General Information for a Participant in a Clinical Trial

To Whom It May Concern:

You or a relative may be asked to participate in a clinical study (clinical trial) that is being conducted in the department or clinic where you are treated. Furthermore, you are invited to contact your treating physician regarding the possibility of joining the clinical study being conducted in the department/clinic and that is relevant to your condition or disease.

We would like to call your attention to questions that participants or potential participants in a clinical trial frequently ask:

What is a clinical trial (study)?

A clinical study has been defined by the Ministry of Health as a study that examines medical treatment in human subjects. The medical treatment may be through a drug, device, food additive or any procedure such as surgery or a test.

Who is in charge of the clinical trial?

Each study has a **principal investigator**: An authorized physician or authorized dentist, a senior staff member at the hospital, who has been authorized by the hospital director to conduct the clinical trial. At times, additional doctors (subinvestigators) and study coordinators, people who have been trained to conduct clinical studies, participate with them and help the investigator conduct the study.

How is a clinical trial approved at the hospital?

The hospital has a special ethics committee called the Helsinki Committee, which is made up of senior physicians, public representatives and other individuals who are involved in clinical studies such as nurses, pharmacists, public representatives and representatives of hospital management.

The institutional Helsinki Committee is an independent committee, which reports to the Ministry of Health. It meticulously examines the study plan (protocol), and its job is to ensure that the rights, safety and welfare of the participants who are enrolled in the trial are safeguarded. The Committee approves the study and, later, even conducts ongoing follow-up of the course of the trial and ensures that it is conducted properly and in accordance with all the rules and procedures designed to protect the health and rights of the participants.

The informed consent process

So that you can consider whether you would like to participate, you will be asked to carefully read an informed consent form that explains clearly and in detail the essence of the study, how it is conducted, what benefit it provides and what risk or discomfort it entails. This form also specifies your rights as a participant in the trial

and how you should behave during the study. Additionally, you will be invited to ask any question and may request to receive any additional information you need to decide whether to participate in the study. If you decide to participate, you will be asked to sign the consent form in the presence of the study doctor, who will also sign the form. You will receive a signed copy of the consent form so that you will be able to consult with anyone you feel appropriate.
Remember that your or a relative's participation in a clinical trial is solely of your/their own free will. You have the right to refuse to participate in the trial or to stop your participation at any time, and this, clearly, will not negatively impact your rights to receive the optimal medical treatment for your disease.

Is there any benefit or risk in participating in a clinical study?

The study may help treat your or your relative's disease, but you must know that there are studies that will not necessarily help you directly, but are designed to improve the treatment or diagnosis in similar conditions. At times, there may be a certain risk involved in participating in a trial. The doctor will explain the advantages and risks to you in detail and ensure that you have understood.

Is participating in a clinical study beneficial?

Participating in a clinical study is done voluntarily and is solely your decision. People participate in clinical studies for a variety of reasons such as finding optimal treatment for the problem from which the patient or others are suffering, contribution to the scientific effort to advance medicine and finding a solution for various medical problems of patients in the future, or to advance science.
You have the right to consult with any person, including your family physician and relatives, before you make the decision to participate in the trial.

What is required of a patient who participates in a clinical study?

- Signing the informed consent form after receiving all the information, understanding the content and receiving answers to all questions.
- To receive the most effective and appropriate treatment for the patient, strictly follow the instructions provided by the study team.
- The patient must provide their family physician with a letter containing information about the clinical trial in which they are participating.
- The patient must inform any other medical practitioner treating them of their participation in the study (for example, a dentist or if receiving treatment at other clinics or hospitals).

Who funds the clinical study?

Clinical studies that are sponsored by commercial companies are funded by the companies. The commercial contract is overseen by the hospital and the Ministry of Health.

There are studies that are funded by research funds, non-profit organizations, universities, international research organizations and government funding. The contract with them is overseen by the hospital.

What about insurance?

Whenever participating in a clinical study, the patient is insured by the company sponsoring the study or the medical institution.

Will the patient's identity be kept confidential?

The name of the patient and their personal details will remain confidential and will not be published. Representatives of companies or health authorities may be exposed to identifying information when inspecting the medical records and files in the hospital. In any event, information that leaves the hospital will not contain your identifying information.

Where can information regarding studies performed in Israel and around the world be found?

- The Ministry of Health website (a digital registry of clinical studies being conducted in Israel) https://my.health.gov.il/CliniTrials/Pages/Home.aspx lists active clinical trials that include medical intervention and that have an impact on clinical endpoints, such as studies with medicinal preparations and advanced therapies in Phases I, II, II, IV and clinical trials of medical accessories and devices.
  The digital registry contains information about studies that are conducted at the various medical centers in Israel.
  The purpose of the registry is to make the current information about clinical studies accessible to patients and their relatives who are interested in participating in a study and to investigators and health care professionals as well as the general public.
  The information is updated quarterly, in accordance with the requirement of the Ministry of Health procedure.
- The Ministry of Health website has a link to the registration site of the **NIH**, which includes a list of most of the interventional studies that are conducted in Israel (the information is in English). - http://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/ClinicalTrials/Pages/default.aspx
- On the NIH registration site, it is possible to find out whether a study on a certain subject is being conducted anywhere in the world - http://clinicaltrials.gov.il

You may call the principal investigator or the study team with any questions or inquiries.

If you have questions regarding your rights in the study or if you want to raise ethical issues, or in any case of discomfort, you may direct the questions to the study team or the principal investigator. Do not hesitate to put your claims in writing and direct them to the Public Inquiries Unit at the medical center, and they will be answered immediately.

Additional information can also be found on the medical center's website - https://www.tasmc.org.il/Pages/default.aspx