



Studies and Agreements Register Unit Research Ethics Committee

Crta. De Canyet, s/n - 08916 Badalona Tel. +34 93 497 89 74 (Ext: 3968) Email: uadec.germanstrias@gencat.cat Website: www.ceicgermanstrias.cat

REQUIREMENTS FOR THE ADMINISTRATIVE MANAGEMENT OF AN ADDENDUM TO THE AGREEMENT

In order to start the **administrative management of an addendum** to the agreement, you must submit the following documents to <u>uadec.germanstrias@gencat.cat</u>:

- The institution's Agreement addendum template in <u>Spanish</u> or <u>English</u> with track changes.
- ① Depending on the reason for the Addendum, you shall submit the following documents:

ADDENDUM DUE TO CHANGES IN THE FINANCIAL REPORT

If the modification of the financial report is deemed to be a **relevant amendment**, you shall submit the following:

- 1. ANNEX I: Updated financial report in which the version and/or date are specified.
- 2. ANNEX II: REC's approval of the relevant amendment to modify the financial report.

ADDENDUM DUE TO A CHANGE OF PRINCIPAL INVESTIGATOR

If the change of Principal Investigator takes place in the **Germans Trias i Pujol University Hospital**, you shall submit:

- The Principal Investigator and collaborators statement of responsibilities for <u>clinical trials with</u> <u>medicinal products or medical devices</u> or <u>Research Project / PAS</u> signed by the new Principal Investigator.
- 2. ANNEX I: REC's approval of the relevant amendment to change the PI.

ADDENDUM DUE TO A CHANGE OF SPONSOR

You shall submit the following:

- 1. ANNEX I: Document issued by the sponsor delegating functions and responsibilities.
- **2. ANNEX II: REC's approval** of the relevant amendment to change the sponsor.