Date:

To

Prof. / Dr. \_\_\_\_\_\_\_\_\_\_\_ the Principal Investigator

Department:

Re: **Helsinki Committee Approval**

We have been convinced that the clinical trial, the details of which appear hereinafter, does not contradict the principles of the Helsinki Declaration and the Public Health Regulations (Clinical Trials in Human Beings) 1980 and the Guidelines for Clinical Trials in Human Subjects 2014.

This approval is an interim stage in the clinical trial approval procedure. The investigator shall be able to begin conducting the trial only upon receiving the Director’s approval (Form 7).

**Trial Details**

|  |  |
| --- | --- |
| Application number at the institutional committee: | Trial type: preparation / medical device / advanced therapies / genetic / no investigational product / existing data and questionnaire research. |
| Trial title (English): |
| Name of investigational product: | Name of manufacturer: |
| Multicenter trial in Israel: ☐Yes ☐ No |
| Name and address of Sponsor: | Name and address of Sponsor's representative: |

**Trial Documents**

|  |  |  |
| --- | --- | --- |
| Trial Protocol - Name/Number: | Version:  | Date:  |
| Consent Form - Name/Number: | Version:  | Date:  |
| Investigator's Brochure - Name/Number: | Version:  | Date:  |
| Product Quality Document - Name/Number: | Version:  | Date:  |
| Form 11  | Version: | Date:  |

**The clinical trial is**

☐ a special clinical trial, which the Director of the medical institute is authorized to approve without further approval by the Ministry of Health.

☐ a non-special clinical trial, and therefore further approval by the Ministry of Health is required.

**Terms and Restrictions:**

**Deviation from procedure requirements, approved:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Helsinki Committee Chairman | Signature | Date of Discussion | Date of Approval |
|  |  |  |  |

Note: This approval is a prerequisite for NIH website registration. The investigator shall forward the registration no. to the Helsinki Committee.

CC: Director of the Medical Institution

 Clinical Trial Division, Pharmaceutical Administration, Ministry of Health