



HUGTiP REC SUBMISSION REQUIREMENTS: SUBSTANTIAL AMENDMENTS CLINICAL RESEARCH WITH MEDICAL DEVICES (CLINICAL TRIAL)

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

1. **Application from the sponsor/applicant listing all 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](#) / **Proof of payment of fee to the REC** (when applicable).

>> If the substantial amendment only involves an **addition of a new site, change of Principal Investigator** and/or **change of sponsor**, you shall send the following documentation:

1. **Cover letter.**
2. Proof of **insurance cover** or updated **financial guarantee** (if applicable)
3. [Invoice request form](#) / **Proof of payment of fee to the REC** (when applicable).

And, **in addition**, the following **specific documents**:

ADDITION OF NEW SITES	CHANGE OF P. INVESTIGATOR	CHANGE OF SPONSOR
<ol style="list-style-type: none">4. Updated financial report (if applicable).5. Updated document on the suitability of the investigators.6. Documents that must be submitted to each new site:<ul style="list-style-type: none">▪ Summary CV of the Principal Investigator▪ Suitability of the facilities	<ol style="list-style-type: none">4. Updated document on the suitability of the investigators.5. Summary CV of the new Principal Investigator.	<ol style="list-style-type: none">4. Document issued by the sponsor delegating functions and responsibilities.



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](#).