Requirements for study protocols according to the Human Research Act (HRA)

a) and on the basis of **Chapter 2** (Medicinal products, products under article 2a par. 2 Therapeutic Products Act, and transplant products) of the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, **ClinO**) (link)

b) and on the basis of **Chapter 4** (Other clinical trials) of the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, **ClinO**) (link)

c) and on the basis of the Ordinance on Clinical Trials with Medical Devices (**ClinO-MD**) (link)

d) and on the basis of the Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, **HRO**) (link)

a) and on the basis of chapter 2 (Medicinal products, products under article 2a par. 2 Therapeutic Products Act, and transplant products) of the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, **ClinO**)

Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection.	HRA, Art. 16
Study registration	HRA, Art. 56 ClinO, Art. 64-67
Declaration of interest	ClinO, Art. 3, 1b
Communication of results to the participants	ClinO, Art. 8a
Information about genetic examinations	ClinO, Art. 7a
Consequences of revocation of consent regarding data and material: Anonymization possible? If not: consent of patient required	ClinO, Art. 9
Storage of biological material and health related data	ClinO, Art. 18
Significant changes must be authorized by the competent EC for category A trials and by the competent EC and by Swissmedic for category B and C trials.	ClinO, Art. 29 and 34
Non-substantial changes	ClinO, Art. 29, 6 and Art. 34, 5
Notification of safety and protective measures to the competent EC and to Swissmedic	ClinO, Art. 37
Notification of the first visit of the first participant in Switzerland and completion, discontinuation or interruption of a clinical trial to the competent EC and to Swissmedic	ClinO, Art. 38
Reporting of SUSARs to the competent EC and to Swissmedic	ClinO, Art. 41-42
Safety and Progress Report to the competent EC and to Swissmedic	ClinO Art. 43
Submission, notification and reporting on the use of radiation sources to the competent EC for category A, B and C trials, to the FOPH, and to Swissmedic for category B and C trials	ClinO, Art. 36, Art. 36a, Art. 44
Data retention requirements: 20 years	ClinO, Art. 45

b) and on the basis of **chapter 4** (Other clinical trials) of the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, **ClinO**)

Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection.	HRA, Art. 16
Study registration	HRA, Art. 56 ClinO, Art. 64-67
Declaration of interest	ClinO, Art. 3, 1b
Communication of results to the participants	ClinO, Art. 8a
Information about genetic examinations	ClinO, Art. 7a
Consequences of revocation of consent regarding data and material: Anonymization possible? If not: consent of patient required	ClinO, Art. 9
Storage of biological material and health related data	ClinO, Art. 18
Significant changes must be authorized by the competent EC	ClinO, Art. 29
Non-substantial changes	ClinO, Art. 29, 6
Notification of safety and protective measures to the competent EC	ClinO, Art. 37
Notification of the first visit of the first participant in Switzerland and completion, discontinuation or interruption of a clinical trial to the competent EC	ClinO, Art. 38
Reporting of SAEs to the competent EC	ClinO, Art. 63
Safety and Progress Report to the competent EC	ClinO Art. 43
Data retention requirements: 20 years	ClinO, Art. 45

c) and on the basis of the Ordinance on Clinical Trials with Medical Devices (**ClinO-MD**)

- A "clinical investigation" according to article 2 lit. a^{bis} ClinO-MD is equivalent to a "clinical investigation" according to article 2 (45) MDR.
- A “performance study” according to article 2 lit a^{ter} ClinO-MD is equivalent to a "performance study" according to article 2 (42) IVDR.

Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection.	HRA Art. 16
Study registration	HRA, Art. 56 ClinO-MD, Art. 41
Publication of study results	ClinO-MD, Art. 42
Declaration of interest	ClinO, Art. 3, 1b
Communication of results to the participants	ClinO, Art. 8a
Information about genetic examinations	ClinO, Art. 7a
Consequences of revocation of consent regarding data and material: Anonymization possible? If not: consent of patient required	ClinO, Art. 9
Storage of biological material and health related data	ClinO, Art. 18
Significant changes must be authorized by the competent EC for category A trials, and by the competent EC and Swissmedic for category C trials	ClinO-MD, Art. 15 and 20
Non-substantial changes	ClinO-MD, Art. 15, 5 and Art. 20, 4

Notification of safety and protective measures to the competent EC and to Swissmedic	ClinO-MD, Art. 34 and 36, 4
Notification of completion, discontinuation or interruption of a clinical trial to the competent EC and to Swissmedic	ClinO-MD, Art. 36-38
Reporting of SAEs and device deficiencies to the competent EC and to Swissmedic	ClinO-MD, Art. 32-33
Safety and Progress Report to the competent EC and to Swissmedic	ClinO-MD, Art. 35 and 38
Submission, notification and reporting on the use of radiation sources to the competent EC for category A and C trials and to Swissmedic for category C trials	ClinO-MD, Art. 14, Art. 18, Art. 39
Data retention requirements: 10 years (15 years for implantable medical devices)	ClinO-MD, Art. 40

d) and on the basis of the Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, **HRO**)

Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection.	HRA, Art. 16
Storage of biological material and health related personal data	HRO, Art. 5
Information about genetic examinations	HRO, Art. 8a
Communication of results to the participants	HRO, Art. 9a
Handling of data and samples in the event of revocation of consent	HRO, Art. 10
Significant changes must be authorized by the competent EC	HRO, Art. 18
Notification of safety and protective measures to the competent EC	HRO, Art. 20
Reporting of SE to the competent EC	HRO, Art. 21
Notification upon completion or discontinuation of a research project to the EC	HRO, Art. 22
Submission, notification and reporting on the use of radiation sources to the competent EC and the FOPH	HRO, Art. 19, Art. 23
Data retention requirements for research projects with persons: 10 years	HRO, Art. 23a
Definition of anonymisation and coding of data and biological material	HRO, Art. 25-26