

Required documents/information for research projects with the exception of clinical trials, according to the Human Research Ordinance, HRO

Remarks:

The document list on the upload screen/s in BASEC will be generated automatically depending on your entries on screens 1-3.

In BASEC you will find links to templates and further information under each document category on the upload-screens. (All templates are also available on www.swissethics.ch/en/templates)

Some information necessary for **further use studies** is already asked in the application form.

Contracts with sponsors or grand providers for **further use studies** are required if existing although the item was forgotten in the appendix of the ordinance.

Documents that have to be signed are the following: protocol (item 4), contract(s)/letter of delegation (item 9, 38), insurance (item 10), and staff list (item 13).

Combined trials with medicinal products and medical devices need all the required documents from both types.

Other important documents not falling within these categories can be uploaded in the miscellaneous category "Varia".

If you have questions that are not answered in the document or in the FAQ section in BASEC, please contact the competent ethics committee or swissethics.

R = This document/information is required. In BASEC this is labelled with an asterisk < * >

A = Mandatory if applicable (for example a contract between an investigational site and the sponsor is mandatory while the document is not requested in an investigator-initiated trial with no external sponsor or any other external collaborator). In BASEC this is labelled with an asterisk in parentheses < (*) >.

Document number in BASEC	Study type	Research projects with the exception of clinical trials					
		including persons (Sampling / Collection)		including deceased	including embryos & fetuses	further use of health related data and/or biological material	
		Risk A	Risk B			with consent, with consent to be sought	without consent
1	Covering letter	R	R	R	R	R	R
2	Synopsis of the study plan <i>A separate synopsis is not required for research projects (HFV, ORH, ORUm) if the protocol is shorter than 20 pages. (Multicentre clinical trials in the language of the Lead EC or in English. Monocentric trials in the language of the EC.)</i> <i>Template (.docx) in DE, FR, IT, EN available at swissethics.ch</i>	R	R	R	R	R	R
3	Participant information sheet and informed consent (ICF) <i>Template for drafting information for participants (.docx) in DE, FR, IT available at swissethics.ch</i>	R	R			R	
4	Study plan (protocol) (signed and dated)¹ <i>Project Plan Template (HRO Art. 6) for Human research other than clinical trials, (.docx) in EN available at swissethics.ch</i>	R	R	R	R	R	R
5	CRF (Case Report Form) <i>Draft acceptable provided the final document is available within the next 30 days (monocentric) or 45 days (multicentric).</i>	A	A				
6	Investigator's / Project Leader's CV, dated	R	R	R	R	R	R
8	Details on infrastructure suitability and availability at the location where the trial is executed	A	A				
9	Agreement between sponsor/commissioned institution / grant provider or other third parties and the investigator <i>Regarding trial financing, the allocation of tasks, the investigator's compensation and the publication.</i> <i>Template (.docx) in EN available at swissethics.ch</i> <i>Draft acceptable provided the final document is available before the inclusion of the first patient / participant, resp. before the health related data and/or biological material is used.</i>	A	A	A	A	A	A

¹ For further use studies involving health-related personal data and/or biological material with consent, a description of the scientific question is sufficient.

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		Risk A	Risk B			with consent, with consent to be sought	without consent
10	Insurance <i>General Insurance Conditions (GIC) for clinical trials in Human Research (.pdf) in DE, FR, EN and Insurance (template) for clinical trials (.docx) in DE, FR, IT, EN available at swissethics.ch</i>	A	R				
11	Other documents handed over to study participants <i>Such as advertisements used in recruitment, patient journals, questionnaires, scores, translations of study documents, recruitment letters etc.</i>	A	A				
12	Details on nature and scope/value of compensation for participants	R	R	A	A		
13	Other personnel <i>Template (.docx) in EN available at swissethics.ch</i>	A	A				
14	Information on secure handling of biological material and personal data, and in particular on the storage thereof <i>According to art. 18 ClinO (in DE, FR, IT) and art. 5 ORH (in DE, FR, IT).</i>	R	R	R	R	R	R
15	Information on reviews of this proposal by other Ethics Committees, or Regulatory Authorities (Foreign or Swiss)	A	A	A	A	A	A
30	Proof of secure and correct coding <i>Please consult Art. 26 (DE, FR, IT) of the Human research Ordinance HRO.</i>					R	
31	Authorizations granted by ethics committees in Switzerland <i>Any authorizations granted by ethics committees in Switzerland for the sampling of biological material or the collection of health-related personal data.</i>					A	
32	Application documents for research projects involving deceased persons <i>Please provide all further documents as listed in Annex 2, chapter 6 of the Human Research Ordinance HRO. (DE, FR, IT).</i>			R			
33	Application documents for research projects involving embryos and fetuses from induced abortions/spontaneous abortions including stillbirths <i>Please provide all further documents as listed in Annexe 2, chapter 7 of the Human Research Ordinance HRO (link in DE, FR, IT).</i>				R		

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Document number in BASEC	Study type	including persons (Sampling / Collection)		including deceased	including embryos & fetuses	further use of health related data and/or biological material	
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34	Table with values of estimated effective radiation dose <i>The calculation of the effective dose must take into account all radiation sources used in the study and must include the uncertainty according to Art. 28 (DE, FR, IT) Radiological Protection Ordinance from 1994</i> <i>If you do not already have tables with values of the estimated effective radiation dose you can download the template of the table from screen 6, point 34 in BASEC.</i>	A	A				
35	Required authorisation for the use of ionising radiation according to article 28 of the radiological protection act <i>See: Article 28 of the Radiological Protection Act of 22 March 1991 (link in DE, FR, IT).</i>	A	A				
36	Further documents as listed in Annex 2, chapter 3 of the HRO <i>Provide all further documents as listed in Annex 2, chapter 3 of the Human Research Ordinance HRO (DE, FR, IT).</i>	A	A				
37	Further documents as listed in Annexe 3, chapter 5 of the ClinO <i>Please provide all further documents as listed in Annexe 3, chapter 5 of the Ordinance on Clinical Trials ClinO (link in DE, FR, IT).</i>	A	A				
38	Sponsor's delegation letter, signed <i>If the sponsor's representative or the CRO acts as applicant, a delegation letter of the sponsor is required. If this information is contained in a contract, please upload this document.</i>	A	A	A	A	A	A
39	Miscellaneous / Varia <i>Please only add documents that don't fall in one of the above categories.</i>	A	A	A	A	A	A
40	Pharmaceutical Quality Dossier for non-IMP (Investigational Medicinal Product) <i>A template for the Pharmaceutical Quality Dossier is available on the swissmedic Webpage (licensing / clinical trial application) or you can download the template here.</i>	A	A				

Required documents/information for local sites in multicentric studies.

Document number in BASEC		Research projects with the exception of clinical trials
1	Covering letter	optional
2	Synopsis of the study plan in English or local language <i>If the synopsis/information about the synopsis provided on the main upload screen (screen 6) is neither in English nor in the language of the EC responsible for this additional site, please upload a separate version. Template (.docx) in DE, FR, IT, EN available at swissethics.ch.</i>	A separate synopsis is not required for research projects (HFV, ORH, ORUm) if the protocol is shorter than 20 pages. In English or in the local language
3	Participant information sheet and informed consent (ICF) <i>Template for drafting information for participants (.docx) in DE, FR, IT available at swissethics.ch</i>	adapted to the local site(s)
4	Signed study plan or signature page of the study plan <i>Signed study plan or signature page of the study plan or protocol, signed and dated by the local investigator. The signature page has to include the <u>title</u>, <u>version</u> and <u>date</u> of the study plan/protocol. Clinical Protocol Template for (.docx) in EN available at swissethics.ch</i>	signature page signed by local investigator
6	Investigator's / Project Leader's CV , dated	CV of the local project leader
7	Local investigator's proof of GCP training	-
8	Details on infrastructure suitability and availability at the location where the trial is executed	optional
9	Agreement between sponsor/commissioned institution and local investigator <i>Draft acceptable provided the final document is available within the next 30 days (monocentric) or 45 days (multicentric). Document about trial financing, the allocation of tasks, the investigator's compensation and publication. Template (.docx) in EN available at swissethics.ch</i>	local document/s (upload of drafts is acceptable for the first submission)
10	Insurance <i>General Insurance Conditions (GIC) for clinical trials in Human Research (.pdf) in DE, FR, EN and Insurance (template) for clinical trials (.docx) in DE, FR, IT, EN available at swissethics.ch</i>	[required only for risk category B]
11	Other documents handed over to study participants <i>Such as advertisements used in recruitment, patient journals, questionnaires, scores, translations of study documents, recruitment letters etc.</i>	local document/s (optional)
13	Other Personnel <i>Template (.docx) in EN available at swissethics.ch</i>	Staff list/s when other persons are involved
39	Miscellaneous / Varia <i>Please only add documents that don't fall in one of the above categories.</i>	other important documents [local details on further use studies (description of data/material) can be uploaded here]

Document number in BASEC		Research projects with the exception of clinical trials
32	<p>Application documents for research projects involving deceased persons</p> <p>Please provide all further documents as listed in Annex 2, chapter 6, of the Human Research Ordinance HRO. (Link in DE, FR, IT).</p>	local document/s (only for projects involving deceased)
33	<p>Application documents for research projects involving embryos and fetuses from induced abortions/spontaneous abortions including stillbirths</p> <p>Please provide all further documents as listed in Annex 2, chapter 7, of the Human Research Ordinance HRO (link in DE, FR, IT).</p>	local document/s (only for projects involving embryos and fetuses)
34	<p>Table with values of estimated effective radiation dose</p> <p>The calculation of the effective dose must take into account all radiation sources used in the study and must include the uncertainty according to Art. 28 (DE, FR, IT) Radiological Protection Ordinance from 1994</p> <p>If you do not already have tables with values of the estimated effective radiation dose you can download a template of the table here.</p>	local document/s (if radiation is involved)
35	<p>Required authorisation for the use of ionising radiation according to article 28 of the radiological protection act</p> <p>See: Article 28 of the Radiological Protection Act of 22 March 1991 (link in DE, FR, IT).</p>	local document/s (if radiological examinations are involved not using standard clinical equipment)

The numbers on the local screen don't necessarily correspond to the numbers in the main document screen

Further use of biological material and/or health-related personal data: please upload the consent document(s) in field no. 3. If you are unable to obtain a legal consent please upload in the field "Varia": The designation of the biological material or health-related personal data of which further use is to be made, the designation of the group of persons who are to be entitled to pass on the biological material or the health-related personal data and the designation of the person who is to be entitled to receive the biological material or the health-related personal data.

Research involving deceased: Also provide the documents in field no. 32

Research involving embryos and fetuses: Also provide the documents in field no. 33

Research involving ionising radiation in any form: Also provide the documents in field no.

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