



Research Ethics Committee

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**HUGTiP REC SUBMISSION REQUIREMENTS: SUBSTANTIAL AMENDMENTS
OBSERVATIONAL STUDY WITH MEDICINAL PRODUCT**

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

1. **Application from the sponsor/applicant** to make a substantial amendment to the Observational Study with Medicinal Product addressed to the Research Ethics Committee **listing the documentation submitted for assessment**.
2. **Summary and justification of changes**.
3. **New version** (with track changes, and updated version and date) of the **documents** that have been modified due to the amendment.
4. Any **new documentation** emerging as a result of the amendment.
5. [Invoice request form](#) to pay the fee to the REC (if applicable).

>> If the substantial amendment only involves a **change of Principal Investigator** from the HUGTiP and/or associated site, or a **change of sponsor**, in addition to the aforementioned documentation, you shall send the following **specific documents**:

CHANGE OF P. INVESTIGATOR ¹	CHANGE OF SPONSOR
Principal Investigator and collaborators statement of responsibilities signed by the new PI of the study.	Document issued by the sponsor delegating functions and responsibilities .

¹ The HUGTiP REC shall assess and authorise any change of Principal Investigator in the HUGTiP and/or associated sites regardless of the kind of study and the REC that initially assessed the study.