

Checklist as of January 2014 HRO Appendix 2 Item 5

**Application documentation for the further use of biological material or health-related personal data in case of lack of consent and information according to Article 34 HRA**

Document templates are available at [www.swissethics.ch](http://www.swissethics.ch).

No.	Document	Date/ version number	Reference to other documents, if ap- plicable	Cantonal ethics commit- tee (KEK): Comments (leave blank)
0	<b>Covering letter</b> <ul style="list-style-type: none"> <li>- billing address must be included</li> <li>- to be signed by the applicant (project manager or sponsor)</li> </ul>			
1a	<b>Base form</b> <ul style="list-style-type: none"> <li>- to be signed by the project manager and, if applicable, by the sponsor</li> </ul>			
1b	<b>Synopsis of the research plan for KEK members</b> <ul style="list-style-type: none"> <li>- in the national language of the KEK in charge</li> </ul>			
2	<b>Project plan</b> <ul style="list-style-type: none"> <li>- including reasons according to Art. 34, Lit. A and b HRA</li> <li>- to be signed by the project manager and, if applicable, by the sponsor</li> </ul>			
3	<b>Description of intended research purposes for which the biological material or health-related personal data are to be used</b> <ul style="list-style-type: none"> <li>- including a declaration stating in which way scientific interests outweigh the concerned individual's interests</li> </ul>			
4	<b>Description of the biological material and/or the health-related personal data that are to be used</b>			
5	<b>Description of the group of persons who are to be authorised to pass on the biological material and/or health-related data</b>			
6	<b>Description of the persons who are to be authorised to receive the biological material and/or health-related data</b>			
7	<b>Description of the persons responsible for the safe-keeping of the released data</b>			
8	<b>Description of the group of persons who are to be authorised to access the biological material and/or health-related data</b>			

9	<b>Proof of safe handling of biological material and personal data</b> <ul style="list-style-type: none"><li>– namely its/their safekeeping</li></ul>			
10	<b>Details regarding the duration of safekeeping</b>			
11a	<b>Project manager's CV and proof of technical qualification (according to Art. 4 HFV)</b> <ul style="list-style-type: none"><li>– signed and dated</li></ul>			
11b	<b>List of persons involved in the research project</b> <ul style="list-style-type: none"><li>– including their position and corresponding technical skills</li></ul>			
12	<b>Details on available infrastructure at the location where the project is executed</b>			

**Ethics committee**

Place/date:

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Scientific secretariat