

CERTIFICATE OF SECURITY IN LIEU OF AND EQUIVALENT TO LIABILITY INSURANCE

For the attention of the Swiss Association of Ethics Committees (template)

The _____ hereby confirms that it provides security in lieu of and equivalent to liability insurance to the beneficiary person or enterprise indicated below and that such security satisfies the requirements of the Human Research Act (HRA) and corresponding ordinances (ClinO, ClinO-MD, HRO). In particular, it is confirmed that

- the injured party will be able to assert its claims in Switzerland (in the event of a dispute, file a claim with a Swiss court of law);
- in the event of a legal succession, the security shall remain binding on the guarantor's successors; and
- the availability of the secured sum is guaranteed even in the event of financial difficulties on the part of the guarantor.

Note: This certificate is not valid unless signed by the guarantor.

| | |
|---------------------------------|--|
| Guarantor: | |
| Beneficiary¹: | |

| | | |
|----------------------|--|--|
| Insured risk: | <input type="checkbox"/> Medicinal products/ transplant products: <input type="checkbox"/> Other clinical trials | Category: <input type="checkbox"/> A ² <input type="checkbox"/> B <input type="checkbox"/> C |
| | <input type="checkbox"/> Medical devices | Category: <input type="checkbox"/> A ¹² <input type="checkbox"/> A ²² <input type="checkbox"/> C1 <input type="checkbox"/> C2 <input type="checkbox"/> C2 |
| | <input type="checkbox"/> Research projects | Category: ³ <input type="checkbox"/> B |

¹ Sponsor or (in case of Art. 3, para. 2 HRO) investigator.

² Note: Coverage for clinical trials of category A (for medicinal products, transplant products, medical devices, as well as for other clinical trials) 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 ClinO, Art. 3 Abs. 1 ClinO-MD).

³ For "non-clinical" trials, i.e. research projects according to Art. 6f. HRO, trials of category A are always exempt from the liability guarantee (Art. 13 HRO).

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| | | |
|-------------------------|--|--|
| Type of security | <input type="checkbox"/> Bank guarantee ⁴ <input type="checkbox"/> Fund ⁵ <input type="checkbox"/> Portfolio ⁶ <input type="checkbox"/> State liability pursuant to cantonal law ⁷ <input type="checkbox"/> Third-party guarantee ⁸ <input type="checkbox"/> Other security ⁹ | |
| | Clinical trial or research project (name): | |
| | Number of participants: | |

| | |
|--------------------------|--|
| Reference number: | |
| Study reference: | |

| | |
|------------------------------------|--|
| Secured amount¹: | CHF for the clinical trial, for the research project of which CHF per test subject for bodily injury CHF per test subject for property damage |
|------------------------------------|--|

| | |
|-------------------------------|---------------|
| Duration¹⁰: | from until |
|-------------------------------|---------------|

| | |
|----------------------------|--|
| Claims handling by: | |
|----------------------------|--|

Signatures and stamp:

⁴ Please attach.

⁵ Please attach fund bylaws.

⁶ Please attach schedule .

⁷ Please specify and confirm applicability as well as the fact that research projects pursuant to HRA are covered.

⁸ Please attach.

⁹ Please attach.

¹⁰ Note: The extended coverage period is 10 years after completion of the clinical trial (Art. 13, para. 3 ClinO) or research project (Art. 13, para. 3 HRO).