

<ALPHA>

**INSURANCE FOR CLINICAL TRIALS (VALID FOR MEDICINAL PRODUCTS, TRANSPLANT PRODUCTS, MEDICAL DEVICES AND OTHER CLINICAL TRIALS)**

**Certificate of insurance for the attention of the Swiss Association of Ethics Committees (template)**

The \_\_\_\_\_ hereby confirms that it provides insurance coverage to the policyholder or sponsor (if different from policyholder) as indicated below in accordance with the provisions agreed upon in the policy and that this coverage satisfies the requirements which the Human Research Act (HRA) and the Ordinance on Clinical Trials in Human Research (ClinO) stipulate for insurance coverage for human clinical trials.

The indicated limits may have been reduced by previously paid claims.

Note: Insurance certificates should correspond to this template from the point of view of content; their formal layout is up to the insurers.

Note: This certificate of insurance is not valid without the insurer's signature.

<b>Insurer:</b>	
<b>Policyholder:</b>	
<b>Sponsor (if different from policyholder):</b>	

<b>Insured risk:</b>	Medicinal products/transplant products:	Category: <input type="checkbox"/> A* <input type="checkbox"/> B <input type="checkbox"/> C
	Medical devices:	Category:† <input type="checkbox"/> A2 <input type="checkbox"/> C1 <input type="checkbox"/> C2 <input type="checkbox"/> C3

\* Insurance coverage for clinical trials of category A is required only if applicable measures for collecting health-related personal data or for sampling biological material are connected with *more than merely minimal risks and stresses* (Art. 12, lit. b ClinO).

† Clinical trials of medical device of category A1 conducted under the Ordinance on Clinical Trials with Medical Devices (ClinO-MD) are exempted from liability coverage.

	Other clinical trial:	Category: <input type="checkbox"/> A* <input type="checkbox"/> B
	Clinical trial (name):	
	Number of participants:	

<b>Policy number:</b>	
<b>Study reference:</b>	
<b>Insured amount<sup>‡</sup>:</b>	CHF            for the clinical trial  of which CHF            per test subject for bodily injury CHF            per test subject for property damage

<b>Duration<sup>§</sup>:</b>	from until
------------------------------	---------------

<b>Claims handling by (insurer):</b>	
--------------------------------------	--

**Signatures and stamp:**

<sup>‡</sup> Cf. Annex 2 of ClinO (<http://www.admin.ch/opc/en/classified-compilation/20121176/index.html> ).

<sup>§</sup> The extended coverage period is 10 years after completion of the clinical trial (Art. 13, para. 3 ClinO).