Annex 1/A

Pre-admission (registration) request for a clinical trial

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

The planned duration of the study:

(Planned) date of submission of the NNGYK 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 income**), 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.

Budapest,

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Clinical Director (if not the Principal Investigator)

Head of Investigation

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-univ.hu.