Germans Trias i Pujol Hospital

Institut Català de la Salut

ADMINISTRATIVE MANAGEMENT OF AGREEMENT

In order to **start managing the agreement** it is mandatory for **the study to be registered at the site:**

- **Clinical trials with medicinal products** or **medical devices** will be registered by **requesting the suitability of the facilities document** to the secretariat of the HUGTiP Research Ethics Committee.

- **Other kind of studies** will be registered by **submitting the initial assessment or feasibility review application** to the HUGTiP REC.

Once the study is registered, it will be possible to manage the agreement by sending to this email address **uadec.germanstrias@gencat.cat** the following requirements **depending on the type of study and procedure:**

	CLINICAL TRIAL	OBSERVATIONAL STUDY WITH MEDICINAL PRODUCTS RESEARCH PROJECT
AGREEMENT	**1.** The Site's Clinical trial **agreement template** in Spanish or English with track changes including the Sponsor's financial report. **2.** Signed document on the **Suitability of the facilities** of the HUGTiP. **3.** **Collaboration agreement with the Pharmacy Department** in Spanish or English filled out and signed (if applicable). **4.** **Insurance certificate** in which the Site and Principal Investigator are specified. **5.** Invoice Request Form **6.** The **Principal Investigator's local documentation**: ▪ PI and collaborators statement of responsibilities ▪ Collaboration agreement with the departments involved **7.** **REC's approval** (when available). **8.** **Authorisation from the AEMPS** (when available) **9.** Document issued by the **sponsor delegating functions and responsibilities** (if applicable).	**1.** The site's **agreement template** for: ▪ EOM in Spanish or English with track changes including the Sponsor's budget, or ▪ RESEARCH PROJECT in Spanish or English with track changes including the Sponsor's budget. **2.** **Proof of the assessment application** sent to the HUGTiP REC (email in PDF format). **3.** Invoice Request Form **4.** REC's approval (when available). **5.** **Authorisation from the Autonomous Community** (if applicable and when available). **6.** Document issued by the **sponsor delegating functions and responsibilities** (if applicable).
ADDENDUM TO THE AGREEMENT	**1.** The institution's **Agreement addendum template** in Spanish or English with track changes Depending on the reason for the Addendum, you shall submit the following documents: - **ADDENDUM DUE TO CHANGES IN THE FINANCIAL REPORT** **ANNEX I:** Updated financial report in which the version and/or date are specified. **ANNEX II:** REC's approval of the relevant amendment to modify the financial report. - **ADDENDUM DUE TO A CHANGE OF PRINCIPAL INVESTIGATOR** The **Principal Investigator and collaborators** statement of responsibilities signed by the new Principal Investigator. **ANNEX I**: REC's approval of the relevant amendment to change the PI. - **ADDENDUM DUE TO A CHANGE OF SPONSOR** **ANNEX I**: REC's approval of the relevant amendment to change the sponsor.	

The **administrative management of the agreement** carries a **€1,500 (+ VAT) fee** that the sponsor will pay once all the parties sign the agreement. The invoice will be previously issued by the Institute for Health Science Research Germans Trias i Pujol (IGTP).

This fee is **applicable** to all **billable agreements**. The fee payment will not depend on the effective conduct of the study or the receipt of approval from the Research Ethics Committee and/or the AEMPS.

In case of non-billable agreements with independent non-commercial sponsors, it will be possible to request a fee waiver by sending a letter signed by the sponsor to this email address **uadec.germanstrias@gencat.cat**.

Contact Information
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