Germans Trias i Pujol Hospital

Institut Català de la Salut

Research Ethics Committee

Crta. De Canyet, s/n - 08916 Badalona
Tel. 93 497 89 56
E-mail: ceic.germanstrias@gencat.cat

RESEARCH PROJECT
SUBMISSION REQUIREMENTS: INITIAL APPLICATIONS

Applications must be submitted to avaluacionsceic.germanstrias@gencat.cat and must include the following documentation:

1. **Sponsor/Applicant Cover Letter or Email** with this information:
   - **Study identification details:** Study code, Title, Sponsor, CRO, Principal Investigator, Department.
   - **List of submitted documents**
   - **Applicant's contact details: C**ontact person, Telephone number, Email address, Postal address
2. **Full Study Protocol,** structured in accordance with current legislation and including the study code, version number and date in the header or footer of the document. (**For projects sponsored by HUGTiP/IGTP, use of the Protocol template is mandatory.)**
3. **Protocol Synopsis,** in Spanish or Catalan (mandatory when the protocol is submitted in English).
4. **Patient Information Sheet and Informed Consent Form (PIS/ICF)** in Catalan and/or Spanish and written in language appropriate for the target study population. The document must include the study code, version number, and date in the header or footer. If informed consent is not required, a duly justified request for a waiver of informed consent must be submitted **(For projects sponsored by HUGTiP/IGTP, use of the REC Patient Information Sheet and Informed Consent Form).is MANDATORY.)**
5. Any addtional materials intended for prospective study participants
6. **Financial Report Form**
7. **Principal Investigator Documentation**
8. **Invoice request form** for payment of the Ethics Committee review fee (where applicable), Alternatively, a Temporary Fee Waiver Request may be submitted where funding has been applied for and the outcome is still pending.

RESEARCH PROJECT APPROVED BY ANOTHER SPANISH RESEARCH ETHICS COMMITTEE
SUBMISSION REQUIREMENTS FOR LOCAL FEASIBILITY REVIEW

Research projects that have already received a favourable opinion from another Spanish CEI/m must be submitted to the HUGTiP CEIm for local feasibility review and site acceptance, in accordance with the principle of mutual recognition between Research Ethics Committees.

The following documentation must be submitted to avaluacionsceic.germanstrias@gencat.cat

1. **Application Form.**
2. **Favourable Opinion issued by the reviewing REC.**
3. **Study Protocol bearing the version number and date approved by the reviewing REC.**
4. **Patient Information Sheet and Informed Consent Form bearing the version number and date approved by the reviewing REC and including:** The name of our institution; The local Principal Investigator and contact details; The Data Protection Officer's contact details: dpd@ticsalutsocial.cat.
5. **Principal Investigator and Collaborators Commitment Form** and **Acceptance Form signed by the Heads of the Departments involved.**

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RESEARCH PROJECT
SUBMISSION REQUIREMENTS: RESPONSES TO REQUESTS FOR CLARIFICATION

Once a request for clarification has been issued by the REC, applicants must submit an email to avaluacionsceic.germanstrias@gencat.cat including the following documentation:

1. **Point-by-Point Response letter.**
2. **Updated documents** (all revised documents must include: tracked changes and updated version and date)
3. **Any new documentation** generated as a consequence of the responses to the requests for calrification.

RESEARCH PROJECT
SUBMISSION REQUIREMENTS: SUBSTANTIAL AMENDMENTS

Applications for substantial amendments should be submitted to avaluacionsceic.germanstrias@gencat.cat and must include the following documentation:

1. **Application Letter** for a Substantial Amendment, including the justification for the proposed changes and a complete list of the submitted documentation.
2. **Summary and Justification of Changes**.
3. **Updated versions** of all amended documents, including track changes, an updated version number and date.
4. **Any new documentation generated** as a consequence of the amendment**.**
5. **Invoice Request Form** for payment of the REC evaluation fee (where applicable).

Additional Requirements for Specific Types of Substantial Amendments

>> If the substantial amendment relates to a change of Principal Investigator or Sponsor, the following additional documentation must be submitted:

PRINCIPAL INVESTIGATOR CHANGE	SPONSOR CHANGE
Principal Investigator and Collaborators Commitment Form signed by the new Principal Investigator	Sponsor Transfer Letter

[1] The HUGTiP CEIm must review and approve any change of Principal Investigator at HUGTiP and/or its affiliated centres, regardless of the type of study, or the REC that originally reviewed the study.