



NOTIFICATIONS RELATING TO RESEARCH PROJECTS/OBSERVATIONAL STUDY WITH MEDICINAL PRODUCT

Regardless of the study's first assessing REC, the following notifications regarding all started studies must be sent to the email address notificacionsceic.germanstrias@gencat.cat

Notifications that the REC **MUST** receive

- Annual follow-up report of the study.
- **Final report of results** (must be submitted within a maximum period of 1 year from the end of the study)
- **Relevant incidents occurred during the course of the study:** halt, interruption, safety measures, etc.
- **Update of this site's research team (collaborators).** The study must be active and the corresponding annual follow-up reports must have been submitted.
To add new collaborators, the notification must be accompanied by the [Principal Investigator and collaborators statement of responsibilities](#) signed by the Principal Investigator and the new collaborators.
- **Substantial modifications previously assessed** by another REC.
- **Changes and/or updates** of contact person with the REC, CRO, study monitor, etc. **not specified** in substantial amendments.
- **Modifications in the financing of the study or in the financial report of the study** submitted in the initial financial report which **do not involve** changes in the compensation for the participants and/or the investigators.
- **Favourable opinion from the Catalan General Department for Health Regulation, Planification and Resources for PAS-prospective observational studies** (if applicable).

Notifications that the REC **MUST NOT** receive

The HUGTiP REC shall not accept the following notifications:

- **Notifications** addressed to **other institutions**.
- **Non-substantial modifications**, administrative changes, etc.