GENERAL INSURANCE CONDITIONS (GIC) RESEARCH PROJECTS ACCORDING TO THE HUMAN RESEARCH ORDINANCE HRO

Edition 2022

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1. Contract data

Insurance of clinical trials in the context of human research

1.1 Policy number

1.2 Policyholder

1.3 Sponsor

1.4 Project leader

1.5 Insured research project

- Title of duty
- Trial centres
- Reference number
- Category of research project

1.6 Number of participants

Projected number of participants in the research project:

1.7 Insured amounts

The insured amounts for the entire policy period (incl. extended reporting period) are:

- for the total indemnification of all claims in connection with the research project a maximum of CHF XXX
- of which a maximum per participant for bodily injury of CHF XXX
- of which a maximum per participant for property damage of CHF XXX

1.8 Deductible

In the event of loss, the policyholder shall bear a deductible of CHF XXX per event.

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1.9 Policy period

Begin:	Date
End:	Date
Premium due:	Premium payable in advance upon begin of policy period
Method of payment:	Single premium

1.10 Premiums

Premium per participant	CHF XXX
Minimal premium	CHF XXX
Advance premium	CHF XXX
Tax	5%

2. Definitions

In this contract the following terms shall be understood as defined below:

2.1 Bodily injury

Bodily injury is deemed to be any loss arising from the death, physical injury or other health impairment of participants.

Such losses shall include the economic consequences of insured bodily injuries, namely expenses, loss of earnings including consideration of future development, loss of ability to carry out household services, loss of ability to support dependents, as well as immaterial damages (pain and suffering).

2.2 Property damage

Property damage is deemed to be any loss arising from the destruction of, damage to or loss of property, including any resulting financial loss or loss of revenues of the injured party.

2.3 Losses resulting from violations of data privacy

Violations of data privacy are deemed to be material and immaterial losses resulting from violations of personal integrity.

2.4 Research project

Any project in which biological material is sampled or health-related personal data is collected from a person

- in order to resolve a scientific issue; or
- to further use the biological material or the health-related personal data for research purposes (Art. 6 HRO).

2.5 Participants

All patients and test persons taking part in the insured research project.

2.6 Project leader

Person or institution responsible for the conduct of the research project in Switzerland and for protection of the participants at the research site (Art. 3 para. 1 HRO).

Usually, the project leader is also responsible for initiating the research project, namely for its initiation, management and financing (Art. 3 para. 2, 1st half-sentence HRO).

2.7 Sponsor

Person or institution domiciled or represented in Switzerland that takes responsibility for initiating the research project in Switzerland, unless the project leader does so (Art. 3 para. 2, 2nd half-sentence HRO).

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3. Insured interest

The insurance covers the liability of the person or institution pursuant to Art. 2.6 (project leader) or Art. 2.7 (Sponsor) above for bodily injury and property damage pursuant to the human research legislation suffered by a participant in the research project pursuant to Art. 1.5 above, for whose initiation such person or institution is responsible.

Also insured are claims for losses arising from violations of data privacy in connection with the insured research project. Such losses shall be deemed to be bodily injury.

4. Insurer's indemnification

In the context of an insured event, the insurer's duty to indemnify shall consist of compensating founded claims and defending against unfounded claims. Indemnification, inclusive of all interest on damages, loss reduction costs, costs of expert opinions, attorney fees, court costs, arbitration costs, mediation costs and other costs (such as indemnification of the opposing party's legal costs) shall be limited by the amounts insured and/or sublimits stipulated in the policy and/or contract conditions, less the agreed deductible.

All claims with the same cause shall be deemed to be a single event (serial loss). The number of injured parties, claimants or parties entitled to compensation is irrelevant

The compensation for participants shall be reduced proportionally if the sum of all indemnifications exceeds the above-referenced maximum amount per policy period.

The indemnification and its limits shall be governed by the terms of the insurance contract (including those governing the insured amounts and deductibles) that were in effect pursuant to Art. 6 below at the time the loss occurs.

5. Insureds

The liability of the sponsor who initiates the clinical trial pursuant to Art. 1.5 above is insured.

6. Territorial limits and trigger

The insurance covers losses caused in the context of a clinical trial carried out in Switzerland and which occur anywhere in the world.

Losses occurring during the policy period are insured.

In the event of uncertainty, bodily injury shall be deemed to have occurred at such time as a participant consults a physician for the first time for symptoms of the relevant health impairment, even if causation is only established at a later date.

Notwithstanding the expiry of the policy period, losses occurring within 120 months of the termination of the clinical trial shall also be insured (extended coverage period).

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7. Limitations of cover

7.1 Other legal claims

The insurance does not cover claims based on a legal basis other than the Human Research Act.

7.2 Felonies and major criminal offences

The perpetrator's liability for losses caused in connection with an intentional perpetration of a felony or major criminal offence is not insured.

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8. Premium

8.1 Premium calculation

The premium shall be calculated based on the number of participants taking part in the research project during the policy period.

In the event of a change in the number of participants, the premium shall be increased or reduced, as the case may be, in accordance with the change in the number of participants and premium per participant. The minimum premium remains reserved.

8.2 Payment of premium

The advance premium pursuant to Art. 1.10 above shall become due on the date stated in the invoice.

9. Claims

9.1 Duty to notify

Should an event occur whose foreseeable consequences could be relevant for the present insurance, or if a liability claim is made against an insured, the policyholder shall immediately notify the insurer of such circumstance.

If police investigations or criminal proceedings are instituted against an insured, or if the injured party files a suit, the policyholder shall also immediately notify the insurer of such circumstance.

9.2 Claims handling and litigation

The insurer shall conduct negotiations with the injured party in its own name or shall act as the insured's representative, and any settlement that it reaches with the injured party shall be binding on the insured. The insurer is entitled to pay damages directly to the injured party, without having to deduct any deductible that may apply. In the event of such payment, the policyholder shall reimburse the deductible, waiving any and all objections.

The insureds shall refrain from negotiating directly with the injured party or its representatives in respect of claims for damages, from acknowledging any liability or claim or from concluding any settlement or paying any compensation, unless the insurer gives its approval. Moreover, the insureds shall of their own accord provide the insurer with all relevant information on the case, immediately inform the insurer of all steps taken by the injured party, provide the insurer with all evidence and documents (particularly including all summonses, writs, judgments, etc.) and otherwise support the insurer to the best of their ability in the handling of the claim (contractual fidelity).

If no agreement can be reached with the injured party, and legal proceedings are commenced, the insureds shall leave the management of the civil proceedings to the insurer. The latter shall bear the legal costs pursuant to Art. 4 above. If legal costs are awarded to an insured, such award shall revert to the insurer, to the extent that such coasts are not awarded for the insured's personal outlays.

9.3 Assignment of rights

The insured may not assign rights under this insurance contract to injured or third parties without the insurer's consent.

9.4 Remedies for breach

In the event of the insureds violating their duty of notification through fault, they shall bear the consequences of such failure themselves.

Moreover, in the event of a breach of the duty of contractual fidelity through fault, the insurer's duty to indemnify shall be nullified to the extent that it would be otherwise increased by such breach

9.5 Recourse

If provisions of the insurance contract or the Swiss Insurance Contract Act limit or cancel coverage, but such circumstance cannot be invoked against the insured by law, the insurer shall have a right of recourse against the project leader or the sponsor to the extent that it could otherwise reduce or refuse indemnification.

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10. Duties

10.1 Duties of policyholder, project leader and sponsor

The policyholder, project leader or sponsor is obligated to obtain confirmation from the participant to the effect that he or she

a. will immediately inform the investigator of other illnesses or symptoms, as well any treatment with medication.
b. will immediately notify the investigator of any bodily injury that might be the result of the research project.
c. will undertake or undergo all purposeful measures that may serve the determination of the cause or extent of, or the alleviation of such incurred bodily injury.

10.2 Breach of duties

In the event of the policyholder, project leader or sponsor culpably breaching the duties imposed by this contract or by law, the compensation may be reduced by the extent to which the occurrence or scope of the loss was influenced by this.

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11.1 Policy period

The present contract is concluded for the duration stated in the contract data.

If the clinical trial is not concluded by the stated end of the contract, the policyholder shall immediately inform the insurer in order to allow a prolongation of the contract.

11.2 No termination in the event of claim

The insurer waives its right to terminate the contract in the event of claim.

11.3 Notifications to the insurer

The insureds shall only be deemed to have legally complied with their duties of notification if the required notices are addressed to the insurer's head office or to such office as may be stated in the policy.

11.4 Provision of information to third parties

The insurer is entitled to inform third parties (e.g. the competent authorities) to whom the insurance coverage is confirmed of the suspension, amendment or cessation of the policy.

11.5 Place of jurisdiction and applicable law

The policyholder or claimant may choose one of the following jurisdictions:

a. The seat of the insurer's head office.
b. The domicile or seat of the policyholder or claimant.

This insurance contract shall exclusively be governed by and construed in accordance with the laws of Switzerland and the precedents of its courts.

12. Signing of the contract