Germans Trias i Pujol Hospital

Institut Català de la Salut

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HUGTiP REC SUBMISSION REQUIREMENTS: INITIAL ASSESSMENT APPLICATION CLINICAL TRIAL WITH MEDICINAL PRODUCTS

For the **HUGTiP REC to act as an Ethics Committee for Research with medicinal products** (CEIm in Spanish), you must **previously inquire the Technical Secretary** (ceic.germanstrias@gencat.cat) providing basic information about the study, the number of participating sites and the estimated submission date.

Once the Technical Secretariat has accepted your request, you shall proceed to obtain the suitability of the facilities document.

Finally, you must submit the assessment application via the **Clinical Trials with Medicinal Products Portal of the AEMPS** including the following documents:

DOCUMENTATION PART I (REC and AEMPS)

1. A **cover letter** that must:

- Specify, if applicable, whether the sponsor considers that the trial is a **low-intervention trial** and provide suitable justification.
- Include a full list of **auxiliary medicinal products**.
- Specify (cross-reference) where the description of the **arrangements for recruitment of subjects** and the **management of biological samples obtained** in the trial can be found.
- Provide a statement by the sponsor that data will be collected and processed in accordance with **existing data protection legislation**.
- Specify (cross-reference) where is the **reference safety information for the investigational medicinal products**.
- **Include any other information that could be useful** for the assessment of the study.

2. Application form.

3. Sponsor authorization of the applicant (if applicable)

4. Protocol structured according to current legislation.

5. Protocol summary.

6. Investigator's Brochure or summary of product characteristics of the investigational medicinal product.

7. Investigator's Brochure or summary of product characteristics of the auxiliary medicinal products.

8. Scientific advice and Paediatric Investigation Plan (if applicable).

9. Justification as to why the clinical trial is a low-intervention clinical trial (if this is not included in the cover letter).

DOCUMENTATION PART II (REC)

10. Documents related to the procedures and materials used for the recruitment of subjects.

11. Patient Information Sheet/s and Informed Consent Form/s.

12. Document on the suitability of the investigators. You must include a list of the trial's participating sites and principal investigators, as well as the planned number of trial subjects in each site.

13. Proof of insurance cover or financial guarantee listing all participating sites and principal investigators.

14. Financial report

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

16. Documents that must be submitted to each participating site:

- **Summary CV** of the Principal Investigator.
- **Suitability of the facilities** document

ⓘ 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**

ⓘ If you need more information about how to obtain the **suitability of the facilities** document you can visit the "**suitability of the facilities**" section of our website.