

Research requiring authorisation or notification

Research on humans

Research on humans, studies based on human tissue samples or individual medical data.

Research projects with humans must be approved by an official ethics committee and comply with federal and cantonal laws regulating research on humans. Depending on the type of research or the group examined (e.g. people in special need of protection), studies must be announced to and authorised by the concerned authorities.

It is the responsibility of the researcher to assess the [legal Framework](#) applying to the studies and to take the required measures. The [Federal Office of Public Health \(BAG\)](#), the Swiss Agency for therapeutic products ([Swissmedic](#)) and the [Swiss Ethics Committees for Research involving humans](#) provide a comprehensive overview of the legal basis for research on humans.

Clinical trials must be conducted following the [Guidelines for good clinical practice by the ICH](#).

Research on human embryonic stem cells

The [federal office of public health](#) (FOPH) provides a comprehensive overview of the legal basis of research involving human embryonic stem cells (in G,F). The appropriate regulations for research involving human embryonic stem cells are given by the respective [law](#) (StFG) and [regulations](#) (VStFG).

Research projects involving human embryonic stem cells must be approved by an ethics committee and require permission from the FOPH.

Research on animals

Research on vertebrates, reptantia and cephalopods requires an authorisation by the responsible Canton (*i.e.* its veterinary office). Legally relevant are the [Tierschutzgesetz](#) and the [Tierschutzverordnung](#). All important forms as well as the corresponding explanations can be downloaded from the site of the [Swiss Federal Veterinary Office](#) (FVO). Additionally, the [Ethical Principles and Guidelines for Experiments on Animals](#) pertaining to animal experiments of the Swiss Academy of Medical Sciences (SAMW) and the Swiss Academy of Sciences (SCNAT) must be taken into consideration.

Please note: Knockouts and transgene animal models are regarded as genetically modified organisms (GMO) and therefore need to be separately notified to the Federal Office for the Environment (FOEN). In the case of research on animals that are genetically modified, the category "Research on pathogens or GMO" must consequently also be completed.

Research on GMO or pathogens

Concerns research in which genetically modified organisms (GMO) are produced or used and/or in which pathogenic organisms are involved. Such research, either in the lab or in the field, requires authorisation or confirmation of notification from the Federal Office for the Environment (FOEN).

A comprehensive overview on the legal basis for research on GMOs or pathogenic organisms is given by the [coordination centre for biotechnology](#) of the FOEN. Genetic methods which lead to GMOs as defined by law, are listed in Annexe 1 of the [regulations on the contained use of organisms](#) (ESV). Central to the evaluation of projects with GMOs is the risk assessment undertaken by the researcher (annex 2, ESV). This risk assessment includes the grouping of the utilised organisms as well as the classification of the activities performed. Depending upon the result of the risk assessment either notification or official authorisation will be necessary.

The legal foundation for the execution of [experimental releases](#) of genetically modified or pathogenic organisms can be found in the [release regulations](#) (FrSV).

Access and Benefit Sharing

Please note that this declaration does not require authorisation nor confirmation of notification.

With this declaration and following the applicant's information duty towards the SNSF, you indicate that your research falls under the [Access and Benefit Sharing \(ABS\) stipulations of the Nagoya Protocol](#).

The Nagoya Protocol (*Nagoya Protocol on **Access** to Genetic Resources and the Fair and Equitable **Sharing** of **Benefits** Arising from Their Utilization*) is an international agreement on the environment that defines the implementation of the provisions of the UN Convention on Biodiversity (CBD) adopted in 1992. This protocol was ratified by the EU and 50 other countries, among which Switzerland, and came into force in October 2014. The adhesion of Switzerland to the Protocol was integrated into the Federal Act on the Protection of Nature and Cultural Heritage (NCHA) in the same month.

The [federal ordinance on the NCHA](#) came in force on 1 February 2016. It places investigators to carry out due diligence on and/or notify research that involves genetic resources a country that is signatory to the Nagoya Protocol. The compliance to due diligence and notification duty falls under the responsibility of the investigators.

Further information is available on the homepage of the ["Swiss Information System Biodiversity"](#) and [of the FOEN](#).