terminate his participation in the research at any time.

c. A minor or person suffering from a limitation which precludes giving an informed consent shall not participate in research unless this is essential for the purposes of the research itself. In these instances, informed consent is required in writing in advance by the guardian of the minor or of the person with the limitation. However, the Faculty Ethics Committee may approve anonymous research on minors, such as surveys, based on the informed consent of the Educational Authorities and the Parents Committees only.

d. In research in the social sciences, when the methodological needs require that the true purpose of the research not be revealed, the researcher is allowed, with the approval of the Faculty Ethics Committee, to postpone giving that part of the explanation regarding the purpose of the research until after the completion of the experiment. As soon as possible after the completion of the experiment, the researcher shall give the participant the explanation as stated in section (a) above and ascertain that the participant understands the reasons and justification for the procedures taken.

8. Giving Personal Results

a. In planning the research one should consider whether it is desirable to give the participants the results of the research that are personally relevant to them. In any event, one should not give the participant the results of the research that pertain to him directly when their scientific significance is not sufficiently clear to the researcher.

b. In genetic research it is sometimes found that participants who view themselves as family are not genetically related. Results regarding genetic relations shall not be given in any event.

9. Research on Anonymous Samples

a. In research on anonymous samples, where there is no fear of harm to an individual, one may use, in addition to the anonymous samples for which informed consent was

given in advance, also samples taken in the past not in accordance with these Regulations, or samples received from outside agents.

b. In giving consent to have samples taken, the participant must note in writing if he agrees that in the future anonymous use can be made of these samples (i.e. after removal of the identification markings) also for other research. If the participant declares that he agrees to have the samples used in the future, as stated, the samples may be used for additional research without additional consent.

c. Despite that which is stated in section (b) above, if it is anticipated that in the additional research some information of importance to the participant may be found (and to genetic family members), an additional detailed informed consent by the participant shall be required (see article 7a) for participation in the new research. In instances where it is not possible, with a reasonable effort, to secure a new informed consent, the researcher may carry out the research after securing complete separation of the samples from all identifying details.

d. The transfer of samples for the purpose of research for outside agents, even if they are transferred as anonymous samples, requires the approval of the Faculty Ethics Committee in order to ascertain that the research meets the ethical standards set in these Regulations.

10. Confidentiality of Personal Information

In any event, the researcher, or any administrative/ technical employee assisting him or her, shall not use the knowledge of private information about the participant (such as name, address, family status, health condition or economic situation, etc.) and shall not reveal such information except for the purposes for which the research was done.

11. Discipline

Carrying out research without approval of the Faculty Ethics Committee or the Central Ethics Committee (unless the research is of the type of research that does not require approval as stated in article 4b above) or contrary to these Regulations or the regulations of the Faculty Ethics Committee, shall constitute a disciplinary violation.