

AGEK

Arbeitsgemeinschaft der Schweizerischen Forschungs-Ethikkommissionen für klinische Versuche
Communauté de travail des Commissions d'éthique de la recherche en Suisse

CT CER

Example of a positive statement for a research project that will be carried out abroad

This research project was evaluated according to the ICH-GCP (International-Conference on Harmonisation - Good Clinical Practice) guidelines. It conforms with the conditions that have to be met for research studies in Switzerland, namely:

- scientific validity and relevance of the research project and of the results that are to be expected;
- favourable benefit-risk ratio;
- consent of the study subjects;
- protection of the private sphere and confidentiality;
- procedure for compensation in the case of personal damage or injury;
- professional qualification of the Swiss research scientists involved in the project;
- Definitions of the qualifications that are required of the other research scientists involved.

Whether the project can be accepted from ethical points of view depends on the local circumstances, which could not be assessed. In particular, the present statement does not consider the following points:

- procedure and documentation for recruitment of the study subjects, especially the information sheets and consent forms written in the local language;
- appropriate cover for possible personal damage or injury (details of the type of damage covered and the envisaged amount of the compensation);
- the adequacy of the local infrastructure (material, premises, personnel etc.) with regard to the best possible protection of the study subjects;
- Professional qualification of the non-Swiss research personnel.

The responsible ethical research committee(s) of the place(s) where the project is carried out should assess the points listed above.