

**List of the persons conducting the clinical trial / research project at the site,
indicating their responsibilities and relevant professional knowledge¹**

Protocol Number:

Protocol Title:

BASEC Project ID Nr (if available):

Site:

Full name Principal Investigator (ClinO) / Project Leader (HRO):

Study staff: Full name	Education	Actual function ²	GCP-training (yes/no)	Study task / responsibility ³

1) The 'Staff list' should be used in accordance with the Ordinance on Clinical Trials (ClinO) [Annex 3](#) (1.10, 2.11, 3.9, 4.4) and with the Ordinance on Human Research with the Exception of Clinical Trials (HRO) [Annex 2](#) (1.8, 5.11, 7.9). The 'Staff list' does not fulfill the requirements set by ICH-GCP E6R2 Art. 4.1.5, and as such it can't be use as 'delegation log'.

2) e.g. study nurse, study coordinator, pharmacist, ...

3) e.g. Make eligibility decision, obtain informed consent, administer study drugs/ implant devices, make physical exams and other investigations, assess safety events and report SAEs, make data entry and make corrections in CRF,...

Note: The submission of the list of people with important roles in this project, not mentioned elsewhere, to the Ethics Committee is optional. Yet, the Ethics Committee might request the list e.g. for high risk projects (e.g. phase I clinical trials).

Signature: _____
Principal Investigator (ClinO) / Project Leader (HRO)

Place and date: _____