As of December 2010

Re: Institutional Review Board and Human Subjects Protection at the Technion

Below are procedures applying to research proposals that include trials involving human subjects. These procedures were drawn up at the request of the Ministry of Health (Public Health Regulations from 1980, and amendments from 1984).

1. Experimental or applied research in which treatment or an invasive test is conducted on humans, or a new drug is used, or a familiar drug is applied for a new purpose for which it was not intended at the outset, will be defined as "clinical research whose main purpose is treating the patient," or "clinical research in combination with professional treatment" (hereinafter: "therapeutic clinical research").
2. Clinical or applied research conducted on humans that is not included in the definition of therapeutic clinical research will be defined as "clinical research whose main purpose is purely scientific" (hereinafter: "non-therapeutic clinical research").
3. A proposal by a researcher at the Technion to conduct therapeutic clinical research in a hospital, clinic, or institute affiliated with a hospital, will be submitted to the Institutional Review Board and Human Subjects Protection at the Technion. The application should also include the approval of the hospital's Helsinki Committee. The Institutional Review Board and Human Subjects Protection will forward the proposal to the Executive Vice President for Research, together with confirmation that it meets the principles of the Helsinki Declaration as it has been approved by the Helsinki Committee in the hospital.
4. A proposal by a researcher at the Technion to conduct therapeutic clinical research (as defined above) outside a hospital framework will be submitted to the Clinical Institutional Review Board and Human Subjects Protection together with approval from the Helsinki Committee of a hospital, one of whose doctors will be part of the research team. The Review Board will recommend to the Executive Vice President for Research whether to approve the research as stated in Section 3.
5. A proposal by researcher at the Technion to conduct non-therapeutic clinical research, such as observation of various physiological conditions, or trials without the use of invasive measures that could endanger the patient, such as electrical records of activity in the body, records of states of sleep, blood pressure measurements, etc., will be given to the Institutional Review Board and Human Subjects Protection with a declaration that it is a non-therapeutic clinical study, and an undertaking to uphold all the accepted conditions in each of the institutes authorized to conduct physiological tests as above. The Institutional Review Board

and Human Subjects Protection will examine whether it is therapeutic or non-therapeutic research. If it concludes that it is therapeutic research, the researcher will be required to present the Review Board with confirmation from the Helsinki Committee of a hospital, as stated above (Sections 3, 4). If the Review Board is persuaded that it is non-therapeutic research, it will recommend that the Executive Vice President for Research authorize it without approval from a hospital's Helsinki Committee.