Application submission, authorisation and notification procedure for human research projects involving radiation sources

**Procedure for:**

- Clinical trials with any form of an experimental intervention
- Concomitant examinations with radiation sources
- Trials, in which Art. 28 para. 2 ClinO is not applicable

**Applicant**

- Application submission
  - Studies with an effective dose < 5 mSv with sealed or unsealed radioactive sources
  - or
  - Studies with an effective dose < or > 5 mSv and with units (RX, BES) or with authorised RPH for nuclear medical routine examinations

**Ethics committee**

- Formal examination
  - Examinining scientific, legal and ethical aspects; observance of the Radiological Protection Act (incl. dose estimate)
  - 45 days

**FOPH**

- Confirmation

**Project start**

- Authorisation
  - 7 days

**Project execution**

- Communication
  - Assessment
  - Approval, revoke of approval, suspension

**Project completion**

- Final report
  - Archiving

**Final phase**

- Final report

**Notice**

- Exception: No final report to the FOPH for nuclear medical routine examinations with authorised RPH or with units (RX, BES)

**Relevant legal texts:**

- Authorisation phase
  - Art. 25, 28 ClinO, Annex 3 nr 5 ClinO
  - Art. 28 RPO (Dose limit)

- Implementation phase
  - Art. 41, 42 ClinO

- Final phase
  - Art. 44 ClinO

1 RX: X-rays
2 BES: imaging with accelerators
3 RPH: radiopharmaceuticals