Checklist as of January 2014 ClinO Appendix 3 Items 2_6

Application documentation for category B and category C clinical trials involving therapeutic products and transplant products

Document templates are available at www.swissethics.ch.

No.	Document	Date/ version number	Reference to other documents, if applicable	Cantonal ethics committee (KEK): Comments (leave blank)
0	**Covering letter** – billing address must be included – to be signed by the applicant (investigator or sponsor)			
1a	**Base form, including synopsis (in layman's terms) of the study plan for the patients, in the national language(s) spoken at the location where the trial is executed** – to be signed by the investigator and, if applicable, by the sponsor			
1b	**Synopsis of the study plan for KEK members** – in the national language of the KEK in charge			
2	**Study plan** – to be signed by the investigator and, if applicable, by the sponsor			
3	**CRF (Case Report Form)**			
4a	**Information sheet and declaration of consent** – in the national language(s) spoken at the location(s) where the trial is executed, for the responsible persons and contacts on site – if necessary, including specific information for persons incapable of judgement (e.g. urgent care patients, patients suffering from dementia), under-age persons, authorised representatives (e.g. parents) or the pregnant partner of a participant in the trial – separate information on sub-studies (e.g. additional MRI, pharmacokinetic examination) – information for the further use of data and samples for future research purposes			
4b	**Recruitment documentation** – namely advertisement, advert text or recruitment letters to the patient or family physician			

No.	Document	Date/ version number	Reference to other documents, if applicable	Cantonal ethics committee (KEK): Comments (leave blank)
5	**Additional documentation to be handed to the participant** – patient ID, journals, questionnaires/scores in the appropriate national language, **or other documentation to be used in the course of the study** – e.g. interview guide, questionnaire, scores			
6	**Details on nature and scope/value of compensation for participants**			
7	**For clinical trials involving category B medicinal products,** the technical information as well as indications on usage deviation according to study information (IB)			
8	**For clinical trials involving category C medicinal products,** the study information (IB)			
9	**For clinical trials involving category C medical devices without conformity assessment,** the documentation per Appendix 4, No. 3.4, Lit. a			
10	**For clinical trials involving category C medical devices with conformity labelling** which are being used outside their intended use/not according to the user guide, the documentation according to Appendix 4, No. 3.5, Lit. a-d			
11a	**Investigator's CV and proof of GCP training (according to KlinV, Art. 6)** – signed and dated			
11b	**List of other persons involved in the clinical trial** – including their position and corresponding technical skills			
12	**Details on infrastructure suitability and availability at the location where the trial is executed** – e.g. number of simultaneously conducted studies, number of competing studies, reasonable utilisation of machinery used for the trial, etc.			
13	**Details on the safe handling of personal data**			

No.	Document	Date/ version number	Reference to other documents, if applicable	Cantonal ethics committee (KEK): Comments (leave blank)
14	**Agreement between sponsor/commissioned institution and investigator** – regarding clinical trial financing, the allocation of tasks, the investigator's compensation and the publication – to be signed by all parties			
15	**Proof of insurance** – or other proof of guarantee for any damage or injury, including the relevant agreements between the sponsor or the institutions/person in Switzerland commissioned by the sponsor, and the investigator			
16	**For clinical trials involving gene therapy, details per Appendix 4, No. 4**			
17	**Foreign ethics committees' decisions or opinions on the clinical trial** – including possible restrictions and their justification			

Application documentation for the FOPH

Additional application documentation for clinical trials involving examinations with sources of radiation which require an FOPH opinion according to Article 29, Paragraph 2

Document templates are available at www.swissethics.ch.

No.	Document	Date/ version number	Reference to other documents, if applicable	Cantonal ethics committee (KEK): Comments (leave blank)
1	**Details on the radiopharmaceutical's properties, namely with regard to pharmacokinetics, quality, stability, radiochemical purity and radionuclide purity** http://www.bag.admin.ch/themen/strahlung/10463/10927/index.html?lang=en			
2	**In the case of approved radiopharmaceuticals, the technical information**			
3	**In the case of non-approved radiopharmaceuticals, details regarding the radiopharmaceutical's production methods and quality control, the names of the persons in charge as well as details regarding their technical qualifications**			
4	**The names of the persons in charge of administering the radiopharmaceutical to humans as well as details on their technical qualifications**			
5	**Details according to the FOPH form for clinical trials involving radiopharmaceuticals or radioactively marked substances**[1] http://form.stronline.ch/index.php?lang=de#			

The ethics committee must be notified in writing that the documentation has been sent to the FOPH.

Ethics committee

Place/date:

Scientific secretariat

[1] The form can be obtained from the Federal Office of Public Health, Radiological Protection Division, 3003 Bern, or downloaded from www.bag.admin.ch.