INTERMODEL EU

Simulation using Building Information Modelling Methodology of Multimodal, Multipurpose and Multiproduct Freight Railway Terminal Infrastructures

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D10.2 – POPD – Requirement No. 2
Protection of Personal Data Requirements

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Statement of originality:

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Executive Summary

This deliverable provides information on the H - Requirement No. 2, concerning protection of personal data requirements according to the current applicable international, EU and national law.

However, in accordance to the nature of the research carried out under the INTERMODEL EU project, human participants are not required.

In the case where the consortium could consider to gather the opinion of human experts, the information will be collected in a completely anonymous way, as established in the Data Management Plan and those experts will be part of the consortium members / stakeholders which already have their own procedures for data protection.

If the opinion of external experts or potential users is needed in the future, the information will be also collected in an anonymous way complying with EC directives and national regulations regarding POPD.

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1. Introduction

1.1 Scope

The scope of this document is to present the informed consent procedures that must be implemented before the start of relevant research.

It is important to point out that the research carried out under INTERMODEL EU project does not imply the process of personal data. However, a consent form and information sheet will be provided to all individuals who will participate in the case of studies before giving their consent.

1.2 Audience

The intended audience of this document is the INTERMODEL Consortium.

1.3 Definitions / Glossary

The main terms used in this deliverable are described as follows:

POPD – Requirement: Details on the procedures and criteria that will be used for the protection of personal data must be provided**.**

1.4 Abbreviations

The abbreviations used in the present document are:

GA: Grant Agreement

POPD: Protection Of Personal Data

REA: Research Executive Agency

1.5 Structure

- **Introduction:** contains an overview of this document, providing its Scope, Audience, and Structure.
- **Project information**: contains a description of the ethics requirements that the project should comply with and the type of information to be managed.
- **Conclusions**: gathers the main issues concerning POPD requirements.
- **Appendix I**: which includes the consent and complaint forms.

2. Project Information

In accordance with the information related to the ethics requirements of the INTERMODEL EU project, regarding the ethical report to be submitted in the sixth month, it is appropriate to set up a framework, if necessary, regarding the scope and the subject of this specific activity. First, it is necessary to bear in mind that the general relevant principles are, on one hand, those of ethics nature and, on the other hand, those following the application of international, European and National laws. Second, the Project Grant Agreement, which regulates and defines the project activities, contains a list of ethics requirements that represent relevant operative criteria.

However, it should be pointed out that INTERMODEL EU project does not involve research including human participation. And the type of data that will be collected for the research carried out throughout the project is related to terminals such as volumes, modal splits, equipment, etc.

The issues related to ethics within the project were categorized according to a scheme – based on different characteristics identified – which is referred as 'Ethics requirements'.

Specifically, the criteria on the basis of which the ethical verification must be carried out and formulated is focused on:

a) Evaluation of the detailed information provided about the procedures used for data collection, for data storage, for data protection, for the eventual elimination of data collected, always checking that the data processing complies to the national legislation of the individual countries in which the data is collected and processed, together with the European Union legislation;

b) Evaluation of detailed information to be provided in relation to the informed consent procedures;

c) Adoption of informed consent procedures and their actual implementation;

d) Verification of the communication of the details on types of treatment of sensitive data;

e) Presence of specific authorization given through the informed consent procedures to collect and process personal data;

f) Anticipation of the submission to the REA of the authorizations of the approval of the competent authorities, which concern individual ethical issues different from the collection of personal data;

g) Designation, if required, of an external independent Ethics Advisor, appointed to oversee the potential ethical concerns involved in the research;

h) Adoption of models for the collection of informed consent as well as information sheets that should have a language and terms that are easily understood by the participants in the research.

2.1 POPD – Requirements

2.1.1 POPD – Requirements n.1

Ethics requirement description

Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.

Verification of the activities carried out by partners

Data management is described in deliverable D14.1 'Data management plan', which includes standards and methodology for data collection, storage and preservation.

In case that external opinion is needed, candidates will be informed that their personal details will be incorporated into a file owned by IDP Ingeniería y Arquitectura, with the aim of carrying out the study, guaranteeing rights of access, rectification, cancellation and opposition.

A unique identifier will be assigned for each expert, in a way that any opinion kept for its treatment will be anonymised, because personal details will not appear and the relation with the user identifier will have restricted access.

The anonymised information will be introduced into and treated in an automated data file belonging to IDP Ingenieria y Arquitectura Iberia, S.L., properly enrolled before the Data Protection Spanish Agency. Such data will be confidential and IDP will be responsible for the file and will be located at Avda. Francesc Macià 60, 3rd floor, Torre Mil·lennium building, 08208 Sabadell, Barcelona, Spain. The access restriction policy will be defined by the designated Data Protection Officer.

2.1.2 POPD – Requirements n.2

Ethics requirement description

Detailed information must be provided on the informed consent procedures that will be implemented.

Verification of the activities carried out by partners

No questionnaires or surveys on sensitive personal data will be carried out. Thus, as the data handled will be related to design and operation of intermodal terminals/hinterland mobility/railway connection between different terminals, it is concluded that the project does not require the definition of consent procedures.

In the case where the consortium could consider to gather the opinion of human experts, the information will be collected in a completely anonymous way, as established in the Data Management Plan and those experts will be part of the consortium members / stakeholders which already have their own procedures for data protection.

If the opinion of external experts or potential users is needed in the future, the information will be also collected in an anonymous way complying with EC directives and national regulations regarding POPD.

In accordance with the current legislation, candidates will be informed that their personal details will be incorporated into a file owned by IDP Ingeniería y Arquitectura, with the aim of carrying out the study, guaranteeing rights of access, rectification, cancellation and opposition.

Experts selected will be informed through their email address, and they will receive the consent form for their participation in the study, which will be subject to data protection rules and guarantees. The Consent form is included in Appendix I as well as the Participant Complaints form.

2.1.3 POPD – Requirements n.3

Ethics requirement description

Justification must be given in case of collection and/or processing of personal sensitive data.

Verification of the activities carried out by partners

As explained in deliverables D10.1 'H – Requirements' and D14.1 'Data management plan', no personal sensitive data is expected to be collected. The only personal information collected will be essential information to contact with the external expert, if necessary. Contact details will be given a unique identifier, in a way that data will be anonymised.

2.1.4 POPD – Requirements n.4

Ethics requirement description

Copies of ethical approvals for the collection of personal data by the competent National Data Protection Authority must be submitted to the REA.

Verification of the activities carried out by partners

In case opinion from external experts is required, the anonymised information will be introduced into and treated in an automated data file belonging to IDP Ingenieria y Arquitectura Iberia, S.L., properly enrolled before the Data Protection Spanish Agency. Such data will be confidential and IDP will be responsible for the file and will be located at Avda. Francesc Macià 60, 3rd floor, Torre Mil·lennium building, 08208 Sabadell, Barcelona, Spain. The access restriction policy will be defined by the designated Data Protection Officer.

2.1.5 POPD – Requirements n.5

Ethics requirement description

Templates of the informed consent forms and information sheet must be submitted.

Verification of the activities carried out by partners

As already abovementioned, a template of the informed consent form and information sheet is included in Appendix I.

2.1.6 POPD – Requirements n.6

Ethics requirement description

An external independent Ethics Advisor must be appointed to oversee the ethical concerns involved in this research. A report by an Ethics Advisor must be submitted to the REA with the financial reports.

Verification of the activities carried out by partners

There is no need for an external independent Ethics Advisor appointed to oversee the potential ethical concerns involved in the research, as the data collected will not include any sensitive personal data.

3. Conclusions

Data collected throughout the project does not include any type of sensitive personal data, and will be provided by some of the partners within the Consortium according to the GA.

In the case where the consortium could consider to gather the opinion of human experts, the information will be collected in a completely anonymous way, as established in the Data Management Plan and those experts will be part of the consortium members / stakeholders which already have their own procedures for data protection.

If the opinion of external experts or potential users is needed in the future, the information will be also collected in an anonymous way complying with EC directives and national regulations regarding POPD.

References

D(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.

D 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Appendix I

- Consent to Participate in a Research Study within the INTERMODEL EU Project
- Research participant complaint form

Consent to Participate in a Research Study within the INTERMODEL EU Project

Title of Study: _____

Stakeholders:

Name: _____ **Dept:** _____ **Phone:** _____

Name: _____ **Dept:** _____ **Phone:** _____

Name: _____ **Dept:** _____ **Phone:** _____

[*sample text in brackets*]

Introduction

- You are being asked to be in a research study of [*general statement about the specific study within the INTERMODEL EU Project*].
- You were selected as a possible participant because [*how subject was identified will be explained, including any exclusionary criteria*].
- We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Purpose of Study

- The purpose of the study is [*research question and purpose in lay language will be explained*].
- Ultimately, this research may be [*published as part of a deliverable within the INTERMODEL EU Project, scientific paper/publication, etc.*].

Description of the Study Procedures

- If you agree to be in this study, you will be asked to do the following things: [*procedures and tasks will be explained; identification of any procedures that are experimental; description of length of time for participation, frequency and duration of procedures; etc*.]

Risks/Discomforts of Being in this Study

- There are no reasonable foreseeable (or expected) risks. There may be unknown risks.

Benefits of Being in the Study

- The benefits of participation are [*explanation of benefits of participation that will be gained by the participants and/or other. If a benefit is not likely to occur to each participant this section will not be included]*.
- There are no expected benefits.

Confidentiality

- This study is anonymous. We will not be collecting or retaining any information about your identity.

Right to Refuse or Withdraw

- The decision to participate in this study is entirely up to you. You may refuse to take part in the study *at any time* without affecting your relationship with the investigators of this study. Your decision will not result in any loss or benefits to which you are otherwise entitled. You have the right not to answer any single question, as well as to withdraw completely from the interview at any point during the process; additionally, you have the right to request that the interviewer not use any of your interview material.

Right to Ask Questions and Report Concerns

- You have the right to ask questions about this research study and to have those questions answered by the INTERMODEL EU Consortium before, during or after the research. If you have any further questions about the study, at any time feel free to contact us, [*name*] at [*email*] or by telephone at [*phone number*]. If you like, a summary of the results of the study will be sent to you. If you have any other concerns about your rights as a research participant that have not been answered by the investigators, you may contact [*name*], [*organization position*] at [*phone number*].
- If you have any problems or concerns that occur as a result of your participation, you can report them to the INTERMODEL EU Consortium at the number above. Alternatively, concerns can be reported by completing a Participant Complaint Form, which can found on the INTERMODEL EU website at http://www.intermodeleu.eu/

Consent

- Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

Subject's Name (print): _____

Subject's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

RESEARCH PARTICIPANT COMPLAINT FORM

As a participant in research conducted within the INTERMODEL EU Project, you have the right to report any concerns you have about the way the research was conducted or possible misconduct by the researcher. The INTERMODEL EU Project Consortium will keep this report confidential and conduct an investigation if necessary. Please be as specific as possible in completing this form.

Study Title: _____

Principal Investigator: _____

Department: _____ **Phone:** _____

Date(s) you participated in the study: _____

What did your participation require? _____

Describe what specifically concerned you about the study.

☐ I prefer to submit this report anonymously.
☐ I prefer to provide the following contact information.

Your name: _____

Phone number: _____ **Email:** _____