D2.4 GUIDELINES ON LEGAL AND ETHICAL ISSUES

Project: Monitoring of Environmental Practices for Sustainable Agriculture Supported by Earth Observation

Acronym: ENVISION

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 869366.

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1 Overview

In all EU Horizon projects, ethics and ethical compliance is an integral part of research. The ethical evaluation starts from the proposal phase and carries on throughout the project implementation. Ethical research conduct relative to the applicable legal framework is also significant for the quality and afterlife of research results.

Task 2.4 looks into the Ethical and privacy issues of the ENVISON project. This deliverable, D2.4 Guidelines on legal and ethical issues, will include the ethical considerations and legal restrictions of data used in ENVISION, as well as moral considerations regarding the use of human subjects in project activities. This task will be completed with D2.5 Privacy Risk Assessment for ENVISION, which will comprise a risk log that summarises the main identified privacy risks, to provide a secure and safe environment for collecting, sharing and consulting personal data.

The deliverable at hand presents in Chapter 2 the ethical and relevant legal framework to the ENVISION project. Moreover, in Chapter 3 an Analysis of ethical and legal restrictions of data and decision-making processes used in ENVISION is presented. Chapter 4 presents the guidelines on decision-making processes relevant to critical issues and finally, Chapter 5 examines the Considerations of post-project exploitation.

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2 Analysis of the ethical and legal framework

2.1 Ethical Issues in Research

Fundamental ethical principles apply to all scientific research and ethical issues may arise in all possible domains of scientific research. Ethics is strongly related to research, and researchers often face Ethics as a barrier in the progress of scientific research. Nonetheless, the boundaries set in research by ethical restrictions are there to safeguard the rigidity of research activities and strengthen the willingness of subjects to participate in a research protocol. The European Commission interprets research ethics into a collaborative and constructive process. Specifically for Horizon projects, researchers are asked to consider ethics at the conceptual stage of the proposal, resulting to the enhancement of the research quality.

Research ethics is of crucial importance in all scientific domains. Based on these basic principles, research ethics are constantly being adapted to specificities of various research domains by professional or academic associations (e.g., ESF INTERNAL CODE OF CONDUCT).

Amongst the Golden Rules of Ethical Research Conduct[1] relevant to the project research domain, the following must be ensured:

- Respect the integrity and dignity of persons.
- Follow the "Do no harm" principle. Any risks must be clearly communicated to the subjects involved.
- Recognise the rights of individuals to privacy, personal data protection and freedom of movement.
- Honour the requirement for informed consent and continuous dialogue with research subjects.
- Respect the principle of proportionality: not imposing more than is necessary on your subjects or going beyond stated objectives.
- Respect biodiversity and do not impose irreversible changes that threaten the environment or ecological balance.
- Build on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from your research must be considered.

2.2 Legal framework in ethics in H2020 projects

As mentioned earlier ethics is a high priority in EU funded research and all activities implemented in the Horizon 2020 framework must comply with ethical principles, as well as relevant national, EU and international legislation. The Lisbon Treaty (forming the constitutional basis of the EU) makes explicit reference to the Charter of Fundamental Rights[2] of the European Union. The Charter focuses on the right to the integrity of a person, protection of personal data and family life, as well as rights in the field of bio-ethics, academic freedom and freedom of scientific research:

1 https://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf
2 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0389:0403:en:PDF

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Article 3: Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular.
a. The free and informed consent of the person concerned, according to the persons.
b. The prohibition of eugenic practices, in particular those aiming at the selection of persons.
c. The prohibition on making the human body and its parts as such a source of financial gain.
d. The prohibition of the reproductive cloning of human beings.

Article 7 Respect for private and family life

Everyone has the right to respect for his or her private and family life, home and communications.

Article 8: Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

Article 13: Freedom of the arts and sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

The legislation regulating Horizon 2020, focuses on two types of ethics requirements relevant to the phases of:

- grant preparation
- the ongoing project

At the grant preparation phase the Regulation establishing Horizon 2020 (Regulation 1291/11-12-2013) defines the Ethical principles in Article 19:

Article 19 Ethical principles

1. All the research and innovation activities carried out under Horizon 2020 shall comply 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. Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.
2. Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.
3. The following fields of research shall not be financed: (a) research activity aiming at human cloning for reproductive purposes; (b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable; (c) research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
4. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.
5. The fields of research set out in paragraph 3 of this Article may be reviewed within the context of the interim evaluation set out in Article 32(3) in the light of scientific advances.

All ethics requirements due after the project start are automatically included in the grant agreement in the form of deliverables. These deliverables are known as 'ethics deliverables' and are placed in an automatically generated work package called 'ethics requirements'. ARTICLE 34 — ETHICS AND

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RESEARCH INTEGRITY included in the Grant Agreement describes a project's ethics requirements with details on the obligation to comply with ethical and research integrity principles, activities raising ethical issues, and the consequences of non-compliance.

Ethics fundamental principles of research integrity in H2020 projects

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- **accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

In addition to the applicable legislation, there are also several guidance documents related to ethics in EU research that should be followed by Horizon 2020 consortia and beneficiaries, such as the "European Code of Conduct for Research Integrity"[3], the "Ethics for researchers - Facilitating Research Excellence in FP7"[4] or "Horizon 2020 Guidance — How to complete your ethics self-assessment"[5], as well as **domain-specific guidance.**

To support the significance of ethics within the ENIVISION project the Executive Board has assigned the role of the Ethics Manager (EM) to Ms. Maroulla Schiza (ETAM), who will ensure that all activities such as the engagement of citizens and local actors, as well as the use of data, are conducted in an ethical manner, and take into account sex and gender considerations.

2.3 Legal framework on data used in ENVISION

The data that will be handled within the project can be categorized into two basic domains: heterogeneous types of available data (EO-based, in situ, open data, and historical on-field check data) and Personal Data.

- **Open Data**

The Open Data Directive' (Directive (EU) 2019/1024) entered into force on 16 July 2019. It is built around two main pillars, transparency and fair competition. The goal of this Directive is to:

- stimulate the publishing of dynamic data and the uptake of Application Programme Interfaces (APIs).
- reduce the exceptions which allow public bodies to charge more than the marginal costs of dissemination for the re-use of their data.
- broaden the Directive's scope to:
    - data held by public undertakings, under a specific set of rules. The Directive will apply to data which the undertakings make available for re-use;

3 https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf

4 https://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf

5 https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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- research data resulting from public funding – Member States will be asked to develop policies for open access to publicly funded research data. New rules will also facilitate the re-usability of research data that is already contained in open repositories.
- strengthen the transparency requirements for public–private agreements involving public sector information, avoiding exclusive arrangements.[6]

Member States have to transpose Directive (EU) 2019/1024 by 16 July 2021. At the moment the EU Member States have implemented the rules of the Public Sector Information (PSI) directive (Directive 2003/98/EC) that was amended by the Directive 2013/37/EU.

- **Personal Data**

The EU Legislation on the protection of Personal Data is governed by the following legislative documents:

- Regulation (EU) 2016/679 - General Data Protection Regulation (GDPR)
- Directive (EU) 2016/680 on the protection of natural persons regarding processing of personal data connected with criminal offences or the execution of criminal penalties, and on the free movement of such data
- Regulation (EU) 2018/1725 on the protection of natural persons regarding the processing of personal data by the EU institutions, bodies, offices and agencies
- Guidelines on Transparency under Regulation 2016/679 (wp260rev.01)
- Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679 (wp251rev.01)
- Guidelines on Personal data breach notification under Regulation 2016/679 (wp250rev.01)
- Guidelines on Consent under Regulation 2016/679 (wp259rev.01)
- Guidelines on the application and setting of administrative fines (wp253).
- Guidelines on the Lead Supervisory Authority (wp244rev.01)
- Guidelines on Data Protection Officers ('DPOs') (wp243rev.01)
- Guidelines on the right to "data portability" (wp242rev.01)
- Guidelines on Data Protection Impact Assessment (DPIA) (wp248rev.01)

- **National Implementation in Consortium countries**

The GDPR has been effective on a European level since the 25th of May 2018 and EU countries were required to implement it in the National Legislation. The status of the GDPR in the Consortium countries is presented in the following[7]:

BELGIUM

Law: Act of 30 July 2018 on the Protection of Natural Persons with Regard to the Processing of Personal Data

6 https://digital-strategy.ec.europa.eu/en/policies/open-data
7 https://www.dataguidance.com/

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Summary: The Act of 30 July 2018 on the Protection of Natural Persons with Regard to the Processing of Personal Data ('the GDPR Implementing Law') incorporates elements of the GDPR that allow for Member State specifications or restrictions.

CYPRUS

Law: Law 125(I) of 2018 Providing For The Protection of Natural Persons with respect to the Processing of Personal Data and for the Free Movement of Such Data

Summary: Law 125(I) entered into force on 31 July 2018 and implemented certain provisions of the General Data Protection Regulation. To ensure the proper application of the GDPR, Cyprus has adopted certain guidelines issued by the Article 29 Working Party ('WP29') and has also issued its own guidelines and opinions.

GREECE

Law: Law 4624/2019 on the Personal Data Protection Authority, Implementing the General Data Protection Regulation (Regulation (EU) 2016/679) and Transposing into National Law Data Protection Directive with Respect to Law Enforcement (Directive (EU) 2016/680) and Other Provisions.

Summary: The Law 4624/2019 and Law 3471/2006 on the Protection of Personal Data and Privacy in the Electronic Telecommunications Sector and Amendment of Law 2472/1997, governing amongst others cookies and other trackers, are the main pieces of the data privacy legislation in Greece.

LITHUANIA

Law: Law No XIII-1426 of 30 June 2018 amending Law No I-1374

Summary: Lithuania implemented the GDPR through Law No XIII-1426. The Lithuanian DPA has also published several guidelines addressing among others biometric data, the processing of personal data in the context of debt collection, as well as security measures and risk assessments.

SERBIA

Law: Law on Protection of Personal Data (Official Gazette of the Republic of Serbia, No. 87/2018 (9-11-2018).

Summary: The main piece of legislation currently regulating personal data protection in the Republic of Serbia is the Law on Protection of Personal Data. The Law except for certain provisions stemming from the fact that Serbia is not a member of the EU has fully implemented GDPR rules. In addition Serbian data protection legislation includes several by-laws and guidelines.

SLOVENIA

Law: The Personal Data Protection Act 2004 is presently enforced. Slovenia has not yet adopted the new Personal Data Protection Act.

Summary: Slovenia is the only remaining EU Member State that has yet to implement the GDPR. The Draft Act is currently progressing through the legislative procedure but there is no set date for its passage in the National Assembly.

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UK
Law: The Data Protection Act 2018
Summary: The UK data protection regime is regulated by the Data Protection Act 2018 and the GDPR has been written into UK law and tailored to become the 'UK GDPR.'

2.4 Ethics and morals regarding the use of human subjects in project activities

There is a strong connection between research ethics and human rights. Both fields influence each other and there are significant overlaps. Data protection poses a central role in research ethics in Europe, and it is at the same time a fundamental human right. Data privacy is linked to autonomy and human dignity. In today's information society, data privacy must be thoroughly protected by the research community.

A major area of concern in this area is gender equality. An extensive assessment on gender considerations and situation analysis, presenting the relevant legal framework of the ENVISION project was presented on D2.3 Gender Situation Analysis and Needs Assessment.

Regarding the human subjects participating in project activities (i.e., Paying Authorities, Certification Bodies, farmers) informed consent is the cornerstone of research ethics. Research participants should analytically be informed on the research methodology and objectives. Additionally, specifics on their participation and any risks that may be involved are to be presented to them. Once the aforementioned are clear to the participants, the researchers should seek participants' consent to take part in the project (Articles 4(11) and 7 GDPR).[8]

Finally, ethics and morals in research practices are based on fundamental principles of research integrity and are provided by relative Codes of Conduct. Codes of Conduct guide researchers in their work as well as in their engagement with the practical, ethical, and intellectual challenges arising in research projects. According to the ***European Code of Conduct for Research Integrity*** these principles are:

- Reliability in ensuring the quality of research reflected in the design, the methodology, the analysis, and the use of resources.
- Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.
- Respect for colleagues, research participants, society, ecosystems, cultural heritage, and the environment.
- Accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and its wider impacts[9].

8 https://ec.europa.eu/info/sites/info/files/5._h2020_ethics_and_data_protection_0.pdf
9 https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf

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3 Ethical and legal restrictions of data and decision-making processes used in ENVISION.

Research projects involving personal data processing need to focus particularly on the following categories of data that may raise ethics risks:

- Processing of 'special categories' of personal data (formerly known as 'sensitive data');
- Processing of personal data concerning children, vulnerable people or people who have not given their consent to participate in the research;
- complex processing operations and/or the processing of personal data on a large scale and/or systematic monitoring of a publicly accessible area on a large scale;
- data processing techniques that are invasive and deemed to pose a risk to the rights and freedoms of research participants, or techniques that are vulnerable to misuse; and
- collecting data outside the EU or transferring personal data collected in the EU to entities in non-EU countries.

According to the Data Management Plan, the ENVISION project handles the following types of Data presented in Table 1.

Table 1: Ethical / Legal restrictions per Work Package (WP)

WP	Types of data	Ethical / Legal Restrictions
WP1	Personal data of consortium	GDPR
WP2	Personal data of users & consortium	GDPR
WP3	Farmers' data personal data, declaration, farm information EO Data Vector Data Laboratory Analyses	GDPR Open data Legal licenses
WP4	Personal data of users Testing procedures related data EO Data Vector Data	GDPR Open data Legal licenses
WP5	Personal data of users	GDPR
WP6	Foreground knowledge	Consortium Agreement
WP 7	Personal data of users & consortium	GDPR

All data produced in the project will be available to the consortium throughout its lifetime. Appropriate licensing agreements will be required for data reuse after the project's conclusion, which will be defined through the business model report during the course of the project.

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The Ethical and legal issues concerning the Project are summarised below:

1. **Protection of personal data**

The Project involves personal data collection and/or processing. The data will be collected for internal use in the project, and not intended for long-term preservation. No personal information will be kept after the end of the project. Furthermore, the Consortium partners handling personal data pay special attention to security and respect the privacy and confidentiality of the users' personal data by fully complying with the applicable national, European, and international framework, and the European Union's GDPR 2016/679.

Even though the participation is voluntary, informed consent will be sought from each individual user before his or her data is even stored. All data subjects are adults and therefore no issues on handling data of children are raised.

In addition, the Privacy Risk Assessment will be carried out in the frames of D2.5 Privacy Risk Assessment for ENVISION.

2. **Collection and/or processing of personal sensitive data**

Processing of 'special categories' of personal data takes place in WP2, and specifically for the elaboration of the Gender Situation Analysis and Needs Assessment and concerns the consortium's personal data.

Specific instructions were presented to the consortium to deliver data in an anonymized form (i.e., Partner X, Team Member X). These were not stored, and were used for statistical purposes. The data produced by the input provided cannot divulge the personal information of a specific member of the Consortium. Additionally, the collection of data has also received ethical clearance from the Information Security Officer that had been appointed.

Financial – Property data of farmers also may fall in this category, but it will be determined in cooperation with the DPOs of the partners involved in the upcoming deliverable (D2.5).

3. **Procedures for data collection, storage, protection, retention and destruction**

The general framework by which data collection, storage, protection, retention and destruction is performed by Partners complies with their national and GDPR.

The ENVISION consortium will provide precise information on what type of personal data they process, how it is processed and which data-flows they enable. Owners of personal data will be able to withdraw their consent for processing their personal data. All partners carry out a personal information assessment in their own context concerning their own collection, storage and/or processing of personal data, prior to the collection of personal data in the frames of the project. They additionally take measures that assure information systems safety. Each partner is liable for inappropriate security at its own premises.

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In terms of data retention and destruction, data will be deleted or fully anonymised as soon as the relevant purpose as stated in the DoA is fulfilled. Regarding data processing, the collected data will be immediately pseudonymised and aggregated, and the original data will not be stored whatsoever. Furthermore, ENVISION has prepared a "Personal Data Protection Policy" and "Terms and Conditions" documents, in order to inform the users of the purposes of data collection.

4. Non-EU countries

The ethical standards, guidelines of Horizon2020, and the European Union's General Data Protection Regulation 2016/679 will be rigorously applied, and the data transfer will comply with the legislation of the country in which the data was collected. Note that as previously mentioned Serbia and the UK – partner countries outside the EU- are already compliant with the GDPR.

5. Gender issues

Gender equality has been established in the consortium and gender considerations have been analytically presented in the relative deliverable (D2.4 Gender Situation Analysis and Needs Assessment).

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4 Guidelines on decision-making processes relevant to critical issues

The aim of this chapter is to produce guidelines for project partners for safeguarding decision-making processes relevant to critical issues for project development (e.g., recruitment of research participants, ensuring privacy and protection of personal information, use of existing data including public data, etc.). The EU through the Horizon Guidance on ethics self-assessment.[10], provides guidelines on project self-assessment. These guidelines will be utilized to evaluate the prevalence of critical ethical issues within the project and the guidelines on their proper management. This process can be repeated when new issues arise within the consortium to evaluate their significance.

- **PROTECTION OF PERSONAL DATA**

The assessment of critical data can be evaluated using the following questions:

PROTECTION OF PERSONAL DATA	YES	NO
Does ENVISION involve the processing of special categories of personal data (e.g., genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)?		
Does ENVISION involve processing of genetic, biometric or health data?		
Does the project involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing (such as, tracking, surveillance, audio and video recording, geolocation tracking etc.) or any other data processing operation that may result in high risk to the rights and freedoms of the research participants?		
Does research involve further processing of previously collected personal data?		
Does research involve publicly available data?		
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved		
Is it planned to import personal data from non-EU countries into the EU? Specify the type of personal data and countries involved		

The critical issues that arise in the ENVISION project are presented, and proposed actions are analysed in the following:

a. <u>Special categories of personal data</u>

Apart from the data gathered for the gender related deliverable previously mentioned (D2.3), financial data fall in the special categories of personal data. Partners that will handle farmers' declarations and property data need to evaluate:

- ✓ technical and organisational measures to safeguard the rights of the research participants (i.e. firewall, encryption, assign a DPO),
- ✓ security measures to prevent unauthorised access to personal data (i.e. assign access rights, use strong codes, secure physical and network areas),

10 https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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- ✓ data collected are relevant and limited to the purposes of the project ('data minimisation' principle),
- ✓ use anonymisation/pseudonymisation techniques.

Necessary documents: Consent forms, Privacy Policy, Copies of ethics approvals

b. Intrusive methods of data processing (such as, tracking, surveillance, audio and video recording, geolocation tracking etc.)

Intrusive methods of data processing need to be assessed over the project implementation. Data feeding on the platform by users might be considered as an intrusive method. Audio and video recordings are also considered as such.
The projects DPO, as well as the involved partner's DPO, need to be advised in this case.

c. Import personal data from non-EU countries into the EU

Personal data may be imported by non-EU countries either via the business case planning or the lighthouse customers related tasks. Additionally, any personal data collected by the Serbian and UK partners transferred within the consortium is also considered a data transfer (non-EU countries).
A declaration confirming the compliance with the laws of the country in which the data was collected will be needed.

Necessary documents: Consent forms, Privacy Policy, GDPR compliance declaration.

- **ENVIRONMENT**

When assessing ethics, it needs to be considered that research may also adversely impact the environment. This may be due to the experimental design of the research itself or undesirable side-effects of the technologies used. According to the self-assessment toolkit, no issues regarding the environment arise.

ENVIRONMENT	YES	NO
Does research involve the use of elements that may cause harm to the environment, to animals or plants?		
Does research deal with endangered fauna and/or flora /protected areas?		

- **HEALTH & SAFETY**

The health and safety of all research participants, either as subjects, researchers or third parties is also of ethical consideration. Risks to researcher safety are according to the nature of the topic of investigation and the research site. Failure to conform to health and safety procedures may lead to physical or psychological harm.

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HEALTH AND SAFETY	YES	NO
Does ENVISION research involve the use of elements that may cause harm to humans, including research staff?		

The goal of ENVISION is to exploit the wealth of data made available to achieve remote field monitoring and will contribute to the minimization of possible health and safety hazards that on site visits may pertain. All partners of the consortium are making sure to ensure Health and Safety conditions within their facilities. Special Covid-19 precautions as per national legislation apply within the Consortium.

- **POTENTIAL MISUSE OF RESEARCH RESULTS**

Misuse of research results concerns research that its results could be misused for unethical purposes with the potential to harm humans, animals, or the environment.

MISUSE	YES	NO
Does ENVISION research have a potential for misuse of research results?		

Data collected apart from personal data does not have a potential for misuse. Personal data are safeguarded by the processes followed described in the previous chapter (i.e., anonymisation, access rights etc.). Risks associated with personal data will be assessed in the relative deliverable (D2.5).

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5 Considerations of post-project exploitation

Research depending on its objectives involves materials, methods or technologies and in any case, generates knowledge. Research results though could be misused for unethical purposes, having the potential to harm humans, animals, or the environment[11]. The risk of misuse of research results cannot be eliminated, but it can be minimised by timely identifying risks and identifying appropriate mitigation measures. H2020 projects have the obligation to minimize such misuse and comply with international, EU and national legislation on concerns about potential inappropriate exploitation of results. Under the Grant Agreement, a breach in such obligations will cause a grant reduction or termination.

To this end, the next deliverable of this task (D2.5: Privacy Risk Assessment for ENVISION) will tackle the minimization of such risk given that result misuse in ENISION is strongly related to misuse of personal data.

As analytically presented in the Data Management Plan (D1.3) partners and their staff members are responsible for the care of the data management in their charge and under their control. Records of these assets are safely kept, and staff may be required to answer for those in their care, which must not be used for any unauthorised non-related to the project purpose or for personal gain. Additionally, staff must not divulge any confidential information to any individual or external organisation. This stands for all non-publicly available ones. Specific restrictions stand for data that contain sensitive information and should be anonymized following the GDPR rules.

Another aspect of ethical considerations is relevant to data that can be reusable, and results produced within the frames of the project. In the case of ENVISION, post-project exploitation refers to the project assets and misuse may be related to IP rights.

Intellectual Property (IP) is defined as a property category of intangible creations of the human intellect. Intellectual Property Rights (IPRs) are a business asset and as such, they should be considered as a powerful tool for exploitation. The most common types of IP[12] may be categorized[13] as follows:

- Trademarks: Marks the origin of products
- Patents: Rights granted for inventions, that are either products or a process that offer new technical solutions
- Designs: Protection rights of the external appearance of the product.
- Copyrights: Related to artwork and audiovisual creations, as well as scientific works

IP is a fundamental component of the project's knowledge management. The exploitation of research results demands additional and often substantial investments. In order to safeguard IP rights of research organizations and companies, it is important to protect them with intellectual property rules. [14]

11 https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/guide_research-misuse_en.pdf
12 http://www.iprhelpdesk.eu/
13 https://www.wipo.int/
14 European IPR Helpdesk, Fact Sheet IP management in Horizon 2020: at the proposal stage, February 2014

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According to the Grant Agreement, all ENVISION partners have agreed to manage IPRs in line with general Commission policies regarding ownership, exploitation rights and confidentiality as described in detail in SECTION 3 of the Grant Agreement "RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS". Universities or other public research organisations that are part of the Consortium must also take measures to implement the principles set out in the Code of Practice, annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities (Points 1 and 2). The basis for IPR management was agreed to be the following[15]:

- Background knowledge: any data, know-how or information (tangible or intangible), including intellectual property rights, is held by the beneficiaries before they acceded to the Agreement, and needed to implement the action or exploit the results. All consortium partners will bring in their expertise and knowledge and will retain full ownership of the IPR of this expertise and knowledge. The beneficiaries must identify and agree (in writing) on the background for the action ('agreement on background'). The beneficiaries will provide each other access, under fair and reasonable conditions (including possible financial terms or royalty-free conditions) to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).
- Foreground knowledge / Results: all newly developed expertise, knowledge and technologies will be owned by the participant(s) in the project that were involved in the development of this specific expertise/technology/methodology. In case several participants have jointly carried out work generating foreground and where their respective share of the work cannot be ascertained, they shall have joint ownership of such foreground. Results are owned by the beneficiary that generates them. Two or more beneficiaries own results jointly if they have jointly generated them and if it is not possible to establish the respective contribution of each beneficiary, or separate them for the purpose of applying for, obtaining or maintaining their protection. Depending on the business strategies of the partners involved, they shall establish appropriate agreements.

ENVISION partners defined in the Consortium Agreement (CA) the background knowledge they brought into the project. Background knowledge offered by specific partners is analytically presented in Attachment 1 of the CA. In line with the CA, all IP (both background and foreground) within the context of ENVISION will be managed under the framework of WP6 - Commercialization and exploitation. Specifically, IPRs will be defined through Task 6.2 Business plan development aiming to serve as a guide for exploitation of the project's results and market uptake onto other EU countries, considering relative legislation.

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