

Guidance for providers of courses on Research Ethics and GCP

Requirements for courses on Research Ethics and GCP

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. Course recognition is based on the learning objectives. The learning objectives for courses on Research Ethics and GCP (Investigator level and Sponsor-Investigator level) can be found on www.swissethics.ch.

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

Duration of Investigator level: 2 days / minimum 12 hours. Duration of Sponsor-Investigator level: Investigator level plus 1 day / minimum 6 hours (minimum 18 hours total).

The training may combine face-to-face-, online training and self-study or homework assignments.

Swissethics recommends knowledge assessments to be implemented at the end of the courses.

c) Recognition process

As of now, course providers can apply for recognition of their courses according to the new learning objectives (application form on www.swissethics.ch). The completed form is sent to swissethics by email. The course provider will receive a letter confirming recognition by swissethics. 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. The course provider may be audited by swissethics at any time to confirm adherence to the learning objectives.

d) Validity of course providers' recognition

Expiry of current recognitions: the courses for Sub-Investigators, Investigators and Sponsor-Investigators currently recognized by swissethics (previously Swissmedic) between 2009 and 2014 keep their recognition until December 2015.

The new recognitions are issued for an indefinite time.