

Guidance for providers of courses on Research Ethics and GCP

Requirements for courses on Research Ethics and GCP

Preface

swissethics recognises GCP courses and GCP Refresher courses based on the requirements given here below and based on the published learning objectives.

It is mandatory for an Investigator of a clinical trial to have attended a recognised GCP course Investigator level, and for a Sponsor-Investigator to have attended a recognised GCP course Sponsor-Investigator level.

It is not required for an Investigator or for a Sponsor-Investigator to attend a GCP Refresher course, and it is voluntary for the course providers to obtain or not swissethics recognition of their GCP Refresher courses. Nonetheless, the Ethics Committees can request the researchers to re-take a GCP course or to take a GCP Refresher course, if the Ethics Committees consider the knowledge had not been maintained.

a) Learning objectives

The course requirements published by swissethics have been revised following the introduction of the new Human Research Act and the accompanying ordinances. Courses recognition is based on the learning objectives. The learning objectives for courses on Research Ethics and GCP (Investigator level, Sponsor-Investigator level and GCP Refresher) can be found on www.swissethics.ch.

b) Other requirements (length of course, assessment of the course success)

The requirements for the duration of the courses is as follows:

- GCP course Investigator level: 2 days / minimum 12 hours.
- GCP course Sponsor-Investigator level: Investigator level plus 1 day / minimum 6 hours (minimum 18 hours total).
Note: An Investigator can assume the role and responsibilities of the Sponsor in a sponsor-investigator clinical trial if he/she has taken both the Investigator and the Sponsor-Investigator course.
- GCP Refresher course: recommended minimum 3 hours.

The training may combine face-to-face-, online training and self-study or homework assignments. Even if online training is recognized, swissethics strongly recommends completing (part of the) course by face-to-face training. swissethics recommends knowledge assessments to be implemented at the end of the courses.

c) Recognition process

Course providers can apply for recognition of their courses according to the learning objectives (application form for the recognition of GCP courses and of GCP Refresher course can be downloaded from www.swissethics.ch). The completed form(s) is(are) sent to swissethics by email. The course provider will receive a letter confirming recognition by swissethics. The course provider may be audited by swissethics at any time to confirm adherence to the learning objectives.

d) Validity of course providers' recognition

The validity of this recognition has no limitation, however may expire if swissethics revises the learning objectives due to updates in GCP or the national regulations.