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

**Clinical trials with any form of an experimental intervention**

**Concomitant examinations with radiation sources**
**Trials, in which Art. 28 para. 2 ClinO is applicable**

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**Relevant legal texts:**
- Implementation phase: Art. 41, 42 ClinO
- Final phase: Art. 44 ClinO

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**Application submission**
- Studies with an effective dose > 5 mSv and with an unauthorised RPH or with authorised RPH for non-nuclear medical routine examinations or with other sealed or unsealed radioactive sources

**Project start**

**Authorisation phase**
- Application
- Examining the observance of the Radiological Protection Act (incl. dose estimate)
- Confirmation
- Formal examination 7 days
- Evaluation of scientific, legal and ethical aspects 45 days
- Opinion
- Authorisation 45 days

**Implementation phase**
- Communication
- Assessment
- Changes, notifications and reporting
- Approval, revoke of approval, suspension

**Project execution**

**Final phase**
- Notice
  - Exception: No final report to the FOPH for nuclear medical routine examinations with authorised RPH or with units (RX1, BES2)

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**FOPH**
- Request
- Notification of decision

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

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**Evaluation of scientific, legal and ethical aspects**

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**Application**
- Formal examination 7 days
- Evaluation of scientific, legal and ethical aspects 45 days
- Opinion
- Authorisation 45 days

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**Right to free choice**
- Communication
- Assessment

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**Approval**
- Communication
- Assessment
- Changes, notifications and reporting
- Approval, revoke of approval, suspension

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**Revocation**
- Communication
- Assessment
- Changes, notifications and reporting
- Approval, revoke of approval, suspension

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**Suspension**
- Communication
- Assessment
- Changes, notifications and reporting
- Approval, revoke of approval, suspension

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**Notice**
- Exception: No final report to the FOPH for nuclear medical routine examinations with authorised RPH or with units (RX1, BES2)

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