i4Driving Validated ethics assessment plans and approval from ethics committee

D3.1 | 31.03.2023

D3.1 Validated ethics assessment plans and approval from ethics committee

Project Acronym	Grant Agreement #	Project Title	Deliverable Reference #	Deliverable Title
i4Driving	101076165	Integrated 4D Driver Modelling under Uncertainty	D3.1	Validated ethics assessment plans and approval from ethics committee

AUTHORS

Johan Olstam	VTI
Tanja Niels	TUM
Johannes Lindner	TUM
Eva Garcia	CTAG
Francesco Galante	UNINA

DISSEMINATION LEVEL

X	P	PUBLIC
	C	CONFIDENTIAL

Disclaimer

Funded by the Horizon 2020 programme of the European Union

Grant Agreement No 101076165

Version History

Revision	Date	Authors	Organisaton	Description
V0.1	24.01.2023	Johan Olstam	VTI	Outline draft
V0.2	22.02.2023	Johan Olstam, Tanja Niels, Johannes Lindner, Eva Garcia, Francesco Galante	VTI, TUM, CTAG and UNINA	Added descriptions of ethics approval procedures per country. Outlined remaining chapters
V0.3	27.02.2023	Johan Olstam, Tanja Niels, Johannes Lindner, Eva Garcia, Francesco Galante	VTI, TUM, CTAG and UNINA	First complete draft of all chapters
V0.4	03.03.2023	Johan Olstam, Tanja Niels, Johannes Lindner, Eva Garcia, Francesco Galante	VTI, TUM, CTAG and UNINA	Review and revision of all chapters by main authors. Added draft of executive summary.
V0.5	03.03.2023	Johan Olstam	VTI	Version for internal review
V0.6	17.03.2023	Johan Olstam & Eva Garcia	VTI and CTAG	Revision based on the review comments
V0.7	21.03.2023	Johan Olstam, Tanja Niels & Eva Garcia	VTI, TUM and CTAG	Version for final review by the coordinator
V1	30.03.2023	Lucia Schlemmer and Maria Rodrigues	PAN	Final review

Executive Summary

The i4Driving project includes both driving simulator experiments and test track experiments for collecting and analysing data on driving behaviour. Conducting driving simulator experiments and test track experiments implies human participants and thereby a need to ensure that relevant ethical and personal integrity aspects are considered in a correct way. The aim of this deliverable is to describe the ethical and personal integrity aspects connected to the driving simulator experiments that need to be considered and documented. The deliverable includes a specification of the ethics and GDPR policies that are applied in the project. The deliverable also presents an overview of the ethical approval application process and relevant national regulations for the countries of the experiment sites. Finally, the ethical issues and risks that need to be considered for the driving simulator experiments within i4Driving are listed together with risk assessments and suggestions for mitigation measures for each identified issue/risk. The issues/risks are categorised into the following: risks for physical effects / injuries; risks for psychological effects; and other ethical aspects to consider. The risk probabilities for the driving simulator experiments are judged to be in general low or (at maximum) moderate and the consequences are also estimated to be moderate at most.

The country and site-specific descriptions show that there are large similarities between the different institutions/partners and countries. This is beneficial for aligning the experimental design and the ethical consideration discussions and approval writing within the project. The next step is to finalise the experimental design and set up which will provide the necessary details to fill in the ethical approval applications to the national ethics committees.

Contents

List of Tables

1 Introduction

The i4Driving project includes both driving simulator experiments and test track experiments for collecting and analysing data on driving behaviour. As indicated by Campos J. L. et al., (2017), driving simulators are great tools for evaluating driving performance. Conducting driving simulator experiments and test track experiments implies human participants and thereby a need to ensure that relevant ethical and personal integrity aspects are considered in a correct way. In i4Driving, the driving simulator experiments and test track experiments are divided into two different work packages, and each of the work packages includes a deliverable that specifies ethics assessment plans for the respective experiments. The aim of this deliverable is to describe:

1. The ethical aspects connected to the driving simulator experiments that need to be considered and documented;
2. How the project will work for ensuring that all relevant ethical and personal integrity aspects connected to the driving simulator experiments are considered correctly;
3. What is required to get the necessary national ethics approvals in each country; and
4. How data related to the driving simulator experiments will be handled to fulfil General Data Protection Regulation (GDPR) regulations.

The deliverable is structured as follows. Chapter 0 presents the ethics policy that will be followed within the i4Driving project for the driving simulator experiments. Chapter 0 explains how personal integrity and GDPR aspects are considered. Chapter 0 presents overviews of the ethical approval application process and relevant national regulations for the countries of the experiment sites. The ethical issues and risks that need to be considered for the driving simulator experiments within i4Driving are listed in chapter 5 together with risk assessments and suggestions for mitigation measures for each identified issue/risk. The deliverable ends with concluding remarks and a description of the next steps in the ethical approval process. Since the sub aims 0-0 (mainly described in chapters 0-0) apply to both the driving simulator experiments and the test track experiments, these chapters are almost identical in the current deliverable D3.1 (“Validated ethics assessment plans and approval from Ethics committee”) and D5.1 (“Validated ethics assessment plan and approval from Ethics committee”).

2 Ethics policy

Investigation with human participants should consider their rights and safety protections for all the participants involved in the different studies. To ensure this, the i4Driving research, including driving simulator experiments, will be monitored by the i4Driving ethical board consisting of the coordinator Panteia, the WP3 leader VTI, and the WP5 leader TUM. i4Driving will follow the national ethical requirements of each relevant country and the European Commission's ethical requirements and guides (such as the "Ethics and data protection" guidelines by the European Commission: DG Research & Innovation (2021). The key points of the i4Driving ethics policy with respect to the driving simulator experiments are:

- **Informed consent:** First, researchers are required to get informed consents using language that is sufficiently understood by participants, without forgetting the importance to avoid or minimise participants' exposure to potential physical, emotional or psychological damage, including unjustified deception. The informed consent form must also include a section on how the data will be stored, used and distributed. It can also include a section where the participant can consent that the data may be used in follow-up projects. An example draft of an informed consent form is presented in Annex A: Example of informed consent-form for the driving simulator experiments . This also includes that participants get enough time to consider whether they want to participate or not, that they can ask questions before deciding to participate and that invitations or ads for the study are not phrased in coercive language. Participants should not feel obliged to participate (e. g. if they are employed by the company conducting the study).
- **Free withdrawal:** Even if the informed consent form is signed by the participant before the experiment, the participant has the right to change their mind at any time and withdraw before the specified end of the experiment (clarified in informed consent forms). The participant will be asked to sign two copies of the informed consent form. One copy will be kept by the investigator/supervisor and one copy will be given to the participant. The participant will be informed about that no penalty or loss of benefits will occur because of either not participating or withdrawing from the study, independently of when the withdrawal is done. The reimbursement will not be affected by the withdrawal.
- **Reimbursement**: Following the suggestion in D9.2: Ethics and Data Privacy Manual (Touliou et al. 2021) in the Panacea project, reimbursement in the form of incentive payments should not be provided. In the cases where reimbursement/incentives are foreseen, claimants (research interviewees) should be made aware of the status of the payment in opt-out letters using the following terminology: 'If you do take part in the experiment, you will receive XX € in cash, as compensation for your time and other costs incurred through participation in the experiment. This will not affect your entitlements to benefit in any way'. Before performing data collections with research participants, the reimbursement mechanisms will be revisited by the i4Driving Ethical Boards and approved.
- **Premature termination:** The experiment supervisor can decide to terminate the study if the minimum requirements for conducting the test in safe conditions and driver well-being are questionable/ doubtful, for example if the participant is suffering from nausea or feeling sick or if the instructions are not followed.
- **Deception:** No deception will take place within the driving simulator experiments in i4Driving. The exception might be the Turing test in which the participant will not know if he or she is interacting with another real human. However, it can be questioned if this counts as deception and the participant will be informed of the possibility of interacting with other real humans in the digital environment before the experiment.
- **Target user groups:** The target user group of i4Driving consists of non-professional drivers holding a driving license for at least driving a car. The Turing tests will also include professional vehicle inspectors.

- **Acknowledgement on video/sound recording sessions and photo or video screen capturing facilities:** In the cases that the experiment is video and/or sound recorded, or photos or screen captures are done, the participants should give their consent before the start of the trials (this should be part of the informed consent forms). If the participant does not agree to this, there are two options: either none of the above will take place (this is only an option if video is used as a complement in the analysis) or the experiment will not be conducted (this option is chosen if analysis of the video and or audio is required).
- **i4Driving policy on privacy, transparency, confidentiality and risk assessment** and acknowledgement to the participants of i4Driving studies, personal data protection and assurance on secure handling of private data are discussed in detail in Chapter 0.
- **Partner's responsibility related to ethical issues** (based on the description in D9.2: Ethics and Data Privacy Manual (Touliou et al., 2021) in the Panacea project):
    - Each project partner is responsible for ensuring its own compliance with all laws and regulations applicable to the experiments. Such laws include, but are not limited to, those in respect of rights of privacy, intellectual property rights and healthcare.
    - Each partner is responsible to ensure that it has all necessary participant consents to permit distribution and use of any data and any other information provided to other i4Driving project partners.
    - Any project partner which provides any data or information to another partner in connection to the project will not include any personal information relating to an identified or identifiable natural person or data subject. Raw video data will not be shared with other partners. If a video is shared it must be anonymised. In cases where the project would like to use video or other recordings for dissemination (not only data analysis), the participant will be contacted and asked specifically for each occasion with specified material.
    - To this end, the providing project partner will anonymise all data delivered to other partners to an extent sufficient to ensure that a person without prior knowledge of the original data and its collection cannot, from the anonymised data and any other available information, deduce the personal identity of participants.
    - All partners responsible for an experiment are responsible for ensuring that the approved ethics approval applications are made publicly available as an appendix to the relevant deliverable.

The i4Driving consortium declares that the research targets of i4Driving follow Article 6 (2§) of Directive 1982/2006/EC. Therefore, i4Driving will not touch any of the following fields of research:

- Research activity aiming at human cloning for reproductive purposes;
- Research activity intended to modify the genetic heritage of human beings which could make such changes heritable; and
- 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.

Furthermore, i4Driving does not include any research involving the use of human embryonic tissue, human foetuses, human foetal tissue, other human tissues, genetic information, people unable to give consent, pregnant women, nor animals.

3 GDPR policy

The collection, processing and storage of personal data must be done in accordance with data protection laws and regulations, including the GDPR of the European Union (EU). In the driving simulator experiments, personal data will be collected from participants, such as their names, gender, nationality and contact information. Depending on the hypotheses to test in the experiments, sensitive data, such as their driving behaviour and biometric data might be needed. To ensure data protection in the i4Driving project, the following steps will be taken:

1. **Informed consent:** Before collecting any personal data, participants must be informed about all relevant aspects of the research and the data that will be collected. In particular, the consent includes the following aspects regarding data protection:
    - Research purpose
    - Data collection and storage
    - Data transfer and communication
    - Data ownership
    - Data connection with personal information and separate storage
    - Commercial exploitation of data
    - Data storage duration
    - Granting access to data
    - Data supervision

    Participants must be given the opportunity to refuse to participate or to withdraw their consent at any time without penalty or loss of benefits. Participants must be informed about their rights to access, rectify and delete their data, as well as the right to lodge a complaint with the supervisory authority. Personal data can only be stored for as long as necessary according to GDPR. The consent form will be signed twice, one copy for the supervisor and one for the participant.
2. **Minimise the data collected:** Only the minimum amount of personal data should be collected. This data should be limited to what is strictly necessary for the i4Driving research project and should not be collected for any other purposes.
3. **Data security:** The personal data collected must be kept secure and confidential. Adequate technical and organisational measures must be taken to ensure the security of the data, such as encryption, access control, and backup and disaster recovery procedures.
4. **Conduct risk assessments:** A risk assessment must be conducted, considering a.o. unauthorised access, theft, or loss of data, and it must be ensured that appropriate measures are taken to mitigate these risks.
5. **Ensure third-party service providers are compliant:** If third-party service providers are used, such as data storage providers or cloud service providers, they must be compliant with data protection laws and regulations, and appropriate contracts must be in place to ensure the security of the personal data.
6. **Appoint a data protection officer (DPO):** If required by the GDPR, a DPO should be appointed to oversee the compliance with data protection laws and regulations and to provide advice on data protection issues. Many institutions of the i4Driving consortium, like TUM, already have a DPO.

3.1 Data pseudonymisation process

The purpose of data pseudonymisation is to ensure that personal data cannot be re-identified or linked back to the individual from whom it was collected, but still ensure that it is possible to delete data for a specific participant if the participant demands that their data should be deleted in hindsight. Pseudonymisation provides a safeguard against accidental or unauthorised release of personal and confidential information in

breach of any applicable legislation. There are different ways in which personal data can be modified to conceal identities:

- **Data Masking:** This method involves replacing or obscuring personal identifiers with random values/keys. The key is held by members of the research team using the information.
- **Data Aggregation:** This method involves grouping participants into categories and aggregating the data at a higher level, such as by age group. This method can be used to protect personal data while still providing valuable information for research purposes.
- **Data Perturbation:** This method involves adding random noise or error to the personal data to reduce the risk of re-identification. The random noise or error should be small enough to not affect the validity of the research results, but large enough to protect the privacy of the individuals from whom the data was collected.

Regardless of the method used, it is important to consider the following factors when conducting data pseudonymisation:

- **Level of anonymity:** The level of anonymity required depends on the sensitivity of the personal data and the potential risks to the individuals from whom the data was collected. The higher the level of anonymity required, the more complex the data anonymisation process may be.
- **Risk of re-identification:** The risk of re-identification refers to the likelihood that personal data can be linked back to the individual from whom it was collected. The data anonymisation process should aim to reduce the risk of re-identification to an acceptable level.
- **The impact on the research results:** The data anonymisation process should not significantly impact the validity of the research results. The method used should preserve the statistical properties of the data and not affect the ability to answer the research questions.
- **The ethical considerations:** The data anonymisation process should comply with ethical principles, such as informed consent, confidentiality, and privacy. The participants should be informed about the data pseudonymisation process and the potential risks of participating in the study.
- **Storage of the pseudonymisation key:** The pseudonymisation key is needed to ensure that data for a specific participant can be deleted if the participants demand that their data should be deleted in hindsight. After creation, the pseudonymisation key should only be accessible by one designated person at the organisation of the simulator facility.

3.2 Data protection layers

Depending on the type of data and the need for exchanging data between project partners to reach project goals we define the following four data protection layers:

1. **Non-anonymised personal data**: For conducting studies it is necessary to contact the participant via e-mail or phone and know the name of the participant. This step is unavoidable but includes the highest risk for data abuse because data collected in studies can be related to persons. Collecting this data is only necessary for studies to create a key that links participants with their ID to pseudonymise the personal data. Access to the pseudonymisation key and this data is only granted to one designated person at the organization of the simulator facility, who has the duty to protect the data with a safe password. After the conduction of one study, this data must be irreversibly deleted. This is done at the end of the project at the latest. Only name and contact information are allowed to be saved in order to enable deletion of data upon request of the participant in hindsight.
2. **Pseudonymised personal data**: This type of data is raw data collected in studies and linked to a participant with an anonymised ID. The data can contain e.g., age, gender, physiological data (heart rate, …), video data, audio data, photos, or screenshots from videos. Only data that is clearly needed to answer the research questions in i4Driving will be collected. The data must be access protected,

and only accessible to a small group of employees of the institution responsible for conducting the experiment to further process the data. The data will be saved for five years after the project has ended and will be deleted after these five years. Storing the data for this amount of time after the end of the project is necessary to be prepared for project audits.

3. **Internal data**: Data exchange between work packages and institutions is necessary to reach the project goals. This data is pseudonymised and not linkable to a specific person. Only project internal access is granted, to review the outcomes of the project. The data will be saved for 5 years after the project has ended and will be deleted after these 5 years. Storing the data for this amount of time after the end of the project is necessary to be prepared for project audits.
4. **Public data**: To support research and reuse the outcomes of the i4Driving project, public data might be published. Public data may only include anonymised personal data if there is no risk of re-identification if combining one or several of the data types.

4 Overview of the ethical approval process for the different sites

4.1 VTI, Sweden

Not all activities involving human participation require ethics approval. However, there is both EU and national legislation which must be followed when performing driving simulator experiments. Particularly, for tests involving the following:

- Healthy human participants, the relevant Swedish legislation is: Sveriges Riksdag (2003) and European Commission (2023).
- Participants with addictions (e.g., alcohol, drugs), the relevant Swedish legislation is: Sveriges Riksdag (2003). Participants need to be able to understand and sign the informed consent form. This legislation is most likely not relevant for i4Driving since no experiments including participants with addictions are planned.
- Illiterate or participants with co-morbid conditions, the relevant Swedish legislation is: Sveriges Riksdag (2003). Participants need to be able to understand and sign ethical informed consent. This legislation is most likely not relevant for i4Driving since no experiments including participants with illiterate or participants with co-morbid conditions are planned.

In Sweden the ethical controls are audited by the national authority Etikprövningsmyndigheten (https://etikprovningsmyndigheten.se/for-forskare/sa-gar-det-till/) and ethics approval applications are submitted via an online system called Ethix (https://www.etikprovningsansokan.se/epm/login). The application should include: a research plan and CV for responsible researcher and relevant appendices (written in Swedish) as: advertising material for recruiting participants; information given to the participants in connection with the experiment; questionaries, interview guides, etc.; list of variables if data from already available register will be used. Decisions on an application are commonly given within 60 days after a complete application is submitted.

The instructions to the participant and the informed consent form are provided in common language, so it is understood by diverse participant groups. The participants are also given sufficient time to reflect their decision of giving or withholding consent. In case of involvement of people who do not understand the informed consent form, the participant's guardian can sign the informed consent form.

Private information is being recorded, however there is not an established Data Protection Authority issuing procedures / standards that must be followed before performing tests with human participants and their personal / private data, except GDPR and the routines set up by the Data Protection Officer (DPO). Written procedures for protecting privacy are not established, since VTI has set routines, but they vary and are data dependent. Vehicle simulator data are safely stored on protected disks according to GDPR. It is also clarified to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be protected in full, since the keys between the participants' name and number are kept by one person in a safe offline or online place, depending on data types and volumes. Persons and their professions who are authorized to have access to the data collected and / or who have access to any data storage devices, are identified (electronically and on paper). There is an appointed DPO that can be reached at dataskyddsombud@vti.se; 0046 13 204000.

Every experiment is evaluated for any side-effects since it is always mandatory to think about that as a part of the ethical approval procedure. There are written procedures for safety for employees and volunteers within the group. They cover how to be prepared, what protection anybody involved in the study should wear and what questions to ask.

The technical measures applied to ensure data protection are storing data on a local server protected with a password. The operational measures applied to ensure data protection are checklists and cleaning procedures. Procedures to perform risk-assessment concerning breach of privacy and / or breach of safety

include a specific template with the risk and its consequences are used and this is mandatory in every major project. VTI is insured against risks as a result of breach of privacy and safety by "Kammarkollegiet". Other organisations do not need to get involved for conducting research and manage the risk. The general testing/ experimental protocol in place covers preparation before arrival, at arrival and during testing. It identifies what should be done and what information the participants need to have.

4.2 TUM, Germany

For driving simulator experiments, the ethics committee at TUM (https://www.ek-med-muenchen.de), as part of the German Association of Medical Ethics Committees (AKEK), must approve the ethics proposal. The committee in question follows numerous ethical and legal regulations, which are listed in the appendix/webpage of Ethikkommission der Technischen Universität München (2023).

4.2.1 Approval procedure

The first step is the **application form**. The application form includes questions regarding the burden for participants, the inclusion of vulnerable groups, use of biomaterial, location and cooperation, study design, medical products, data privacy, insurance, financing, responsible persons.

A mandatory step is also to provide study participants with **information material** about study conduction and possible risks. Moreover, an **informed consent** must be signed by the study participant. It includes the information that the study participant is voluntarily participating in the study and agrees on the data processing. In the preparation of the consent documents ethics proposal applicants at TUM are supported by the online tool eTICS (https://etic.med.tum.de) for legal correctness and understandability.

The next step is a **study protocol for prospective data collection**. This protocol includes general project information, responsibilities, scientific background, project goals, and parameters of interest. It follows a detailed description of the participant pool (Inclusion and exclusion criteria, number of participants, recruitment) and a detailed experiment description including methodological approach, informed consent procedure, description of data sources and collection, description of the data type to be collected and the expected duration of data collection. This document also holds a risk-benefit assessment to compare the study outcomes with the individual risk of the study participant. The last part of the document includes a detailed description of the data management.

The remaining documents are a curriculum of the study director and a form to declare conflicts of interest. For the driving simulator experiments, the appendix includes all questionnaires, recruiting material, confirmation of insurance and conditions, contracts with cooperation partners, data transfer agreement, approval notices from public funding bodies and a statement from the data protection commissioner.

The ethics committee at TUM meets roughly every 4 weeks. A minimum 2 weeks before a meeting of the ethics commission, the ethics proposal must be submitted in full to an online tool (https://ethikpool.mri.tum.de). The duration of ethics approval, therefore, ranges from 2-6 weeks. Depending on the funding of the research, the cost varies from 150-1.500€. If the research is 100% funded by the government, the cost would usually be 150€.

4.2.2 Data Privacy

Data from the driving simulator experiments are safely stored on protected disks according to GDPR. Depending on the size and type of data, secure servers are used to store the data, which are only accessible inside the TUM network and password-secured access must be granted to specific employees identified by their TUM-ID. Thus, persons who are authorised to have access to the data collected and/or who have access to any data storage devices are identified (electronically and on paper).

The informed consent and additional information material clarifies to the participants that all data collected in the activities they are participating in will be kept entirely confidential and that their anonymity will be

protected in full. The keys between participant names and numbers are kept by one person in a safe offline or online place. There is an appointed DPO at TUM that can be reached at beauftragter@datenschutz.tum.de.

4.3 CTAG, Spain

Spanish legislation establishes the norms about ethical approval of biomedical studies, stating that these tests should have the approval of ethics committees (Distefar, 2023; Eurec, 2023). Studies with human participants without biomedical nature do not require an approval from an ethics committee but the studies are still obligated to respect ethical aspects, as their rights, dignity, or information about the test where they will be participating in.

All the studies with participants conducted at CTAG pay special attention to the ethical aspects of the people involved in them, with special emphasis on the following aspects:

- An informed consent is carefully explained to all participants, which they must understand and sign if they agree to take part in the study. This informed consent form includes: purpose and procedure of the study, safety systems for the driving simulator and prototype cars, data protection issues. The document ends with a paragraph with the acceptation of the informed consent that participants should sign if they agree with it. Before signing, researchers should be sure that participants understand the information provided regarding the test (an example of an Informed consent form is provided in Annex A: Example of informed consent-form for the driving simulator experiments).
- All the participants will take voluntary part of the study and they could withdraw their participation at any time.

Moreover, as tests are performed with the supervision of psychologist, he or she, follows the Ethical Code of Conduct for Psychologists (Deontological Code). This code is regulated by National Official College of Psychologists, it works as a mandatory guide to avoid malpractice from an ethical perspective (Spanish version of this Deontological code is provided in COP (2023)). This code ethical standards are based on the following main values (see Rangi & Stoffe (2015) for more details):

- Human dignity
- Caring about the well-being of people
- Integrity in relationships
- Responsibility

Besides, in this code it is pointed out the psychology profession is governed by principles common to any professional deontology: respect for the individual, defence of human rights, sense of responsibility, honesty, sincerity with the subjects, prudent application of instruments and techniques, professional competence, firmness in the objective and scientific basis of their professional activities. In addition, when research requires the psychologist to resort to deception or tricks, he or she must ensure that this will not cause long term harm to any of the subjects and must always inform them of the nature and experimental need for the deception at the end of the session or research. Finally, it indicates that psychological research in normal situations, whether experimental or observational, must always be carried out with respect for the dignity of the individuals, their beliefs, their privacy and their modesty.

Additionally, data from the study regarding participants will be treated according to the requirements and recommendations of the Organic Law 3/2018, of December 5th, on the Protection of Personal Data. This national standard follows the GDPR law. The AEPD (Spanish Data Protection Authority, https://www.aepd.es/es) develops resources and tools to promote compliance with the GDPR.

4.4 UNINA, Italy

Research and experimentations involving human beings in the biomedical and non-biomedical fields at UNINA must be evaluated, approved and monitored by the **university ethics committee** (https://www.comitatoeticofedericoiicardarelli.it/) from an ethical point of view, in compliance with current national, European and international legislation. The ethics committee, in full independence and autonomy, expresses a collective opinion on the requests presented by researchers belonging to the University of Naples Federico II, with particular attention to the protection of rights and confidentiality provided for by the legislation on protection of personal data, with respect for the autonomy in decision-making and well-being of the participants. The ethics committee in carrying out its activities is inspired by the ethics principles recognized by the main research ethics declarations at international level, by the Charter of the Fundamental Rights of the European Union, by the Italian Republican Constitution and by other documents products in Europe.

The request for an opinion on driving simulator or on-road experimentation, which also establishes an authorisation request to conduct the same, must be addressed by the Principal Investigator to the President of the ethics committee and accompanied by the informed consent information and declarations, study protocol, principal investigator CV, personal data processing information and authorisation, and study synopsis (written in Italian if all submitted documents are in English).

The request for ethical approval follows the regulation of UNINA's ethics committee (Università degli studi di Napoli Federico II, 2014), drawn up pursuant to the Decree of 8 February 2013 of the Italian Minister of Health, and have to include information on Principal Investigator and her/his eventual substitute, other researchers involved, site(s) and equipment, sources of financing, expected date start and duration of study, study summary and schematic representation of the protocol, number and typology of participants, potential risks and their management, data privacy and FAIR & Open Access practices.

Legally effective informed consent is mandatory for participation as a subject in research experiments. The informed consent form must contain adequate information (study's general purposes and design, possible risks/discomforts and benefits, voluntary participation and withdrawal, confidentiality) to allow the potential participant to make an informed decision about participation in the study and document their voluntary agreement to participate. Researchers are required to facilitate the potential participant's comprehension of the information, provide sufficient time and opportunity for the potential participant to ask questions and have those questions answered and minimize the possibility of coercion or undue influence. The ethics committee will rule on the correctness, completeness and comprehensibility of the information provided to the potential participants, considering their age, education level and psycho-physical conditions.

The experimental protocol to be submitted to the ethics committee must include project summary and general information, rationale and background information, study goals and objectives, study design and methodology, subjects selection and recruitment, safety considerations (potential risks and measures identified for their prevention and/or mitigation), data management and statistical analysis, expected outcomes, data protection and storage, dissemination and publication policy, ethical considerations relating to the study.

In addition to reading and signing the informed consent form, the participants interested in participating in the experiment are required to give written consent to the processing of personal data. The processing in question essentially concerns personal data capable of revealing the state of health and has a scientific research purpose, thus falling within the general category discipline of the Personal Data Protection Code (Italian Legislative Decree no. 196 of 30 June 2003), as amended by Legislative Decree no. 101 of 10 August 2018, which also established that the Italian Data Protection Authority (GPDP) is the supervisory authority responsible for monitoring application of the General Data Protection Regulation (GDPR, EU Regulation No. 2016/679).

The ethics committee opinions, positive or negative, are validly expressed unanimously or by a majority of those present. Moreover, the ethics committee can suspend the issuance of an opinion once to request modifications, clarifications or additional documentation. In such case, the principal investigator must respond within six months, otherwise they must repeat the request for opinion ex novo. The principal investigator can be summoned by the ethics committee in the event of a particularly complex project. In the case of experimental protocols involving a minimum risk and burden for research participants, the ethics committee can provide formal exemption or apply a rapid assessment according to a specially prepared procedure.

The UNINA ethics committee meets when convened by its president, usually at least once a month. The calendar of meetings is established every year in the first useful meeting. For the request to be inserted into the order of the day, it must be sent 10 days before the committee is due to meet. If this does not happen, the matter will be examined in the following meeting. The duration of ethics approval typically ranges from 1-2 months starting on receipt of a valid request. According to current legislation and depending on the type of experimentation, the charges for the functioning of the ethics committee are paid by the promoters who commission the trials, except for the provisions of the legislation for "non-profit" studies.

5 Ethical aspects to consider for the driving simulator experiments

For the driving simulator experiments in i4Driving, we identified several risks and issues that need to be considered. Those risks are described in

Table 1 - Table 3. The description also includes a preliminary risk assessment, an estimate of the severeness of consequences and proposed mitigation measures. The risk assessment is an important input to necessary discussions on whether the motives for exposing the participants to situations that might be perceived as unpleasant are strong enough in relation to the risk of and the magnitude of unpleasantness.

The most important document in the ethics approval is the informed consent form that the participants must understand and agree on before taking part in the study. This document already includes a description of all risks that could be identified beforehand, the study objective and how their participation contributes to advance research. It also includes a disclaimer about data protection. Not listed but applied as mitigation measure for all issues, is the possibility to withdraw their participation at any time without consequences, and the possibility that the test leader can terminate the session prematurely.

The identified risks and issues connected to the i4Driving driving simulator experiments are listed in

Table 1 - Table 3. The risks and issues are categorised into the categories: risks for physical effects / injuries (

Table 1); risks for psychological effects (

Table 2); and other ethical aspects to consider (Table 3). The probability and consequence of the risk are assessed using a five-grade scale ranging from 1 (very low) to 5 (very high), where 5 (very high) refers to severe injuries for the consequence assessment.

Table 1 Risks for physical effects / injuries in connection with the driving simulator experiments.

Issue	Mitigation	Probability	Consequence
1. Safety risk when entering or leaving the simulator cockpit.	Support by staff, safety barriers on ladder or platform, visual light signal for knowing when it is safe to leave the simulator cabin, emergency stop if the participant unbuckles his/her seat belt or opens the cockpit door to leave the simulator, etc.	1 (very low)	2 (low)
2. Risk for unpleasantness or minor injuries if the moving platform of the simulator performs an emergency stop.	Systems that ensure safe stop of the moving platform in moving base simulators even at emergency stops of the simulator.	1 (very low)	1 (very low)
3. Participants that are not fit to drive due to sickness, fatigue, emotional upset, drugs, alcohol, etc. might have a higher risk for simulator sickness, experience unpleasantness or injuries when entering or leaving the simulator cockpit.	Ensure that participants are fit, healthy well-rested before entering the simulator to drive – i.e. no sickness, fatigue, emotional upset, drugs, alcohol, etc. Need to be specified in the consent form.	2 (low)	3 (medium)
4. Drivers might not be fit to travel home from the simulator facility in a safe way.	Ensure that drivers are fit to travel home from the simulator facility in a safe way – i.e., there is a risk that participants are fatigue or feeling unpleasant after the experiment and might need to be supervised before traveling home or that they need to be transported home and not drive themselves.	2 (low)	3 (medium)
5. Participants exposing the experiment supervisor or other staff to dangerous or unpleasant situations due to acting in a dangerous, non-compliant, or unsuitable way.	Ensure clear instructions to the experiment supervisor and other staff on how to act in such situations and who to contact in case help is needed.	1 (very low)	3 (medium)

Table 2 Risks for psychological effects in connection with the driving simulator experiments.

Issue	Mitigation	Probability	Consequence
6. Crashes in a simulator may have an unknown psychological impact on participants.	Monitor drivers throughout the whole drive and abort the experiment if needed. If needed, debrief the participant before or after leaving the simulator cockpit.	2 (low)	2 (low)
7. In the Turing tests the participants will interact with other vehicles that might be driven by another human in another driving simulator. There might be a risk that participants think that collisions or critical situations in the virtual world might negatively affect the human(s) driving the other driving simulators negatively.	Explain for the participants that there is no risk for injury or unpleasantness of other humans in other simulators that the participant might interact with in the virtual environment.	1 (very low)	1 (very low)
8. Participants might experience simulation sickness (SS) and the sense of presence (SP). There is potentially a higher risk of simulator sickness for near crash situations, strong braking or acceleration and sharp curves.	Participants screening for susceptibility to various forms of motion sickness leads to a reduction of the frequency of simulator sickness. Designing high quality and resolution scenarios could increase sense of presence, thus decreasing the severity of simulation sickness symptoms. Moreover, driving time in the simulators should not be too long (about 20-30 minutes driving) and without too fast or sharp turns and rapid accelerations/decelerations (if it is not necessary). Ensure good air quality and temperature inside the simulator cabin and monitor drivers throughout the whole drive and abort the experiment if needed. Participants will also continuously be monitored and the experiment will be terminated by the test supervisor if needed.	2 (low)	3 (medium)
9. For the Turing tests there might be a higher risk of simulator sickness since the participants might be driven by another human or a model and not drive the simulator themselves.	All mitigation measures already proposed for the issue 7 are here valid. Moreover, placing participants in the driver seat since the visual system and the movement of the simulators are designed for a person in the driving seat and not the passenger seat. Monitor drivers throughout the whole drive and abort the experiment if needed.	3 (medium)	3 (medium)
10. Participants showing anxiety for participating in a virtual environment.	Clearly explain the set up and start each experiment with a training part with clear instructions that this is not part of the experiment and that the aim is to make the participant familiar with driving the simulator car.	1 (very low)	1 (very low)

Table 3 Other ethical aspects to consider in connection with the driving simulator experiments.

Issue	Mitigation	Probability	Consequence
11. Participant concerns about personal data processing.	Explain the Personal Data Protection Policy in the informed consent and explain that the participant can withdraw from the experiment at any time.	3 (medium)	2 (low)
12. Exposing the participants to too many or too critical situations might both influence the participant wellbeing but also imply a risk of biased results.	Careful design of experiments and conducting pilot tests with internal staff and/or experienced simulator drivers before starting experiments with the real participants.	3 (medium)	3 (medium)
13. Lack of perceived risk for participant (which could result in that participant "play" rather than drive as he or she do in normal traffic) or participants that intentional or unintentional are not behaving as they would do in real driving.	Clarify in the informed consent form that premature termination of the study can happen in the case of non-compliant behaviour (in relation to the instructions).	2 (low)	3 (medium)

6 Concluding remarks and next steps

This deliverable describes the ethics policy and GDPR considerations that will be utilised in the driving simulator experiments conducted within the i4Driving project. Since the driving simulator experiments will be conducted at simulator facilities in different countries, the deliverable also describes the ethics approval process in the relevant countries. The country and site-specific descriptions show that there are large similarities between the different institutions/partners and countries. This is beneficial for aligning the experimental design and the ethical consideration discussions and approval writing within the project.

Monitoring to ensure fulfilment of the ethics policy and GDPR consideration will be done by the i4Driving ethical board consisting of the coordinator Panteia, the WP3 leader VTI and the WP5 leader TUM.

The next step is to finalise the experimental design and set up which will provide the necessary details to fill in the ethical approval applications. The final and accepted ethical approval applications will be included in D3.2 Experimental setup for the driving simulator experiments and D3.5 Report on the Turing test of the probabilistic 4D library of human driver models.

7 References

7.1 Reports, articles and papers

Campos J. L., Bédard M., Classen S., Delparte J. J., Hebert D. A., Hyde N., Law G., Naglie G., & Yung S. (2017). Guiding Framework for Driver Assessment Using Driving Simulators. *Frontiers in Psychology*, *8*(1428). https://doi.org/https://doi.org/10.3389/fpsyg.2017.01428

COP. (2023). *Codigo deontologico del psicologo* . http://www.cop.es/pdf/CodigoDeontologicodelPsicologo-vigente.pdf

Distefar. (2023). *The Royal Decree that regulates observational studies with medicines for human use approved*. https://distefar.com/en/the-royal-decree-that-regulates-observational-studies-with-medicines-for-human-use-approved/

Ethikkommission der Technischen Universität München. (2023). *Grundlagen*. https://www.ek-med-muenchen.de/index.php?option=com_content&view=article&id=102&Itemid=705&lang=de

Eurec. (2023). *Research Ethics Commitees (REC) in Spain*. http://www.eurecnet.org/information/spain.html

European Commission: DG Research & Innovation. (2021). *Ethics and data protection* . https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

European Commission. (2023). *EU:s regler för skydd av personuppgifter*. https://commission.europa.eu/law/law-topic/data-protection/eu-data-protection-rules_sv

Rangi, S., & Stoffe, D. (2015). *Annex 2.d.1 Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries Deliverable 1.1 in the SATORI project*. https://satoriproject.eu/media/2.d.1-Psychology.pdf

Sveriges Riksdag. (2003). *Lag (2003:460) om etikprövning av forskning som avser människor*. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2003460-om-etikprovning-av-forskning-som_sfs-2003-460

Touliou, K., Panou, M., & Bekiaris, E. (2021). *D9.2: Ethics and Privacy Protection Manual*.

Università degli studi di Napoli Federico II. (2014). *regolamento del comitato etico Università degli studi di Napoli Federico II*. http://www.comitatoeticofedericoii.it/sites/default/files/files_wysiwyg/Regolamento.pdf

7.2 Web-pages

Etikprövningsmyndigheten: https://etikprovningsmyndigheten.se/for-forskare/sa-gar-det-till/

Ethix: https://www.etikprovningsansokan.se/epm/login

Ethics committee at TUM: https://www.ek-med-muenchen.de

eTICS: https://etic.med.tum.de

TUM ethics commission online tool: https://ethikpool.mri.tum.de.

AEPD (Spanish Data Protection Authority: https://www.aepd.es/es

UNINA ethics committee: https://www.comitatoeticofedericoiicardarelli.it/

GPDP (Italian Data Protection Authority): https://www.garanteprivacy.it/web/garante-privacy-en

Annex A: Example of informed consent-form for the driving simulator experiments

Informed Consent

ID (Identification number):

Purpose

This study is part of the i4Driving research project (https://i4driving.eu/). We invite you to participate in it as a licensed driver and standard population sample.

Procedure

The test will consist of [one/two/three [to be decided] session(s)] with an approximate duration of (normally, around one hour considering time for filling in questionnaires).

Upon reading and signing this informed consent form, a general information questionnaire will be completed. This will be followed by driving simulator training session. During the simulation, you always maintain communication with the control room. A rest break will be made between each session. Finally, the participant will fill in a questionnaire where his/her experience from the drive will be collected. Audio and video will be recorded during the sessions, as well as simulation data.

DRIVING SIMULATOR SAFETY SYSTEMS [Adjust based on the used simulator facility, CTAG example below]

Before proceeding to test the simulator, read the following instructions carefully and if you have any questions or doubt, ask the supervisor.

Before starting the simulation:

- You must close all the doors of the vehicle. These have a sensor and the simulation will not start while one remains open.
- - The seat belt must be fastened. CTAG Driving Simulator has a dynamic platform that simulates the movements of a real car; therefore, you must wear your seat belt.
- - The technician who goes with you will indicate the position of the emergency button. Make sure you can reach it without any problems.

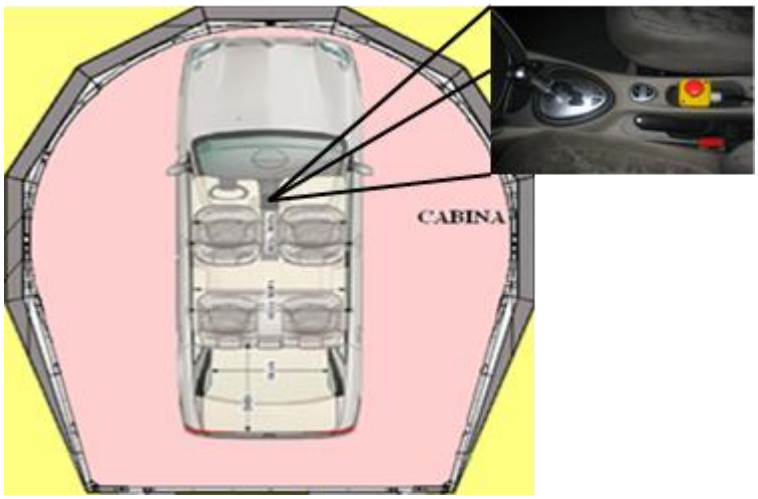

Figure 1: Position of the emergency stopper inside the instrumented vehicle.

During the simulation:

- You always have direct communication with the control room through a microphone installed in the car. If at any time you start to feel unwell (dizziness, nausea, etc.) or notice any anomaly, please notify the supervisor immediately.
- If for any reason you want to stop the simulation, you can do it in three ways:
  - Advising the technical staff ([the one who is inside the car or the one in the Control Room depending on simulator facility]).
  - Pressing the emergency button.
  - Opening one of the car doors.
- When the simulation stops, whether due to an emergency stop or not, do not leave the cabin until instructed to do so by technical staff.
- Before leaving the cabin, check that the "ladder position" indicator is illuminated in green.

In any case, always follow the instructions of the technical staff and ask any questions you may have.

Risks

Driving in virtual environments (driving simulator) can cause the following side effects:

- Tearing
- Vomiting or retching
- Nausea
- Headache
- Etc.

For these reasons, it is not suitable to use this technology if you suffer or have suffered epileptic convulsions, heart problems, or those who have eaten an abundant meal shortly before running the test. Similarly, if you are pregnant or think you may be pregnant, you should **not** participate in this trial.

Tests in the driving simulator must **not** be carried out if you are under the influence of any substance that may affect your performance (drugs, alcohol or medication).

Cost and compensation

Participation in this experiment does not imply any cost for the participant, nor does it imply compensation (or it implies a compensation of? €). Participants will not obtain personal benefits regardless of the exploitation of the results carried out by [CTAG/TUM/UNINA/VTI] or the i4Driving project.

Confidentiality

The recordings of the participation in this experiment will be kept confidential following the requirements and recommendations according to [adjust based on country, for Spain it is **Organic Law 3/2018, of December 5th**], on the Protection of Personal Data.

These recordings could identify you personally, especially as far as video recordings are concerned. Each study participant will be assigned a unique identification number by which that participant will be referenced throughout the experiment. In this way the personal identification of each participant will be reduced.

In case of publication of data obtained in the experiment, your personal data will not be revealed, avoiding any linkage with the answers. Any general information about your health obtained during the experiment will not be stored.

Use of collected information.

Two types of data will be collected during the study:

- Simulator driving data:
  The simulation data includes both the data from the questionnaires and those obtained from the systems integrated into the simulator. These data collected during the simulations will be analysed together with the results of other participants.
- Audio and video recording in real time:
  The videos include, in addition to the image, all the environmental sounds and the voice of the subject inside the cabin during the simulation. The video and sounds during the simulation will be used to examine the behaviour of the subject while driving.

[CTAG/TUM/UNINA/VTI] may include this data in final reports or other publications or media (for scientific, educational, promotional, legislative or research purposes). These data may be used individually or jointly with those of other participants, but they will not be presented in a way that allows personal identification, the processing will not go beyond your appearance in the videos recorded during the trials.

Voluntary participation

Participation in this study is entirely voluntary. You can choose not to take part in it. If you agree to participate in this study, you have the option to withdraw at any time without jeopardy. If you do not decide to participate or drop out, your decision will not have any penalty or loss of benefit. If you withdraw before data collection is completed your data will be destroyed.

Participation in the study implies that you know and meet the minimum requirements to be able to participate in it:

- Be at least 20 years old.
- *Not having worked on the i4Driving project (it does not matter if you have participated in other studies with the driving simulator). (Only relevant if participants are employed at VTI/TUM/CTAG/UNINA. This should be avoided but might be the case e.g. during pilot experiments).*
- Hold a valid driver's license for driving a car.
- Having more than two years of experience as a car driver.
- Not being under the influence of any substance that may affect your behaviour as a driver.

Under certain circumstances, your participation in the study may be concluded without your consent if considered appropriate by the project researchers.

Acceptance of informed consent

Participant

After reading this document, your signature indicates that you have read this document, the study has been explained to you, your questions have been answered correctly, you have received a copy of this consent

form for your own records, and you agree to participate in the study called "i4Driving test in driving simulator".

o Yes, I agree.

o No, I do not agree.

Name of participant: Signature of participant

Date: _ _ / _ _ / _ _ _ _

Researcher

I have explained and discussed this document with the participant. I believe that the participant has understood the risks, benefits, and procedures involved in participating in this research study.

Name of researcher: Signature of researcher:

Date: _ _ / _ _ / _ _ _ _

Consent agreement regarding the processing of personal data in the test of i4Driving

I, _____ , hereby consent the processing of my personal data [CTAG (Automotive Technology Centre of Galicia)/TUM/UNINA/VTI] for testing purposes in connection with the EU research project i4Driving project (Integrated 4D driver modelling under uncertainty; https://i4driving.eu/), internally within the project as well as externally in publications.

The overarching objective is to develop a new library of credible driver models that can capture the large heterogeneity in human driver behaviours. The library of driver models is e.g., needed to provide a human traffic safety baseline in safety assessment of automated driven vehicles. To develop the driver models and capture the heterogeneity among drivers there is a need to study human driving behaviours both in "uncritical" and safety critical situations in daily traffic. Sufficient system complexity is needed to make a robust and meaningful analysis of road safety.

I will not be externally mentioned with my real name, and I will not be identifiable. The publication of the results from the project will be in a form so that it will not be possible to trace data back to named individuals.

I am aware and I was informed that I can withdraw my consent at any time by contacting the Data Protection Officer of the project at the following email address [add e-mail address], or the researchers responsible for the tests at [add e-mail address]. I understand which are my rights with regards to the processing of my personal data and I have been provided an information sheet together with this consent agreement.

Name of participant: Signature of participant

Date: _ _ / _ _ / _ _ _ _

Name of researcher: Signature of researcher:

Date: _ _ / _ _ / _ _ _ _

Information sheet

Information on how we process your personal data

We are the data controllers - how do you get in contact with us?

[**CTAG** (Automotive Technology Centre of Galicia)/TUM/UNINA/VTI] will process your personal data in the framework of the i4Driving research project.

Mr/Ms. ??, as i4Driving Data Protection Officer (DPO) is responsible for the processing of personal data that we collect from you. You can also contact the researchers responsible for coordinating these tests Mr/Ms. ?? for any question, query or request.

You can find our contact information below:

Data Protection Officer: [add name and e-mail address]

Responsible researcher: [add name and e-mail address]

Purpose and grounds for the processing of personal data

We process your personal data for the purpose of understanding participants' current thoughts and feelings about the specific i4Driving experiment.

Participation in the experiment is completely voluntary and no negative consequences will result from declining to take part in the experiment. Likewise, no monetary compensation will be provided for participation (or yes if there is a recruitment process with agency, not for [CTAG/TUM/UNINA/VTI] workers).

You will be asked to take part in a driving simulator study. The experiment will last about one hour. During the study we will request your personal insights on the user experience you will be going through.

Categories of personal data

The processing of personal data will be limited to the following categories and will not include the processing of any special category of data under article 9 of the GDPR:

- Age
- Gender
- Educational level
- Possession of driver license
- Employment status
- Person's image (the processing will not go beyond your appearance in the videos recorded during the trials)
- [… adjust based on the final experimental design]

Your personal data will be exclusively used for the purpose described in the context of the project and they will not be processed for any other purpose without your prior consent.

How will data be collected?

During the test session you will also be video recorded. Your personal data will be collected under the basis of your free consent.

We store your personal data in a secure way and we adopt measures to protect your data until the data processing finishes. More specifically:

- All collected data will be securely anonymized and will remain confidential.
- The study will include video and audio recordings from your drive in the simulator. If transcription from recorded opinions is necessary, it will not contain information that would allow individuals to be linked to specific statements.

No data will be shared with third parties that are not part of the i4Driving project. Only a small subset of this data will be part of the *shared Open Data* for present and future research in the area. This data is not linked to the original user, and the publication of this data will be in a form so that it will not be possible to trace data back to identifiable individuals.

Likewise, only previously anonymized data may be used by the rest of project partners in the i4Driving project and their use will be strictly limited to the purposes of the i4Driving project.

Deletion of your personal data

Your personal data will be permanently deleted from all databases in the term of five years after the end of the i4Driving project, estimated by ??.

Your rights

In accordance with the General Data Protection Regulation (GDPR), you have several rights related to our use of your information:

- Right of access: you have the right to access and request a copy of the information we hold about you at any moment without providing any justification.
- Right to rectification: you have the right to request the correction of any information you believe it is inaccurate or incomplete.
- Right to erasure: you have the right at any time to withdraw your consent and your personal data will be deleted.

If you want to exercise your rights, you have to contact us at the following emails: [add e-mail address]

You also have the right to fill a complaint at the corresponding Data Protection Authority.

For Spanish participants: at the Spanish Data Protection Agency by means of the complaint procedure envisaged in its official website ([add relevant webpage as e.g. https://www.aepd.es/es). Press the option "The Agency" and then "Contact".

More information

If you have any further questions or want clarification regarding this research and/or your participation, please contact:

Researcher name: [add name and e-mail address]