

Swiss Confederation

Authorisation of pilot trials under Art. 8a NarcA Checklist – Application requirements

Data	documents, evidence	Enclosure/attachment
	Information on the activity of the public or private organisation submitting the application	
	Designation of a responsible person who will supervise the pilot trial	
	Extract from the Swiss criminal record excerpt for the person responsible for conducting the trial that must have been issued within the last six months	
	Information on the aim and benefit of the pilot trial	
	Description of the trial (study protocol), particularly regarding the content, methodology and approaches, number of participants, what information participants will be given, funding and timeframe	
	Designation of the research management	
	Information on what type of cannabis products will be made available (see also product quality requirements: Art. 9 NarcPT)	
	List of points of sale that will dispense those cannabis products	
	Information on the involvement of relevant cantonal and communal authorities and consent from the relevant communes regarding the planned points of sale	
	Information on the envisaged quantities to be dispensed and sale price (Art. 16 NarcPT)	
	Information on cultivation, import, manufacture and distribution of cannabis products (applications in accordance with Art. 24 NarcPT)	
	A description of the precautionary measures taken to ensure participant safety and to protect public order and public safety	
	Information on the monitoring of participants' state of health	
	Information on prevention, youth protection and health protection measures and strategies	
	Evidence that a licence application has been submitted to the competent ethics committee in accordance with Art. 45 of the Federal Act of 30 September 2011 on Research involving Human Beings (HRA), or that a confirmation has been requested stating that such an authorisation is not required. A decision/confirmation from the ethics committee should be enclosed with the application.	
Place,	date Signature responsible person	