

# Ethics Management Plan

## Introduction to DOME Ethical aspects

The DOME solution raises Ethics issues regarding three different aspects:

1. Involvement of human participants;
2. Processing of personal data; and
3. Use of Artificial Intelligence (AI).

## Involvement of Human Participants

The involvement of human participants in the DOME activities is very limited, and regards the participation of adult volunteers, capable of providing a valid (informed) consent to their participation to DOME, in requirements assessment and feedback consultations and surveys, and similar tasks. As such, their participation does not require any kind of authorization by Ethics authorities or committees, and is allowed from an Ethical, personal and fundamental rights viewpoint provided that they receive an adequate information sheet, customised to the specific activity in which they are involved, and sign a proper informed consent form.

Requirements, needs, and feedback will be collected mainly from the stakeholders members of the Consortium, most of all in the first phases; therefore, their participation in those tasks is part of their contribution to the solution implementation, and is covered by the project Agreements and internal policies. However, additional information could be collected also by external stakeholders and users.

External stakeholders' personal data will be processed following the rules and procedures described in the DOME Data Management Plan and connected procedures.

### a) Criteria and procedures to identify and recruit external participants

The DOME Consortium is committed to complying with ethical principles and applicable international, EU and national law. The Consortium ensures respect for people and for human dignity, protecting the values, rights and interests of the research participants and avoiding any bias.

The responsibility for recruiting research participants ethically lies with the DOME task leaders undertaking the task. Task leaders can approach the PEO and the internal Ethics Helpdesk for advice and assistance during the selection process.

The partners will advertise the DOME activities in an open and transparent manner to recruit the volunteer stakeholders. In practical terms, this will likely involve, but is not limited to: participation to events, workshops and conferences; announcements / adverts through established communications channels (e.g. circular emails); meetings offering an opportunity for Q&A with DOME partners; and direct engagement based on knowledge from existing networks, whether through email or phone.

When conducting any surveys, questionnaires, workshops or webinars where personal information is gathered and stored, the partners will pay attention to privacy, data protection, and data management. External stakeholders' personal data will be processed following the rules and procedures described in the DOME Data Management Plan and connected procedures.

### b) Informed Consent Procedures

Informed Consent is a voluntary agreement to participate in specific DOME activities such as workshops, interviews, and surveys, based upon an informed and free decision. Informed consent will be sought in DOME from all external human participants involved in the tasks and activities, as collection of feedback. Regarding partners' staff directly working on DOME (as e.g. staff from organisations/companies member of the DOME Consortium), it is not necessary to seek additional informed consent since their participation is already included in their contractual obligations, and they are fully aware of DOME, its goals, and the activities to be carried out.

Obtaining consent involves first informing the research participants about their rights, the purpose of the project, the procedures that will occur, and the potential risks and benefits of participation.

Before requesting consent, the staff in charge of the activity must make sure that the potential participant has received written and, as appropriate, verbal information. This information must be provided in such a way that the potential participant understands the contents. This means drafting the DOME information sheet in accessible language. The Consortium partners' staff will assure that the participants will have the opportunity to ask questions about DOME and receive detailed and appropriate answers.

Human participants will be provided with adequate information on DOME and their involvement in it. In order to help partners in this process, a DOME Information Sheet and a Consent Form template for partners to give to external participants involved in DOME will be provided. The templates can be adjusted and customised if necessary and appropriate.

The participants will be informed that their personal data will remain confidential and properly protected. Informed consent for participation must be signed, dated and kept on file.

The consent of the data subject is one of the available legal grounds for the processing of personal data under the General Data Protection Regulation (Regulation (EU) 2016/679) GDPR, Article 6.

As such, informed consent for human participation in DOME activities overlaps with, but is distinct from, consent for the processing of personal data. In many cases, participating in a DOME activity will also involve the processing of personal data (for example, processing names and contact details to arrange a workshop or technology testing). However, these two consent requirements are conceptually and legally distinct. Owing to the mentioned significant conceptual overlapping, it is usually clearer and more practical if these two types of informed consent are dealt with together within the same information sheet and informed consent form.

"Consent" under the GDPR, Article 4 is defined as "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her".

For consent to the processing of personal data to be "informed", the data subject must similarly be provided with detailed information about the envisaged data processing in an intelligible and easily accessible form, using clear and plain language.

The Article 7 of the GDPR indicates the exact conditions required for a valid consent:

1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.
2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.
3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.
4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.

The informed consent should also include the prior provision of information to the data subject on the data subject's rights as guaranteed by the GDPR and the EU Charter of Fundamental Rights, in particular the right to withdraw consent or access their data, the procedures to follow should they wish to do so, and so forth.

As required by the Article 13 GDPR, the information sheet accompanying the informed consent form should contain in an accessible way information on the following data subject rights:

- The right of access by the data subject (Article 15 GDPR);
- The right to rectification (Article 16 GDPR);
- The right to erasure ("right to be forgotten"), including the withdrawal of consent (Article 17 GDPR);
- The right to restrict the processing (Article 18 GDPR);
- The right to data portability (Article 20 GDPR);
- The right to lodge a complaint with a supervisory authority (Article 57 GDPR).
- Use of Artificial Intelligence

In the development of all AI DOME models, partners fully respect and comply with rules, regulation and recommendations regarding the use and implementation of AI tools, first of all specifying the process for how each model will be evaluated within DOME and therefore the method for ascertaining whether it is able to justify the results.

Specific attention will be given to data processing, since data, and usually personal data, are a key ingredient for AI. The Article 22 of the GDPR explicitly prohibits decisions affecting a data subject solely based on automated decision-making, unless authorised by a Union or Member State law with suitable safeguards (Article 22(2)(b)) or by explicit consent (Article 22(2)(c)). Data subjects also have the right in such cases to obtain from the data controller under Article 14 of the GDPR, "meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject". Of course, other important aspects of AI linked to other regulations beyond the protection of personal data will be taken into consideration as well in subsequent versions of this document.

A detailed analysis and description of the rules, legal basis, principles, procedures, and methodologies through which Ethics issues related to AI will be addressed in DOME is provided in next Subsection.

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