

ETHICS ASSESSMENT TOOLKIT

This toolkit is designed in the context of [FERMI](#) (Fake nEws Risk Mltigator) [Project 101073980], a Horizon Europe project that studies and attempts to counter the root causes, spread and implications of disinformation and fake news. The purpose of this toolkit is to support FERMI consortium members in the process of conducting an ethics assessment. Ethical compliance is a prerequisite for all EU-funded projects. Since ethics issues can emerge at any stage of the research process, it is of vital importance to be informed and properly equipped to understand, identify and properly communicate/address these.

By offering some basic steps this document assists the reader in conducting an ethics self-check i.e., assessing respective project related actions, in terms of ethics stance and status, and offer some relevant direction to ensure that the FERMI project adheres to the highest ethical standards. Provided that ethical considerations are not static, meaning these do not end with proposal submission, the aim of this document is to assist towards identifying potential ethical issues in research activities and ensuring compliance with European Commission guidelines thought the project lifecycle i.e., from proposal submission to project execution and project completion.

PARTNERS



STEP 1: UNDERSTANDING THE ETHICAL FRAMEWORK

The initial phase of this toolkit instructs you to start by reading some important documents to understand the ethical framework. The first step guides readers through familiarising themselves with essential documents and principles that underpin ethical conduct relevant for the project's scope. By comprehending these documents, readers will be equipped to align with legal requirements and to navigate the complex ethical landscapes of the project and work towards ensuring adherence to the highest standards of research integrity.

REVIEW KEY DOCUMENTS

- [REGULATION 2021/695](#)

The “Regulation (EU) 2021-695 of the European Parliament and of the Council of 28 April 2021¹” is a critical document as it sets out the foundational legal and ethical framework establishing Horizon Europe i.e., European Union's flagship programme for research and innovation covering the period from 2021 to 2027). The regulation outlines the programme's objectives including strategic priorities, budget, funding eligibility and ethical standards rules for participation and dissemination, and outlines the structure for its implementation.

Articles 18 & 19 are of particular importance for this context.

! Article 18² “**Eligible actions and ethical principles**” underlines eligible actions for research and that all activities carried out under Horizon Europe must adhere to respective ethical principles and be compliant with applicable EU, national, and international laws.

! Article 19³ “**Ethics**” outlines the ethical framework and compliance requirements for actions. Here you will find vital information regarding (a) ethical compliance and law adherence, (b) conducting ethics self-assessment, (c) processes of ethics screening and assessments, (d) processes of approval and documentation, (e) ethics checks and, (f) non-compliance consequences.

¹ Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0695>

² Idem, Article 18, p. 29

³ Idem, Article 19, p. 29-30

- EUROPEAN CODE OF CONDUCT FOR RESEARCH INTEGRITY

The "**European Code of Conduct for Research Integrity**"⁴ provides a self-regulatory framework which is applicable to research across all scientific and scholarly fields and has been acknowledged by the Commission as the reference document. Therein you will find principles and guidelines on how to uphold research integrity across all scientific and scholarly disciplines. Emphasis is placed on the importance of reliability, honesty, respect, and accountability in research practices.

- HOW TO COMPLETE YOUR ETHICS SELF-ASSESSMENT

The document "**How to Complete your Ethics Self-Assessment**"⁵ is a comprehensive guide by the European Commission to assist applicants and beneficiaries of EU funded projects in ensuring their proposals comply with ethics. If there is a need to conduct an "Ethics Self-Assessment" (in FERMI this was needed), this is an essential part needed in the proposal evaluation process, the self-assessment is a preparatory step completed by researchers and is used in the broader evaluation entitled the *Ethics Appraisal Procedure* conducted by the European Commission (EC).

The aim of this document is to help identify and address potential ethics issues that may arise from projects while enhancing the selection process and contributing to the responsible implementation of projects. Herein you will also find European Commission's "Ethics Issues Table", which includes guidance for researchers/applicants during the preparation of project proposals, the table helps identify potential ethical issues that might arise from respective research activities. Ethic Topics included are enlisted below, FERMI's context requires special attention as it intersects with various topics (e.g. AI, Humans, Personal data).

Human embryonic stem cells (hESCs) and human embryos (hEs)	Non-EU countries
Humans	Environment, health and safety
Human cells or tissues	Artificial intelligence (AI)
Personal data	Other ethics issues
Animals	Crosscutting issue: potential misuse of results

⁴ ALLEA (2023) The European Code of Conduct for Research Integrity – Revised Edition 2023.

Berlin. DOI 10.26356/ECOC. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf

⁵ European Commission (2021). How to Complete Your Ethics Self-Assessment, Version 2.0. European Commission. Published on 13 July 2021. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

- THE EUROPEAN TEXTBOOK ON ETHICS IN RESEARCH

"**The European Textbook on Ethics in Research**"⁶ is an educational resource produced by the European Commission, aiming to support training in research ethics. Herein you will find key issues related to research ethics, such as consent, the treatment of vulnerable subjects, privacy, balancing harms and benefits, and justice in research.

- ETHICS AND DATA PROTECTION

The document "**Ethics and Data Protection**"⁷ is a guide by the European Commission which emphasises the intersection of ethics with data protection in EU research. Here you will find critical information such as, General Data Protection Regulation (GDPR)⁸ compliance and the ethical handling of personal data within research activities, and ethical and legal data management approaches, including discussions on the ethical implications of research involving dual-use items, the potential for misuse of research findings, and other related issues particularly important for the FERMI context.

- FERMI DELIVERABLES & INTERNAL PROTOCOL ON ETHICAL PROCEDURES

Key documents produced within the context of FERMI that are of particular importance in providing input for the respective ethical framework are:

- ✓ "**D1.4 FERMI Data Management Plan**" which includes the "**Internal Protocol on Ethical Procedures**". The Protocol outlines the main ethical requirements and principles that need to be observed during the Project's execution. Its main purpose is to safeguard that the rights and freedoms of the research participants shall be respected throughout the research,
- ✓ "**D7.1 H - Requirement No. 1**", is the first ethics deliverable and concerns the involvement of human participants in the FERMI project's research activities,
- ✓ "**D7.2 POPD - Requirement No. 2**", is the second ethics deliverable, which addresses the handling of personal data and,
- ✓ "**D7.3 AI - Requirement No. 3**" which is the third ethics deliverable and addresses the role of artificial intelligence in FERMI.

⁶ European Commission, Directorate-General for Research and Innovation (2010), European textbook on ethics in research, Publications Office. Available at: <https://data.europa.eu/doi/10.2777/51536>

⁷ European Commission (2021). Ethics and Data Protection. Brussels: European Commission. Available at:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

⁸ For a particular focus on GDPR regulation see: Regulation (EU) 2016/679 of the European parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (GDPR). Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679>

ETHICAL PRINCIPLES & REQUIREMENTS

Of particular importance in reviewing these key documents is to comprehend and utilise the core ethical principles and in turn requirements. The principles serve as the foundation for ethical research conduct, guiding researchers in making decisions that uphold the integrity and social responsibility of the work carried out. As analysed in the "European Code of Conduct for Research Integrity", the four core ethical principles are: Reliability, Honesty, Respect and Accountability⁹. While ethical principles are the foundation, ethical requirements translate ethical principles into actionable directives, which can provide clear expectations for behavior. Particularly analysed for/in the FERMI context can be found on chapter 3.2 "What are the main ethical requirements that need to be observed when conducting research?" of "D1.4 - FERMI Data Management Plan".

LEGAL COMPLIANCE

These key documents will assist you in building a basis towards understanding the EU legal framework, including but not limited to, fundamental rights, data protection, content moderation, as these apply to your research. Since the FERMI project aims to develop an AI tool to identify disinformation and fake news (D&FN), with the ultimate purpose of seeking a unified EU method for assessing risks from such sources, i.e., D&FN. One of the main concerns towards achieving its goals is to constantly protect fundamental rights and freedoms which may be affected by the implementation of measures to combat the spread of fake news. While at the same time, adhering to the EU's data protection framework, particularly the GDPR, is crucial. Additionally, the Law Enforcement Directive¹⁰ is pertinent for the project's law enforcement aspects. The FERMI researchers must also particularly consider EU regulations on online content moderation, including the Terrorist Content Online Regulation and the Digital Services Act.

STEP 2: IDENTIFY POTENTIAL ETHICAL ISSUES

When conceptualising, designing, and implementing your respective research activities consult the documents enlisted in Step 1. Use the Commission's Ethics Issues Table: This tool will help in identifying common ethical issues related to human participants, personal data, AI, safety and environmental impact etc. In parallel, consider the project's context while reflecting on your research activities, goals and output, relevant methodologies, and data handling processes to identify unique ethical concerns. For the FERMI context these include all the internal documents enlisted under "FERMI Deliverables & Internal Protocol on Ethical Procedures".

⁹ ALLEA (2023) The European Code of Conduct for Research Integrity – Revised Edition 2023.

Berlin. DOI 10.26356/ECOC. Available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf.

¹⁰ See: Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (Law Enforcement Directive). Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L0680>

STEP 3: COMPLETE THE ETHICS ASSESSMENT

Use the template provided below “Ethics Assessment Template” to record your research activities, potential ethical issue, mitigation strategy and review and monitoring procedures. Document the nature of the ethics concerns, how these apply to your research activities, and the steps you will take to mitigate the risk. Collaborate with your project team to review and refine accordingly, this stage can reveal overlooked ethical considerations.

STEP 4: CONTINUOUS MONITORING AND UPDATING

Ethical compliance is an ongoing process, you need to regularly review and update your ethics assessment to reflect any relevant changes in your research activities or trace any emerging ethical concern. Continuously consult FERMI’s ethics and legal partners, including the Ethics Advisory Board, as a resource for advice and feedback on ethical concerns/matters.

ETHICS ASSESSMENT TEMPLATE

Research Activity Overview	<i>Describe the planned research activity, including the purpose and output, the methodology and tools, using as a basis how this is described in the Grant Agreement.</i>
Potential Ethical Issues Identified	<i>Describe any potential ethics issue which might arise as a result of the conceptualised research/project activity consulting the key documents enlisted herein and any additional relevant document/source.</i>
Mitigation Measures	<i>Describe your mitigation strategy by consulting key documents enlisted herein and any additional relevant document/source. Ensure respective ethical principles addressed and ethical requirements adhered.</i>
Review & Monitor	<i>Review and update according to relevant project partners, especially ethics and legal partners’ feedback when/if necessary. Outline the plan for ongoing monitoring as described within key project documents, if not available and/or updated modify accordingly.</i>
Additional Notes	

CLOSING NOTES

This document has been produced by [Convergence](#) as the assigned Social Sciences and Humanities (SSH) partner of FERMI and task leader of “Training activities for all: Increasing understanding and digital trust” and is part of the training package material which complement the respective training activities undertaken throughout the project. In particular, this toolkit has been drafted following the internal workshop (for FERMI consortium members) on legal and ethical requirements which took place on 21/03/2024 at Brussels, presented by the assigned Ethics partner of FERMI, Vrije Universiteit Brussel (VUB), and specifically from Dimitra Markopoulou¹¹.

The information presented in the workshop was derived primarily from D1.4 (FERMI Data Management Plan) and in particular the parts of the deliverable relevant to the ethics and legal partners of FERMI (VUB & Katholieke Universiteit Leuven (KUL)) contributions. This final version of the document has been edited by Convergence based on the information and material derived from (a) the workshop, (b) respective deliverables and (c) relevant secondary literature (which has been critically evaluated regarding the quality, validity as well as the reliability of the data), all references can be found in footnotes. Although this toolkit has been drafted in the context of FERMI, it can be utilised as a guide for other EU funded R&I projects, provided that the reader carefully modifies the steps described herein to fit the context of respective proposals and projects.

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