**Specifications on research on humans**

The federal office of public health1 (BAG) and the Swiss Ethic Commissions for clinical research2 provide a comprehensive overview of the legal basis of science on humans (in G,F,I).

As part of the public health sector, science on humans is however in the sovereignty of the Cantons. Therefore please note that some Cantons have own additional laws and regulations concerning science on humans.

Clinical trials have to be conducted following the Guidelines for good clinical practice by the ICH3.

Please, put a cross in that (those) box(es) that apply to your research:

|  |  |  |
| --- | --- | --- |
|  | The project contains the collection of samples and data from human subjects4,5 | |
|  | The project accesses existing samples or data from human subjects6 | |
|  | The project contains clinical trials of medicaments, medical products or immuno-biological substances (i.e. *Heilmittel*7,8). | |
|  | The respective permission by Swissmedic | |
|  | will be filed subsequently | is enclosed |
|  | The project contains clinical trials using somatic gene therapy *in vivo* or using medical products that contain genetically modified micro-organisms7,8 | |
|  | The respective permission by Swissmedic | |
|  | will be filed subsequently | is enclosed |
|  | The project contains clinical trials with genetically modified grafts (i.e. *ex vivo* gene therapy; covered by the Federal laws on transplantation9,10). | |
|  | The respective permission by the BAG | |
|  | will be filed subsequently | is enclosed |
|  | The project contains clinical trials with human or animal grafts (covered by the Federal laws on transplantation9,10). | |
|  | The respective permission by the BAG | |
|  | will be filed subsequently | is enclosed |

BAG (**G**,F,I):

2 CH Ethic commission:

3 ICH-GCP:

**Guidelines SAMS:**

4 Scientific examinations in humans:

5 Genetic examinations in humans:

6 Guidelines for biobanks :

**Federal laws:**

7 Law on *Heilmittel* (**G**,F,I):

8 Ordinance on clinical trials with *Heilmittel* (G,F,I):

9 Federal determination on transplantation:

10 Ordinance on transplatation:

|  |  |  |
| --- | --- | --- |
| Patients’ data can generally only be used for scientific purposes if they are either in an anonymised form or if the patient has given his/her informed consent. If neither case is feasible, the expert commission on the professional secret in medical sciences11 has to be asked for permission. | | |
|  | The project requires the permission by the expert commission on the professional secret in medical sciences, and the respective permission | |
|  | will be filed subsequently | is enclosed |

|  |  |  |
| --- | --- | --- |
| In Switzerland, every scientific project involving science on humans has to be approved by an official ethics commission2. | | |
|  | The approval by an ethics commission | |
|  | will be filed subsequently | is enclosed |

**Declaration:**

I hereby declare that I acknowledge the Swiss Acadamy of Medical Sciences’ ethical guidelines, which apply to my research (SAMS; *Scientific examinations in humans, genetic examinations*). I further assert that I will conduct my projects following these guidelines.

Applicant:

Datum: Unterschrift:

11 Commission on the professional secret: