



01/2022

Helsinki Declaration

The Helsinki committee of **Assuta Medical Center, Ashdod**, acts in accordance with the "Public Health Regulations (Medical Experiments Involving Human Subjects-1980) Including all subsequent amendments until 1999" and according to the "procedure of conducting clinical trials on human subjects-2016-2021" of the Pharmaceutical department of the Ministry of Health, based on ICH guidelines for Good Clinical Practice: ICH-GCP (E6), Harmonized Tripartite Guideline, of Clinical Practice and the standard instructions for conducting clinical trials on human subjects and Medical Devices EN540, International Standard Organization (ISO); ISO 14155-1; ISO 14155-2: Clinical Investigation of Medical Devices for Human Subjects;

The full compliance with the requirements of the above mentioned procedures, aiming to ensure the rights, safety and good being of the subjects participating in the study, with compliance with The Helsinki Declaration, and data collected during the study will be reliable.

Sincerely,

Chairman of the Helsinki Committee

Name: Prof. Joseph Pikkell 21570

Signature: _____

Date: _____

פרופ' יוסף פיקל
יו"ר ועדת הלסינקי, מ"ר
בית חולים האוניברסיטאי
אסוטה אשדוד

3rd January 2022