

## **Project Report**

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# **PollinERA Deliverable - D7.4 Ethics and Security Plan (ESP)**

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## D7.4 Ethics and Security Plan (ESP)

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Lead beneficiary: Aarhus University

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D7.4 Ethics and Security Plan

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## 1 Preface

This deliverable is a review of ethical and security implications of activities and research undertaken as part of the PollinERA project. This ESP is a ‘living document’ and will be updated if additional ethical and security issues are identified and detail actions needed to ensure compliance with EU and national regulations.

## 2 Summary

Various activities and research studies undertaken as part of the PollinERA project have ethical and security implications. This report outlines the project’s consideration of its obligations and its commitments for ethical and security issues with respect to:

### 2.1 Animal studies

Laboratory tests and field studies will be conducted on arthropods, however prospective test species will not be endangered or covered by the European Union Directive 2010/63/EU on the protection of animals for scientific purposes (EC, 2010). Tests will follow the highest experimental and safety protocols, as well as complying with all international, EU, and national health and safety laws and guidelines to ensure human and environmental safety.

### 2.2 Use of genetic material

The use of biological material (genetic resources) as part of research studies is anticipated within PollinERA. Genetic resources/materials (e.g. pollen, nectar, plant material, insects) will originate from countries within the European Union. At the time of writing this report, it is anticipated that no genetic resources or associated traditional knowledge (aTK) will be used by partners from countries (external to EU) with regulations on access and benefit-sharing (ABS). Material Transfer Agreements (MTAs) will be obtained for transferring biological material between partners and/or other providers, when necessary.

### 2.3 Use of Artificial Intelligence

PollinERA will utilise various machine learning tools (AI) for the development and testing of a variety of in silico models. However, the usage of AI is considered as posing ‘minimal or no’ risk to public safety or rights, since only toxicity data sets will be used. Furthermore, the specific purpose and modalities of AI use within PollinERA will not relate to important aspects of personal interest, such as recruitment, education, and healthcare or law enforcement.

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### 2.4 Human participants and protection of personal data

Human participants will be involved in the PollinERA project as part of its multi-actor and co-development approach, as well as Social Science and Humanities studies (e.g., participatory workshops). The involvement of selected individuals (adults) as part of these activities is not foreseen as having any adverse consequences for them. No physical injury, financial, social, or legal harm will be posed to the participants, and potential psychological risks will not exceed the daily life standard. However, engagement with individuals will entail the collection and processing of 'ordinary/general' personal data (e.g., contact details). Personal data will be collected from participants as (data subjects), in accordance with EU General Data Protection Regulation (GDPR) 2016/679 and ethical research protocols (e.g., legal basis/informed consent) in relation to processing and protection of personal data. Guiding principles and confirmations for human participation in project activities are outlined in this report, whilst protocols for protection of personal data will be detailed in the project's Data Management Plan.

### 3 List of abbreviations

ABS	Access and benefit sharing
AI	Artificial Intelligence
aTK	Traditional Knowledge associated with Genetic Resources
ESP	Ethics and Security Plan
EU	European Union
INC-PAS	Institute of Nature Conservation, Polish Academy of Sciences
MAT	Mutually agreed terms
MTA	Material Transfer Agreement
PIC	Prior Informed Consent
SLU	Swedish University of Agricultural Sciences
SSH	Social Science and Humanities
UJAG	Jagiellonian University
ULUND	Lund University
UNIBO	Bologna University

### 4 Animal studies

#### 4.1. Assessment of ethical and security issues

PollinERA will carry out laboratory effect tests to determine the vulnerability of a variety of pollinator species to pesticides, assessing the impact (lethal and sublethal) of multi-pesticide exposure. Additionally, PollinERA will involve the monitoring and collection of wild insect pollinators for laboratory species determination and pesticide residue screening and quantification. Hence, the PollinERA project will inevitably involve studies using a variety of pollinator arthropod species as model organisms (anticipated to be wild bees, hoverflies, butterflies, and moths). At the time of writing this report, study species have not been determined but they will be non-endangered arthropod species. Arthropods are not covered in the [European Union Directive 2010/63/EU on the protection of animals for scientific purposes \(EC, 2010\)](#), Article 1, §3. Tests will follow the highest experimental and safety protocols, as well as complying with all international, EU, and national health and safety laws and guidelines to ensure human and environmental safety. Laboratory and field work and testing will be conducted in Sweden, Italy, and Poland using the specialized facilities and resources of partners (ULUND, SLU, UNIBO, UJAG, and INC-PAS). No live animals will be imported or exported between partner countries, except the transfer of experimental data.

As animal studies in PollinERA will only involve arthropods, the use of test species for scientific purposes does not raise specific ethical issues. These animal studies will not require specific authorisations, training certificates or personal licenses related to animal experiments. The PollinERA consortium is fully aware of the importance of ethical consideration regarding the use of animals, as well as potential sensitivities regarding

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certain arthropod species and their use in animal studies (e.g. the inclusion of honey bees in the Norwegian Animal Welfare Act (10/07/2009))<sup>1</sup>.

### 4.2. Confirmations

The PollinERA consortium confirms that:

1. If relevant, copies of authorisations for animal experiments will be kept on file and submitted to the relevant competent authorities upon request.
2. If applicable, copies of training certificates/personal licenses of the staff involved in animal experiments will be kept on file.
3. Studies involving arthropods (e.g., honey bees) will be attentive towards adhering to the principles of the 3 R's (Replacement, Reduction, Refinement).

## 5 Use of genetic material

### 5.1 Assessment of ethical and security issues

The usage of biological material (genetic resources) as part of research studies is anticipated within PollinERA. Genetic resources/materials<sup>2</sup> (e.g. pollen, nectar, plant material, insects) used will originate from countries all within the European Union (e.g., Sweden has no specific legislation governing access to Swedish genetic resources). At the time of writing this report, it is anticipated that no genetic resources or associated traditional knowledge (aTK)<sup>3</sup> will be used by partners from countries (external to EU) with regulations on access and benefit-sharing (ABS). It is anticipated that consortium partners will not need informed consents and agreements under the Nagoya Protocol or [EU's ABS Regulation \(EU\) No 511/2014](#). However, genetic material samples are likely to be transferred between partners and/or other providers, and Material Transfer Agreements (MTAs) will be sought when needed.

### 5.2 Confirmations

The PollinERA consortium confirms that:

1. If relevant, partners will comply with the European Parliament and its compliance measures for genetic material users under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (also called the ABS Regulation).
2. When necessary, partners will demonstrate compliance with access legislation for countries from where resource/the knowledge originates and is regulated by the country, given its sovereign rights.
3. If applicable, partners will obtain prior informed consent (PIC) and establish mutually agreed terms (MAT) and by declaring due diligence in accordance with the ABS Regulation.

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<sup>1</sup> § 2. Scope: The Act applies to conditions which affect welfare of or respect for mammals, birds, reptiles, amphibians, fish, decapods, squid, octopi and honey bees.

<sup>2</sup> Genetic materials are considered to be any material of plant, animal, microbial or other origin containing functional units of heredity (genetic information) and genetic resources, genetic material of actual or potential value.

<sup>3</sup> Traditional knowledge possessed by indigenous peoples or local communities that is relevant for the use of the genetic resources.

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4. If relevant, partners will establish MTAs between partner institutes whenever biological/genetic material samples are transferred.
5. Partners will not utilise biological/genetic material from species covered by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and implemented through [EU Council Regulation \(EC\) No 338/97](#).

## 6 Use of Artificial Intelligence

### 6.1 Assessment of ethical and security issues

The development and testing of a variety of in silico models within PollinERA will rely on and exploit machine learning tools considered as AI (e.g., artificial neural networks and deep learning). However, these methodologies are considered as posing ‘minimal or no’ risk to public safety or rights, since only toxicity data sets will be used. Furthermore, the specific purpose and modalities of AI use within PollinERA will not relate to important aspects of personal interest, such as recruitment, education, and healthcare or law enforcement, as defined by proposed EU harmonised rules on artificial intelligence ([Artificial Intelligence Act](#)) but are restricted to identifying physiological linkages between pesticides and physiological responses in model organisms.

### 6.2 Confirmations

The PollinERA consortium confirms that:

1. Partners will not be developing AI systems that pose unacceptable risks or are considered a threat to people, that involve:
  - a. Cognitive behavioural manipulation of people or specific vulnerable groups.
  - b. Social scoring: classifying people based on behaviour, socio-economic status or personal characteristics
  - c. Biometric identification and categorisation of people
  - d. Real-time and remote biometric identification systems, such as facial recognition
2. Partners will not be developing high risk AI systems, that negatively affect safety or fundamental rights of EU citizens and institutions, and systems that may require registration in an EU database.
  - a. AI systems that are used in products falling under the EU’s product safety legislation.
  - b. AI systems within the following areas:
    - i. Management and operation of critical infrastructure
    - ii. Education and vocational training
    - iii. Employment, worker management and access to self-employment
    - iv. Access to and enjoyment of essential private services and public services and benefits
    - v. Law enforcement
    - vi. Migration, asylum, and border control management
    - vii. Assistance in legal interpretation and application of the law

## 7 Human participants and the protection of personal data

### 7.1 Assessment of ethical and security issues

PollinERA, as part of its multi-actor and co-development approach (WP5 and 6), as well as in the farmland pesticide and pollinator co-monitoring (WP4), will engage with target audience to ensure regulatory relevance of risk assessment methods, models, and acceptance of the integrative risk assessment approach developed as part of the project. These interactions will be facilitated with selected key national and European stakeholders, the External Advisory Board and related networks and communities, using a variety of engagement activities, for example: participatory workshops. The involvement of relevant target audience as part of these activities is not foreseen as having any adverse consequences for participants. No physical injury, financial, social, or legal harm will be posed to the participants, and potential psychological risks will not exceed the daily life standard. However, engagement with target audience will entail the collection and processing of personal data. Personal data will be collected from participants (as data subjects), and the ethical considerations related to the protection of personal data are raised and addressed in the following sections.

#### 7.1.1 Methods for human participation in SSH

The primary method for stakeholder participation and 'data collection' will be through workshops and a limited number of personal (face-to-face or online) interviews. These activities will be targeted stakeholder representatives of the project's two main user groups: namely 1) Risk assessors (in regulatory authorities and industry) - users of the tools and 2) Risk managers (at central EU level and national level). Workshops and personal interviews will only collect textual data/narratives covering a variety of topics related to ERA for pollinators.

Workshop and personal interviews will be audio recorded to allow for complete transcription of the narratives, i.e. converting audio-recordings to text for qualitative content analysis. Content analysis will be done using specialist qualitative data analysis software (NVivo) that is designed specifically for gaining insights from narratives and mixed-methods data. Audio-recordings will be destroyed following transcription. Transcripts will be stored in pseudonymised format on secured institutional servers as text files.

#### 7.1.2 Criteria for participation

Overall inclusion/exclusion criteria

- General inclusion criteria for participation in PollinERA Social Science and Humanities (SSH) research activities and in the pesticide and pollinator co-monitoring will be all participants (data subjects) are of adult age (over 18 years) and able to give informed consent. Specific inclusion criteria for SSH stakeholders are involved in Environmental Risk Assessment and associated activities by means of assuming an active role in e.g. associations, governmental or non-governmental organisations.
- No children/minors, vulnerable population groups, or individuals unable to provide informed consent will be involved.

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### 7.1.3 Informed consent procedures

Participants will be given written and oral information on the purpose and nature of research studies they participate in within PollinERA project. Informed consent will be obtained in written and/or electronic format (e.g., acceptance email) by providing all participants with informed consent forms and study information in the national language or English. The informed consent information will inform persons about the purpose, duration, and possible adverse events of the studies in a clear and unambiguous way.

Informed consent information will be clearly state to the participants that participation is voluntary, neither involving costs nor benefits, that refusal to participate will involve no penalty and that participants may withdraw from participation at any time without penalty, that the data obtained from the study will be pseudonymised and treated confidentially and that the participant's privacy will be protected. The informed consent form will also contain information about data protection, handling, and retention. If necessary (e.g., conducting quantitative surveys) ethical approval from relevant ethics review boards (ERB) will be sought to gain approval of informed consent (e.g. provision of participant information and informed consent forms).

PollinERA does not foresee any possible adverse effects from participating in its planned studies, nor stigmatization, discrimination, discomfort, or risk, nor possible incidental findings with an impact on the mental and physical health of the participants.

### 7.1.4 Personal Data and protection policies

PollinERA will only collect personal data from the involved human participants that are necessary to achieve the objectives of the research. These include contact and organisational details (role/responsibilities/experience/expertise), and primarily attitudinal (attitudes, beliefs, perceptions, opinions, and views) and behavioural (management, decision-making) characteristics, which will all exclusively relate to ERA and its context.

The collection of personal data will be limited to what is strictly necessary for the purposes of the research study for qualitative data analysis. Sensitive personal information relating e.g. to personal health, ethnicity, sexual lifestyle, political opinion, religious or philosophical conviction falls beyond the scope of PollinERA and will not be probed for.

It is not anticipated that confidential data, such as information on private businesses, sensitive business practices, finances or income will be collected from participants. However, data of this nature maybe provide by participants and indicated as confidential but nevertheless voluntarily provided. This information will be strictly treated as data given in confidence or data agreed to be kept confidential between the researchers and the participants. This data will be kept secret and out of the public domain. Any reporting based on these data will be done in aggregated and non-identifiable form only. This will be explained to the participants as part of the informed consent.

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We are not aware of and do not expect any critical ethical implications of the research results such as stigmatisation or adverse impacts on dignity, autonomy, integrity, privacy of persons.

After collection, data/transcripts will be pseudonymised, stored in a de-identified format, kept securely, and shared for study purposes and in dissemination activities only in pseudonymised or aggregated form. Transcriptions of workshops and interviews will not include the name(s) of participants. Similarly, field study site information will not include the name(s) of involved stakeholders. Instead, unique personal identifiers will be attributed to participants/stakeholders and used in the transcripts or with the quantitative data records. Personal identifiers and transcripts will be stored and secured separately. These will be retained for a period of 10 years scientific integrity reasons. Access to the personal identifiers will be strictly limited to the principal investigator of the consortium partner who facilitated the workshop, performed the interview or field site selection.

PollinERA research activities involving human participants and personal data have been designed following a risk-based approach. Taking into account appropriate technical and organisational measures to safeguard the rights and freedoms of the study participants and to protect the data, the activities have been defined as low-risk.

Based on general principles for SSH research and usage of personal data all researchers involved in PollinERA are asked to commit to work on trusted networks, to use trustworthy devices, and to protect their institutional accounts and associated login data in line with their institutional guidelines and data protection policies.

Participant data will only be stored on secure storage services, i.e. on password-protected central disk spaces/storage (such as personal disk space and shares at institutional level), external encrypted cloud services which are backed-up automatically and protected by institutional security systems. The use of personal data in paper or any other physical form (e.g. printed transcripts, non-digital images) will be kept in a secured areas (e.g., locked filing cabinet).

Access to personal data will be strictly limited to the researchers who are directly involved in the analysis of the concerned data. The principal researcher will ensure this data is password protected and communicate passwords in person or in encrypted format (not in written). Passwords will be changed at regular intervals. Access conditions will be arranged and agreed upon during project meetings and decisions included in the minutes of the meeting.

There will be no transfer of personal data from the EU to a non-EU country within PollinERA.

Further details are provided in the PollinERA Data Management Plan deliverable, which details principals for FAIR data and usage and protection of personal data in compliance with [EU General Data Protection Regulation \(GDPR\) 2016/679](#).

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### 7.2 Confirmations

The PollinERA consortium confirms that:

1. Copies of informed consent forms and information in English (and other languages as necessary) will be kept on file and made available upon request.
2. The privacy, rights, and personal data of participants in research will be protected in accordance with EU GDPR requirements.
3. It will follow requirements/process detailed in the PollinERA Data Management Plan (DMP). This document will ensure the collection, processing, and storage of personal data follows EU GDPR rules and research activities adhere to international guidelines for medical (e.g. Declaration of Helsinki) and social research (e.g. EC Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research, 2010), as well as Horizon Europe ethical standards.
4. The host institution of the project coordinator, Aarhus University (AU), will appoint a Data Protection Officer (DPO) and the contact details of the DPO will be made available to all data subjects involved in the research as part of the informed consent literature.



[www.pollinera-horizon.eu](http://www.pollinera-horizon.eu)

### Project partners



LUND  
UNIVERSITY



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