

## Guidance for researchers regarding Research Ethics and GCP Training

### a) Requirements for training for investigators in clinical research

Based on legal requirements<sup>i</sup>, swissethics defines the following levels of training in Research Ethics and GCP are mandatory for researchers in clinical studies.

<b>Clinical research</b>	
• Investigator <sup>ii</sup> in clinical research <sup>iii</sup>	Course Investigator level
• Sponsor-Investigator <sup>iv</sup> in clinical research	Courses Investigator level + Sponsor-Investigator level

### b) Recommendations for training in non-clinical research and training for other study team members in clinical research

The Ordinances don't specify which type of training is needed for study team members or for non-clinical researchers<sup>v</sup>. Swissethics strongly recommends that researchers involved in non-clinical research projects as well as study team members of both clinical and non-clinical research have basic knowledge of Research Ethics. This can be achieved by the following training:

<b>Clinical research</b>	
• Study team members in clinical research (esp. those involved in study procedures associated with risks for the safety of participants and/or scientific integrity of data)	Course Investigator level

<b>Non-clinical research<sup>vi</sup></b>	
• Investigator in non-clinical research	For all 3 groups: Course Investigator level (especially the part "Introduction to Research Ethics")
• Sponsor-Investigator in non-clinical research	
• Study team members in non-clinical research (especially those involved in study procedures associated with risks for the safety of participants and/or integrity of data)	

### **c) Maintaining knowledge in research ethics and GCP**

Swissethics recommends that after the initial Training in Research Ethics and GCP has taken place, that the knowledge is maintained by regular research activity, e.g. conducting clinical trials, attending continuing education related to research or GCP refresher courses, being exposed to GCP inspections etc.

The Ethics Committees can request the researchers to re-take a GCP course, if the Ethics Committees consider the knowledge has not been maintained.

Note: As of 1 May 2017, the integrated addendum to the GCP guidelines E6(R2) is applicable in Switzerland. The researchers in possess of a GCP certificate recognized by swissethics, but who have not taken a GCP course with the integrated addendum E6(R2), are requested to study the new guidelines in addition. A version of the integrated addendum E6(R2) – with the changes highlighted – is available on [www.ICH.org](http://www.ICH.org). Direct link to the document [here](#).

### **d) Lack of or foreign course certificates**

Researchers without a course certificate recognized by swissethics (previously Swissmedic) or with a foreign certificate have to attend a recognized course. Even if online training is recognized, swissethics strongly recommends completing (part of the) training by face-to-face training.

### **e) Recognized course providers**

The up-to-date list of recognized course providers and the list of the course learning objectives can be found on [www.swissethics.ch](http://www.swissethics.ch). Course certificates from swissmedic/swissethics recognized courses dated before 1<sup>st</sup> January 2016, will remain valid.

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<sup>i</sup> Art. 6 ClinO

<sup>ii</sup> Art. 2 lit. d ClinO

<sup>iii</sup> Art. 3 lit. I HRA

<sup>iv</sup> Art. 2 lit. c and d ClinO

<sup>v</sup> Art. 4 lit. b HRO

<sup>vi</sup> Art. 1 lit. a HRO