**Application form for recognition of GCP Refresher Courses**

**Course provider details:**

Company / Institution: Insert name of company or institution

Address: Insert address of company or institution

**Applicant:**

Name: Insert name of applicant

Address: Insert address of applicant (must be in Switzerland)

Telephone: Insert telephone number of applicant

Email: Insert email address of applicant

**Course title:** Insert the title of your course(s)

**Self-declaration of the course provider on the Course Learning Objectives:**

The applicant acknowledges that the following learning objectives are covered in the above mentioned GCP Refresher Course.

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| --- | --- |
| **Learning contents**  **Part 1: Basic principles** | Treated in agenda item no |
| Name and explain the different types of research, i.e. Clinical Trials, Human Research Projects, research involving the further use of biological material or health-related personal data | Insert item no |
| Name and describe the applicable laws, regulations and standards in Switzerland | Insert item no |
| **Part 2: Planning and preparation** |  |
| Identify and describe the roles, responsibilities and working relations of all those involved in the clinical trial, e.g. Investigator(s), Sponsor(s), CRO, Monitor, Ethics Committee, competent authorities | Insert item no |
| Assess the feasibility of the clinical trial in terms of patient recruitment, logistics and resources | Insert item no |
| Assess the costs of the clinical trial, define funding and budgeting for the clinical trial | Insert item no |
| Ensure coherence and traceability of study procedures and documentation (e.g. Quality management system and SOPs) | Insert item no |
| Ensure tasks assignments in study team | Insert item no |
| Identify and describe the key study documents (e.g. Protocol, patient information, data source, contracts, …) | Insert item no |
| **Part 3: Execution** |  |
| Describe submission and reporting requirements towards competent authorities | Insert item no |
| Explain the informed consent process (e.g. with reference to vulnerable groups but not only) | Insert item no |
| Ensure protocol adherence throughout the study (from screening to patient randomization and treatment, implementation of significant protocol amendments, …) | Insert item no |
| Correctly handle and store the study medication or medical devices | Insert item no |
| Name the implemented measures to prevent or minimise risks and to ensure the safety of the participants | Insert item no |
| Identify, document and report safety events and safety documents | Insert item no |
| Implement proper measures for surveillance (e.g. monitoring, audits). Inspections | Insert item no |
| Handle study end procedures and reporting obligations | Insert item no |

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| **Additional Learning Contents**  **Part 4: Update on legal and ethical norms, advanced topics** Note: The content of Part 4 may be subjected to changes, at discretion of the course provider | Treated in agenda item no |
| E.g. Name relevant changes to current laws, regulations and processes, including new and updates to ethical guidelines. identify and describe current pressing issues | Insert item no |
| E.g. Identify and describe cutting edge topics: e.g. Dynamic consent, vulnerable populations, adaptive study designs, data protection laws. BASEC, … | Insert item no |

Please attach the following documents to your application:

* Course program with a brief description of the agenda items
* Access to online course (if applicable)
* Access to online tools (if applicable)
* Materials provided for self-study (if applicable)
* Evaluation form

By signing this form the applicant confirms that:

* swissethics will have access to the course slides and other course material.
* swissethics will charge a fee of 500 CHF to process the application and possibly audit the course in the future.
* Any substantial changes in the course program and content will proactively be forwarded to swissethics.
* swissethics is allowed to audit the course at any time and has the right to withdraw the recognition if the course doesn’t fulfill the learning objectives.

Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please send the completed and signed application and the documents to [info@swissethics.ch](mailto:info@swissethics.ch).

*N.B. To be completed by swissethics:*

*Date Application received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Application formally complete: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Place and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*