Annex 3

Notification form for the Chief Pharmacist of the University about the start of a clinical trial

..... (name) Principal Investigator I declare that I am familiar with the procedures of the Central Coordinating Office for Clinical Research and the Institute for Pharmaceutical Organization of the University Pharmacy. In accordance with these conditions, I would like to inform the Chief Pharmacist about the following newly initiated clinical trial:

1. Basic data

Title of the study:	
Test unique SE identifier	
Protocol number:	
Clinical trial phase	
Name of manufacturer or conducting company	
Address of manufacturer or conducting company	
Name of Principal Investigator	
Name of test site and ward	
Name of the investigational medicinal product	
Name of the investigational medicinal product	
Name of premedication	
Storage conditions of the test product	
OGYÉI decision number	

The Chief Pharmacist will delegate a Quality Assurance Pharmacist for each new clinical trial of a medicinal product, who will be responsible for the quality assurance of the clinical trial in accordance with the provisions of the Decree EüM No 41/2007. (September 9.) and registration of data according to § 33 of the above EüM Decree. According to the legislation, a register must be available in the institutional pharmacy, which must contain the name of the investigational medicinal product, the manufacturing number, the test number, the expiry date and the storage instructions for each consignment received. The Pharmacist-in-Chief will inform the Principal Investigator and the Central Clinical Trials Coordination Office of the pharmacist assigned to the trial by means of an admission declaration after the registration procedure has been completed.

2. Arrival of the test product

☐University Pharmacy premises

☐Clinic ward

If the Principal Investigator wishes to have the investigational medicinal product delivered to the clinic 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.

In addition, the Principal Investigator is obliged to inform the Quality Assurance Pharmacist assigned to the study by the Institute for Pharmaceutical Organisation of the University Pharmacy in accordance with the provisions of the Regulation No. (September 9.) and registration of data according to § 33 of the above EüM Decree. The condition for the use of the submitted clinical trial product is the use of the clinical trial product in accordance with the provisions of EüM Decree 41/2007. (September 9.) registration as an institutional pharmacy under the above EüM Decree.

3. Providing a control preparation

☐by Sponsor to University Pharmacy premises

☐by Sponsor to Clinic ward

☐by Sponsor through wholesaler to University Pharmacy premises

☐Purchase by University Pharmacy

4. Delegation of pharmacists

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

☐Wishes to employ a pharmacist employed by a EGYGYSZI

☐You wish to employ a university staff member with a different qualification

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

- Name:
- Availability:

5. Tasks related to investigational medicinal products

☐Delivery and storage of investigational medicinal products

☐Issue of test medicine (factory box)

☐Preparation of study drug (aseptic conditions)

☐Preparation of study drug (aseptic section)

☐Preparation of study drug (cytostatic)

☐Purchase of control medicine

According to the Clinical Research Investigations Policy, a separate record of investigational medicines received for clinical investigation and used in the treatment of a patient must be kept in the institutional pharmacy. The head pharmacist of the institution shall be responsible for

keeping the register. The **pharmacy registration fee** is assigned to this task, the amount of which is set at **EUR 250** per pharmacy and the source of which is **to be provided by the trial site** (the trial site's own costs for the trial). Accordingly, the test site acknowledges that the amount of the pharmaceutical registration fee will be transferred from the test site's health care operating budget to the University Pharmacy and Institute of Pharmaceutical Organization at the time of the issuance of the invoice for the first test fee, if no patient enrollment is made, at the close of the test.

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

Budapest,

Principal Investigator