Ethics approval, review and incident reporting obligations for projects funded by NIH and other US federal entities

Initial approval

In line with the Terms of the Federalwide Assurance (FWA) for the Protection of Human Subjects, the principal investigators of all projects involving research with humans that are funded by NIH and other US federal entities are required to submit their project to the Commission cantonale d’étiquette de la recherche (CCER) for initial approval prior to implementation. The CCER is the registered Institutional Review Board (IRB) of UNIGE. A copy of the CCER’s decision must be submitted to the UNIGE Research Service for information.

Link to submission information on CCER website: http://ge.ch/sante/commission-cantonale-dethique-de-recherche-ccer/soumission-dun-dossier (in French).

Federalwide Assurance (FWA) for the Protection of Human Subjects: FWA00020634
Institutional Review Board (IRB): IRB00003116 - Commission Cantonale d’Ethique de la Recherche de Genève IRB #1

Continuing review

The principal investigators of projects falling under the FWA are required to request review by CCER on an annual basis, even in the absence of modifications and/or incidents. A copy of the CCER’s decision must be submitted to the UNIGE Research Service for information.


Changes in approved research activity

The principal investigators of projects falling under the FWA are required to report in writing any changes in an approved research activity to the CCER secretariat and to ensure that such changes are not initiated without review and approval by CCER, except when necessary to eliminate apparent immediate hazards to the research subjects. A copy of the CCER’s decision must be submitted to the UNIGE Research Service for information.

Incident reporting

The principal investigators of projects involving research with humans that are funded by NIH and other US federal entities are required to report in writing to the CCER secretariat, the UNIGE Research Service, the head of the US federal entity conducting or supporting the research (or its designee) and the US Office for Human Research Protections (OHRP) any:

- Unanticipated problems involving risks to research subjects or others;
- Serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of CCER; and
- Suspension or termination of approval by CCER.

For any questions, please get in touch with the UNIGE Research Service at euresearch@unige.ch.