Germans Trias i Pujol Hospital

Institut Català de la Salut

Research Ethics Committee
Crta. De Canyet, s/n - 08916 Badalona
Tel. +34 93 497 89 56
Email: ceic.germanstrias@gencat.cat
Website: www.ceicgermanstrias.cat

HUGTiP REC SUBMISSION REQUIREMENTS: SUBSTANTIAL AMENDMENTS IN PART I AND/OR PART II (CLINICAL TRIALS WITH MEDICINAL PRODUCTS)

You shall submit the online assessment application via the Clinical Trials with Medicinal Products Portal of the AEMPS including the following documents:

1. Cover letter.

2. Application form for substantial amendments.

3. Summary and justification of changes.

4. Comparative table of changes versus previous version.

5. New version of modified documents.

6. New documents.

7. Documents supporting the changes (if applicable).

8. Consequences of the modification, which must include:

- An updated overall **assessment** of the **risk-benefit ratio.**
- Possible **consequences for the subjects** included in the trial.
- Possible **repercussions** on the assessment of the **results**.

9. Invoice request form **/ Proof of payment of fee to the REC** (when applicable).

>> If the substantial amendment only involves an **addition of a new site, change of Principal Investigator** and/or **change of sponsor**, you shall send the following documentation:

1. Cover letter.

2. Application form for substantial amendments.

3. Proof of **insurance cover** or updated **financial guarantee**.

4. Invoice request form **/ Proof of payment of fee to the REC** (when applicable).

And, **in addition**, the following **specific documents:**

ADDITION OF NEW SITES	CHANGE OF P. INVESTIGATOR	CHANGE OF SPONSOR
5. Updated **financial report** (if applicable). **6.** Updated document on the suitability of the investigators. **7. Documents** that must be submitted to each **new site:** ▪ **Summary CV** of the Principal Investigator ▪ **Suitability of the facilities document**	**5.** Updated document on the **suitability of the investigators**. **6. Summary CV** of the Principal Investigator.	**5.** Document issued by the **sponsor delegating functions and responsibilities.**

ⓘ If you need more information about the practical aspects involved in the implementation of Royal Decree 1090/2015 you can visit the website of the Spanish Agency of Medicines and Medical Devices