**COMMITMENT TO CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA**

**Date:**

Protocol code:

Foundation Code No.:

EUDRACT No.:

Mr./Ms. ........................................................., and respectively acting in the name and on behalf of ....................................... with VAT no. ................... and registered office at ...................................................., authorised for this purpose, in accordance with the powers of attorney issued at ........................................, dated .................. before the notary Mr./Ms.

# MANIFEST

1. **NAME OF CRO** has appointed Mr./Ms. **,** whit TAX ID No.: **,** to carry out the tasks of hospital coordination, assistance and support to the **PRINCIPAL INVESTIGATOR** related to the Referenced Study (hereinafter **"CRC (Clinical Research Coordinator)”**).

The tasks that the **CRC (Clinical research Coordinator)** will perform are as follows:

• Support to the research team to provide the highest quality of the results of the Study.

• Support to the research team in the collection and recording of data.

• Support to the research team in the resolution of Discrepancies.

• Support to the research team in the notification of Serious Adverse Events.

• Relationship with the CRA assigned to the study to schedule monitoring visits/calls

• Attend to monitoring calls and eventual monitoring visits, when applicable.

• Updating the researcher's file.

• Assists the research team in coordinating study activities

1. That by means of this agreement, **NAME OF CRO**

**AGREES**

* + To comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, as well as the rest of the current regulations on the protection of personal data that may be applicable.
  + Not to use the data and files owned by the Hospital to which it has access for a purpose other than that foreseen in the tasks of the **CRC** in the facilities of the hospital center, and not to communicate them to a third party other than **SPONSOR/NAME OF CRO.**
  + To treat the clinical-care data of the patients participating in the study in a dissociated way, to process them by computer means in safe conditions, and not to maintain any file, manual or automated, that allows to identify the codes of the patients with the data collection notebook of each patient.
  + The access by the **CRC** to the data and files mentioned, will be limited to the visualization of the personal data to which it accesses for the development of the tasks described in its work of assistance and support to the **Principal Investigator** or its collaborators. These checks will be carried out "in situ" and at no time will these data be recorded or collected by the **CRC**.

And in proof of conformity with all the above, sign this document on the date indicated above.

**NAME OF CRO,**

Position:

Signed: Mr./Ms.