ETHICS

LISA Mid-Term Review

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LISA
LASER IONISATION AND SPECTROSCOPY OF ACTINIDES

This Marie Sklodowska-Curie Action (MSCA) Innovative Training Networks (ITN) receives funding from the European Union's H2020 Framework Programme under grant agreement no. 861198

Ethics in EC projects

- **Horizon 2020 - Regulation 1291/2013: Ethical principles (Article 19)**

  → compliance with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols

- **Horizon 2020 - Regulation 1290/2013 (Rules for Participation and Dissemination): Ethics Reviews (Article 14)**

  → The Commission shall systematically carry out ethics reviews for proposals raising ethical issues:

  - verification of the respect of ethical principles and legislation
  - research carried out outside the Union: the same research would have been allowed in a EU Member State

- **Model Grant Agreement: Ethics (Article 34)**

  → The beneficiaries must carry out the action in compliance with:

  (a) ethical principles (including the highest standards of research integrity)

  (b) applicable international, EU and national law.

Ethics in EC projects

1. Ethics **Self-Assessment** (preparation phase: by the applicant)
2. The Ethics **Review** (before the finalisation of GA: by EC ethics experts) → Ethics Assessment

✓**Identify all potential ethical issues of the Ethics Issues table**

1. **Human embryo/foetuses**
2. **Human beings**
3. **Human cells/tissues**
4. **Personal data**
5. **Animals**
6. **Non-EU countries**
7. **Environment, health & safety**
8. **Dual-use**
9. **Exclusive focus on civil applications**
10. **Misuse**
11. **Other ethics issues**

Related to

- **research objectives**
  e.g. dual use
- **research methodology**
  e.g. clinical trials, protection of data
- **potential impact** of research
  e.g. dual use, environmental damages

✓**Explain in sufficient detail how these ethics issues will be addressed and how the national legal and ethical requirements of the countries where the tasks raising ethical issues will be performed will be met** (+ inclusion of copies of already obtained ethics committee advice, required notification or authorisation).

Ethics in LISA

	Title	Lead benificiary
WP1	Management	CERN
WP2	Novel techniques and technologies for actinide research	CERN
WP3	Medical & Societal Applications	KUL
WP4	Enhanced understanding of the actinide atomic structure	JGU
WP5	Exploring the limits of nuclear existance	JYU
WP6	Training	KUL
WP7	Outreach, dissemination, and communication	CERN
WP8	Ethics requirements	CERN

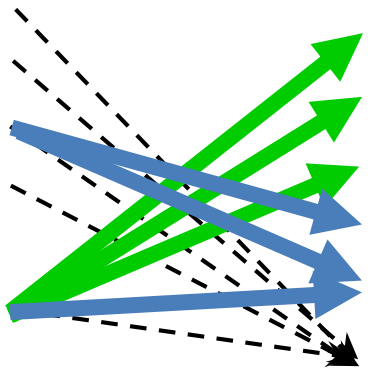
In dissemination part: LISA-4-Society actions

- **Radioecology Field Study in Chernobyl:** Demonstrate skillset directly in the field
- **225Ac for medical applications:** Overview complete chain from production to delivery

ESR #	Host institution	Project title	WP	Academic secondment	Research Center secondment	Industrial secondment
1	KUL	Optimized production of 225Ac by the ISOL method for medical applications	3		TRIUMF, CERN	LIOP
2	CERN	Development of high-resolution in-source hot-cavity RILIS methods for actinides	2	JGU	TRIUMF	
3	CERN	Target developments for extraction of actinides from thick ISOL targets followed by laser-induced molecular break-up and/or ionization	2	JGU	TRIUMF	
4	JYU	High-resolution laser spectroscopy of actinide elements for nuclear structure	5	JGU	GSI	
5	JGU	Laser spectroscopic investigations on the actinide atomic and nuclear structures	4	JYU, NU	TRIUMF	MSL
6	UGOT	Electron affinity measurements by collinear laser photodetachment spectroscopy on negative ions	4		CERN	
7	KUL	In-gas-jet resonance ionization spectroscopy of actinides	5		GANIL	PAN
8	GANIL	In-gas-jet laser spectroscopy optimization for high resolution measurement of actinides	2	JYU, JGU		PAN
9	MSL	Development of low-noise, high-power, tuneable, pulsed, narrow-linewidth Ti:Sa amplifier for ion beam spectroscopy applications	2	JGU, NU, UNIMAN	CERN	
10	GSI	Laser spectroscopy of the heaviest actinides, in particular Lr to study atomic and nuclear properties	5	JYU		
11	JGU	Tailor-made optimized actinide target preparation and characterization for LISA	5	JYU	GANIL	
12	LUH IRS	Multi-element ultra-trace detection of radionuclides in environmental samples	3	IER	LLNL	MSL
13	FSU	Developing atomic structure calculations for heavy and superheavy atoms and ions	4	TAU, UJK		
14	RUG	Relativistic coupled cluster (CC) and configuration interaction (CI) investigations of properties of heavy and superheavy elements	4	TAU, UNSW		
15	HUB	C-Wave laser development as a turn-key solid-state alternative to CW dye laser	2		CERN	LIOP

Ethics in LISA

Human embryo/foetuses
Human beings
Human cells/tissues
Personal data
Animals
Non-EU countries
Environment, health & safety
Dual-use
Exclusive focus on civil applications
Misuse
Other ethics issues



Research with radioisotopes
Research with lasers
Environmental protection
Handling of participants personal data
Non EU country ethics requirements
Distribution of radio-isotopes for use in pre-clinical and clinical studies

D 8.1 NEC – Requirement 1
- Research outside EU is legal in at least one EU member state.
- Info of imported/exported materials to EU must be kept on file
- Copies of import/export authorisations must be kept on file

D 8.2 EPQ – Requirement 2
- Information on possible harm to the environment and how to mitigate the risk must be kept on file
- Copies of authorizations for facilities must be kept on file
- Applicable health and safety procedures demonstrating compliance to legislation must be put together

MS 2 Formation of the Ethics Committee

Ethics Committee LISA

- is composed of 5 members independent of the research program:

Ria Bogaerts	UZ Leuven/KU Leuven	→ chair
Niki Bergans	UZ Leuven/KU Leuven	→ personal dosimetry
Iain Darby	DSRL Dounreay	→ environmental impact
Sture Lindegren	University of Göteborg - Dept. Radiation Physics	→ preclinal and clinical studies
Sami Rinta-Antila	University of Jyväskylä - Dept. Physics	→ radiation protection

- evaluates the compliance of all parts of the research program with the best practices in terms of ethics
- presents its findings in an initial Ethics report, assessing how the ethical issues in the research proposals are addressed and reporting on the deliverables of WP8
- assists the Steering Committee if a program is found to require adjustments in its practice

Timing of related deliverables and milestones

- Milestone MS2: formation of the Ethics Committee, June 30 → August
- Deliverables D1.3, D 8.1 and D8.2, Oct 31 → new date

Ethics Committee LISA: overview of steps

Get acquainted with the project, the research proposals and ethical issues as identified in the GA

- identify which elements are needed to make a thorough assessment (cfr GA)
- develop a questionnaire to request the necessary information and send it to the beneficiaries

Gather the necessary information and authorisations to make an assessment

- assess the collected information and check compliance with applicable legislation
- ask additional information or documents if needed

Ethics Report

- point out the necessity to inform the Ethics Committee prior to the start of new activities or if ethical issues arise in the course of the project
- request annual updates on progress

Support and assessment on ethics issues throughout the project

Ethics Questionnaire

- questions relate to
  - available information and clarification of procedures
  - copies of relevant documents: authorisations, training certificates, quality systems SOPs
  - pertinent ethical questions arising from the specificity of the research

- for each topic also free feedback can be given

Health and safety issues related to production and handling of radioisotopes

If the ESR uses radioisotopes in the research that will be carried out in the beneficiary's institute:

- Which radioisotopes?

- **Radiation safety authorization** from the regulating authority
- Quality assurance system with respect to ionizing radiation (how are procedures kept up to date?) and specific **QA procedures** for the tasks to be carried out
- **Radiation safety assessment** of the facility in which the ESR will work and of the tasks that will be performed
- **Security** measures
- **Emergency procedures** relevant for the facility, equipment and tasks carried out by the ESR.

- Measures taken for personal protection
- Personal dosimetry and medical follow-up
- Radiation protection training

If this research involves handling of open sources:

- Authorization of the radioisotope laboratory from the regulating authority
- Match between planned research activity and approved category of the laboratory

Health and safety issues related to production and handling of radioisotopes

If this research results in the production of radioactive waste:

- Authorized radioactive waste handling plan
- Disposal of specific waste generated by the project activities
- Handling of contaminated parts resulting from the project activities

If the ESR uses radioisotopes/handle open sources when sent on secondment to a partner organization:

- Handling of radiation health and safety issues by partner organization:
  safety, security, quality assurance procedures, training requirements, …
- Transfer of personal dose data

Health and safety issues related to production and handling of radioisotopes

Remarks (cfr also Grant Agreement)

- institutes with outstanding experience in production and handling of radioisotopes:
  - ICRP recommendations, European directives (2013/59/Euratom - Basis Safety Standards) and national legislations are fully implemented in all aspects of use of radionuclides
  - extensive institutional support of radiation protection experts
    → issues are known, it should be relatively easy to provide info

- secondments:
  - agreements to be made between both institutes concerning all issues at institute/task level and personal level and transfer of dosimetry results
  - if the work involves new risks, a prior health assessment should be made
  - good practice: provide a procedure with steps to be followed in case of incident and role of all parties involved

Use of laser radiation

If the ESR works with laser radiation in the research that will be carried out in the beneficiary's institute:

- Which class of lasers?

- Quality assurance system with respect to laser safety and **applicable QA procedures**
- **Laser safety assessment** of the facility in which the ESR will work and of the tasks that will be performed.

- Measures taken for personal protection.
- Medical follow-up
- Laser safety training

If the ESR uses lasers when sent on secondment to a partner organization:

- Handling of laser safety by the partner organization

Use of laser radiation

Remarks (cfr also Grant Agreement)

- institutes with outstanding experience in use of laser radiation:
  - European directives (Regulations 2016/425 on Personal Protective Equipment and Directive 2006/42/EC on machinery) and national legislations are fully implemented
    → issues are known, it should be relatively easy to provide info

- first General Training event on safety and ethics will be focused on laser safety training (IREPA)

Collection of environmental samples (field study)

If the research that will be conducted by the ESR involves the collection of environmental samples:

Complete investigation plan?

- Risk assessment and guidance by qualified expert

- If contaminated land or materials are involved:
  - What contamination is involved?
  - Have the hazards from the contaminated materials been addressed in the risk assessment?
  - Compliance to national regulations relating to the contamination
  - Authorized waste handling plan
  - Guidance by qualified expert

- Permits for the collection, removal, transportation, storage and disposal of (contaminated) samples

- Are cross-border transportation and removal zones with specific regulations considered?
  (e.g. exclusion zones, areas of special scientific, historical or cultural interest or environmental protection)

- In case of detection of unexpected violations of legislation and increased danger to the local population and other biota: data management policy for presentation, storage and dissemination of the results

Collection of environmental samples (field study)

Remarks (cfr also Grant Agreement)

- activity limited to a single beneficiary (LUH IRS):
  - extensive expertise with field studies (Clemens Walther)

- additional complexity due to involvement of non EU-countries (Japan, Ukraine): sometimes it is difficult to retrieve information and one must rely on a statement from a local expert to demonstrate compliance with EU legislation

Research in non-EU countries

If the ESR carries out research in a non-EU country:

- Which non-EU country?
- What type of research ? (production of radioisotopes, laser research, collection of field samples…)
- Which aspects of the research (health and safety issues, environmental impact…) relate to legal requirements? (reference to previous sections is possible)

If the research involves transport of material in or out the EU:

- Which type of materials will be imported/exported?
- Sender and recipient?
- Material Transfer Agreement
- Import or export authorisations?

Remark (cfr also Grant Agreement):

Apart from import/export issues, D8.1 focuses on legality of research in at least one EU country: will be handled based on information provided in the other sections

Handling of participants personal information

If personal data from the ESR or from other participants in LISA related events have to be collected:

- Data protection and handling policy

If the data are held by third parties (including partner organisations):

- Data use and the retention policy

Remarks (cfr also Grant Agreement):

- Limited to field studies or possibly to collecting of data for training or conferences
- No sensitive personal data are involved, risk is not high
- Principle of data minimisation and informed consent (cfr GDPR)
- Transfer to non-EU countries: increased risk
    - Japan: adequacy decision (guarantees as those under the EU law will continue to apply)
    - Ukraine: Law No.2297-VI on Personal Data Protection is similar to the EU Data Protection Directive

Distribution of radioisotopes for use in pre-clinical and clinical studies

If Ac-225 (or other isotopes) will be distributed for preclinical or clinical studies:

- Ethical questions related to the ability to provide clinical amounts:
  - Can this be accomplished? How?
  - Procedures to ration or increase the supply?
- Ethical approvals for
  - Production of Ac-225 at the production site
  - Transport to customer and partners
  - Preclinical animal studies
  - Clinical studies
- Ethical and legal requirements for road and air cargo transport (ADR)
- Radiation safety
  - For researchers in preclinical settings
  - For patients in clinical settings
  - For medical personnel in clinical settings

Remark (cfr also Grant Agreement):

- No direct medical research in LISA, but apart from the legal and ethical aspects aspects of the delivery, the ethics of the medical studies will be assessed through the reports of the local ethics committees.

Dual use, exclusive focus on civil applications and possible misuse

If the beneficiary's institute has relations with/support from partners involved in military applications (i.e. nuclear or laser research applications):

- If this can possibly lead to or be linked with military applications:
  describe this in detail and provide all relevant information.

If shipment of radioisotopes in the framework of LISA falls under the non-proliferation treaty (cfr. Euratom 302/2005 - EU safeguards related to nuclear material):

- Which radioisotopes?
- Authorisations and ethical approvals?

Remark (cfr also Grant Agreement):

- No dual use items or technology are foreseen to be imported/exported nor are any military applications envisaged.

Timing

Current situation:

- The work on the questionnaire is completed, it was sent to the members of the SC as feasibility test (e.g. are the questions clear and focused enough?)
- The first feedback has been received and is generally positive.
- The questionnaire will now be sent to all beneficiaries.

Future steps:

- Collect the information: 3 weeks to one month
- Make an assessment: 3 weeks to one month
- Write the report: 2 weeks