## Annex 3

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

(na	ma) Principal Investigator I declare that I am
familiar with the procedures of the Central Co Institute for Pharmaceutical Organization of the	me) Principal Investigator I declare that I am ordinating Office for Clinical Research and the University Pharmacy. In accordance with these Pharmacist about the following newly initiated
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	
of a medicinal product, who will be responsible accordance with the provisions of the Decree E of data according to § 33 of the above EüM must be available in the institutional pharmine investigational medicinal product, the manufact and the storage instructions for each consigniform the Principal Investigator and the Cer	Assurance Pharmacist for each new clinical trial e for the quality assurance of the clinical trial in üM No 41/2007. (September 9.) and registration Decree. According to the legislation, a register macy, which must contain the name of the cturing number, the test number, the expiry date nment received. The Pharmacist-in-Chief will stral Clinical Trials Coordination Office of the an admission declaration after the registration
2. Arrival of the test product	
☐University Pharmacy premises	
□Clinic ward	

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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
$\square$ 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
<ul><li>Name:</li><li>Availability:</li></ul>
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

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## Regulations for clinical research trials

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

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