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
Double contraception method. In particular, abstinence is not accepted	
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 CEC and the competent authority	ClinO, Art. 29 and 34
Non-substantial changes	CinO, Art. 29, 6 and Art. 34, 5
Notification of safety and protective measures to the CEC and the Agency	ClinO, Art. 37
Notification and reporting upon completion, discontinuation or interruption of a clinical trial to the CEC and the Agency	ClinO, Art.38
Reporting of SAEs , SUSARs to the CEC and to the Agency	ClinO, Art. 40-41 (IMP) ClinO, Art. 42 (MD)
Annual Safety Report to CEC (lead EC, local EC) and to the Agency	ClinO Art. 43
Reporting on investigations involving radiation sources to the FPOH	ClinO, Art. 44