Annex 3

**Notification form for the Chief University Pharmacist on the initiation of a clinical trial of a medicinal product**

Szöveg beírásához kattintson vagy koppintson ide. (name) as Principal Investigator I declare that I am familiar with the procedures of the Central Clinical Research Coordination Bureau and the University Pharmacy Pharmacy Drug Management Institute. I want to inform the Chief Pharmacist of the following newly initiated clinical trial of a drug following the terms and conditions set out in these regulations:

1. Fundamental data

|  |  |
| --- | --- |
| Study title |  |
| Study unique SE identifier |  |
| Protocol No. |  |
| The phase of the clinical trial |  |
| Name of manufacturer or company conducting the study |  |
| Adress of manufacturer or company conducting the study |  |
| Principal Investigator’s name |  |
| Name of site and department |  |
| Name of the medicinal product subject to trial |  |
| Storage conditions of the trial preparation |  |
| OGYÉI decision number  |  |

The Chief Pharmacist will delegate a pharmacist responsible for quality assurance for each new clinical trial of a medicinal product, who will be responsible for recording the data required by Article 33 of Decree No 41/2007. (IX. 9.) of the Ministry of Health. According to the legislation, a register must be available in the institute pharmacy containing the name of the investigational medicinal product, the manufacturing number, the trial number, the expiry date, and the storage instructions for each consignment received. The Chief Pharmacist shall inform the Principal Investigator and the Central Clinical Trials Coordination Office of the identity of the pharmacist assigned to the trial by employing a declaration of acceptance at the end of the registration procedure.

2. Receipt of the investigational medicinal product

[ ] To the premises of the University Pharmacy

[ ] To the Clinical department

If the Principal Investigator wishes to have the investigational medicinal product delivered to the clinical department, it is the responsibility of the Principal Investigator to store the investigational medicinal product separately from the patient care medicinal product and to follow the protocol requirements.

In addition, the Principal Investigator is obliged to provide the Quality Assurance Pharmacist assigned to the study by the Institute for Pharmaceutical Organisation of the University Pharmacy with access to the data according to Article 33 of the Decree 41/2007. (IX. 9.) of the Ministry of Health. The use of the clinical trial product submitted is subject to registration in the pharmacy register of the institute under Regulation No. 41/2007. (IX. 9.) Minstry of Health.

3. Provision of control product

[ ] Supplied by the sponsor to the premises of the University Pharmacy

[ ] Sponsored by the sponsor to the clinic department

[ ] By sponsor through a wholesaler to the premises of the University Pharmacy

[ ] Purchased from University Pharmacy [In this case, please complete item 5]

[ ] Funded by a clinic

4. Pharmacist delegation

The Principal Investigator declares that he is responsible for the pharmacist's part of the protocol

[ ] Wants to employ a pharmacist employed by the EGYGYSZI

[In this case, please complete item 5]

[ ] Will employ a university staff member with other qualifications

If the Principal Investigator does not wish to delegate a university pharmacist for a clinical trial, he/she is personally responsible for the pharmacist's part of the trial protocol. Person to be delegated

* Name:
* Contact data:

5. Additional pharmacist services

[ ] Delivery and storage of trial medicinal product

[ ] Dispensing of the trial product (factory box)

[ ] Preparation of trial product (aseptic)

[ ] Assembly of the trial product (sterile)

[ ] Assembly of the trial product (cytostatic)

[ ] Purchase of control medicine

A pharmaceutical registration fee is to be provided from the clinical share of the trial fee.

The completed and signed registration form must be sent electronically in PDF format only to klinikaikutatas@semmelweis-univ.hu .

Budapest, Szöveg beírásához kattintson vagy koppintson ide.

Principal Investigator: