Germans Trias i Pujol
Hospital

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Research Ethics Committee
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HUGTiP REC SUBMISSION REQUIREMENTS: INITIAL ASSESSMENT APPLICATION CLINICAL RESEARCH WITH MEDICAL DEVICES (CLINICAL TRIAL)

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 send an email to **avaluacionsceic.germanstrias@gencat.cat** including the following documents:

1. **Cover letter from the external sponsor/applicant** to conduct the **Clinical Research with Medical Devices**.
2. **Full clinical investigation plan (protocol**) structured according to current legislation, and including code, version and date in the header or footer of the document.
3. **Summary of the clinical investigation plan** in Spanish or Catalan.
4. **Patient Information Sheet/s and Informed Consent Form/s.**
5. **Investigator's Brochure** (or, failing that, the summary of product characteristics).
6. Copy of the AEMPS' **authorisation application form** (if applicable).
7. Information about the **regulatory status of the product** (in process of obtaining the CE marking, approved by the FDA, by other countries outside the EU, etc.)
8. **Documents related to the procedures and materials used for recruitment of subjects.**
9. **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.
10. **Proof of insurance cover or financial guarantee** listing all participating sites and principal investigators.
11. **Financial report.**
12. **Documents that must be submitted to each participating site:**
    - **Summary CV** of the Principal Investigator
    - **Suitability of the facilities**
13. Invoice request form **/ Proof of payment of fee to the REC** (when applicable).

ⓘ If you need more information about the legislation applicable to this type of studies 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.