Annex 1/A

Application for pre-admission (registration) to conduct a clinical trial

Principal Investigator	
Test site:	
Name of the contact person of the investigator:	
Telephone number of the contact person of the investigator:	
Contact email address of the investigator:	
Title of the study:	
Protocol number:	
Phase:	
Type of study (drug, device, non-interventional, IIT)	
Name of the contact person of the principal/CRO:	
Telephone number of the contact person of the client/CRO:	
E-mail address of the contact person of the client/CRO:	

1. The investigation will require the involvement of service provider(s):

[ ] Imaging examination
[ ] Pathology examination
[ ] Laboratory test
[ ] University pharmacy services
[ ] Name of other subspecialty/clinic:

The planned duration of the study:

(Planned) date of submission of the OGYÉI licence application:

Number of patients planned for clinic:

2. Declaration by the Principal Investigator: (Select the appropriate section!)

[ ] The material and personnel conditions for the study are fully available at the clinic, so no additional collaborator is required.
[ ] University block coordinator assistance required:
[ ] The material and personnel conditions for the study are not fully available at the clinic, so additional collaborators are needed. Name and function of external collaborator:
[ ] The study is low-cost, so **the cost per patient enrolled is less than 12% of the total study fee revenue** per patient.

[ ] The study involves high-cost diagnostic or therapeutic procedures, so **the cost per patient included exceeds 12% of the total study fee revenue** per patient.
[ ] The study involves low-cost diagnostic or therapeutic procedures (the per-patient cost of the study, excluding staff costs, is **less than 12% of the total per-patient fee revenue**), but the institutional part of the study is intended to **cover additional staff costs.**

[ ] The study involves high-cost diagnostic or therapeutic procedures, so the out-of-pocket **costs per patient** included, excluding personnel costs, **exceed 12% of the total study fee revenue per patient.** The institutional share of the out-of-pocket costs is intended to **cover personnel costs** in addition to the out-of-pocket costs.

As stated in the Clinical Research Investigations Regulations, separate records of investigational medicinal products received for clinical trials and used in the treatment of patients 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.

Budapest, ____-__-__

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Clinical Director Head of Investigation
(if not the Principal Investigator)

A synopsis of the study in Hungarian must be attached to this registration application.
The completed and signed registration form must be sent electronically in PDF format to klinikaikutatas@semmelweis.hu.