Date:

To

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

Department:

Dear Prof. / Dr.,

Re: **Extension of Approval to Conduct a Clinical Trial in Human Beings**

As per your application dated: \_\_\_\_\_\_\_\_ approval is hereby granted to extend validity of approval to conduct the clinical trial according to application documents

**Trial Details**

|  |  |
| --- | --- |
| Application number at the institutional committee: | Trial type: preparation / medical device / advanced therapies / genetic / no investigational product / existing data and questionnaire research. |
| Application number at the Ministry of Health: | NIH registration number: |
| 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: |  | Date:  |
| Form 11 - Version: | Version: | Date: |

By the power vested in me by the Director General of the Ministry of Health, as the “director” authorized to approve clinical trials in human beings, at at the medical institution, after your application to extend validity has been approved by the institutional Helsinki committee on: \_\_\_\_\_\_\_/after the application has been approved by the Ministry of Health on: \_\_\_\_\_\_\_\_\_\_[[1]](#footnote-1), and after having been convinced that the clinical trial complies with the principles of the Helsinki Declaration and the Public Health Regulations (Clinical Trials in Human Beings) 1980, and that the contract between the sponsor, the principal investigator and the medical institution complies with the requirements of 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 clinical trial 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. Treatment will only be administered after an explanation has been given to the patient or legal representative thereof, and after the patient or said representative have signed the informed consent form attached to the application.
3. Any amendment or addition to the clinical trial protocol or any deviation thereof will require written approval by the medical institution’s Helsinki committee and/or the Ministry of Health.
4. The clinical trial’s principal investigator is to report to the medical institution’s Helsinki committee and to the sponsor of any serious adverse event (SAE) that occurs during the clinical trial (as specified in article 13 of the procedure), or of trial discontinuation (as specified in article 15 of the procedure). The institutional Helsinki committee will review the report and forward its statement of opinion to the Ministry of Health.
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 committee a progress report describing the progression of the trial. The committee will make its decision regarding the continuation of the trial known to the director of the medical institution. The director shall issue a new approval for the clinical trial.
6. Upon completion of the clinical trial, the principal investigator will 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. In clinical trials involving provision of services: medical tests to be conducted or medical equipment, medical agents or implants to be supplied, the principal investigator is obliged to inform the attending physician in the community of the patient’s participation in the trial.
9. 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.
10. Supply of the investigational product (IP) or medical device to the medical institution where the clinical trial is conducted, is the responsibility of the trial sponsor. IP storage and dispensing to patients are the responsibility of the principal investigator. When medications are concerned, such actions will be performed in accordance with the institutional pharmacy, unless otherwise decided upon by the Helsinki committee.
11. Retention of documents: all application documents, approvals and all records collected during the course of the clinical trial must be kept for **at least 15 years as of trial completion**.
12. Other limitations:
13. 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

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CC: Pharmacy Director

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

 Clinical Trial Division, Pharmaceutical Administration - Ministry of Health

1. Delete as appropriate [↑](#footnote-ref-1)