Guideline and Reminder for Swiss Specific Requirements in study protocols

Study registration	HRA, Art. 56
Declaration of interest	ClinO, Art. 3b
Code without initials and without the full date of birth	swissethics
Storage of biological material and health related data	ClinO, Art. 18
Consequences of revocation of consent regarding data and material: Anonymization possible? If not: consent of patient required	ClinO, Art. 9
Data retention requirements/achieving: 10 years for IMPs 15 years for implantable medical devices	ClinO, Art. 45
Significant changes must be authorized by the competent EC and Swissmedic	ClinO, Art. 29 and 34
Non-substantial changes	CinO, 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