***Statement of CEO/person acting on behalf of CEO***

**Concerning**

**Name of Institution:** [Guidance: Use the name of the Institution, and not the name of the Campus. In case of a private practice, mention “Private Practice”.]

**PI:**

**CTC name and internal number (if applicable):**

**Sponsor:**

**Title:**

**I hereby confirm that the clinical investigation (see details above) may be carried out at our Institution taking into account internal procedures of the Institution and the confirmation of the following elements:**

* **This Institution has all the facilities and equipment to conduct the clinical investigation and expects to be able to include the planned number of participants.**
* **This Institution has suitable human resources and warrants that all investigators and other individuals involved in conducting the investigation have the suitable qualifications, expertise and training in relation to their role in the clinical investigation, in compliance with EU Regulation 2017/745.**
* **The Institution will participate in the negotiation of an agreement (or legal contract) that describes the mutual legally enforceable obligations between the Sponsor(s), the CRO or its/their representatives with regard to financial provisions and other contractual elements that matter between legal entities.**
* **Declaration of the Principal Investigator (PI):**

As PI I declare I have read the protocol and all related documentation as part of the application dossier, I have no ethical or scientific objections and I, together with my study staff, can perform the study in accordance with the protocol. All necessary precautions are taken at the study site to protect the safety of the study subjects.

I confirm study participants will be correctly informed about the standard of care (and what will be charged to the participant and their health insurance) and what interventions/examinations are extra for the investigation (always paid by the clinical investigation budget).

Signature of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name:

Date review Application Dossier**:** (dd/mm/yyyy)

**Signature CEO/person acting on behalf of CEO of the Institution**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Print Name**:

**Date:** (dd/mm/yyyy)