

Professional qualifications of the investigators and project leaders of research projects

For clinical trials the professional qualification is defined in ClinO art. 6 and for non-clinical trials in HRO art. 4. The ordinances require the investigator resp. the project leader to be able to practice their profession independently.

For clinical trials of medicinal products or transplantation, the medical profession (completed specialty training) is obligatory for the role of the "principal investigator".

Physiotherapists, nursing staff or other persons from the health sector can, upon completion of their professional training, be investigator resp. project leader for clinical trials with other interventions and non-clinical trials in accordance with HRO. Physicians during their specialty training would not yet fulfil this qualification, since strictly speaking they are not yet allowed to work independently in a specialty responsibility. This results in the illogical situation that, for example, a trained nurse, but not a physician during his specialty training, may assume the role of project leader of an observational research project.

The ethics committees reserve the right to decide on a case-by-case basis which qualification is considered sufficient on the basis of an overall analysis and risk assessment of the project submitted. It is certainly possible that a physician during his specialty training could be responsible for an observational research project (e.g. with blood tests and questionnaires). However, it must generally be ensured that an institution and/or a higher ranking specialist (specialist, senior physician, etc.) assumes the overall responsibility as sponsor.

The Ethics Committee will always make a decision of a case-by-case basis. In case of questions concerning the investigator's qualification, these can be forwarded via BASEC to the competent Ethics Committee. The Ethics Committee will always make a decision on a case-by-case basis.