i4Driving Validated ethics assessment plans and approval from ethics committee

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i4Driving
integrated 4D driver modelling under uncertainty

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V0.3	03.03.2023	Tanja Niels, Johannes Lindner, Eva Garcia, Francesco Galante, Johan Olstam	TUM, CTAG, UNINA, VTI	Revision of document
V0.4	03.03.2023	Tanja Niels	TUM	Version for internal review
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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 test track 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 test track experiments within i4Driving are listed together with risk assessments and suggestions for mitigation measures for each identified issue/risk. The issues/risks are categorized into the following categories: risks for physical effects / injuries; risks for psychological effects; and other ethical aspects to consider.

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1 Introduction

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. In i4Driving, the driving simulator experiments and the test track experiments are divided into two different work packages, and each of the work packages includes a deliverable that specifies the 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 GDPR regulations.

The deliverable is structured as follows. Chapter 0 presents the ethics policy that will be followed within the i4Driving project for the test track experiments. Chapter 3 explains how personal integrity and GDPR aspects are considered. Chapter 4 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 test track experiments within i4Driving are listed in chapter 0 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 2-4 (mainly described in chapters 2-4) apply to both the driving simulator experiments and the test track experiments, these chapters are very similar in both deliverables 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 test track experiments will be monitored by the i4Driving ethical board consisting of the coordinator Panteia, the WP3 leader VTI, and the WP5 leader TUM. The i4Driving committee will follow national as well as 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 test track experiments are:

- **Informed consent:** First, researchers are required to get informed consent using language that is sufficiently understood by participants, without forgetting the importance to avoid or minimize 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 test track 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 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 it should be avoided to apply reimbursement in the form of incentive payment. 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 field test experiments in i4Driving.
- **Target user groups:** The target user group of i4Driving consists of non-professional drivers holding a driving license for at least driving a car.
- **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 to 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 anonymized. In case the project would like to use video or other recordings for dissemination (not only data analysis), but the participant will also be contacted and asked specifically for each occasion with specified material.
  - To this end, the providing project partner will anonymize 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 anonymized 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;
- 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 General Data Protection Regulation (GDPR) of the European Union (EU). In the i4Driving test track 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 should 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 & storage
    - Data transfer & 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 organizational 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 unauthorised access, theft, or loss of data, and it must be ensured that appropriate measures are taken to mitigate these risks.
5. **Ensure that 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 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 pseudonymization:

- **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 pseudonymisation 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 pseudonymisation 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 pseudonymisation 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 participant demands 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 test track 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 organisation of the test track 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 to enable deletion of data upon request of the participant in hindsight.
1. **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 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.

2. **Internal data**: Data exchange between work packages and institutions is necessary to reach the project goals. This data is anonymised 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 ends 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.
3. **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 TUM, Germany

For test track 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).

4.1.1 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, and 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 test track 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. 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€.

4.1.2 Data Privacy

Data from vehicle simulators and controlled test track 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.

4.2 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, such 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 the 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.
- All the participants will voluntarily take part in the study and they can withdraw their participation at any time.

Moreover, as test are performed with the supervision of a psychologist, he or she follows the Ethical Code of Conduct for Psychologists (Deontological Code). This code is regulated by the 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's 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 RGPD.

5 Ethical aspects to consider for the test track experiments

For controlled test track experiments, we identified several risks that need to be considered. Besides pure driving experiments, we may combine test track experiments with Augmented Reality (AR) technology at the test site at TUM. Of course, this makes the consideration of additional and slightly different ethical aspects necessary. All risks are described below. The description also includes a preliminary risk assessment, an estimate of the severeness of consequences, and 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 test track experiments are listed below in Table 1 - Table 3. The risks and issues are categorised into the following 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 test track experiments.

Issue	Mitigation	Probability	Consequence
1. Crashed in test track with objects or other road users	Designing safe scenarios taking into consideration possible risks. If other road users (e.g., cars) are included in the experiments, those vehicles are driven by professional drivers. AR will be used to avoid as many possible physical collision objects as possible	1 (very low)	5 (very high)
2. Lack of perceived risk for participant (which could result in speeding, for example)	Clarification in informed consent form, premature termination of the study in case of non-compliant behaviour	2 (low)	3 (medium)
3. Motion sickness in test track experiments involving Augmented Reality (AR)	Participants screening for motion sickness, intensive pretesting to avoid issues because of technical performance, provide water and snacks at the test site.	3 (medium)	1 (very low)
4. Participants who are not fit to drive due to sickness, fatigue, emotional upset, drugs, alcohol, etc. might have a higher risk for motion sickness, experiencing unpleasantness or injuries when entering or leaving the vehicle cockpit.	Ensure that participants are fit to drive before entering the vehicle cockpit – i.e., no relevant sickness, fatigue, emotional upset, drugs, alcohol, etc. This will also be specified in the consent form.	2 (low)	3 (medium)

Table 2. Risks for psychological effects in connection with the test track experiments

Issue	Mitigation	Probability	Consequence
5. Anxiety for participating in experiments with an unfamiliar vehicle (especially if a vehicle with new technologies is used for the experiment).	Detailed explanation on functionalities and training before testing	3 (medium)	1 (very low)
6. Anxiety for participating in Augmented Reality (AR) experiments (Test subjects drive in a real car while wearing AR headset to visualize other road users)	Training before testing, familiarize with AR technology without car, explain to the participant that they have the possibility to quit if they feel uncomfortable at any time during their participation.	5 (very high)	1 (very low)
7. Traumatic effects because of (near) crash event in Augmented Reality (AR) experiment	Avoid frequent occurrences of these events, model digital road users in a way, to find a trade-off between unnatural and natural appearance (e.g., avoid faces and vulnerable user groups like children)	1 (very low)	3 (medium)
8. Exposing the participants to too many or too critical situations might both influence the participant's wellbeing but also imply a risk of biased results.	Careful design of experiments and conducting pilot tests with internal staff and/or AR-experienced drivers before starting experiments with the real participants.	2 (low)	3 (medium)

Table 3. Other ethical aspects to consider in connection with the test track experiments.

Issue	Mitigation	Probability	Consequence
9. Concern about personal data processing	Explanation of Personal Data Protection Policy in informed consent	3 (medium)	2 (low)

6 Concluding remarks and next steps

This deliverable describes the ethics policy and GDPR considerations that will be utilised in the test track experiments conducted within the i4Driving project. Since the test track experiments will be conducted 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 are 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 D5.2 "Evaluation criteria and detailed description of field experiments".

7 References

7.1 Reports, articles, and papers

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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

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

7.2 Webpages

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

Annex A: Example of informed consent-form for the test track studies

Informed Consent

ID (Identification number):

Purpose

This study is part of the i4driving research project. 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 the informed consent form, a general information questionnaire will be completed. This will be followed by training on the test track (and with the AR setup). During this run you will be accompanied by a researcher. Participation in this project consists of the normal driving of a passenger vehicle (including the use of an AR setup). Please carry out normal driving, following the traffic regulations. A rest break will be made between each session. Finally, the participant will fill in a questionnaire where his/her feelings/experience from this drive will be collected. Audio and video will be recorded during the sessions, as well as driving data including corresponding simulation data in the case of studies using AR.

Risks

Participation in these tests does not carry more risks than regular driving or performing any type of manoeuvre with your vehicle. Tests must **not** be carried out if you are under the influence of any substance that may affect your performance (drugs, alcohol or medication). Additionally, those people who are under special health circumstances or any other condition which may affect their performance as a driver should not participate in the study. We require you to indicate this to be able to assess whether you can continue the study.

Costs and compensation

Participation in this study does not imply any cost to the subject, nor does it imply compensation (or it implies a compensation of [amount (€)]). Participants will not obtain personal benefits regardless of the exploitation of the results carried out by [**CTAG/TUM**] 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 the 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:

- Driving data:
  The data includes both the data from the questionnaires and those obtained from the systems integrated into the car. These data collected during the driving runs will be analysed together with the results of other participants.
  In driving experiments in which AR-tools are used, the information displayed in the virtual world – mainly movement of other road users – is recorded in form of trajectory data relative to the ego vehicle. This data will be merged with the real-world driving data.
- Audio and video recordings in real time:
  The videos include, in addition to the image, all the environmental sounds and the voice of the subject inside the car. The video and sounds during driving will be used to examine the behaviour of the subject while driving.

[CTAG/TUM] may include these 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 consequences. 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 on the test track; Only relevant if participants are employed at TUM/CTAG. 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 track experiment".

- Yes, I agree.
- 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 (Technical University of Munich)] 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 needed, for example, 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 regarding the processing of my personal data and to this effect 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** (Technical University of Munich)] will process your personal data in the framework of the i4Driving research project.

Mr./Ms. [add name], 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. [add name]) 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 test.

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

You will be asked to take part in a test track study. The experiment should 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 based on 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. If transcription from recorded opinion 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 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 the project partners in the i4Driving project, and their use will be strictly limited to the purposes of the 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 December 2030.

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 via the following email address: [add e-mail address].

You also have the right to file 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]