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

**Concerning**

**Name of Institution:**

**PI:**

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

**Sponsor:**

**Title:**

**CIP number:**

**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 site has all the facilities and equipment to conduct the clinical investigation and expects to be able to include the planned number of subjects.**
* **Availability and expertise of staff**
* **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 subjects will be correctly informed about the standard of care (and what will be charged to the patient 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:** (dd/mm/yyyy)

**Signature Institution**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Print Name**:

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