



HUGTiP REC SUBMISSION REQUIREMENTS: INITIAL ASSESSMENT APPLICATION RESEARCH PROJECT

You must send your application to avaluacionsceic.germanstrias@gencat.cat including the following documentation:

- 1. Letter/email from the sponsor/applicant to conduct the research project** addressed to the Research Ethics Committee in which you request the assessment of the project. It must include the following information:
 - **Study identification data:** Study code, title, sponsor, CRO (if applicable), Principal Investigator, Department/Unit.
 - **List of submitted documents**
 - **Identification data of the applicant:** contact person, telephone number, email address, postal address.
- 2. Full project protocol** structured according to current legislation, and including **code, version and date** in the header or footer of the document.
- 3. Summary of the protocol** in Spanish or Catalan.
- 4. Patient Information Sheet and Informed Consent Form (PIS/ICF)** in Catalan and/or Spanish, which must be written in language understandable to a lay person. It must include the **code, version and date** in the header or footer of the document. **Failing that, you shall provide a justified request for waiver of PIS/ICF.**
- 5. Any other documentation addressed to potential participants** in the study.
- 6. [Financial report form](#)** of the study.
- 7. [Principal Investigator documentation](#)** in its **original** format (PI and collaborators statement of responsibilities, collaboration agreement with the departments involved and form for the use of biological samples with research purposes). Signatures must be handwritten or electronic, and all documents must be submitted in PDF format.
- 8. Favourable opinion** from an accredited REC (if applicable).
- 9. [Invoice request form](#) to pay the REC's fee** (if applicable) or **[temporary waiver of fees](#)** (if you have applied for a grant pending approval)