Annex 1/A

**Pre-admission (registration) request for a clinical trial**

|  |  |
| --- | --- |
| **Investigator:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Test site:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Name of the contact person of the investigator:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Telephone number of the contact person of the investigator:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Contact email address of the investigator:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Title of the study:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Protocol number:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Phase:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Type of study (drug, device, non-interventional, IIT)** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Name of the contact person of the principal/CRO:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **Telephone number of the contact person of the client/CRO:** | Szöveg beírásához kattintson vagy koppintson ide. |
| **E-mail address of the contact person of the client/CRO:** | Szöveg beírásához kattintson vagy koppintson ide. |

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: Szöveg beírásához kattintson vagy koppintson ide.

The planned duration of the study:

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

Number of patients planned for clinic:

1. **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: Szöveg beírásához kattintson vagy koppintson ide.

[ ] 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: Szöveg beírásához kattintson vagy koppintson ide.

[ ] 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, Szöveg beírásához kattintson vagy koppintson ide.

................................. .............................................

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-univ.hu.](mailto:klinikaikutatas@semmelweis-univ.hu)