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

a) and on the basis of the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, **ClinO**) [for HRO see page. 2]

Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection.	HFG Art. 16
Study registration	HRA, Art. 56
Declaration of interest	ClinO, Art. 3b
Code without initials and without the full date of birth	swissethics
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 and Swissmedic	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 and reporting upon completion, discontinuation or interruption of a clinical trial to the competent EC and to Swissmedic	ClinO, Art.38
Reporting of SAEs , SUSARs to the competent EC and to Swissmedic	ClinO, Art. 40-41 (IMP) ClinO, Art. 42 (MD)
Annual Safety Report to the competent EC and to Swissmedic	ClinO Art. 43
Reporting on investigations involving radiation sources to the FOPH	ClinO, Art. 44
Data retention requirements/achieving: 10 years for IMPs 15 years for implantable medical devices	ClinO, Art. 45

b) 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.	HFG Art. 16
Storage of biological material and health related personal data	HRO Art. 5
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
Notification and reporting on the use of radiation sources to the FOPH	HRO Art. 23
Definition of anonymisation and coding of data and biological material	HRO Art. 25 and HRO Art. 26