**Z01\_Ethical Issues – Form for the application of an ETH Zurich Medlab Fellowship**

Revised January 2021

**Ethical Issues demanding authorization or notification**

ETH MedLab Fellowship candidates who intend to perform research requiring authorization or notification in their project must declare this in the table below. This applies to research on humans, on human embryonic stem cells, on animals, on GMO/pathogens, and on research involving developing countries. The table below gives important information on the process of the ethical evaluation and an overview of the bodies in charge.

The Evaluation Committee points out that grants can usually only be transferred if all required authorizations or notifications are available. ETH MedLab Fellowship candidates and their host professors are therefore recommended to submit the requests for these documents to the concerned authorities parallel to the evaluation by the Evaluation Committee. Copies of the authorization or notification can either be scanned and sent by e-mail or by regular mail, once a fellowship has been accepted for funding.

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| Research on humans **Research on humans: Yes No**  **If yes, you intend to …**  collect samples and personal data Yes No  use existing samples or personal data Yes No  do clinical trials of pharmaceutical products Yes No  do in-vivo somatic gene therapy Yes No  do ex-vivo somatic gene therapy Yes No  do clinical trials with transplants Yes No | Research projects on or 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 authorized 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 (FOPH/BAG)](https://www.bag.admin.ch/bag/en/home.html), the Swiss Agency for therapeutic products ([Swissmedic](https://www.swissmedic.ch/swissmedic/en/home.html" \t "blank)) and the [Swiss Association of Research Ethics Commissions](https://swissethics.ch/en/) 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](https://www.ich.org/).  Research projects with humans that are not regulated by the [Human Research Act](https://www.admin.ch/opc/en/classified-compilation/20061313/index.html) should be evaluated by the [ETH Zurich Ethics Commission](https://ethz.ch/services/en/organisation/boards-university-groups-commissions/ethics-commission.html). More information on their review process can be found [here.](https://ethz.ch/en/research/ethics-and-animal-welfare/research-ethics.html) |

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| Research on Human Embryo / Foetus **Research on human embryonic stem cells Yes No** | The [Federal Office of Public Health](http://www.stemcells.bag.admin.ch/themen/hes/) (FOPH/BAG) provides a comprehensive overview of the legal basis of research involving human embryonic stem cells. 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 animals Yes No**  **If yes, you intend to work with**  lab-rodents Yes No  other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Yes No | Research on vertebrates, cephalopods and *reptantia (Panzerkrebse)* requires an authorization by the responsible canton (*i.e.* its veterinary office). Legally relevant are the federal act on animal welfare and the federal ordinance on animal welfare. All important forms as well as the corresponding explanations can be downloaded from the site of the [Swiss Federal Veterinary Office](https://www.blv.admin.ch/blv/en/home/tiere/tierversuche.html) (FVO). Additionally, the [ETH Policy on Experimental Animal Research](https://rechtssammlung.sp.ethz.ch/Dokumente/425en.pdf), the [Ethical Principles and Guidelines for Experiments on Animals](https://private.aaalac.org/intlRefs/IntRegs/Siwtzerland/Ethical%20Principles%20and%20Guidelines%20for%20Experiments%20on%20Animals.pdf) pertaining to animal experiments of the Swiss Academy of Medical Sciences (SAMW) and the Swiss Academy of Sciences (SCNAT) must be taken into consideration. Note also that knockouts and transgene animal models are regarded as genetically modified organisms (GMO) and the category «Research on pathogens or GMO» below must consequently also be completed.  For more information contact [the ETH Animal Welfare Officers](https://ethz.ch/en/the-eth-zurich/organisation/staff-units/stab-forschung.html). |
| Research on GMO or pathogens **Research on GMO or pathogens Yes No**  **If yes, you intend to…**  release GMO/pathogens for human or animals Yes No  release pathogens for plants, fungi or lichens Yes No  do experiments on GMO in contained systems Yes No  work with pathogens in contained systems (cl. 2, 3, 4) Yes No  work with pathogens in contained systems (cl. 1) Yes No | 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 authorization or confirmation of notification from the [Federal Office for the Environment (FOEN)](https://www.bafu.admin.ch/bafu/en/home.html).  A comprehensive overview on the legal basis for research on GMOs or pathogenic organisms is given by the [coordination centre for biotechnology](http://www.bafu.admin.ch/biotechnologie/index.html?lang=en) of the FOEN. Genetic methods which lead to GMOs as defined by law, are listed in Annex 1 of the [regulations on the contained use of organisms](http://www.admin.ch/ch/d/sr/8/814.912.de.pdf) (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 utilized organisms as well as the classification of the activities performed. Depending on the result of the risk assessment either notification or official authorization 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](http://www.admin.ch/ch/d/sr/8/814.911.de.pdf) (FrSV). |
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| Research Involving Developing Countries **Research Involving Developing Countries Yes No**  If yes, you confirm that you respect the principles of research in partnerships Yes No  If you use local resources of developing countries,  you are aware of actions to be taken regarding access and benefit sharing Yes No | Within the ETH Fellowship Program, research proposals involving developing countries will need to address the principles of research partnership as stated in the [KFPE’s Guide for Transboundary Research Partnerships](https://kfpe.scnat.ch/en/11_principles_7_questions) in a satisfactory and convincing manner. If a research project uses local resources (genetic resources, animals and plants), please refer to the «[good practice for academic research on genetic resources](http://abs.scnat.ch/downloads/documents/ABS_GoodPractice_2009.pdf)» of the SCNAT for informations on actions to be taken regarding access and benefit sharing. |
| Research areas excluded from funding According to a decision of the ETH Zurich Executive Board, ETH’s internal research promotion system will not fund research requiring security classification, such that publications are prohibited. Therefore, the ETH Zurich MedLab Fellowship Program will not support classified research. The control of dual-use goods in Switzerland is regulated by the Federal Act on the Control of Dual-Use Goods and of Specific Military Goods of December 13th, 1996. | |
| Compliance with legal regulation By checking the box below and signing the cover sheet, you declare that you are aware of the legal regulations at federal and cantonal level relevant to your research project concerning human research, research with human embryonic stem cells, research on animals, research with GMO/pathogens and on research involving developing countries. You confirm that all measures have been taken to ensure that the regulations will be respected. Similarly you are committed to upholding the professional and research-ethical rules in your work.  **Relevant regulations noted and accepted Yes No** | |