Date:

To

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

Department:

Dear Prof. / Dr.,

Re: **Extending validity of a study with existing data and questionnaires**

As per your application dated: \_\_\_\_\_\_\_\_ approval is hereby granted to conduct the study according to application documents

**Trial Details**

|  |  |
| --- | --- |
| Application number at the institutional committee: | Application number at the Ministry of Health:  |
| Trial title (English): |
| Name of sponsor: |
| Multicenter trial in Israel: ☐Yes ☐ No |
| Name and address of Sponsor: | Name and address of Sponsor's representstive: |

**Trial Documents**

|  |  |  |
| --- | --- | --- |
| Trial Protocol - Name/Number: | Version:  | Date:  |
| Consent Form - Name/Number: | Version:  | Date:  |
| Form 11: | Version:  | Date: |

By the power vested in me by the Director General of the Ministry of Health, as the “director” authorized to approve studies with existing data and questionnaires, at the medical institution, after your application has been approved by the institutional Helsinki sub-committee on: \_\_\_\_\_\_\_\_, and after having been convinced that the study complies with the principles of the Helsinki Declaration and the Procedure for Clinical Trials in Human Beings, I hereby approve to conduct the trial, subject to the following conditions:

**Conditions of Approval**

1. The study will be conducted in accordance with the principles of the Helsinki Declaration, the requirements of the Procedure for Clinical Trials in Human Beings in Israel (2014), and the requirements of current international procedures.
2. The study will be performed only after an explanation has been given to the participant or legal representative thereof, and after he or said representative have signed the informed consent form attached to the application.
3. Any amendment or addition to the study plan or any deviation thereof will require written approval by the medical institution’s Helsinki sub-committee.
4. The principal investigator in the study must report to the Helsinki sub-committee about study discontinuation.
5. Extending validity of the clinical trial: **three months prior to the expiration of approval issued for the clinical trial**, the principal investigator must forward the medical institution’s Helsinki sub-committee a progress report describing the progression of the study. The committee will make its decision regarding the continuation of the study known to the director of the medical institution. The director shall issue a new approval for the study.
6. Upon completion of the clinical trial, the principal investigator shall submit to the Helsinki Committee a summary report of trial progress and results.
7. The approval is issued to the aforementioned principal investigator and medical institution, and cannot be transferred to others.
8. No information regarding the clinical trial shall be released to the mass media, e.g. the press, radio, TV and Internet, except publications in scientific magazines or medical conventions, and except publication required to recruit trial participants.
9. Retention of documents: all application documents, approvals and all records collected during the course of the clinical trial must be kept for **at least 7 years as of study completion**.
10. Other limitations:
11. Approval valid: \_\_/\_\_/\_\_\_\_\_\_

*G o o d L u c k !*

Sincerely,

Director of the Medical Institution Chairman of the Helsinki Committee

 of the Medical Institution

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CC: Trial Sponsor / its representative in Israel (through the investigator)

 Clinical Trial Division, Pharmaceutical Administration - Ministry of Health