

## OBSERVATIONAL STUDY WITH MEDICAL DEVICE

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- Filled **AGREEMENT** and **BUDGET template** in Spanish (may also be signed in English, but signature in Spanish is mandatory).
  - Protocol
  - Favourable opinión of the **Ethics Comitee (CEIm)**
  - **CAM** authorisation (if the study is a prospective follow-up study)
  - **INSURANCE POLICY** (must include HULP, FIBHULP, and PI)
  - **CONFORMITY OF THE CENTRE'S MANAGEMENT.** - This document is issued by our CEIm and with its issue a HULP CODE is assigned to the study.
- Please contact:

[sol.gracia@salud.madrid.org](mailto:sol.gracia@salud.madrid.org)  
[maribel.arribas@salud.madrid.org](mailto:maribel.arribas@salud.madrid.org)

### ▪ NOTARISED OR APOSTILLED DOCUMENTS

WHO SIGNS THE AGREEMENT?	DOCUMENTATION TO BE PROVIDED
<b>SPONSOR</b> signs the contract on his own behalf	Powers of attorney ( <b>POA</b> ) of legal representative of <b>SPONSOR</b>
<b>CRO</b> signs the contract on behalf of <b>SPONSOR</b>	Powers of attorney ( <b>POA</b> ) of legal representative of <b>CRO</b>
	Delegation Letter from <b>SPONSOR</b> to <b>CRO</b>