Date:

To

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

Department:

Re: **Helsinki Committee / Sub-Committee Approval**

We have been convinced that the study, the details of which appear hereafter, complies with the conditions detailed in the Procedure for Clinical Trials in Human Subjects 2014 for approval of studies with existing data and questionaires.

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 title (Hebrew): | |
| Name of sponsor: | |
| 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: |
| Form 11: | Version: | Date: |

**Terms and Restrictions:**

**Deviation from procedure requirements, approved:**

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

CC: Director of the Medical Institution

Clinical Trial Division, Pharmaceutical Administration, Ministry of Health