Checklist as of January 2014 HRO Appendix 2 Items 1 to 3

Application documentation for human research projects involving the sampling of biological material or the collection of health-related personal data

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 (project manager or sponsor)			
1a	**Base form** – to be signed by the project manager and, if applicable, by the sponsor			
1b	**Synopsis of the research plan for KEK members** – in the national language of the KEK in charge			
2	**Research plan** – to be signed by the project manager and, if applicable, by the sponsor			
3a	**Information sheet and declaration of consent** – in the national language(s) spoken at the location(s) where the project 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 study – separate information on sub-studies (e.g. additional MRI, pharmacokinetic examination) – information for the further use of data and samples for future research purposes)			
3b	**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)
4	**Additional documentation to be handed to the participant** – patient ID, journals, questionnaires in the appropriate national language, **or other documentation to be used in the course of the study** – e.g. interview guide, scores, questionnaire			
5	**Details on nature and scope/value of compensation for participants**			
6	**For category B research projects:** – proof of insurance; or – other proof of guarantee for any damage or injury			
7	**Proof of safe handling of biological material and personal data** – namely its/their safekeeping			
8a	**Project manager's CV and proof of technical qualification (according to Art. 4 HFV)** – signed and dated			
8b	**List of persons involved in the research project** – including their position and corresponding technical skills			
9	**Proof of infrastructure suitability and availability at the location where the project is executed** – e.g. number of simultaneously conducted studies, number of competing studies, reasonable utilisation of machinery used for the research project, etc.			
10	**Agreement between project manager and sponsor or other third parties** – namely regarding project financing, the allocation of tasks, the project manager's compensation and the publication – to be signed by all parties			

Additional application documentation for research projects involving examinations with sources of radiation (e.g. X-ray examinations parallel to a study, CT, radiopharmaceuticals for PET exams)

The following must be submitted to the ethics committee:

No.	Document	Date/ version number	Reference to other documents, if applicable	Cantonal ethics committee (KEK): Comments (leave blank)
1	**Details on essential aspects of radiological protection, in particular calculations/estimations on the effective radiation dose, organ dose and possible tumour dose**			
2	**Required authorisation for the handling of sources of radiation or radioactive substances according to Article 28 of the Radiological Protection Act of 22 March 1991**[1] The radiation thresholds to be observed follow Art. 28, Par. 3–5 of the Radiological Protection Ordinance of 22 June 1994[2]			

Additional application documentation for research projects involving examinations with open or sealed sources of radiation which require an FOPH opinion according to Article 19, Paragraph 2

Applicable for doses of 5 mSV or higher per person per year for the application of i) radiopharmaceuticals not approved in Switzerland, ii) radiopharmaceuticals which are approved but are being used outside a nuclear-medical routine examination, or iii) other open or sealed sources of radiation. In all other cases, in particular cases of X-ray examinations or CT, an FOPH opinion is not required.)

Subject to the conditions set out above, the following must also be submitted to the FOPH:
(The responsible ethics committee must be notified about this submission)

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**			
2	**In the case of approved radiopharmaceuticals, the technical information**			
3	**In the case of non-approved radiopharmaceuticals, details on the radiopharmaceutical's production methods and quality control, the names of the persons in charge as well as details on their technical qualifications**			

[1] SR **814.50**
[2] SR **814.501**

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 research projects involving radiopharmaceuticals or radioactively marked substances**[3]			

Ethics committee

Place/date:

Scientific secretariat

[3] The form can be obtained from the Federal Office of Public Health, Radiological Protection Division, 3003 Bern, or downloaded from www.bag.admin.ch > Themen > Strahlung, Radioaktivität und Schall > Nuklearmedizin und Forschung > Radiopharmazeutika > Gesuchsformular.