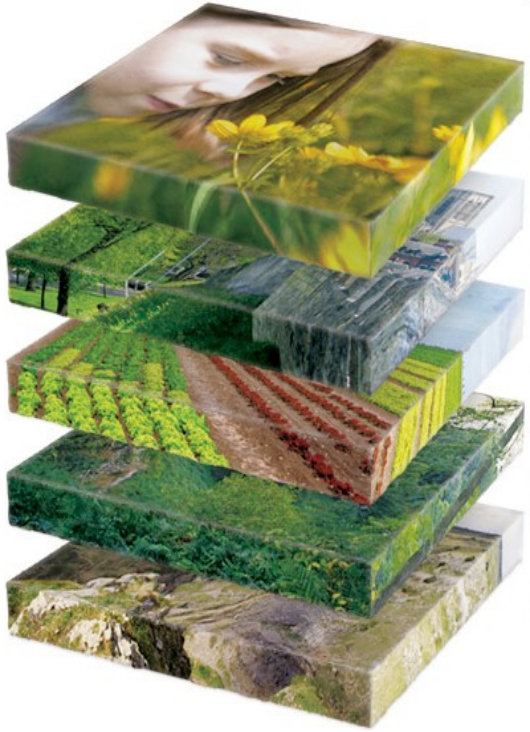
Ethical Considerations in Qualitative Research with Human Participation

Milada Šťastná



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What is qualitative research?

„The true value of something often lies beyond its measurable potential"

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1. **Introduction to Ethical Considerations**
   - Why ethics matter in qualitative research
   - Common ethical challenges
2. **Key Ethical Principles**
   - Informed consent
   - Confidentiality and anonymity
   - Participant well-being
3. **Ethics in Practice**
   - Examples of ethical dilemmas
   - Strategies for managing ethical challenges
4. **Institutional Guidelines and Standards**
   - Ethical review boards and approval processes
   - Codes of ethics for researchers
5. **Conclusion and Q&A**
   - Reflecting on the role of ethics in research
   - Open discussion and questions

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Why ethics matter in qualitative research?

- **Respect for Human Dignity**
  - Ensuring participants are treated with fairness, respect, and autonomy.
- **Building Trust**
  - Ethical practices foster trust between researchers and participants.
- **Protecting Vulnerable Populations**
  - Special care for participants who may be at risk of exploitation or harm.
- **Maintaining Research Integrity**
  - Upholds the credibility and validity of the research findings.
- **Legal and Institutional Compliance**
  - Adhering to ethical guidelines helps avoid legal issues and ensures compliance with institutional requirements.

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Core Principles of Ethical Research

- **Informed Consent**
  - Participants must fully understand the research purpose, methods, potential risks, and benefits before agreeing to participate.
- **Voluntary Participation**
  - Participation should be entirely voluntary, with the right to withdraw at any time without repercussions.
- **Confidentiality and Privacy**
  - Ensuring data protection and keeping participant identities anonymous unless consented otherwise.
- **Avoidance of Harm**
  - Preventing physical, emotional, or psychological harm to participants during and after the study.
- **Beneficence**
  - Maximizing benefits while minimizing potential risks for participants.

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Ethical Challenges in Qualitative Research

Power Dynamics

- Managing imbalances between researchers and participants to avoid coercion or undue influence.

Cultural Sensitivity

- Respecting cultural norms, beliefs, and values when engaging with diverse participant groups.

Emotional Impact

- Addressing potential emotional distress for participants when discussing sensitive topics.

Data Ownership and Sharing

- Clarifying who owns the data and how it will be used, particularly when dealing with community-based research.

Unanticipated Ethical Dilemmas

- Handling unforeseen situations, such as participants revealing harmful behaviours or needing support during the study.

Practical Applications of Ethical Principles

Informed Consent Process

- Providing clear, accessible information about the study's purpose, methods, and risks.
- Ensuring consent is voluntary and can be withdrawn anytime.

Data Confidentiality Risks and Confidentiality Measures

- Employing pseudonyms or anonymizing data.
- Securely storing audio recordings, transcripts, and notes.
- Digital data breaches in electronic storage systems.
- Challenges with ensuring anonymity in small, close-knit communities.

Minimizing Harm

- Offering debriefing sessions or support for participants after discussing sensitive topics.
- Monitoring for signs of discomfort and adjusting methods if necessary.

Feedback and Reciprocity

- Sharing findings with participants or their communities.
- Offering non-monetary tokens of appreciation where appropriate.

Real-World Challenges in Ethical Research

➢ Dynamic Consent Issues

- Participants may struggle to understand complex research terms or implications.
- Maintaining ongoing consent during long-term studies.

➢ Unintended Emotional Impact

- Sensitive topics may evoke unexpected emotional distress for participants.
- Researchers may feel unprepared to offer adequate support.

➢ Cultural and Contextual Variability and Sensitivity

- Navigating differing cultural norms about privacy and consent.
- Balancing the expectations of diverse stakeholder groups.
- Adapting research practices to respect cultural norms and traditions.
- Avoiding biases or assumptions about participant communities.

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Case Studies: Ethical Research in Action

Case Study 1: Researching Vulnerable Populations

- *Study Topic:* ***Experiences of refugees in urban resettlement programs.***
- *Key Ethical Practices:*
  - Emphasis on informed consent using translators and cultural mediators.
  - Debriefing and mental health resources provided after interviews.
  - Community leaders involved in research design to ensure cultural relevance.

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Case Studies: Ethical Research in Action

Case Study 2: Protecting Anonymity in Small Communities

- *Study Topic:* ***Perceptions of healthcare services in a rural area.***
  - *<u>Key Ethical Practices</u>:*
    - Pseudonyms used, and geographic identifiers omitted.
    - Participants reviewed the data presentation to ensure accurate representation.
    - Results aggregated to avoid identification of individual contributors.

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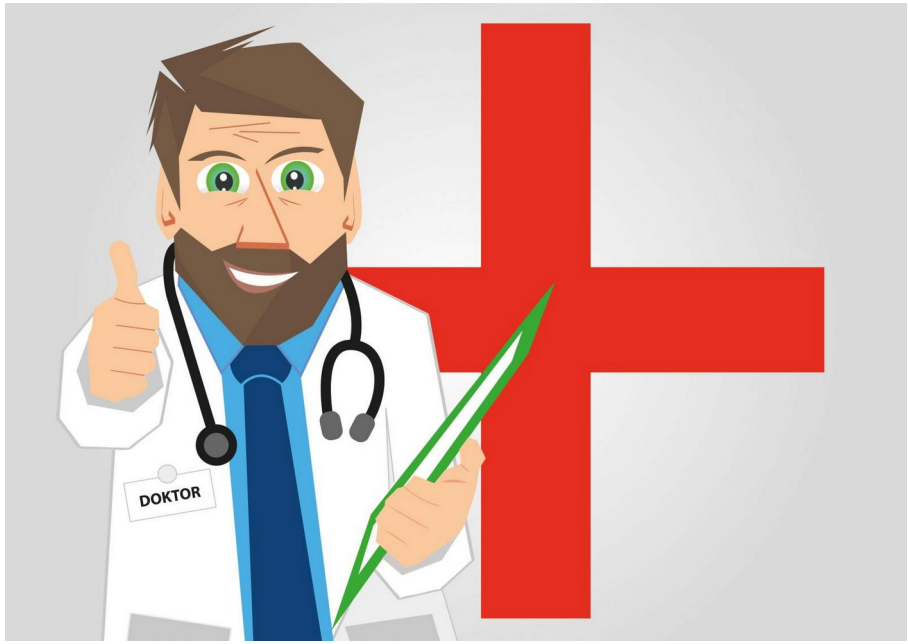
Case Studies: Ethical Research in Action

Case Study 3: Longitudinal Study on Sensitive Topics

- *Study Topic:* ***Coping mechanisms of families with terminally ill members.***
  - *Key Ethical Practices:*
    - Repeated informed consent at each phase of data collection.
    - Emotional support provided to participants.
    - Clear communication about the use and timeline of data sharing.



Institutional Guidelines and Standards

Role of Ethical Review Boards and Approval Processes

Purpose of Ethical Review Boards (ERBs):

- Ensure research complies with ethical standards.
- Protect the rights, dignity, and welfare of participants.
- Provide an impartial review of research proposals.

Key Functions of ERBs:

- Evaluate risks and benefits to participants.
- Assess informed consent procedures.
- Monitor adherence to confidentiality and data protection protocols.

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Codes of Ethics for Researchers

Guiding Principles for Ethical Research Conduct

1. **What Are Codes of Ethics?**
   - Set of guidelines outlining professional standards and ethical responsibilities for researchers.
   - Ensure integrity, transparency, and accountability in research.
2. **Core Ethical Principles:**
   - **Respect for Persons:** Upholding dignity, autonomy, and informed consent.
   - **Beneficence:** Prioritizing participants' welfare and minimising harm.
   - **Justice:** Ensuring equitable treatment and avoiding exploitation.
   - **Integrity:** Maintaining honesty and avoiding misconduct (e.g., plagiarism, falsification).
3. **Examples of Ethical Codes:**
   - APA (*The American Psychological Association*) Code of Ethics.
   - European Code of Conduct for Research Integrity; Helsinki declar.
   - Institutional and disciplinary-specific guidelines.
4. **Responsibilities of Researchers:**
   - Avoid conflicts of interest.
   - Ensure data privacy and confidentiality.
   - Obtain informed consent ethically and transparently.
   - Report findings honestly, including limitations and errors.
5. **Why It Matters:**
   - Builds trust among participants and the broader community. Promotes credibility and reliability of research outcomes. Encourages ethical decision-making in complex scenarios

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Example from MENDELU

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Mendelova univerzita v Brně

Ethics Committee

(including Research)

Application Form for Ethical Approval of Research

BEFORE COMPLETING THIS FORM APPLICANTS SHOULD REFER TO:

1. Code of Conduct for employees, students and graduates of Mendel University in Brno https://is.mendelu.cz/dok_server/slozka.pl?download=236022;id=12342
2. Information about Personal Data Processing http://mendelu.cz/en/31388-information-about-personal-data-processing

WHEN COMPLETING THE FORM APPLICANTS ARE REQUIRED TO:

1. Consider each question carefully and provide details of potential ethical issues which might arise, allowing the reviewer to make an informed decision on whether they have been addressed appropriately. Applicants are expected to provide additional information beyond the initial 'yes'/'no' answer to the questions provided, if requested.

   Failure to provide enough information to allow the reviewer to provide informed approval of ethical issues within the research might result in the need to restart the review process.

2. For all applications, researchers must provide a brief explanation of the potential ethical issues which might arise when carrying out the research and how they are to be addressed. Any other documents relevant to the research (e.g. consent forms) should also be attached to the application.

Title of Project: Social and innovative platform on cultural tourism and its potential towards deepening Europeanisation

Name of Principal Investigator: Prof. Dr. Ing. Milada Šťastná, Department of Applied and Landscape Ecology, Faculty of AgriSciences

Additional Research staff (if applicable): doc. Vaishar, Ing. Zloch, Ing. Tuzová, Ing. Brychta, Mgr. Stodolová

Type of action:	**RIA** (Research and Innovation action) **under H2020**
Proposal number:	870644
Proposal acronym:	**SPOT**
Duration (months):	36 **Project Start Date:** 1. 1. 2020
Grant amount:	**3 000 000.00 EUR**
Activity:	TRANSFORMATIONS-04-2019-2020

Recruitment procedures

		Yes	No	N/A
1	Does your research activity involve persons less than 18 years of age? If yes, please provide further information.		x	
	Not applicable			

		Yes	No	N/A
2	Does your research activity involve people with learning or communication difficulties? (**Note:** all research involving participants for whom provision is made under the Mental Capacity Act 2005 must be ethically reviewed by NHS NRES). If yes, please provide further information.		x	
	Not applicable			

		Yes	No	N/A
3	Is your research activity likely to involve people involved in illegal activities? If yes, please provide further information.		x	
	Not applicable			

		Yes	No	N/A
4	Does your research activity involve people belonging to a vulnerable group, other than those noted above? If yes, please provide further information.		x	
	Not applicable			

		Yes	No	N/A
5	Does your research activity involve people who are, or are likely to become your clients or clients of the section in which you work? If yes, please provide further information.		x	
	Not applicable			

Consent Procedures

6	Please provide details of the consent procedures that you intend to use for obtaining informed consent from all subjects. You should provide details of how you will let subjects know that participation is voluntary and that they can withdraw at any time. You should also provide details of the processes for giving potential subjects adequate time for considering participation and for obtaining written consent. If any of these issues are not applicable to your research or if you do not intend to address them for reasons of research methodology, please provide further information.

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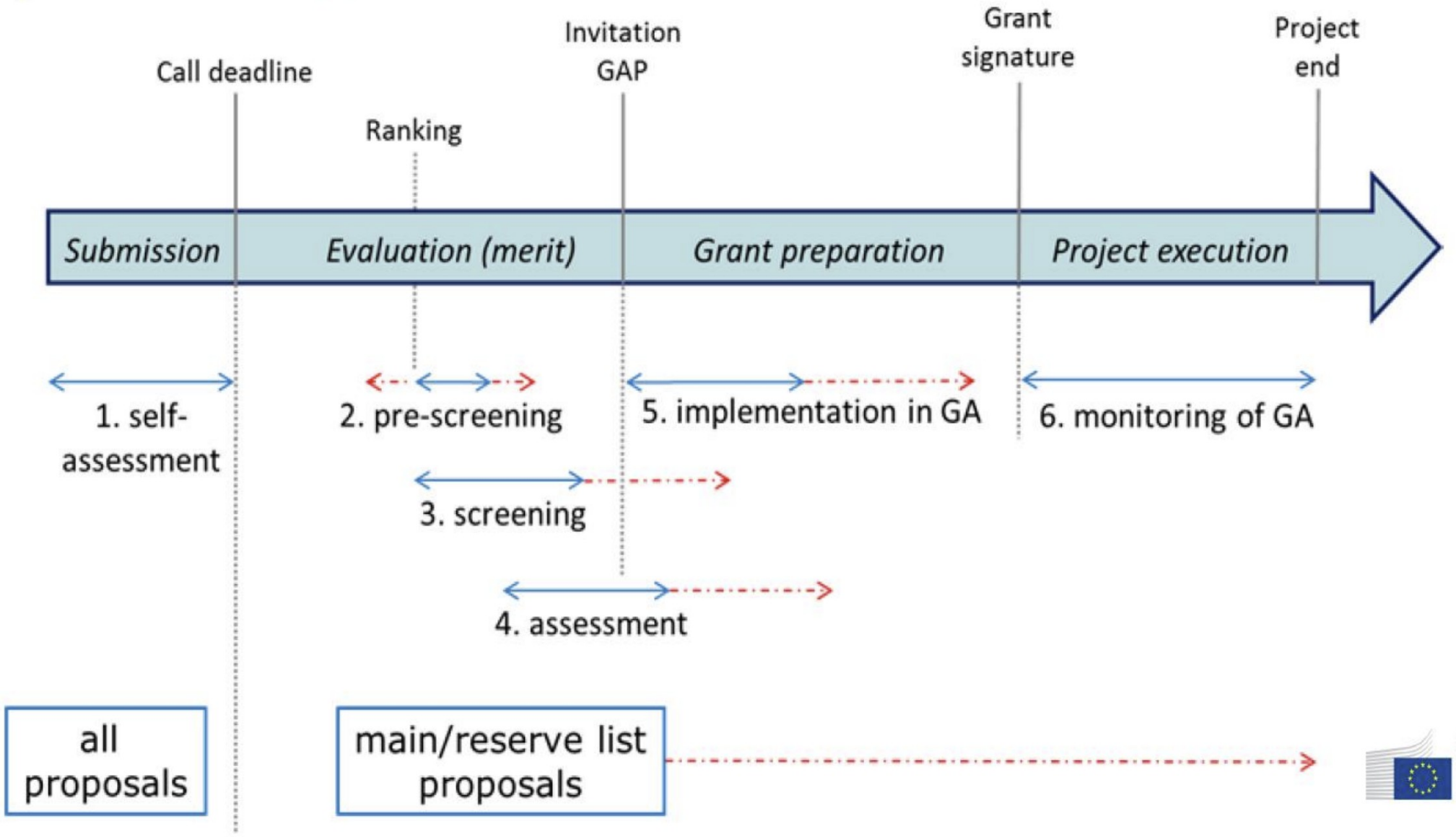
Ethics Appraisal in Horizon Europe

For all activities funded, ethics is an **integral part** of research from beginning to end, and **ethical compliance** is essential to achieve real research excellence.

Ethical research conduct implies the application of fundamental ethical principles and legislation in all research domains. This includes the adherence to the highest standards of **research integrity** as described in the **European Code of Conduct for Research Integrity**.

An ethics review process is carried out systematically in all Horizon Europe proposals, to **identify** those actions raising **complex or serious ethics issues**. Such actions shall be submitted to an **ethics assessment** (article 19.3 of HE regulation 2021/695)

Ethics Appraisal Process – Overview



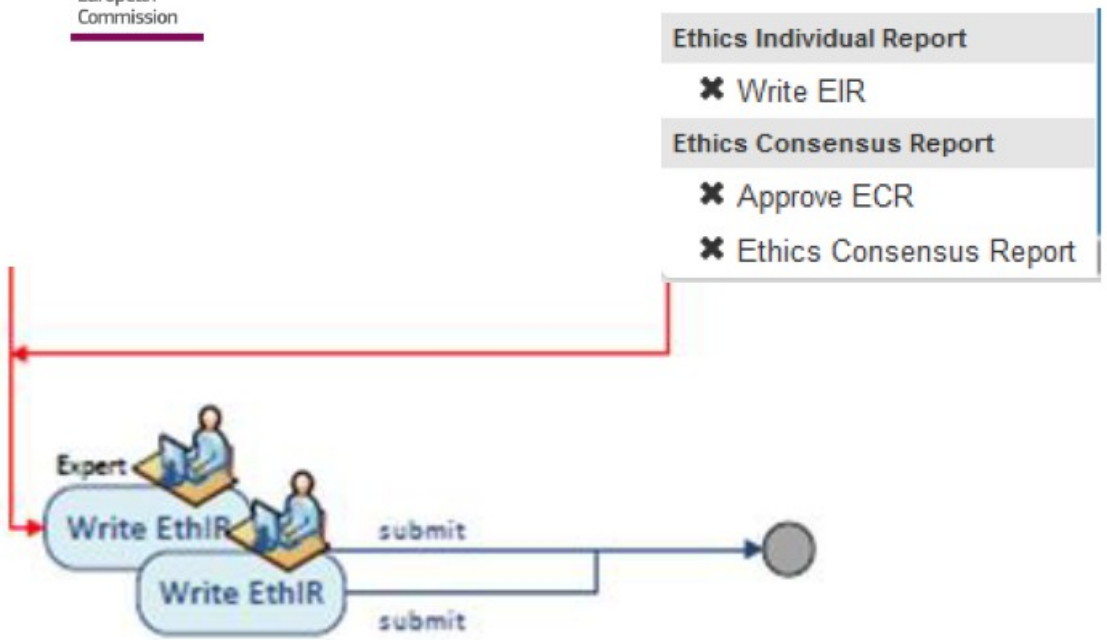
European Commission

EthIR
Remote Phase

European Commission

SCREENING EthIR PHASE

Screening concerns proposals (likely) to be funded WITH ethics issues flagged by the applicant, or proposals with issues detected in pre-screening



Task: Write EIR

- Draft the **Ethics individual Report (EthIR)**
- 2 experts per proposal

Research Executive Agency

Ethics in the application form (proposal template)


Horizon Europe Programme

Standard Proposal Template (RIA, IA)

Application Forms (Part A)
Project proposal – Technical description (Part B)

Version 1.0
10 March 2021

Disclaimer

Similarities and novelties

1. **Part A**: web-based forms generated by the IT system, based on the information entered by the participants through the submission system

- **Ethics Issues Table:** applicants identify ethics issues raised by the project
- **Ethics Self-Assessment** (mandatory, article 19.2(a) HE regulation): now included in Part A. Applicants describe the ethical dimension of their proposal and the compliance with ethics principles

2. **Part B**: is the narrative part of the proposal.

- **No Ethics Supporting Documents submitted in separate annex**

➢ *How to fill in ethics sections?* ***How to complete your ethics self-assessment***

European Commission

4 – Ethics and Securi

Ethics issues table

This table should be completed as an essential part of your proj proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any
- *Indicate in the adjacent box at which page in your ful*
- *provide additional information on that ethics issue in*

For more information on each of the ethics issues and how to a Complete your Ethics Self-Assessment'.

1. HUMAN EMBRYONIC STEM CELLS AND HUM	
Does this activity involve Human Embryonic Stem	
If YES:	Will they be directly derived from emb
	Are they previously established cells
	Are the cell lines registered in the Eu cell lines?
Does this activity involve the use of human embryc	
If YES:	Will the activity lead to their destructio
2. HUMANS	
Does this activity involve human participants?	
If YES:	Are they volunteers for nonmedical st research)?
	Are they healthy volunteers for medic
	Are they patients for medical studies'
	Are they potentially vulnerable individu
	Are they children/minors?
	Are they other persons unable to give
Does this activity involve interventions (physical als treatments, etc.) on the study participants?	
If YES:	Does it involve invasive techniques?
	Does it involve collection of biological s

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Does this activity involve conducting a clinical stuc Regulation (EU 536/2014)? (using pharmaceuticals advanced therapy medicinal products)	
If YES:	Is it a clinical trial?
	Is it a low-intervention clinical trial?
3. HUMAN CELLS / TISSUES (not covered by sectior	
Does this activity involve the use of human cells or tis	
If YES:	Are they human embryonic or foetal cell
	Are they available commercially?
	Are they obtained within this project?
	Are they obtained from another project, I
	Are they obtained from biobank?
4. PERSONAL DATA	
Does this activity involve processing of personal data?	
If YES:	Does it involve the processing of special lifestyle, ethnicity, genetic, biometric and h philosophical beliefs)?
	If YES: Does it involve processing
	Does it involve profiling, systematic mon large scale of special categories of data (such as, surveillance, geolocation track
Does this activity involve further processing of previously c preexisting data sets or sources, merging existing data set	
Is it planned to export personal data from the EU to non-EU	
If YES:	Specify the type of personal data and countri
Is it planned to import personal data from non-EU countries another non-EU country?	
If YES:	Specify the type of personal data and countri

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Does this activity involve the processing of personal dat	
5. ANIMALS	
Does this activity involve animals?	
If YES:	Are they vertebrates?
	Are they non-human primates (NHP)'
	Are they genetically modified?
	Are they cloned farm animals?
	Are they endangered species?
6. NON-EU COUNTRIES	
Will some of the activities be carried out in non-EU	
If YES:	Specify the countries:
In case non-EU countries are involved, do the ac potential ethics issues?	
If YES:	Specify the countries:
Is it planned to use local resources (e.g. animal an live animals, human remains, materials of historic etc.)?	
Is it planned to import any material (other than dat a non-EU country to another non-EU country? For	
If YES:	Specify material and countries involve
Is it planned to export any material (other than dat exports, see section 4.	
If YES:	Specify material and countries involve
Does this activity involves low and/or lower-middle sharing actions planned in the self-assessment)	
Could the situation in the country put the individua	
7. ENVIRONMENT, HEALTH and SAFETY	

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Does this activity involve the use of substances or proces environment, to animals or plants (during the implementa of the results, as a possible impact)?	
Does this activity deal with endangered fauna and/or flora	
Does this activity involve the use of substances or proces including those performing the activity (during the implem use of the results, as a possible impact)?	
8. ARTIFICIAL INTELLIGENCE	
Does this activity involve the development, deployment a yes, detail in the self-assessment whether that could rais rights and values and detail how this will be addressed).	
9. OTHER ETHICS ISSUES	
Are there any other ethics issues that should be taken int	
Please specify: (Maximum number of characters allowed	

I confirm that I have taken into account all ethics issue apply, I will complete the ethics self-assessment as Complete your Ethics Self-Assessment'.

This proposal version was submitted by [Name, FAMILY NAME the Funding and Tenders Portal Submission Service.

ETHICS SELF-ASSESSMENT

If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "How to Complete your Ethics Self-Assessment" and complete the table below.

Ethical dimension of the objectives, methodology and likely impact

Explain in detail the identified issues in relation to:
- objectives of the activities (e.g. study of vulnerable populations, etc.)
- methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.)
- the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)

Compliance with ethical principles and relevant legislations

Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU / national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for activities performed in a non-EU countries, they should also be allowed in at least one EU Member State.

This proposal version was submitted by [Name, FAMILY NAME] on [dd/mm/yyyy HH:mm:ss] Brussels Local Time. Issued by the Funding and Tenders Portal Submission Service.

Example, not complete

H2020 proposals

Main Ethics Issues

1. Human embryos and foetuses (& hESC)
2. Humans
3. Human cells/tissues
4. Personal data
5. Animals
6. Third countries / Non-EU Countries
7. Environment & Health and Safety
8. Dual use
9. Misuse
10. Other issues

Research Executive Agency

HE proposals

1. Human Embryonic Stem Cells and Human Embryos
2. Human participants
3. Human cells / tissues
4. Personal data
5. Animals
6. Non-EU countries
7. Environment & Health and Safety
8. **Artificial Intelligence**
9. Other ethics issues

Ethics Issues – Artificial Intelligence

Part A: Does the proposed activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).

Questions from the guide *How to complete your ethics self-assessment*

- Could the AI system/technique stigmatise or discriminate against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?

- Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?

AI technically robustness assessed under 'excellence'. This assessment also includes AI reliability: AI should function as intended, minimising unintentional and unexpected harm, preventing unacceptable harm and safeguarding the physical and mental integrity of humans.

To take into account the assessment of technical robustness during ethics review

The EU wants to regulate artificial intelligence (AI) to ensure better conditions for the development and use of this innovative technology. AI can create many benefits, such as better healthcare; safer and cleaner transport; more efficient manufacturing; and cheaper and more sustainable energy.

AI Act: different rules for different risk levels

- **Unacceptable risk**

  Unacceptable risk AI systems are systems considered a threat to people and will be banned (*e.g. social scoring*).

- **High risk**

  AI systems that negatively affect safety or fundamental rights.

- **Generative AI**

  Generative AI, like ChatGPT, would have to comply with transparency requirements

- **Limited risk**

  Limited-risk AI systems should comply with minimal transparency requirements that would allow users to make informed decisions.

Ethics Guidance and Supporting Documents

1. How to complete your Ethics Self-Assessment*
2. Ethics and data protection guidance
3. Informed consent guidance
4. Ethics guidelines for trustworthy AI
5. Horizon Europe Regulation (art. 18, 19)
6. General Model Grant Agreement (art. 14)
7. European Code of Conduct for Research Integrity
8. Charter of Fundamental Rights of the European Union
9. Statement of the Commission on human embryonic stem cells/human embryos research

*The 'How to complete your ethics self assessment' includes guidance on all ethics issues and a more complete set of reference documents, specific for each ethics issue.

Conclusion

Key Takeaways on Ethical Considerations in Qualitative Research

- **Ethics as the Cornerstone of Research Integrity:**
  Upholding ethical principles ensures the protection, respect, and dignity of participants.
- **Core Ethical Principles Revisited:**
  Informed consent, confidentiality, and risk minimisation are essential components. Codes of ethics and institutional guidelines provide vital support for researchers.
- **Practical Application is Key:**
  Ethical considerations are not just theoretical—they must be actively implemented at every stage of research.
- **Collaboration and Responsibility:**
  Researchers, institutions, and review boards share the responsibility for maintaining ethical standards.
- **Looking Ahead:**
  Ethical research fosters trust, advances knowledge responsibly, and contributes positively to society.

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Thank you for your attention

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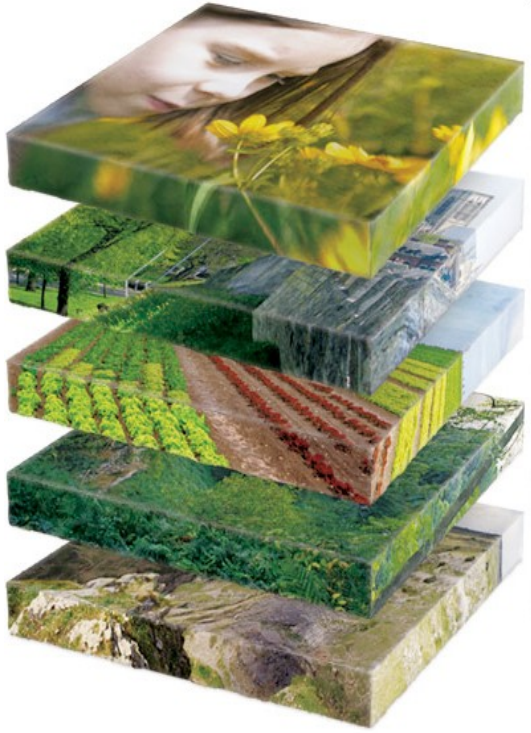

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