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# Ethical, Social and Legal Aspects in ERA PerMed proposals. An evaluator's perspective

# What does ELSA mean?

- Many proposal misunderstand what ELSA research actually means.
- ELSA research means that the project raises research questions which address the ethical, legal, social aspects of the research you carry out and/or the area it addresses.
- In a certain way it is also reflecting and adding to your own research!

# Examples for ELSA Questions from 2022 Call Text

- “Research on the use of tailored prevention approaches and stratification of the healthy society/population, **fair and equal access** to these interventions for all citizens and patients regardless of economic, educational or geographic status, including research on the impact on social inequalities and reflections on interventions for individuals at low and high risk.
- Research on the **acceptance of the public, health professionals and policy makers for access to preventive screening**, e.g. for individuals at high or low risk, based on tailored risk stratification (e.g. based on genetic profiling).
- **Right to know/not to know and sharing of research findings**: balance between citizens’ and patients' rights and research needs.
- Research on **therapeutic education of citizens and patients**, e.g. individual levels of risk awareness and follow-up of health recommendations in relation to the free choice of lifestyle and informed decision making.
- Research on the **role of genetic testing in clinical practice**, the clinical interpretation of test results and on the potential clinical, ethical as well as legal consequences in the context of PM and particularly tailored prevention (including security and use of data).
- Research on **advantages and disadvantages of genetic engineering** (gene transfer technology).”

# Examples for ELSA Questions from 2022 Call Text

- “Research on how to overcome potentially **biased datasets** lacking (sample) heterogeneity of information (e.g. gender, mixed and diverse populations, different cultural perspectives, social inequalities, etc.). This can also include reflections on defining norms within stratification and decision support tools (definition on what is meant by a “normal/healthy” status).
- Research on **how to enable stakeholder exchange and collaboration** (including all different key contributors – academic researchers from different disciplines, healthcare providers, industry/pharma and regulatory authorities as well as citizens, patient representatives and communities, regardless of their social, environmental and economic conditions) in the development of tailored prevention approaches from study onset.
- Development of **strategies for regulatory approval of clinical decision systems** for prevention, based on statistical learning, machine learning and artificial intelligence technologies.
- Research on **ethical, legal and social aspects, when using automated support tools**: availability and suitability of data for training (machine-learning algorithms), requirements on transparent and explainable decision-making, questions of responsibility and liability, potential changes in the role and self-image of physicians, privacy and personal data issues, obligation of information towards patients.”

## **ELSA does NOT mean!**

- **ELSA does not mean that a project is meeting ethical and legal requirements (e.g., informed consent, data protection, protection of vulnerable groups, submission to ethics committees, etc.)**
- **THAT IS IS A SINE QUA NON PREREQUISITE OF ANY RESEARCH!**

# Personal lessons from evaluator's perspective

Proposal regularly mention that they want to integrate ELSA research, **BUT** often

- misunderstand ELSA as meeting regulatory requirements;
- lacked a proper ELSA research question (see above slides);
- lacked proper research methodologies of social sciences how to answer a research question, if existing (surveys, interviews, document analysis, experiments, ....);
- failed to mention how the ELSA research related to the overall research project and impacted the own research and how generating such impact was organized;
- lacked a dedicated work package for ELSA research (ELSA was just mentioned as an add on);
- lacked researchers with the necessary competence & experience in the social sciences, humanities or law to address the research question;

# Personal lessons from evaluators perspective 2

The call text strongly encourages patient involvement (p. 16), **BUT** often projects

- lack proper patient involvement (sometimes only medical experts were involved);
- are unclear **WHO** was involved, **WHY**, **WHEN** and **HOW** and how this was again **Linked/Fed Back To The Research** in other area 1 or 2.



# Personal lessons from evaluator's perspective 3

- The call text strongly encourages inclusion of sex, gender analysis or underrepresented populations (p. 17)
- Proposal regularly mention that they want to integrate ELSA research BUT often gender aspects were limited to composition of research teams and not about whether the project raised any gender related questions.

# Personal recommendations for proposal

- A proper ELSA research question is essential. The call provides good guidance in this respect. Read it and take it serious!
- This is also the case in patient involvement and inclusion of sex, gender analysis or underrepresented populations.
- As in all the other parts of your proposal, describe how you going to answer the ELSA question, what methods will you use, what data you will be used, ...
- ELSA is research not for its own sake. It can help to increase the impact of your research (Because application is eased, different perspectives are integrated, useability is considered from different perspectives, questions and obstacles you might have overlooked were uncovered, ...). What mechanisms will you use to integrate the results of ELSA research in your project? (workshops, reports, guidelines, ...?)
- Try to involve patients (e.g., via patient representatives or self-help groups) throughout the research project. You might benefit from their contribution to increase the impact of your research.
- Consider whether your project raises issues of inclusion of sex, gender analysis or underrepresented populations.

# Personal Recommendations for proposal 2

ELSA research is not an add on but needs proper funding, organization, competence and integration

- Try to find ELSA researchers to collaborate with (e.g., in research communities studying Science and Technology Studies, anthropology, sociology, Responsible Research and Innovation), maybe a match making event can be organized?
- Set up a dedicated WP for ELSA research in which research questions, methods, workflow, interaction with the other WPs and stakeholders is clearly set out.
- Provide sufficient funding for ELSA research
- Use the [Societal Readiness Thinking Tool](#) developed in the [NewHoRRizon](#) project, to identify relevant ELSA research questions and stakeholders you might need to involve in order to increase the impact of your research.

# For further reading and ideas

- [Responsible Research Innovation \(RRI\) - ERA-NET NEURON \(neuron-eranet.eu\)](https://neuron-eranet.eu)
- [Patient and Public Involvement \(PPI\) - ERA-NET NEURON \(neuron-eranet.eu\)](https://neuron-eranet.eu)
- [NewHoRRizon](https://www.newhorrizon.eu)
- <https://rri-tools.eu/>
- [...](#)



Thank you!