**Form A\_03**

**Ethical issues guidelines**

**Proposal ID-No.[[1]](#footnote-1):**

**Ethical issues for the application of a PSI fellow**

PSI Fellow candidates who intend to perform research at PSI will accept the “Guidelines for research integrity at PSI” (see <https://www.psi.ch/en/integrity>) by signing the working contract. Among other topics, guidelines for research planning, execution and for publication of results are outlined in that document. Research on humans, human embryonic stem cells, and animals, GMO/pathogens and on research involving developing countries requires specific considerations.

Eligibility requires authorization and notifications on the ethical issues as outlined on the following pages of this document. The applicant is fully responsible for correct declaration. If research on humans is planned, a submission for parallel evaluation by the ethical commission of the Canton Aargau is recommended. Please refer to:

<https://www.ag.ch/de/dgs/gesundheit/gesundheitsfoerderungpraevention/ethikkommission/ethikkommission.jsp>

Copies of authorization or notification to be sent electronically or by regular mail, once a fellowship has been accepted for funding.

**I have read and understood the regulations on ethical issues on the following pages and I accept them: 🞎 (if yes then please make a cross)**

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

First name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Family name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Electronic signature or written signature and submission of scanned document)

**Ethical Issues demanding authorization or notification**

PSI-Fellow 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 designates the relevant bodies in charge.

The ethical review committee of PSI points out that grants can only be transferred, if all required authorizations or notifications are available. PSI-Fellow candidates and their mentors are therefore recommended to submit the requests for these documents to the concerned authorities parallel to the evaluation by the ethical review committee of PSI. Copies of the authorization or notification can either be sent by email (scanned) or by regular mail, once a fellowship has been accepted for funding.

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| **Research on humans** | **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 (BAG)](https://www.bag.admin.ch/bag/en/home.html), the Swiss Agency for therapeutic products [Swissmedic](http://www.swissmedic.ch/?lang=2) and the [Swiss Ethics Committees for Research](https://swissethics.ch/en/basec) 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/page/efficacy-guidelines).  Research projects on humans1 using non-invasive techniques, not falling into the federal law on drugs (Heilmittelgesetz) or the cantonal law on patients (Patientengesetz), should be evaluated by the ethical commission of Nordwest- und Zentralschweiz (EKNZ / https://www.eknz.ch/. More information on the ethical review process can be found on the mentioned webpage. More information on the ethical review process can be found on the mentioned webpage. |
| **If YES, you intend to …**  collect samples and data1 | Yes | No |
| **If YES, you intend to …**  use existing samples or data1 | Yes | No |
| **If YES, you intend to …**  do clinical trials of pharmaceutical products | Yes | No |
| **If YES, you intend to …**  do In vivo somatic gene therapy | Yes | No |
| **If YES, you intend to …**  do Ex vivo somatic gene therapy | Yes | No |
| **If YES, you intend to …**  do clinical trials with transplants | Yes | No |

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| Research on Human Embryo / Foetus | **Yes** | **No** | The [federal office of public health](http://www.stemcells.bag.admin.ch/themen/hes/) (FOPH) 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](http://www.admin.ch/ch/d/sr/8/810.31.de.pdf) (StFG) and [regulations](http://www.admin.ch/ch/d/sr/8/810.311.de.pdf) (VStFG). Research projects involving human embryonic stem cells must be approved by an ethics committee and require permission from the FOPH. |

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| Research on Animals **Research on animals requiring authorization/notification** | **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](http://www.admin.ch/ch/d/sr/4/455.de.pdf) and the [federal ordinance on animal welfare](http://www.admin.ch/ch/d/sr/4/455.1.de.pdf). 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.html) (FVO). Additionally, the [Ethical Principles and Guidelines for Experiments on Animals](http://www.altex.ch/resources/e_RL_Tierethik1.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. **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. |
| **If YES, you intend to work with**  Lab-rodents | Yes | No |
| **If YES, you intend to work with**  Others: \_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes | No |

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| Research on GMO or pathogens | **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).  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 Annexe 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 (annexe 2, ESV). This risk assessment includes the grouping of the utilized organisms as well as the classification of the activities performed. Depending upon the result of the risk assessment either notification or official authorization will be necessary. The legal foundation for the execution of [experimental releases](http://www.bafu.admin.ch/biotechnologie/01756/index.html?lang=en) 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). |
| **If YES, you intend to…**  release GMO/pathogens for human or animals | Yes | No |
| **If YES, you intend to…**  release pathogens for plants, fungi or lichens | Yes | No |
| **If YES, you intend to…**  do experiments on GMO in contained systems | Yes | No |
| **If YES, you intend to…**  work with pathogens in contained systems (cl. 2, 3, 4) | Yes | No |
| **If YES, you intend to…**  work with pathogens in contained systems (cl. 1) | Yes | No |

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| Research Involving Developing Countries | **Yes** | **No** | Within the PSI-Fellow program, research proposals involving developing countries will need to address the principles of research partnership as stated in the [Guidelines for Research in Partnership with Developing Countries (1998)](http://www.kfpe.ch/key_activities/publications/guidelines/guidelines_e.php) of the KFPE in a satisfactory and convincing manner. If a research project uses local resources (genetic resources, animals and plants), information on Prior Informed Consent, Mutually Agreed Terms and Benefit Sharing will be required according to the manual for «[good practice for academic research on genetic resources](http://abs.scnat.ch/downloads/documents/ABS_GoodPractice_2009.pdf)» of the SCNAT. |
| **If YES, you confirm** that you respect the principles of research in partnerships Yes No | Yes | No |
| If you use local resources of developing countries, you are aware of actions to be taken based on Access and Benefit sharing | Yes | No |

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| Research areas excluded from funding Research areas excluded from funding under Horizon 2020 as stipulated in Art. 6 (2§)[[2]](#footnote-2) are not supported in this program.  According to a decision of the ETH Zurich Executive Board, PSI will not fund research requiring security classification, such that publications are prohibited. Therefore, the PSI-Fellow 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 activating the check 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 affirm that all measures were 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** |

1. <https://www.psi.ch/psi-fellow/list-of-principle-investigators-and-themes> [↑](#footnote-ref-1)
2. i) Research activities aiming at human cloning for reproductive purposes

   ii) Research activities intended to modify the genetic heritage of human beings

   iii) Research activities intended to create human embryos solely for the purpose of research or stem cell procurement [↑](#footnote-ref-2)